U.S. Department of Health and Human Services

Office of Inspector General

Home Health Agencies Used Multiple Strategies To Respond to the COVID-19 Pandemic, Although Some Challenges Persist

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October 2022, OEI-01-21-00110

U.S. Department of Health and Human Services

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Report in Brief

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Why OIG Did This Review

The COVID-19 pandemic required home health agencies (HHAs) to adapt their care to respond to COVID-19's infectious nature, as well as other circumstances from the pandemic. HHAs play an important role in caring for Medicare beneficiaries: in 2020, the first year of the COVID-19 pandemic, HHAs cared for over 3 million beneficiaries. The Centers for Medicare & Medicaid Services (CMS) requires HHAs to prepare for and respond to emergencies and, during those emergencies, CMS can offer regulatory flexibilities and supports (which we refer to collectively as regulatory flexibilities) for various requirements. This report provides insights into HHAs' experiences that will help stakeholders continue managing the response to COVID-19 and prepare for future emergencies.

How OIG Did This Review

We surveyed a nationally representative sample of 400 HHAs, 396 of which participated in Medicare, in fall 2021 to ask about their experiences early in the pandemic and at the time we administered the survey. We projected our results to the 72 percent of Medicare-participating HHAs represented by our sample. In addition, we interviewed 12 HHAs about notable challenges, strategies, or other experiences they identified in their surveys. We also interviewed staff at CMS about its support of—and perspectives on—HHAs' provision of care during the pandemic.

Key Takeaway

Home health agencies (HHAs) developed strategies to respond to challenges during the COVID 19 pandemic, including providing new incentives to maintain staff and seeking alternative sources of personal protective equipment. HHAs have also benefited from CMS support, such as regulatory flexibilities and expanded telehealth allowances, but staffing challenges persist. In light of the expanded use of telehealth, more information is needed to determine its future use across different home health services.

What OIG Found

Like all health care providers, HHAs have experienced multiple challenges to providing care during the COVID-19 pandemic. HHAs have continued to experience longstanding staffing challenges as well as new ones resulting from the pandemic, such as maintaining staffing despite quarantine and isolation protocols. These staffing challenges persist for many HHAs despite efforts to address them. In addition, HHAs faced numerous and widespread infection control challenges, including accessing personal protective equipment (PPE) to limit exposure and spread, but these have mostly eased since early in the pandemic.

HHAs' own strategies to respond to the pandemic included offering paid leave to retain staff and finding PPE from nontraditional sources. HHAs have also benefited from government support—including regulatory flexibilities instituted in response to the declaration of a public health emergency—and this support has mitigated some staffing challenges. For example, by the Federal government's allowing new types of providers to certify and order home health services and complete certain patient assessments, HHAs could more efficiently provide care. Telehealth flexibilities under the public health emergency have also helped HHAs provide care while reducing COVID-19 exposure and dealing with staffing shortages. However, HHAs' challenges with telehealth raise questions about its future role in home health care, and—because of limited reporting requirements—CMS has limited insight into HHAs' telehealth use. Finally, the emergency preparedness plans required by CMS guided HHAs' responses to the pandemic but fell short of fully addressing a global emergency such as COVID-19.

What OIG Recommends and How the Agency Responded

CMS has an opportunity to assess how to best help HHAs prepare for and respond to future emergencies, as well as to evaluate how changes to the home health landscape can better serve patients. To that end, we recommend that CMS evaluate how HHAs are using telehealth—specifically, the types of services provided via telehealth and the characteristics of patients who benefit from these services. We also recommend that CMS—to inform decision-making—evaluate how the regulatory flexibilities it has offered in response to the COVID-19 public health emergency affect the quality of home health care. Finally, we recommend that CMS—in collaboration with the Administration for Strategic Preparedness and Response's (ASPR's) Technical Resources, Assistance Center, and Information Exchange (TRACIE)—apply lessons learned from the COVID-19 pandemic to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks. CMS concurred with all three recommendations.

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BACKGROUND

OBJECTIVES

1. To identify HHAs' key challenges to providing patient care during the COVID-19 pandemic.
2. To identify key strategies HHAs used to address the challenges presented by COVID-19.

The emergence of the COVID-19 pandemic in early 2020 affected health care organizations across the United States. Hospitals reported decreases in elective surgeries, and nursing homes experienced devastating outbreaks among residents. Home health agencies (HHAs) were likewise affected and have reported challenges ranging from procuring personal protective equipment (PPE) to staffing shortages.[1, 2, 3] To continue to serve the millions of Americans who rely on home-based care during the pandemic, both HHAs and the Federal government, including Congress and CMS, took action to address COVID-19-related challenges.[4, 5, 6]

CMS plays a pivotal role in supporting HHA preparations and responses to emergencies, including emerging infectious disease outbreaks such as COVID-19. For example, CMS has supported HHAs during the COVID-19 public health emergency by offering regulatory relief for various requirements that HHAs must meet. CMS also requires HHAs to incorporate internal processes and procedures to prepare for future emergencies.

This study provides insights into HHAs' perspectives on the challenges they experienced during the first months of the COVID-19 pandemic up until the end of 2021, as well as the strategies they used to address these challenges. These strategies include HHAs developing their own approaches to address specific challenges, using emergency preparedness plans required by CMS, and using the flexibilities that the government has offered during the COVID-19 public health emergency. These insights will help CMS, HHAs, and other stakeholders continue managing the response to COVID-19 and prepare for future emergencies to ensure that beneficiaries receive needed care.

Home Health Agencies

HHAs provide skilled nursing and therapeutic services to patients in a home-based setting. HHAs are a critical component of our health care system. They can provide an alternative to inpatient health care settings, when appropriate and feasible. Services that HHAs can provide include post-operative care, occupational therapy, and chronic disease management.[7] Many home health services require hands-on

contact between staff and patients. For example, a physical therapist may test a patient's strength, balance, and coordination to assess rehabilitation needs. In addition, a nurse may change a patient's wound dressing and monitor for signs of infection following an operation.[8] Home health may also include services that do not necessarily require hands-on contact and may be completed remotely, such as behavioral therapy or social services.[9]

Beneficiaries must meet certain conditions to qualify for home health care coverage under Medicare—for example, they must be homebound, which means that they have trouble leaving home without assistance because of injury or illness or have a condition such that leaving their home is medically contraindicated.[10] Prior to receiving home health care, beneficiaries must also meet face to face with a doctor (or other allowed health care provider) related to the primary reason for the home health care.[11] Although beneficiaries must be homebound to be eligible for home health services covered by Medicare, they do not need to be hospitalized prior to receiving care.[12] In 2020, three-fourths of Medicare home health episodes were not preceded by a stay at a hospital or post-acute care institution, and more than 11,400 HHAs provided care to 3.1 million Medicare fee-for-service beneficiaries.[13]

To qualify as an HHA and participate in Medicare, an HHA must demonstrate that it meets regulatory health and safety requirements, or the Conditions of Participation (CoPs). Each CoP covers a broad topic (e.g., emergency preparedness) and then is further defined by a set of specific standards that HHAs must meet.[14, 15] To assess compliance with CoPs, State survey and certification agencies and Accrediting Organizations (as applicable) typically conduct onsite inspections, including observing home visits, on behalf of CMS.[16, 17]

Rural HHAs may experience different challenges to providing home health care compared to HHAs in more populated settings. For example, rural HHAs' patients may be spaced farther apart, requiring more travel time between visits. Some evidence also suggests that, early in the pandemic, rural HHAs experienced different challenges responding to COVID-19 compared to HHAs located in urban settings. This includes potential differences in access to PPE and proportion of patients with COVID-19.[18]

The COVID-19 Pandemic

The virus that causes the disease known as COVID-19 is highly contagious and can cause symptoms including fever, cough, and shortness of breath.[19] COVID-19 can sometimes result in severe illness leading to hospitalization or death.[20] The Centers for Disease Control and Prevention (CDC) identified the first U.S. laboratory-confirmed case of COVID-19 in the United States in Washington State on January 20, 2020, and the disease has since spread nationwide.[21] On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency.[22] On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic, indicating that COVID-19 had spread to several countries or continents, potentially

affecting a large number of people.[23, 24] On March 13, 2020, the President declared a national emergency.[25]

As of September 23, 2022, CDC had reported over 95 million cases in the United States and over one million deaths.[26] Since COVID-19's emergence within the United States, rates of infection and death have varied over time and within different geographic locations. Factors that can affect COVID-19 infection rates include vaccination rates, population density, and the presence of more contagious variants of the COVID-19 virus.[27, 28]

HHA Care During the COVID-19 Pandemic

As the COVID-19 pandemic evolved, HHAs had to adapt their care to respond to COVID-19's infectious nature as well as other circumstances caused by the pandemic, such as decreased staff availability. During the public health emergency, CMS has offered HHAs regulatory relief for various CMS requirements to support HHAs' response to the pandemic. Furthermore, CMS provided guidance to support HHAs in meeting infection control and emergency preparedness requirements.

CMS Guidance on Infection Control. To protect patients and staff, CMS requires HHAs to meet the CoP for infection prevention and control (hereinafter referred to as infection control). This includes following widely accepted guidelines (e.g., hand hygiene) to prevent transmitting infectious diseases as well as educating staff, patients, and caregivers on preventing infections (see Appendix A).[29] During the pandemic, CMS provided HHAs with additional suggestions to address COVID-19. In March 2020, it issued guidance that outlined further infection control recommendations, such as how to screen patients for COVID-19 and use PPE appropriately. CMS also directed HHAs to CDC—with which CMS engaged regularly—for further guidance on infection control for COVID-19. For example, to help address emerging supply shortages due to global disruptions, CMS suggested that HHAs contact local authorities and follow CDC guidelines for optimizing supplies.[30]

HHA Flexibilities During the Public Health Emergency. After declaring a national emergency on March 13, 2020, the President directed the Secretary of Health and Human Services to temporarily waive or modify certain Medicare requirements during the public health emergency.[31, 32] (The Secretary had declared a public health emergency on January 31, 2020.) Beginning in March 2020, CMS issued a series of regulatory waivers and new rules to support HHAs during the public health emergency.[33, 34] (In this report, we refer to regulatory flexibilities, waivers, and new rules as flexibilities.) For example, CMS allowed HHAs additional time to submit patient assessment information. CMS has continued to modify and add to these flexibilities. These flexibilities are available to HHAs nationwide for the duration of the public health emergency and target different aspects of home health care.[35, 36] See Appendix B for a full list of the flexibilities.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (enacted on March 27, 2020) also included statutory changes to help HHAs provide care during the public health emergency. Specifically, the CARES Act allowed additional types of providers (nurse practitioners, clinical nurse specialists, and physician assistants) to certify eligibility for home health care and order home health services.[37]

Telehealth Flexibilities During the Public Health Emergency. Medicare telehealth services refer to services that are provided remotely using technology between a provider and a beneficiary.[38, 39] (Telehealth may also be referred to as telemedicine or telecommunications technology.) Telehealth may include videoconferencing (hereinafter, video) to conduct speech therapy visits; using a blood pressure cuff that automatically sends information to a provider; or a phone call between a nurse and a patient to discuss whether a patient's worsening symptoms warrant an extra home visit.[40, 41] For these technologies to qualify as telehealth, providers must use them to improve a patient's health care.[42] On the basis of this definition, CMS would not consider administrative tasks, such as calling a patient to schedule an in-person appointment, as telehealth. CMS specifies which services it considers telehealth as covered under the Medicare home health benefit (i.e., Medicare does not cover all uses of telehealth).[43, 44]

The CARES Act directed the Department of Health and Human Services (HHS) to encourage HHAs to use telehealth technology for services provided during the public health emergency.[45] In response, CMS issued flexibilities that expanded HHAs' ability to use telehealth and thereby reduced infection risk. For example, CMS allowed HHAs to perform certain Medicare-covered assessments and determine patients' homebound status via telehealth or record review.[46] CMS also allowed the required face-to-face encounter between a patient and authorized health care provider, who certifies the patient as eligible for home care, to take place remotely.[47]

In addition, effective on March 31, 2020, CMS permitted HHAs to use telehealth technology services within the patient's plan of care if these services are related to the patients' needs and do not replace needed in-person visits.[48, 49] CMS made this regulatory change permanent effective January 1, 2021. (See Exhibit 1 for examples of how HHAs can use telehealth—initially, limited to the duration of the public health emergency, but now permanently.)[50] Although HHAs may choose to provide telehealth services, HHAs cannot bill Medicare for telehealth services as equivalent to an in-person visit—without a statutory change, CMS cannot directly reimburse HHAs for telehealth services.[51] However, HHAs can report the costs of providing telehealth services, such as the cost incurred to set up technology, as allowable administrative and general costs within cost reports.[52, 53] HHAs submit cost reports to CMS each year. CMS factors information reported within cost reports, including costs to provide telehealth, into future Medicare payments to HHAs.[54]

Exhibit 1. Examples of how HHAs have been allowed to use telehealth under the Medicare home health benefit, beginning with the COVID-19 public health emergency*

Live video or audio visits between a patient and HHA provider

Examples include:
- Assessing over video whether a patient can move properly after a hip surgery
- Calling to make sure that a patient continues to take medication as prescribed
- Calling to determine whether a patient needs to visit their primary care physician

Electronically transmitting health information for a provider to access later

Examples include:
- A heart rate monitor that automatically sends data to the HHA every 30 minutes
- An HHA nurse who sends a visit report to the patient's doctor via health application software for the doctor to evaluate at a later time

* HHAs are also now able to provide these services under the Medicare home health benefit beyond the COVID-19 public health emergency.
Sources: HHS, *What is telehealth*?, June 29, 2022 (updated September 14, 2022);[55] CMS, *COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing*, updated January 7, 2021;[56] 42 CFR § 409.46.

Since the start of the pandemic, CMS and other sources have reported a dramatic increase in the use of telehealth by Medicare beneficiaries, including HHAs, from that of prior years.[57, 58, 59] A previous OIG study found that Medicare beneficiaries used 88 times as many telehealth services during the first year of the pandemic (March 2020 through February 2021) as they used in the prior year.[60] However, in a recent report to Congress, the Medicare Payment Advisory Commission noted that Medicare beneficiaries and providers had some concerns about whether telehealth offered the same quality of care as did in-person services.[61]

CMS-Required Emergency Preparedness Plans. As of November 2017, CMS requires HHAs, along with other types of providers, to meet the CoP for emergency preparedness.[62] CMS includes four core elements in its emergency preparedness requirements (see Exhibit 2). HHAs must review these elements and update them every 2 years.[63, 64]

Exhibit 2. CMS requires emergency preparedness plans to include four core elements.

Risk assessment and planning	HHAs must perform risk assessments using an all-hazards approach, which considers those emergencies or disasters that are most likely to occur. Individual HHA emergency preparedness plans may therefore vary due to differences in location (e.g., if an HHA is in a tornado-prone area).
Policies and procedures	HHAs must develop policies and procedures based on components of the emergency preparedness plan and risk assessment, such as how to track patients and staff during an emergency.
Communication plan	HHAs must develop emergency communication plans that comply with Federal and State laws. These plans must include important contact information as well as methods for sharing patient information during emergencies.
Training and testing program	HHAs must train staff and test their emergency plans via drills.

Sources: CMS, "Emergency Preparedness Rule: What's New based on the *Medicare and Medicaid Programs*; *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* Final Rule"; CMS, "Frequently Asked Questions (FAQs): Emergency Preparedness Regulation," January 2017.[65]

As of 2019, CMS guidance on emergency planning instructs providers to include emerging infectious diseases as part of their risk assessment's all-hazards planning.[66] In March 2021, CMS updated that guidance to include additional information on incorporating emerging infectious diseases into providers' all-hazards planning. For example, CMS added guidance on assessing PPE needs and screening patients, among other considerations, during an infectious disease emergency. CMS also suggested that providers develop policies to update their emergency preparedness plans during emergencies that last longer than expected.[67]

CMS directs HHAs to various resources to support emergency preparedness. For example, CMS provides online training to health care providers on emergency preparedness.[68, 69] CMS may also refer HHAs to the Administration for Strategic Preparedness and Response's (ASPR's) Technical Resources, Assistance Center, and Information Exchange (TRACIE), which periodically updates EP resources on its website.[70]

Related OIG Work

This study contributes to the Office of Inspector General's (OIG's) work on home health care and on providers' experiences during the COVID-19 pandemic. A 2021 OIG audit assessed infection control practices at eight HHAs and found that six HHAs' infection control policies and procedures complied with CMS requirements and COVID-19 guidance.[71] Another audit is underway to examine HHAs' compliance with

CMS's regulations for telehealth services—i.e., the regulations that were initially limited to the duration of the public health emergency, but subsequently made permanent.[72]

Prior OIG home health work focused on unverified patient lists used in home health surveys and common characteristics of HHAs and physicians found in OIG-investigated cases of home health fraud.[73, 74] OIG has also conducted a series of compliance audits of home health care providers. A complete listing of OIG's ongoing evaluations and audits is available in our online Work Plan at https://www.oig.hhs.gov/.

Methodology

This study used the following data sources: (1) a survey of a random sample of HHAs; (2) interviews with a purposive sample of 12 HHAs; and (3) an interview with CMS staff.

Scope

This study focuses on Medicare-participating HHA experiences from early in the pandemic to the point that OIG surveyed or interviewed HHAs in September through December 2021. As part of the survey and interviews, we asked HHAs about challenges experienced early in the pandemic and in fall 2021. We defined "early in the pandemic" to mean when the respondent HHA's geographic area experienced its first wave of COVID-19 infection.

Data Sources and Analysis

Survey of HHAs. We administered a survey between September and November 2021 to a random sample of 400 HHAs asking about their experiences during the COVID-19 pandemic. Of the 377 eligible Medicare-participating HHAs we surveyed, we received responses from 271, a 72-percent response rate.[75] We analyzed the survey data to determine challenges HHAs experienced during the pandemic; strategies they used to address those challenges; and HHAs' experiences with telehealth, emergency preparedness plans, and regulatory flexibilities. We produce estimates from these data to speak to the experiences of Medicare-participating HHAs represented by our respondents. See Appendix C for a description of our nonresponse bias analysis.

To identify HHAs as rural, we used 2019 Medicare claims data to determine whether HHAs provided services to Medicare beneficiaries in mostly rural counties. We identified 41 HHA survey respondents as rural. We analyzed rural HHAs' survey responses to describe the experiences of rural HHAs in our sample and do not generalize these responses to all rural HHAs.

Interviews with HHAs. We interviewed staff from a purposive sample of 12 HHAs in November and December 2021. We asked HHAs about their experiences during the COVID-19 pandemic on the basis of their responses to our survey. We selected HHAs

that indicated notable challenges, strategies, or other experiences during the pandemic in their survey responses.

Interview with CMS. We conducted one interview with staff in CMS's Center for Clinical Standards and Quality and Center for Medicare regarding their perspectives on HHAs' experiences during the pandemic and the support provided to HHAs by CMS. We conducted this interview on January 21, 2022.

See the Detailed Methodology on page 29 for additional information about our data collection and analysis.

Limitations

We based our findings regarding HHAs on the information reported by HHAs in our survey and during interviews. We did not independently verify the information HHAs provided. We did not evaluate the effectiveness of the strategies HHAs reported using to address challenges during the COVID-19 pandemic. Our results pertaining to HHAs apply only to the population represented by the respondents and cannot be generalized to all HHAs.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Staffing challenges persist despite HHAs' efforts to address them

HHA staffing levels are important to ensuring that patients receive needed and high-quality care. Understaffed HHAs may be not able to send health care providers to patients' homes to the extent required in each patient's plan of care. HHAs without enough staff may also struggle to accept new patient referrals, which could affect beneficiaries' access to home health care.

The pandemic exacerbated longstanding staffing challenges for HHAs and added new ones

The COVID-19 pandemic further strained HHAs' ability to hire and keep staff (see Exhibit 3). HHAs described longstanding (i.e., pre-pandemic) challenges retaining and recruiting staff, including positions that remain vacant because candidates either do not apply or do not qualify for the position. These challenges extended into the pandemic. According to many HHAs, challenges early in the pandemic included difficulty recruiting new clinical staff due to increased competition from other health care facilities or contract agencies (71 percent) and staff leaving to work for these facilities and contract agencies (51 percent). Two HHAs noted difficulty in recruiting and retaining staff because other companies offered higher wages.

> "We have [an] already tight market and a limited number of nursing professionals living in this area, staffing is always an issue. In the light of the pandemic, [it has] made the nurse shortage even more noticeable and challenging." – Senior HHA staff

In addition to longstanding staffing challenges that were exacerbated by the pandemic, many HHAs faced challenges that emerged as a result of the COVID-19 pandemic (see Exhibit 3). Most HHAs (85 percent) had early challenges with limited staff due to personal circumstances related to the pandemic, such as school closures, or because of self-quarantine/isolation requirements. About half of HHAs struggled early in the pandemic to pay contracted clinical staff due to higher contracting costs. Finally, three HHAs that we interviewed also noted challenges with staff uneasiness with caring for COVID-19 patients, which may have resulted in these patients not receiving care or overburdening the staff willing to care for COVID-19 patients. Rural HHAs that responded to our survey also experienced several of these same longstanding and COVID-19-specific challenges. For example, 39 of 41 rural HHAs

reported challenges with limited staff availability to work because of a COVID-19 exposure.

HHAs told us that staffing challenges made it difficult to complete patient visits and accept new patients:

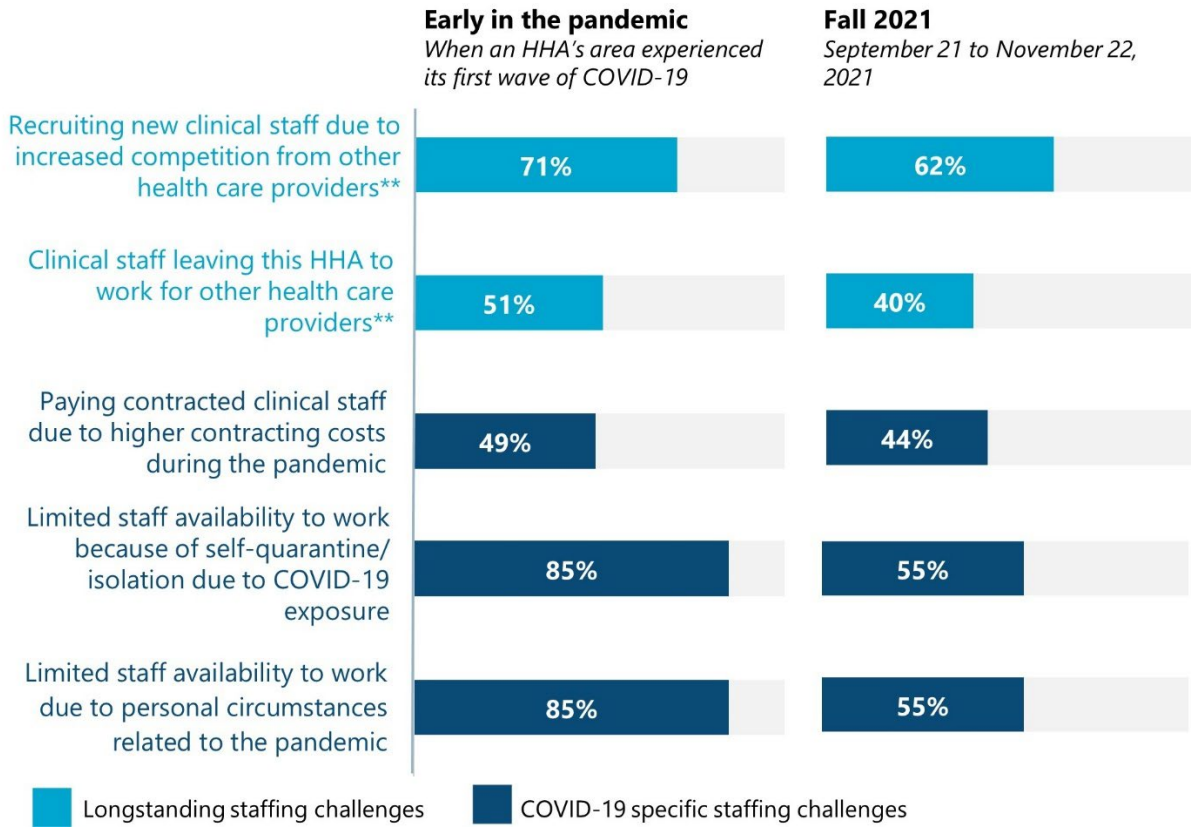
"We could not accept some referrals due to staffing challenges." – Senior HHA staff

"When schools closed [we] had to discharge clients." – Senior HHA staff

"We had the potential to see a lot of patients, but we didn't always have the staff." – Senior HHA staff

According to many HHAs, both longstanding and new staffing challenges persist, despite some improvement over the period of our review (see Exhibit 3). For example, in fall 2021, 62 percent of HHAs still experienced challenges with recruiting new staff due to competition from other facilities or health care contract agencies, and 40 percent still struggled with staff leaving to work for other health care facilities. Moreover, many HHAs continued to struggle with challenges that emerged due to the pandemic. Despite some improvement, about half of HHAs still experienced challenges with limited staff availability due to personal circumstances related to the pandemic or because of self-quarantine/isolation requirements. In addition, HHAs found that the challenge of paying contracted clinical staff—a challenge stemming from higher contracting costs during the pandemic—decreased only slightly from early in the pandemic; 44 percent of HHAs struggled with this in fall 2021.

Exhibit 3. Many HHAs continued to experience staffing challenges well into the pandemic.*



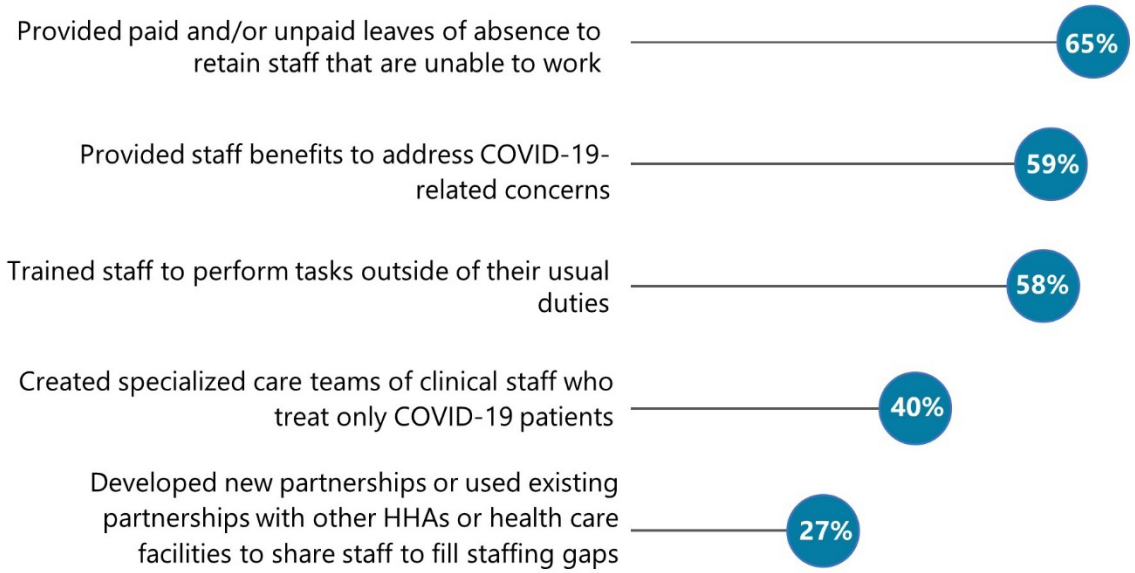
* All differences between the two time points are significant at the 0.05 level (n=271). See Appendix D for more details.
** These providers may include health care contract agencies or other health care facilities, such as hospitals.
Source: OIG analysis of survey data, 2022.

Although none of the challenges were fully resolved by fall 2021, HHA-developed strategies and CMS flexibilities helped HHAs to mitigate some staffing challenges

HHAs developed their own strategies to ensure that patients received care despite staffing challenges (see Exhibit 4). Many HHAs found it useful to assist staff with addressing COVID-19-related concerns, including by providing paid or unpaid leaves of absence (65 percent) or benefits, such as flexible schedules (59 percent). Nearly as many (58 percent) also benefited from training staff to perform tasks outside of their usual duties, such as administrative work or duties in a different clinical area. In addition, 40 percent of HHAs created and found it helpful to have specialized care teams of clinical staff who only treat COVID-19 patients. For example, one HHA that we interviewed created COVID-19 care teams composed of staff who volunteered to see those patients. Furthermore, HHAs reported using COVID-19 relief funds, such as the Provider Relief Fund, to recruit and maintain staff.[76] Two HHAs that we interviewed used these funds to pay staff who were unable to work because of the

pandemic, and two HHAs used the funds to offer hazard pay. However, another two HHAs that we interviewed noted that using financial support to recruit new staff, such as with signing bonuses, had limited effectiveness because of the lack of candidates applying for open positions.

Exhibit 4. HHAs used and found helpful various strategies that they developed to respond to staffing challenges during the pandemic.*



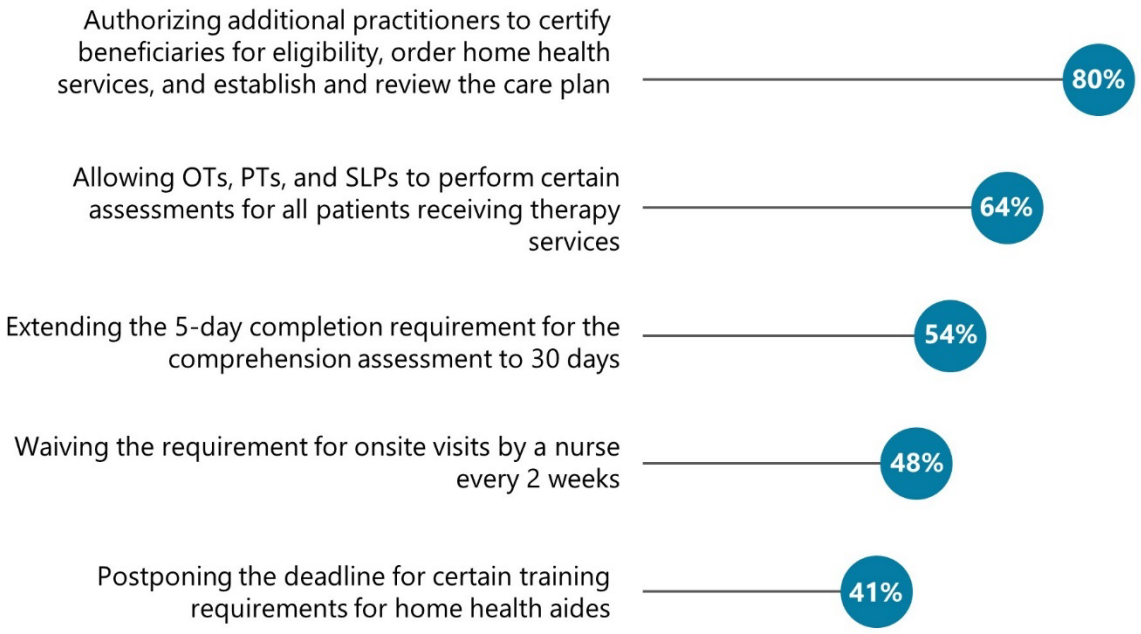
* Surveyed HHAs also had the option to indicate if they used a strategy and did not find it helpful or if they did not use the strategy (see Appendix D).
Source: OIG analysis of survey data, 2022.

In addition to developing their own strategies, HHAs relied on flexibilities that CMS offered to help address staffing challenges (see Exhibit 5). CMS told us that it offered flexibilities that increased time for staff to complete certain assessments and relaxed training requirements to help with staffing constraints. About half of HHAs found each of these helpful (54 percent and 41 percent, respectively). As required by provisions in the CARES Act, CMS permanently amended regulations to authorize nurse practitioners and physician assistants to certify and order home health services in addition to physicians. HHAs told us that it made it easier and faster to admit new patients. One HHA that we interviewed said that this flexibility was "huge" in getting orders for home health services signed and implemented. CMS also expanded the types of HHA staff who may perform initial and comprehensive patient assessments to include occupational therapists (OTs), in addition to registered nurses, physical therapists (PTs), and speech language pathologists (SLPs).[77] Three HHAs that we interviewed told us that this flexibility helped them admit and assess patients more quickly when staffing resources were stretched thin. (See Appendix B for a summary of CMS flexibilities, including their status as of summer 2022.)

Although CMS has taken actions to ease HHAs' staffing challenges, it has limited information on how these flexibilities have affected HHAs' care. In March 2021, CMS issued an update to the State Operation Manual's Appendix Z—Emergency Preparedness Interpretive Guidelines—to provide additional guidance for the requirement that HHAs have policies and procedures that address emergency staffing strategies. However, HHAs have discretion on which staffing strategies they use during an emergency.

CMS receives feedback on the flexibilities via regular and ad hoc engagements with HHA stakeholders. For example, stakeholders have told CMS that the flexibilities are helpful and needed until the end of the COVID-19 public health emergency. CMS told us that it used feedback from stakeholder engagements to inform decision-making on which flexibilities to make permanent. However, CMS is not systematically collecting data to capture how HHAs are using or benefiting from flexibilities that aimed to help with staffing challenges or how flexibilities have affected the quality of patient care.

Exhibit 5. HHAs used and found helpful the various flexibilities that CMS provided for them to respond to staffing challenges during the COVID-19 public health emergency.*



* Surveyed HHAs also had the option to indicate if they used a flexibility and did not find it helpful or if they did not use the flexibility (see Appendix D).
Source: OIG analysis of survey data, 2022.

HHAs' infection control challenges were numerous and widespread early in the pandemic, but these challenges lessened by fall 2021

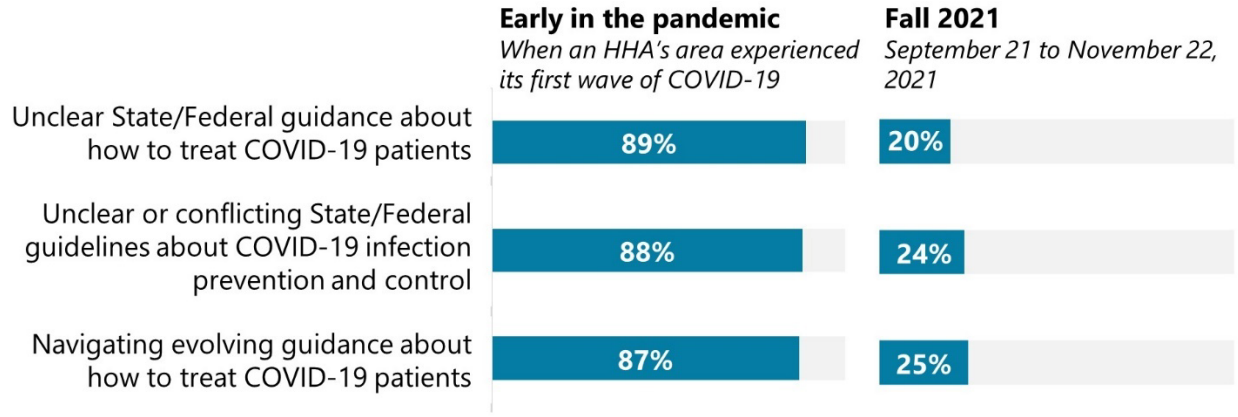
Because of COVID-19's infectious nature, HHAs had to quickly pivot to continue to provide needed care while also protecting patients and staff. Limiting the spread of disease requires an understanding of how to prevent transmission and how to appropriately care for infected patients. Enhanced infection control also requires adequate levels of supplies, particularly PPE. However, limited knowledge of COVID-19 as well as disrupted supply chains impeded HHAs' ability to carry out these important tasks early in the pandemic.

Early on, HHAs struggled to understand and navigate infection control for COVID-19; they relied on government guidance, trainings, and new protocols to help address this

According to HHAs, it was a challenge to mitigate transmission and care for COVID-19 patients at the beginning of the pandemic (see Exhibit 6). Because COVID-19 was a novel disease, information regarding how to care for patients was limited and evolved as understanding of the virus grew. Indeed, early in the pandemic, most HHAs (87 percent) experienced challenges with navigating evolving guidance about how to treat COVID-19 patients. Four HHAs that we interviewed also described struggling to interpret changing guidance to inform their infection control protocols (e.g., changes in appropriate PPE use and post-exposure quarantine requirements). In addition, 88 percent of HHAs experienced challenges with unclear and conflicting Federal and/or State government guidance about COVID-19 infection prevention and control. Likewise, most rural HHAs that responded to our survey (34 of 41) reported experiencing this challenge. HHAs described having to devote sometimes substantial resources to researching government websites to develop infection control protocols. These challenges with guidance affected patient care: 56 percent of HHAs postponed caring for patients with positive COVID-19 diagnoses until they had adequate infection control procedures in place.

> "Having to research and determine what information to base [p]olicies on has been very time consuming."
> – Senior HHA staff

Exhibit 6. Most HHAs experienced challenges with understanding and navigating infection control information early on, although these challenges have decreased.*



* All differences between the two time points are significant at the 0.05 level (n=271). See Appendix D for more details.
Source: OIG analysis of survey data, 2022.

HHAs attempted to mitigate challenges with infection control while their understanding of COVID-19 increased. In addition to continuing to comply with the CoPs for infection prevention and control (see Appendix A), the COVID-19 pandemic required HHAs to take further action to address COVID-19 infection challenges. From the perspective of HHAs, nearly all (97 percent) found it helpful to use available information to develop internal COVID-19 protocols, which can include information on how to respond to an exposure. Moreover, nearly all HHAs found it helpful to increase or improve trainings for staff on COVID-19 treatment (95 percent) and provide staff with PPE training (96 percent). Although HHAs struggled with infection control information early in the pandemic, HHAs still accessed and relied on government sources, including CDC guidance, to inform protocols for minimizing transmission.

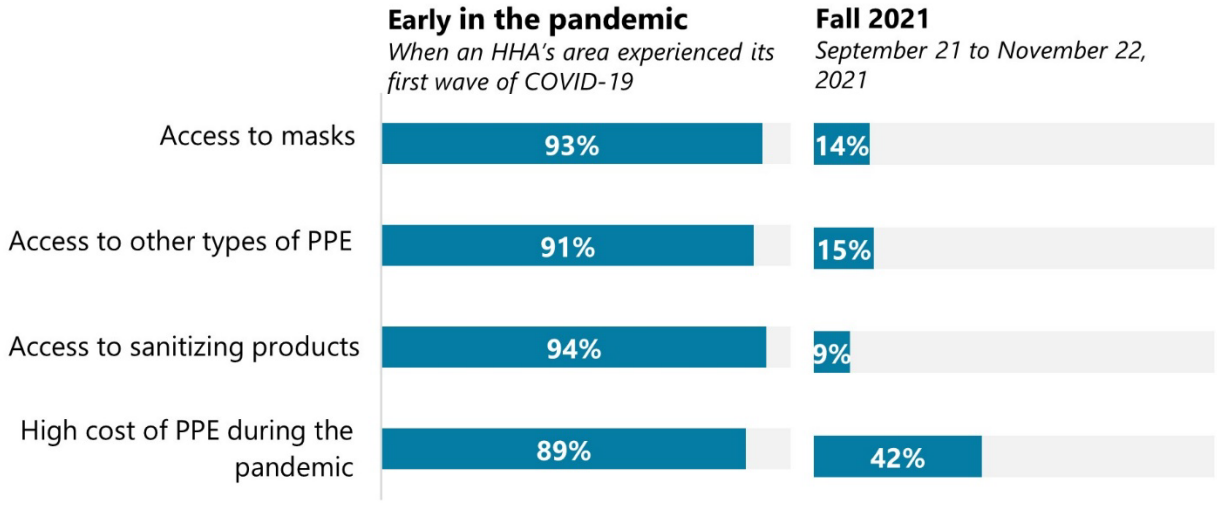
Nearly all HHAs faced challenges with accessing PPE and other critical supplies to control the spread of COVID-19 early in the pandemic, but these challenges eased over time

PPE and sanitizing products are essential for infection control. Their widespread shortages early in the pandemic posed challenges to safely caring for patients (see Exhibit 7). According to HHAs, over 90 percent faced early challenges with accessing supplies such as masks, other types of PPE, and sanitizing products (e.g., sanitizing wipes,

> "[We] [n]ever thought that we would not be able to obtain PPE." – Senior HHA staff

hand sanitizer). Nearly all rural HHAs that responded to our survey also experienced these challenges early in the pandemic: 37 with accessing masks, 37 with accessing other types of PPE, and 38 with accessing sanitizing products (of the 41 rural HHAs that responded to our survey). These challenges with accessing supplies came at a time when HHAs needed to use more supplies than ever to protect patients and staff from COVID-19 infection. One HHA that we interviewed described its limited access to supplies early in the pandemic as "absolutely horrific."

Exhibit 7. Almost all HHAs struggled with accessing supplies early on, but these challenges lessened over time.*



* All differences between the two time points are significant at the 0.05 level (n=271). See Appendix D for more details.
Source: OIG analysis of survey data, 2022.

Until supply chains stabilized, HHAs had to take unprecedented steps to address limited supply access. Over half (57 percent) found it helpful to conserve PPE, such as by re-using PPE normally meant for single use or by prioritizing PPE for the highest-risk activities. In addition, almost half (42 percent) of HHAs found it helpful to develop new, or use existing, partnerships with other HHAs or providers to obtain or pool supplies. Finally, some HHAs (31 percent) found it helpful to access PPE through nontraditional sources, such as nail salons. One HHA that we interviewed characterized its activities to access scarce supplies as follows: "we [HHAs] were just doing what we all could to survive."

> "Some of my staff and myself [sic] went to stores to try and find 90% alcohol to clean our equipment. We made [a]lcohol wipes out of industrial paper towels, we went to hardware stores to get N95 masks."
> – Senior HHA staff

Although most HHAs used telehealth during the pandemic, challenges that HHAs experienced raise questions about telehealth's future role in home health

CMS implemented telehealth flexibilities for many types of providers during the COVID-19 public health emergency, including flexibilities for HHAs. Indeed, as HHAs struggled with shortages of staff and supplies due to COVID-19, telehealth provided an opportunity to safely care for patients while reducing risk of infection. CMS updated regulations in November 2020 to permanently allow HHAs to use telehealth as part of their patients' plans of care, even after the public health emergency ends.[78] This regulatory change makes it vital to understand how HHAs use telehealth and its potential effects on patient care.

HHAs used telehealth to provide a variety of services to patients during the pandemic, including phone calls for status checks and video visits for therapy services

73%

of HHAs used telehealth during the pandemic

Most HHAs (73 percent) used telehealth during the pandemic and used it to conduct visits, share information, and facilitate interactions with outside providers. Of the HHAs that used telehealth, just over three-quarters (78 percent) provided live video or audio visits during the pandemic (see Exhibit 8).[79] Three HHAs that we interviewed noted that remote visits were particularly useful because of COVID-19's infectious nature. For example, HHAs were able to provide services to patients who did not want providers in their homes, especially early in the pandemic. HHAs also described using telehealth to supplement care, such as through status checks for patients with chronic illnesses or COVID-19. One HHA told us that it made "daily phone calls to active COVID patients who were under quarantine to assess the need for an in-person visit." Notably, two HHAs that we interviewed told us that telehealth was useful for continuing to provide patient care despite staffing challenges.

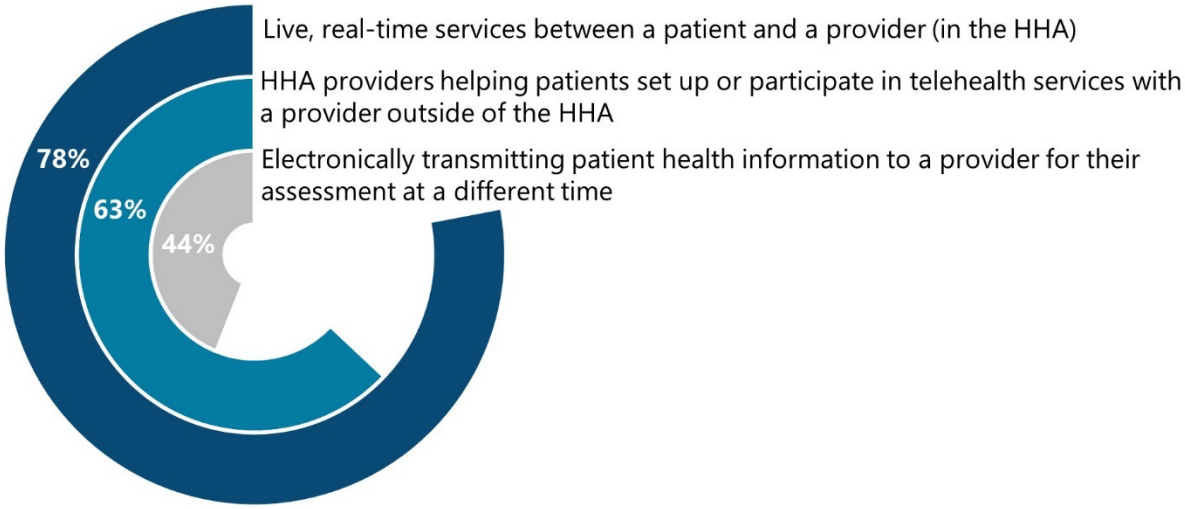
> "[Telehealth] helped us keep patients seen when they needed visits and keep them home and healthy."
> – Senior HHA staff

Although Medicare does not cover this use of telehealth under the home health benefit, nearly two-thirds of HHAs (63 percent) helped patients set up or participate in telehealth services with a non-HHA provider such as a physician. HHAs described using telehealth to facilitate remote communication with physicians and to meet certain requirements for home health care. For example, one HHA that we surveyed wrote that it "assisted patient[s] with telehealth visits with their physicians by setting up appointments and having a clinician with them to report specific vital signs and

other symptoms." Furthermore, half of the HHAs we interviewed reported that they would facilitate video calls between patients and physicians that, prior to the public health emergency, were required to be conducted in person.

Just under half of HHAs (44 percent) electronically transmitted health information to health care providers within and/or outside of the HHA. This may include electronically sending information for a health care provider to later assess. HHAs also reported using telehealth for remote patient monitoring, which involves leaving equipment such as heart rate monitors with patients so that the HHA can continue to monitor vital signs. One HHA that we surveyed told us that it used this for "vital sign assessments for heart failure or other chronic conditions."

Exhibit 8. HHAs used telehealth for different purposes during the pandemic.*



* Among HHAs that used telehealth during the pandemic.
Source: OIG analysis of survey data, 2022.

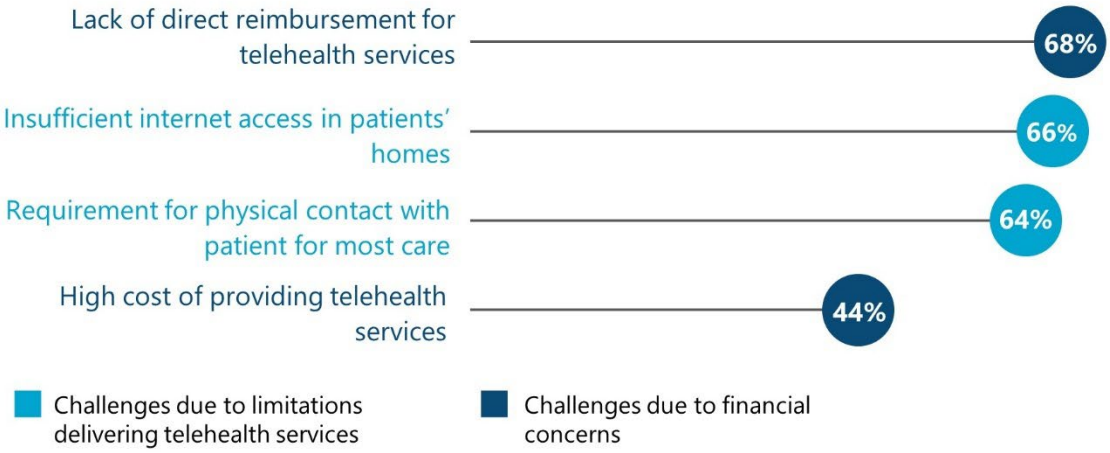
Challenges using telehealth in home health care may limit its future use

From the perspective of many HHAs that used telehealth during the pandemic, providing telehealth services often came with challenges (see Exhibit 9). Some challenges were due to limitations with delivering telehealth services. For example, home-based telehealth requires the patient's home to have access to phone service, internet, and equipment (such as a smartphone). About two-thirds of HHAs found that insufficient internet access in patients' homes was a challenge, and five HHAs that we interviewed told us that patients struggled with accessing phone service and equipment. In addition, almost two-thirds of HHAs found that most home care services require physical contact with patients, such as providing wound care, which

may affect the quality of care provided using telehealth. Three HHAs that we interviewed noted that assessing patients, for example to evaluate mobility when a patient is walking, is difficult to do over video. Other HHAs said that patients may be less capable of taking their own vital signs, such as blood pressure or heart rates, than are health care professionals. As a result, one HHA that we interviewed told us that self-reported health information, whereby patients assess their own vital signs and symptoms and communicate them to the HHA, "doesn't reflect the real situation or condition of the patient… [W]e can't get an accurate picture of our patient because of those limitations."

According to HHAs, they also experienced financial challenges with using telehealth (see Exhibit 9). Almost half of HHAs (44 percent) struggled with the high cost of telehealth. HHAs cannot bill Medicare for telehealth services as equivalent to an in-person visit, and two-thirds of HHAs found that this lack of direct reimbursement was a challenge. HHAs that we interviewed told us that lack of direct reimbursement meant they could not afford to use telehealth more frequently. For example, three HHAs that we interviewed noted that setting up and using telehealth, including purchasing the required equipment, is costly.

Exhibit 9. HHAs that used telehealth during the pandemic experienced challenges in providing telehealth services.



Source: OIG analysis of survey data, 2022.

Rural HHAs may experience greater challenges providing telehealth services compared to HHAs in other settings. Of the 31 rural HHAs that responded to our survey and used telehealth during the pandemic, 25 identified insufficient internet access as a challenge. HHAs serving patients in rural settings reported that their patients often live in locations with limited or no cellular service or internet access and have limited access to equipment necessary to facilitate telehealth services. One rural HHA that we surveyed told us: "We can't provide [t]elemedicine to patients unless there is adequate equipment in the home. In rural eastern Washington state, there is

often not. There is also often not internet or cell phone service in the home, making [t]elemedicine impossible."

HHAs that used telehealth during the pandemic were divided on whether they plan to continue using it after the pandemic, although government support to overcome challenges may influence this. Of the HHAs that used telehealth during the pandemic, 43 percent anticipated that they will not use it afterwards. HHAs said that they temporarily relied on telehealth to help address pandemic-specific challenges, such as monitoring high-risk COVID-19 patients or delivering services to patients who do not want providers in their homes. Almost half of the HHAs we interviewed told us that there is limited incentive to provide telehealth services, including after the pandemic, but that they might reconsider if they received direct reimbursement for these services.

43%

of HHAs that used telehealth during the pandemic will not use it afterwards

On the other hand, over half (57 percent) of HHAs that used telehealth during the pandemic anticipated that they will continue to use telehealth after the pandemic, including in ways that incorporate lessons learned. For example, one HHA that we interviewed created a more detailed telehealth-based virtual assessment for patients it considered at higher risk for rehospitalization, including COVID-19 patients. HHAs also acknowledged that although telehealth is not appropriate for all HHA-based care, telehealth may be better suited to certain home health services. One HHA that we surveyed told us that it thought CMS should reimburse HHAs for telehealth services that supplement in-person care: "provide reimbursement for virtual skilled nursing visits with patients as an adjunct to in-person visits (not as a replacement). This could minimize rehospitalizations."

CMS lacks full insight into HHAs' use of telehealth due to limited reporting requirements

HHAs report limited information about their telehealth use to CMS. CMS requires HHAs to report the direct costs of providing telehealth on their cost reports, but these do not include further detail on the types of services for which HHAs use telehealth.[80] HHAs cannot bill Medicare for telehealth visits as comparable to in-person visits and are currently not required to report telehealth use on their claims. Therefore, CMS is unable to capture specific details on the extent and nature of how HHAs use telehealth. CMS told us that these limitations affect the extent to which CMS can evaluate and review HHAs' telehealth use. For example, CMS cannot track the frequency with which HHAs use telehealth over time or the types of services they provide with telehealth.

CMS plans to assess available information on HHAs' telehealth use and to explore options to gather additional information. For example, in a calendar year (CY) 2021 final rule, CMS allowed HHAs to include remote patient monitoring and other

telehealth technology within cost reports as allowable administrative and general costs. CMS plans to assess these data when it receives those cost reports.[81] In June 2022, CMS issued a CY 2023 proposed rule allowing HHAs to voluntarily report telehealth use on claims starting January 2023.[82] The proposed rule, if enacted, will require this information by July 2023. However, Medicare could not directly reimburse these services without a change in statute. CMS is also soliciting comments on how it intends to capture telehealth use on claims as well as on the appropriateness of telehealth in the home health context. Currently, CMS also engages with HHAs and other stakeholders on both a regular and as-needed basis and may receive feedback on telehealth through these engagements. CMS acknowledges the importance of gaining a more complete picture of HHAs' telehealth use to inform future decision-making.

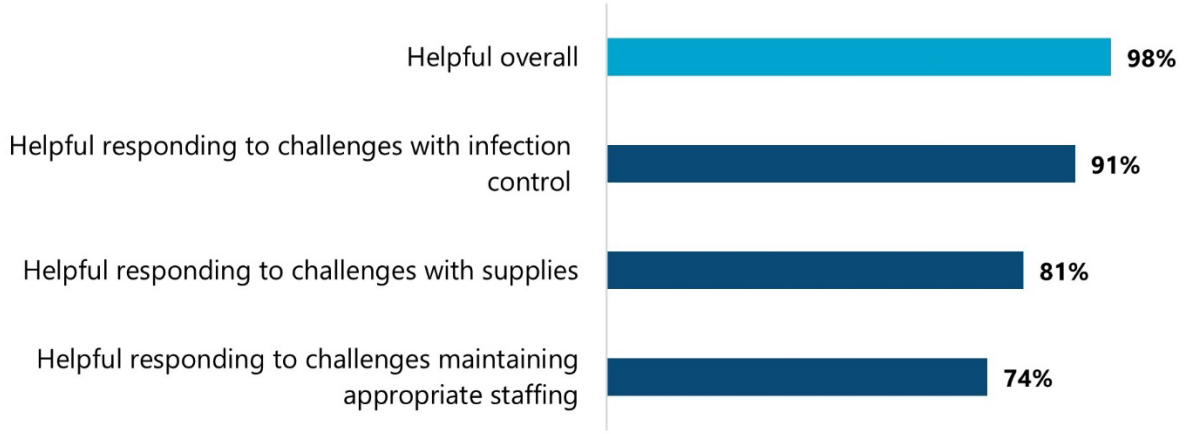
Emergency preparedness (EP) plans guided HHAs' response to the pandemic, but the plans fell short of fully addressing a global emergency such as COVID-19

CMS requires that HHAs conduct risk assessments to inform their EP plans. Risk assessments must use an all-hazards approach to consider a broad range of emergencies that may affect the HHA and its patient population. HHAs have wide latitude to determine the contents and structure of their EP plans. Because each risk assessment is specific to the HHA, EP plans vary on the basis of emergency scenarios HHAs identify and how HHAs plan to address these emergencies. This includes determining how to include emerging infectious diseases as part of their all-hazards risk assessment, as required by CMS in 2019.

Almost all HHAs with EP plans found them helpful with responding to the challenges of the COVID-19 pandemic

Nearly all HHAs (98 percent) that had an EP plan during the pandemic benefited from these plans, including with challenges related to infection control guidelines and accessing supplies (see Exhibit 10). Notably, 91 percent of HHAs with an EP plan during the pandemic found the plan to be helpful with addressing infection control challenges. One HHA that we interviewed told us that, prior to the pandemic, its EP plan included infection control guidelines based on other infectious diseases such as influenza and severe acute respiratory syndrome. Although these guidelines were not specific to COVID-19, they were helpful for reducing its transmission. In addition, 81 percent of HHAs that had an EP plan found them to be helpful with addressing supply challenges. For example, one HHA we spoke with explained that its local health and emergency departments became important resources for help with supplies when it was faced with pandemic-related shortages. That HHA developed relationships with those entities prior to the pandemic through emergency drills required by CMS.

Exhibit 10. HHAs that had EP plans during the pandemic found these EP plans helpful.



Source: OIG analysis of survey data, 2022.

About three-quarters (74 percent) of HHAs also found their EP plans to be helpful with addressing staffing challenges. A couple of HHAs that we interviewed described how their plans supported their responses by outlining each staff member's responsibilities during an emergency. According to one HHA, "if we didn't have an emergency management infrastructure in place I don't know if we would have had as effective of a response. Everyone knew their roles."

Because HHAs' EP plans generally focused on local, temporary emergencies, many fell short in a sustained, global emergency

Although EP plans provided a useful framework for responding to the pandemic, about half of HHAs that had an EP plan found it challenging that their EP plans were more suitable to a local emergency than to a national or global emergency such as COVID-19. CMS instructed HHAs to include emerging

51%

of HHAs with an EP plan found it challenging that their plan was more suitable to a local emergency than to a national or global emergency such as COVID-19

> "It's not like a fire, or earthquake, that hits a certain area or population and you use your EP to get through it, clean up the aftermath and move on. This pandemic is a disaster like no other, that has infiltrated every aspect of society…" – Senior HHA staff

infectious diseases in its 2019 EP plan guidance, and 93 percent of HHAs did so before the pandemic. However, nearly half of the HHAs we interviewed told us that their plans focused on emergencies that were more likely to affect their geographic area, such as weather events. One HHA described how its plan included information on responding to hurricanes, including contacting patients to determine plans for evacuation, but noted that this did not prepare it for COVID-19. Another HHA said that its EP plan did not originally cover situations in which staff could not enter patients' homes, as was the case during the COVID-19 pandemic. This HHA said that prior to the pandemic, it had not considered emergency preparedness "on a global platform."

HHAs adjusted their emergency planning to respond to COVID-19 and identified how CMS could further help them with this planning

To support their COVID-19 response, HHAs developed new, separate response plans as well as adjusting their existing EP plans. In fact, 85 percent of HHAs developed a separate response plan specific to COVID-19. These plans, which CMS does not require, included information on testing staff and patients for COVID-19, treating patients with COVID-19, and work-from-home policies, among other information. One HHA that we interviewed described a flow chart included in its COVID-19 plan that guides staff through determining whether an employee should isolate or quarantine after an exposure. In addition, as of fall 2021, almost all HHAs (97 percent) modified or planned to modify their existing EP plans to apply lessons learned during the pandemic. For example, one HHA that we interviewed updated its EP plan to include screening questions about whether patients had been exposed to any infectious disease, such as influenza. Another updated the supply policy in its EP plan to maintain a 90-day reserve of new supplies.

HHAs expressed that they would benefit from more support from CMS on developing and using their EP plans to meet the challenges of an infectious disease emergency. Of the HHAs that responded to our question, two-thirds (67 percent) said that CMS could better support HHAs by providing more information on the content and implementation of these EP plans during an infectious disease emergency. For example, one HHA suggested that CMS provide examples of guidelines that other HHAs used and found helpful when responding to an emerging infectious disease. Another HHA we surveyed requested that CMS provide more training on using EP plans to respond to an emerging infectious disease emergency.

> One senior HHA staff member recommended that CMS provide "designated training for HHAs to follow as guides for infectious disease emergencies that are at a national or global level."

Amidst the COVID-19 public health emergency, CMS has taken steps to help HHAs with their EP plans. In March 2021, CMS issued updated guidance for EP plans and prompted HHAs to include more information on emerging infectious diseases. CMS also told us that it plans to solicit and use feedback from providers, including HHAs, about their experiences during the public health emergency to make future changes to this guidance. Finally, CMS told us that it coordinates with ASPR TRACIE to offer HHAs additional guidance on emerging infectious diseases, including COVID-19.

CONCLUSION AND RECOMMENDATIONS

The COVID-19 pandemic presented substantial challenges for HHAs and their capacity to care for patients. The challenges included the novel nature of the virus, as well as challenges with staffing, infection control, supply shortages, and emergency planning, among others.

HHAs and CMS took steps to address these challenges as knowledge regarding the pandemic evolved. The regulatory flexibilities that CMS offered helped HHAs as they grappled with how to respond to the COVID-19 pandemic. HHAs used telehealth to fill gaps in their capacity to provide services and adjusted their emergency plans, in addition to other actions. Indeed, as knowledge about the virus increased, supply chains stabilized, and HHAs took steps to continue caring for patients, some of the earliest challenges abated.

However, HHAs' experiences responding to the pandemic point to continued challenges. With HHAs using telehealth in new ways, questions have emerged about whether and how it can best serve beneficiaries in the home health realm. In addition, staffing challenges—which were also present prior to the pandemic—persist, despite HHAs' use of regulatory flexibilities and their own efforts to address staffing.

As the immediacy of the pandemic lessens, CMS has an opportunity to assess how to best help HHAs prepare for and respond to current and future infectious disease outbreaks. Furthermore, changes to the home health care landscape, including expanded telehealth allowances, merit further study to understand how these changes best serve patients.

To that end, we recommend that CMS:

Evaluate how HHAs are using telehealth—specifically, the types of services provided via telehealth and the characteristics of patients who benefit from these services

CMS could use such an evaluation to refine its approach to telehealth in the home health environment. With CMS permanently allowing HHAs to use telehealth as part of a patient's plan of care, understanding the strengths and limitations of telehealth in home health is important to ensuring that patients receive beneficial and high-quality care. For example, home health patients may benefit from certain telehealth services, such as remote patient

monitoring or status checks, but may benefit less from other services through telehealth, such as physical therapy visits or wound care. Examining HHAs' telehealth use and its effects on access, equity, quality of care, and program integrity will provide vital insights into whether and how telehealth can best serve home health patients.

To better determine the types of services provided by telehealth and characteristics of patients who benefit from these services, CMS should collect and analyze data on HHAs' telehealth use. CMS is planning to examine telehealth information included on HHAs' cost reports once HHAs submit these data. CMS's CY 2023 proposed rule for home health allows HHAs to voluntarily report telehealth use on claims starting in January 2023. The proposed rule, if enacted, will require this information by July 23, 2023. CMS is also soliciting comments on how CMS intends to capture telehealth use on claims as well as the appropriateness of home health care via telehealth given the hands-on nature of many home health services. We encourage CMS to analyze claims data, as well as other relevant data it collects or identifies, if any, to evaluate HHAs' use of telehealth.

To inform decision-making, evaluate how the regulatory flexibilities it has offered in response to the COVID-19 public health emergency affect the quality of home health care

CMS has limited information on how flexibilities affected patient care during the public health emergency. CMS obtained feedback on the flexibilities through structured and ad hoc engagements with stakeholders during the public health emergency and used this feedback to inform decisions about which flexibilities to make permanent. However, CMS has not systematically evaluated these flexibilities, including the impact of these flexibilities on the quality of patient care.

CMS should conduct a systematic review to gain insights into how the flexibilities offered during the public health emergency—whether as a whole or individually, and including those that are now permanent—affect the quality of patient care. CMS could collect data from HHAs or analyze claims, assessment data, and/or patient feedback to examine changes in quality of care during the public health emergency that may relate to the flexibilities. CMS could use this review to inform decision-making regarding which flexibilities to use during future emergencies.

In collaboration with ASPR TRACIE, apply lessons learned from the COVID-19 pandemic to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks

CMS has an opportunity to provide additional support to HHAs responding to infectious disease emergencies, including those that are sustained and widespread. Indeed, HHAs told us that they desire and would benefit from more guidance. CMS already provides online trainings on emergency preparedness for health care providers and also collaborates with ASPR TRACIE to support HHAs' emergency preparedness, including by conducting technical reviews of ASPR TRACIE materials for HHAs.

CMS has solicited feedback from providers, including hospitals and nursing homes, on their experiences using their EP plans during COVID-19. CMS should also directly engage with HHAs on their experiences using their EP plans. CMS should share feedback with ASPR TRACIE, and, in collaboration with ASPR TRACIE, use this feedback as well as the findings of this study to inform emergency preparedness trainings and materials (whether as updates to existing resources or to develop new resources). These trainings and materials should reflect lessons learned from the COVID-19 pandemic. To guide these efforts, CMS could review existing CMS and ASPR TRACIE emergency preparedness resources, including those that are currently under development, to identify opportunities to incorporate lessons learned. For identified opportunities, CMS could collaborate with ASPR TRACIE to develop new, or modify existing, resources.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with all three of our recommendations, as detailed below.

First, CMS concurred with our recommendation to evaluate how HHAs are using telehealth—specifically, the types of services provided via telehealth and the characteristics of patients who benefit from these services. In the CY 2023 Home Health Prospective Payment System proposed rule, CMS stated its plans to require that HHAs report the use of telehealth on home health claims beginning July 2023. Collecting this information is vital to understanding the strengths and limitations of telehealth in the home health environment, as well as the characteristics of patients who benefit from telehealth services. We look forward to updates in CMS's Final Management Decision on both its evaluation of HHAs' use of telehealth as well as how patients have benefited from these services.

Second, CMS concurred with our recommendation to evaluate how regulatory flexibilities offered during the COVID-19 public health emergency affect the quality of home health care. CMS stated that it is holding listening sessions seeking feedback from providers, including HHAs, on what flexibilities have been the most or least helpful during the public health emergency. In its Final Management Decision, CMS should detail its efforts to systematically review how the flexibilities offered during the COVID-19 public health emergency, either individually or as a whole, affected the quality of patient care.

Third, CMS concurred with our recommendation to collaborate with ASPR TRACIE to apply lessons learned from the COVID-19 pandemic to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks. CMS stated that it recently published case studies of how 30 nursing homes and hospitals responded to challenges during the onset of the COVID-19 pandemic. In this report, we recommend that CMS engage directly with HHAs on their experiences using EP plans during the pandemic. In its Final Management Decision, CMS should describe its direct engagement with HHAs, as well as its steps to collaborate with ASPR TRACIE, to update and/or develop emergency preparedness trainings and materials for the home health environment.

For the full text of CMS's comments, see the appendix at the end of this report.

DETAILED METHODOLOGY

This study used the following data sources: (1) a survey of a random sample of HHAs; (2) interviews with a purposive sample of 12 HHAs; and (3) an interview with CMS staff.

Scope

This study focuses on Medicare-participating HHA experiences from early in the pandemic to the point that OIG surveyed or interviewed HHAs in September through December 2021. As part of the survey and interviews, we asked HHAs about challenges experienced early in the pandemic and in fall 2021. We defined "early in the pandemic" to mean when the respondent HHA's geographic area experienced its first wave of COVID-19 infection.

Sample

We selected a nationally representative, simple random sample of 400 Medicare/Medicaid-participating HHAs to ask about their experiences during the COVID-19 pandemic. We selected the random sample from among the 11,418 HHAs listed in CMS's Certification and Survey Provider Enhanced Reporting (CASPER) system as of June 2021.[83] Of the 400 sampled HHAs, we removed 19 closed HHAs and 4 HHAs that participated only in Medicaid, bringing the total to 377 HHAs included in our sample.[84]

Survey

We sent an electronic survey to the sampled HHAs between September 21, 2021, and November 22, 2021; 271 HHAs responded, for a 72-percent response rate. We contacted each HHA with at least two letters and a phone call before determining that an HHA was a nonrespondent.[85] We project our sample to the 72 percent of the 11,265 Medicare-participating HHAs represented by our respondents. We conducted a nonresponse analysis to assess whether nonresponding and responding HHAs in our sample differed with regard to certain variables. See Appendix C for a description of our nonresponse bias analysis.

The survey included questions about HHAs' challenges during the COVID-19 pandemic; strategies to address these challenges; and the use of telehealth, regulatory flexibilities, and emergency preparedness plans during the pandemic. It also collected background information about the HHA. We produced estimates from these survey data to describe the experiences of Medicare-participating HHAs represented by our respondents during the pandemic. We performed t-tests to determine statistically significant differences in the proportions of HHAs experiencing challenges early in the pandemic compared to at the time of the survey. Significant

differences were determined at the 0.05 level. See Appendix D for estimates and p-values, where appropriate.

We analyzed open-ended survey responses by categorizing these responses by theme. We used open-ended survey responses to add context to our survey estimates and provide insight into HHAs' experiences during the COVID-19 pandemic, including challenges and strategies used to address challenges. We counted the number of responses that directly answered the survey question to produce estimates from these data.

Rural HHA Analysis

To identify HHAs as rural, we obtained 2019 Medicare claims data for the HHAs in our sample and determined the percentage of care episodes HHAs provided to Medicare beneficiaries in rural Core Based Statistical Areas (CBSAs). We used 2019 Medicare claims data because 2019 is the most recent year for which claims are complete.[86] We defined rural HHAs as HHAs that provided 50 percent or more of their care episodes in rural CBSAs.[87] We identified 41 rural HHAs that responded to our survey (18 percent of respondents with 2019 Medicare claims).[88]

We analyzed rural HHAs' survey responses to describe the experiences of rural HHAs in our sample during the COVID-19 pandemic. We do not generalize these responses to all rural HHAs.

Stakeholder Interviews

We interviewed staff from a purposive sample of 12 HHAs in November and December 2021. We selected these HHAs on the basis of survey responses that indicated notable challenges, strategies, or other experiences that may be useful to CMS, the HHA industry, and other stakeholders. We use data from these interviews to add context to our survey data and provide insight into HHAs' experiences during the COVID-19 pandemic. We do not use these interviews to generalize to all HHAs. Of the 12 HHAs we interviewed, we identified 4 as rural on the basis of their 2019 Medicare claims.

We also interviewed CMS staff in the Center for Clinical Standards and Quality and Center for Medicare on January 21, 2022. We asked about CMS's support of, and perspectives on, HHAs providing care during the pandemic, including (1) guidance that CMS provided to HHAs; (2) HHAs' use of regulatory flexibilities provided by CMS; (3) HHAs' challenges with staffing and PPE; (4) HHAs' use of telehealth; and (5) HHAs' use of emergency preparedness plans and development of COVID-19-specific response plans.

APPENDICES

Appendix A: CMS Conditions of Participation (CoPs): Infection Prevention and Control

CMS requires HHAs to maintain and document an infection control program to prevent and control infections and communicable diseases.[89] To achieve compliance with the CoP for infection prevention and control, HHAs must meet four standards:

- Prevention: HHAs must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.
- Control: HHAs must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases.
- Education: HHAs must provide infection control education to staff, patients, and caregivers.
- COVID-19 vaccination of home health agency staff: As of December 6, 2021, CMS requires COVID-19 vaccinations for HHA staff. HHAs must develop and implement policies and procedures to ensure that all staff receive required vaccinations for COVID-19.[90]

Appendix B: Regulatory Flexibilities and Supports for Home Health Agencies During the COVID-19 Public Health Emergency (PHE)

Regulatory flexibility or support	Relevant regulation (if applicable)	Status as of summer 2022
Extend the 5-day completion requirement for the comprehensive assessment to 30 days	42 CFR § 484.55(b)(1)	Waiver in effect for the duration of the PHE for COVID-19.[91]
Waive the 30-day Outcome and Assessment Information Set (OASIS) submission requirement. HHAs must submit OASIS data prior to submitting their final claim in order to receive Medicare payment.	42 CFR § 484.45(a)	Waiver in effect for the duration of the PHE for COVID-19.[92]
Allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review	42 CFR § 484.55(a)	Waiver in effect for the duration of the PHE for COVID-19.[93]
Allow the required face-to-face encounter for home health services to be conducted via two-way audio-visual telecommunications technology from the patients' home	42 CFR § 424.22(a)(1)(v)(B)	Waiver in effect for the duration of the PHE for COVID-19.[94]
Waive requirement for an onsite visit by a nurse every two weeks	42 CFR § 484.80(h)	Waiver in effect for the duration of the PHE for COVID-19.[95]
Waive requirement for a nurse supervisory assessment of home health aide services every two weeks	42 CFR § 484.80(h)(1)	Waiver in effect for the duration of the PHE for COVID-19.[96]

Authorize "allowed practitioners," in addition to physicians, to certify beneficiaries for eligibility, order home health services, and establish and review the care plan. (Allowed practitioners are defined at 42 § CFR 484.2 as physician assistants, nurse practitioners, or clinical nurse specialists.)	42 CFR § 484.55(a)(2) and § 484.55(b)(3)	Flexibility made permanent in the Coronavirus Aid, Relief, and Economic Security Act.[97]
Postpone deadline to completing requirement that each home health aide receive 12 hours of in-service training in a 12-month period	42 CFR § 484.80(d)	Waiver in effect for the duration of the PHE for COVID-19.[98]
Allow occupational therapists, physical therapists, and speech language pathologists to perform initial and comprehensive assessment for all patients receiving therapy services	42 CFR § 484.55(a)(2) and § 484.55(b)(3)	Occupational therapist flexibility made permanent in the Consolidated Appropriations Act, 2021.[99] Specifically, the rule made permanent the flexibility allowing occupational therapists to complete the initial and comprehensive assessments for patients when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are not initially in the plan of care.
Allow HHAs to use telehealth for visits and services within the patient's plan of care, as long as the telehealth services do not replace needed in-person visits	42 CFR § 409.43(a)	Flexibility made permanent in Calendar Year 2021 Home Health Prospective Payment System Final Rule.[100]

Waive requirements to provide detailed information regarding discharge planning to patients and their caregivers, or the patient's representative in selecting a post-acute care provider, by using and sharing data that includes, but is not limited to, (another) HHA, skilled nursing facility, inpatient rehabilitation facility, and long-term care hospital quality measures and resource use measures	42 CFR § 484.58(a)	Waiver in effect for the duration of the PHE for COVID-19.[101]
Extend deadline to provide a patient with a copy of their clinical record from 4 days to 10 days	42 CFR § 484.110(e)	Waiver in effect for the duration of the PHE for COVID-19.[102]
Postpone requirement for nurse to make an annual onsite supervisory visit (direct observation) of home health aide services	42 CFR § 484.80(h)(1)(iv)	Waiver in effect for the duration of the PHE for COVID-19.[103]
Narrow scope of Quality Assurance and Performance Improvement (QAPI) to concentrate on infection control issues	42 CFR § 484.65(a)–(d)	Waiver in effect for the duration of the PHE for COVID-19.[104]
Exempt HHAs from the Home Health Quality Reporting Program (QRP) reporting requirements. The time period covered by this exemption is October 1, 2019, through June 30, 2020.	42 CFR § 484.245	Waiver no longer in effect. HHAs were required to resume quality reporting data submission on July 1, 2020.[105]
Implement a policy to align Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the	42 CFR § 484.315(b)	Waiver in effect for the duration of the PHE.[106]

Home Health QRP during the PHE for the COVID-19 pandemic, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for the COVID-19 pandemic		
Allow Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payments during emergencies	42 CFR § 484.205(h)(2)(iv)	Waiver in effect for the duration of the PHE for COVID-19.[107]
Allow HHAs that participate in the Review Choice Demonstration (RCD) for Home Health Services to pause their participation for the duration of the PHE		Waiver no longer in effect. CMS resumed RCD operations on August 3, 2020.[108]
Delay cost report filing deadlines for cost reporting periods ending between October 1, 2019, and December 31, 2020	42 CFR § 413.24(f)(2)(i)	Waiver no longer in effect. CMS resumed regular cost report deadlines.[109]

Appendix C: Analysis of Nonresponse Bias

To examine the extent of potential nonresponse bias, we compared whether our 271 respondent HHAs differed from the nonrespondents and the population of 11,265 Medicare-participating HHAs (as of June 2021) on certain characteristics. Specifically, we examined the number of branches operated by HHAs, the location of HHAs in rural or urban Core Based Statistical Areas, and the number of staff employed by HHAs. These characteristics did not significantly differ between our respondent HHAs, nonrespondent HHAs, and all HHAs within our scope. Although these comparisons do not preclude the possibility of nonresponse bias, they suggest that our respondent HHAs are similar to the nonrespondents and the population of Medicare-participating HHAs.

We also examined how our survey results would have changed if all nonrespondent HHAs in our sample had responded differently from our respondent HHAs (e.g., the worst-case scenario). For, example, our projection pertaining to telehealth usage (73 percent) would have changed from 73 percent to 52 percent, which is still a majority. Given that the nonrespondents were similar to the respondents in the characteristics we examined, a more reasonable scenario is that some of the nonrespondents would have agreed with the respondents and the realized bias may be small.

Appendix D: Home Health Agencies' Responses to OIG's Survey

HHA experiences with staffing during the COVID-19 pandemic

Description	Sample size	Point estimate	95% confidence interval
Challenges with HHAs' staffing during the COVID 19 pandemic			
Clinical staff leaving this HHA to work for other health care facilities or health care contract agencies			
Early pandemic challenge	271	50.9%	45.1-56.8%
Pandemic challenge as of fall 2021	271	40.2%	34.6-46.1%
			p-value <0.0001
Recruiting new clinical staff due to increased competition from other health care facilities or health care contract agencies			
Early pandemic challenge	271	70.8%	65.2-75.9%
Pandemic challenge as of fall 2021	271	62.4%	56.5-67.9%
			p-value=0.0018
Paying contracted clinical staff due to higher contracting costs during the pandemic			
Early pandemic challenge	271	48.7%	42.9-54.6%
Pandemic challenge as of fall 2021	271	43.5%	37.8-49.4%
			p-value=0.0475
Limited staff availability to work due to personal circumstances related to the pandemic (e.g., lack of childcare due to school closures)			
Early pandemic challenge	271	84.5%	79.8-88.3%
Pandemic challenge as of fall 2021	271	55.4%	49.5-61.1%
			p-value <0.0001
Limited staff availability to work because of self-quarantine/isolation due to COVID-19 exposure			
Early pandemic challenge	271	85.2%	80.6-88.9%
Pandemic challenge as of fall 2021	271	55.4%	49.5-61.1%
			p-value <0.0001
Strategies used to address challenges with HHAs' staffing during the COVID 19 pandemic			
Provided staff benefits to address COVID-19-related concerns (e.g., childcare, flex time, transportation assistance)			
Used and found helpful	271	59.4%	53.5-65.0%
Used but did not find helpful	271	6.3%	4.0-9.8%
Did not use	271	34.3%	29.0-40.1%
Trained staff to perform tasks outside of their usual duties (e.g., administrative work or duties in a different clinical area)			
Used and found helpful	271	57.6%	51.7-63.2%
Used but did not find helpful	271	4.4%	2.6-7.6%
Did not use	271	38.0%	32.5-43.8%
Provided paid and/or unpaid leaves of absence to retain staff that are unable to work			
Used and found helpful	271	64.6%	58.8-70.0%
Used but did not find helpful	271	10.0%	7.0-14.1%
Did not use	271	25.5%	20.7-30.9%

Created specialized care teams of clinical staff who only treat COVID-19 patients

Used and found helpful	271	39.9%	34.3-45.7%
Used but did not find helpful	271	5.2%	3.1-8.5%
Did not use	271	55.0%	49.1-60.7%

Developed new or used existing partnerships with other HHAs or health care facilities to share staff to fill staffing gaps

Used and found helpful	271	26.6%	21.7-32.1%
Used but did not find helpful	271	6.6%	4.3-10.2%
Did not use	271	66.8%	61.0-72.1%

Use of CMS regulatory flexibilities and supports to help address staffing challenges

Extend the 5-day completion requirement for the comprehensive assessment to 30 days

Used and found helpful	271	54.2%	48.4-60.0%
Used but did not find helpful	271	3.7%	2.0-6.7%
Did not use	271	42.1%	36.4-47.9%

Authorize additional practitioners to certify beneficiaries for eligibility, order home health services, and establish and review the care plan

Used and found helpful	271	80.1%	75.0-84.4%
Used but did not find helpful	271	1.5%	0.6-3.8%
Did not use	271	18.5%	14.3-23.4%

Waive requirement for onsite visits by a nurse every 2 weeks

Used and found helpful	271	48.0%	42.2-53.8%
Used but did not find helpful	271	3.3%	1.8-6.2%
Did not use	271	48.7%	42.9-54.6%

Allow occupational therapists, physical therapists, and speech language pathologists to perform initial and comprehensive assessment for all patients receiving therapy services

Used and found helpful	271	64.2%	58.4-69.6%
Used but did not find helpful	271	4.8%	2.8-8.0%
Did not use	271	31.0%	25.8-36.7%

Postpone deadline to completing requirement that each home health aide receives 12 hours of in-service training in a 12-month period

Used and found helpful	271	40.6%	35.0-46.5%
Used but did not find helpful	271	3.0%	1.5-5.7%
Did not use	271	56.5%	50.6-62.2%

HHA experiences with infection control during the COVID-19 pandemic

Description	Sample size	Point estimate	95% confidence interval
Challenges with infection control during the COVID 19 pandemic			
Unclear State/Federal guidance about how to treat COVID-19 patients			
Early pandemic challenge	271	88.6%	84.3-91.8%
Pandemic challenge as of fall 2021	271	19.6%	15.3-24.6%
			p-value <0.0001
Navigating evolving guidance about how to treat COVID-19 patients			
Early pandemic challenge	271	87.1%	82.6-90.5%
Pandemic challenge as of fall 2021	271	25.5%	20.7-30.9%
			p-value <0.0001
Unclear or conflicting State/Federal guidelines about COVID-19 infection prevention and control			
Early pandemic challenge	271	88.2%	83.8-91.5%
Pandemic challenge as of fall 2021	271	24.4%	19.7-29.7%
			p-value <0.0001
Access to masks (not other types of personal protective equipment (PPE))			
Early pandemic challenge	271	92.6%	88.9-95.2%
Pandemic challenge as of fall 2021	271	13.7%	10.1-18.2%
			p-value <0.0001
Access to other types of PPE (not masks)			
Early pandemic challenge	271	91.1%	87.2-94.0%
Pandemic challenge as of fall 2021	271	15.1%	11.4-19.8%
			p-value <0.0001
Access to sanitizing products (e.g., sanitizing wipes, hand sanitizer)			
Early pandemic challenge	271	94.5%	91.1-96.6%
Pandemic challenge as of fall 2021	271	8.9%	6.0-12.8%
			p-value <0.0001
High cost of PPE during the pandemic			
Early pandemic challenge	271	88.6%	84.3-91.8%
Pandemic challenge as of fall 2021	271	42.4%	36.8-48.3%
			p-value <0.0001
Strategies used to address infection control challenges during the COVID 19 pandemic			
Developed internal COVID-19 infection control protocols for staff			
Used and found helpful	271	96.7%	93.8-98.2%
Used but did not find helpful	271	1.5%	0.6-3.8%
Did not use	271	1.8%	0.8-4.3%
Increased or improved clinical staff training on COVID-19 treatment			
Used and found helpful	271	94.8%	91.5-96.9%
Used but did not find helpful	271	3.3%	1.8-6.2%
Did not use	271	1.8%	0.8-4.3%

Provided PPE training for clinical staff			
Used and found helpful			92.9-97.7%
Used but did not find helpful	271	1.5%	0.6-3.8%
			1.2-5.3%
Found nontraditional sources for PPE (e.g., nail salons, tattoo parlors)			
Used and found helpful			26.2-37.1%
Used but did not find helpful	271	4.8%	2.8-8.0%
			58.0-69.3%
Conserved PPE (e.g., re-used PPE normally meant for single use, prioritized certain types of PPE for highest-risk activities)			
Used and found helpful			51.3-62.9%
Used but did not find helpful	271	8.5%	5.7-12.4%
			29.0-40.1%
Developed new or used existing partnerships with other HHAs or health care facilities to obtain or pool supplies			
Used and found helpful			36.8-48.3%
Used but did not find helpful	271	7.4%	4.8-11.1%
			44.3-56.0%
Postponed accepting patients with positive COVID-19 diagnosis until HHA had adequate infection control protocols			
		44.3%	

Telehealth use during the COVID-19 pandemic

Description	Sample size	Point estimate	95% confidence interval
HHA **used** telehealth during the pandemic	271	72.7%	67.2-77.6%
HHA **did not use** telehealth during the pandemic	271	27.3%	22.4-32.8%
HHAs that provided telehealth services during the COVID 19 pandemic			
Mode of telehealth services during the pandemic			
Live, real-time services between a patient and a health care provider (in the HHA)			
Used	197	78.2%	72.0-83.3%
Did not use	197	21.8%	16.7-28.0%
Patient health information is electronically transmitted to a health care provider for their assessment at a different time			
Used	197	44.2%	37.5-51.1%
Did not use	197	55.8%	48.9-62.5%
HHA providers helped patients set up or participate in telehealth services with another provider (outside of the HHA)			
Used	197	62.9%	56.1-69.3%
Did not use	197	37.1%	30.7-43.9%

Challenges using telehealth during the pandemic			
High cost of providing telehealth services			
Challenge	197	44.2%	37.5-51.1%
Not a challenge	197	55.8%	48.9-62.5%
Insufficient internet access in patients' homes			
Challenge	197	66.5%	59.7-72.7%
Not a challenge	197	33.5%	27.3-40.3%
Lack of direct reimbursement for telehealth services (other than for administrative costs)			
Challenge	197	67.5%	60.8-73.6%
Not a challenge	197	32.5%	26.4-39.2%
Most care required physical contact with patient			
Challenge	197	63.5%	56.6-69.8%
Not a challenge	197	36.5%	30.2-43.4%
Will this HHA continue to use telehealth after the pandemic?			
Yes	197	56.9%	49.9-63.5%
No	197	43.1%	36.5-50.1%

Note: In the survey, we used the term "telemedicine" rather than "telehealth."

Emergency preparedness and response

Description	Sample size	Point estimate	95% confidence interval
COVID 19-specific response plans			
HHAs that had a COVID-19 response plan			
HHA had a COVID-19 response plan	271	84.9%	80.2-88.6%
HHA did not have a COVID-19 response plan	271	15.1%	11.4-19.8%
CMS required emergency preparedness (EP) plan			
Overall, EP plan helpfulness in responding to the pandemic (of those with an EP plan during the pandemic)			
Helpful	267	98.1%	95.6-99.2%
Not helpful	267	1.9%	0.8-4.4%
EP plan helpfulness in responding to infection control challenges due to the pandemic (of those with an EP plan during the pandemic)			
Helpful	267	90.6%	86.6-93.6%
Not helpful	267	3.7%	2.0-6.8%
Not applicable	267	5.6%	3.4-9.1%
EP plan helpfulness in responding to supply challenges due to the pandemic (of those with an EP plan during the pandemic)			
Helpful	267	80.9%	75.8-85.1%
Not helpful	267	12.7%	9.3-17.2%
Not applicable	267	6.4%	4.0-9.9%

EP plan helpfulness in responding to staffing challenges due to the pandemic (of those with an EP plan during the pandemic)			
Helpful	267	74.2%	68.7-79.0%
Not helpful	267	14.6%	10.9-19.3%
Not applicable	267	11.2%	8.0-15.5%
HHAs that experienced the challenge that their EP plan was more suitable to a local emergency than a national or global emergency such as the pandemic (of those with an EP plan during the pandemic)			
Challenge	267	50.6%	44.7-56.4%
Not a challenge	267	49.4%	43.6-55.3%
HHAs that will modify or have modified their EP plan to include lessons learned from the COVID-19 pandemic (of those with an EP plan during the pandemic)			
HHA has already modified OR will modify its EP plan to include lessons learned from the pandemic	267	96.6%	93.7-98.2%
HHA has not modified and will not modify its EP plan to include lessons learned from the pandemic	267	3.4%	1.8-6.3%
HHAs with an EP plan that included an infectious disease component prior to the pandemic. ***Note: Among HHAs that had an EP plan prior to the pandemic.***			
HHA did not have an EP plan with an infectious disease component	254	7.1%	4.5-10.9%
HHA had an EP plan with an infectious disease component	254	92.9%	89.1-95.5%

How could CMS better support HHAs in using EP plans to respond to emerging infectious diseases? (open ended responses)			
HHA suggested information about EP plan content and/or implementation in response to this question	88	67.0%	56.8-75.9%
HHA **did not** suggest information about EP plan content and/or implementation in response to this question	88	33.0%	24.1-43.2%

Rural HHA experiences*

Rural HHA experiences with staffing challenges	
Limited staff availability to work because of self-quarantine/isolation due to COVID-19 exposure	
Challenge	39
Not a challenge	2

Rural HHA experiences with infection control and prevention challenges	
Unclear or conflicting State/Federal guidelines about COVID-19 infection prevention and control	
Early challenge	34
Not an early challenge	7
Access to masks (not other types of personal protective equipment (PPE))	
Early challenge	37
Not an early challenge	4
Access to other types of PPE (not masks)	
Early challenge	37
Not an early challenge	4

Access to sanitizing products (e.g., sanitizing wipes, hand sanitizer)	
Early challenge	38
Not an early challenge	3

Rural HHA experiences with telehealth during the pandemic	
HHA **used** telehealth during the pandemic	31
HHA **did not use** telehealth during the pandemic	10
Challenges with insufficient internal access in patients' homes	
Challenge	25
Not a challenge	6

* We were unable to project due to limited sample size.

Note: Because of rounding, not all percentages may add up to 100 percent.

Appendix E: Agency Comments

Following this page are the official comments from CMS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 22, 2022

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Home Health Agencies Used Multiple Strategies to Respond to the COVID-19 Pandemic, Although Some Challenges Persist (OEI-01-21-00110)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to supporting home health agencies (HHAs) during health emergencies so they may care for people with Medicare in the home setting while protecting them from the spread of infectious diseases. CMS is using lessons learned during the COVID-19 public health emergency (PHE) to improve quality of care and equitable access to CMS benefits, services, and supports.

Throughout the COVID-19 PHE, CMS has used a combination of emergency authority waivers, regulations, enforcement discretion, survey flexibilities, and sub-regulatory guidance to help ensure access to care, give health care providers the flexibilities needed to respond to COVID-19, and help keep people safer. Flexibilities offered during the COVID-19 PHE supported HHAs in addressing staffing challenges, especially early on in the COVID-19 PHE. For example, a statutory change enabled CMS to allow additional practitioners to certify beneficiaries for eligibility, order home health services, and establish and review care plans. The use of telehealth to furnish home health services was finalized on a permanent basis in the calendar year (CY) 2021 Home Health Prospective Payment System final rule.[1] However, such services cannot be reported as a visit on home health claims for the purposes of eligibility or payment.

Many of the waivers and flexibilities will terminate at the end of the COVID-19 PHE or after the 151st day after the end of the PHE, as they were intended to address the acute and extraordinary circumstances of a rapidly evolving pandemic and not replace existing requirements. Some were made permanent through the passage of new laws. For example, Division CC, section 115 of the Consolidated Appropriations Act of 2021, made permanent the flexibility that occupational therapists could conduct initial and comprehensive assessments for patients when certain requirements relating to the plan of care are met.

[1] *Federal Register*: "Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements; Final Rule (85 FR 70298) (November 4, 2020)."

CMS continues to support stakeholders and the people we serve during the current phase of the COVID-19 PHE while looking forward to a health system that successfully emerges from the COVID-19 PHE focused on improving quality and safety. CMS is also monitoring the status of the COVID-19 PHE and has begun phasing out certain flexibilities that are generally no longer needed. To understand how blanket flexibilities and those specific to HHAs were used on the front lines during the COVID-19 PHE, CMS received feedback from the HHA industry, national HHA organizations, and from subject matter experts. This information helped inform waiver disposition decisions and identify groups of waivers that may be helpful in future PHE response activities. CMS recently released fact sheets to summarize the current status of Medicare blanket waivers and flexibilities by provider type, including HHAs.[2]

Long before the COVID-19 PHE began, CMS had acted to strengthen infection prevention and control practices for HHAs and other provider types. CMS took pivotal actions in the 2016 final rule, "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers," which outlined the need for providers to prepare for infectious disease threats.[3] In March 2020, CMS issued guidance to HHAs encouraging them to take appropriate action to address potential and confirmed COVID-19 cases and mitigate transmission, including screening, treatment and transfer to higher level care (when appropriate).[4] CMS also held Open Door Forum calls specific to HHAs since 2016 and added additional COVID-19 calls during the COVID-19 PHE, which continue to date. CMS meets regularly with stakeholders, such as the National Association for Home Care and Hospice, to discuss issues affecting the HHA community. In addition, CMS's Quality Safety and Education Portal provides current trainings on various CMS survey and certification requirements.[5] These trainings are used by surveyors but are also free of charge and available to the public by choosing the "public access" link on the portal.

CMS thanks OIG for its efforts on this important issue and looks forward to working with OIG on this and other issues in the future. OIG's recommendations and CMS's responses are below.

OIG Recommendation

Evaluate how HHAs are using telehealth—specifically, the types of services provided via telehealth and the characteristics of patients who benefit from these services.

CMS Response

CMS concurs with this recommendation. CMS finalized policy changes regarding the use of services furnished via telecommunications systems in the CY 2021 Home Health Prospective Payment System final rule.[6] HHAs can utilize telecommunications technologies in providing care to beneficiaries under the Medicare home health benefit, as long as any provision of remote patient monitoring or other services furnished via a telecommunications system or audio-only technology are included on the plan of care. The use of such telecommunications technology or audio-only

[2] CMS, Home Health Agencies: CMS Flexibilities to Fight COVID-19. August, 18, 2022. Accessed at https://www.cms.gov/files/document/home-health-agencies-cms-flexibilities-fight-covid-19.pdf

[3] Medicare and Medicaid Programs; Emergency Preparedness Requirements, 81 FR 63860, 63862 (Sept. 16, 2016). Accessed at https://www.federalregister.gov/documents/2016/09/16/2016-21404/medicare-and-medicaid-programs-emergency-preparedness-requirements-for-medicare-and-medicaid

[4] CMS, Guidance for Infection Control and Prevention Concerning Coronavirus Disease 2019 (COVID-19) in Home Health Agencies (HHAs). March 10, 2020. Accessed at https://www.cms.gov/files/document/qso-20-18-hha.pdf

[5] CMS, Quality, Safety & Education Portal (QSEP). Accessed at https://qsep.cms.gov/

[6] *Federal Register*: "Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements; Final Rule (85 FR 70298) (November 4, 2020)"

technology must be tied to patient-specific needs as identified in the comprehensive assessment, and may not substitute for an in-person home visit that is ordered on the plan of care. In addition, the law [7] explicitly states that home health services furnished via telecommunications technology cannot be considered a visit for the purpose of patient eligibility or payment.

Currently, the collection of data on the use of telecommunications technology under the home health benefit is limited to a broad category of telecommunications technology costs under administrative costs on the HHA cost reports (reported at the agency level). The CY 2023 Home Health Prospective Payment System proposed rule solicited comments on the collection of data on the use of such services furnished using telecommunications technology on the home health claims (at the individual beneficiary level).[8] Collecting data on the use of telecommunications technology on home health claims would allow CMS to analyze the characteristics of the beneficiaries utilizing services furnished remotely, and could provide a broader understanding of the social determinants that affect who benefits most from these services, including what barriers may potentially exist for certain subsets of beneficiaries. CMS aims to collect such data on home health claims by January 1, 2023 on a voluntary basis by HHAs, and plans begin to requiring this information to be reported on claims beginning July 2023. CMS will consider OIG's recommendation along with comments submitted on the proposed rule when finalizing the rule.

OIG Recommendation

To inform decision-making, evaluate how regulatory flexibilities offered during the COVID-19 pandemic affect quality of home health care.

CMS Response

CMS concurs with this recommendation to evaluate the effects of waivers to the extent it is possible to do so. While it may be difficult to make direct links from waivers to quality and health outcomes, CMS is using lessons learned during the COVID-19 PHE to improve quality of care in home care settings to ensure equitable access to CMS benefits, services and supports. CMS is monitoring the status of the COVID-19 PHE and has begun phasing out certain flexibilities that are generally no longer needed. CMS released fact sheets to summarize the current status of Medicare blanket waivers and flexibilities by provider type, including HHAs.[9]

Given the unprecedented length and scope of the COVID-19 PHE, CMS has systematically reviewed all the emergency measures, regulatory flexibilities, and related programs enacted during the COVID-19 PHE on an ongoing basis since 2020 to assess the appropriateness of continuing those flexibilities or of retaining some as a permanent part of CMS programs, as permitted under the law. To understand how HHAs used flexibilities during the COVID-19 PHE, CMS received feedback from the HHA industry, national HHA organizations, and from subject matter experts. This information helped inform waiver disposition decisions and identify groups of waivers that may be helpful in future PHE response activity. For example, as part of the CY 2022 Home Health Prospective Payment System final rule, CMS finalized the provision for aide supervision for

[7] Section 1895(e)(1)(A) of the Social Security Act. Accessed at https://www.ssa.gov/OP_Home/ssact/title18/1895.htm

[8] *Federal Register*: "Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements; Proposed Rule (87 FR 37600) (June 23, 2022)"

[9] CMS, Home Health Agencies: CMS Flexibilities to Fight COVID-19, September 1, 2022. Accessed at https://www.cms.gov/files/document/home-health-agencies-cms-flexibilities-fight-covid-19.pdf

patients receiving skilled care every 14 days to now allow for one virtual visit per 60-day episode per patient and only in rare circumstances.[10]

CMS is also in the process of holding a series of listening sessions seeking feedback from providers, including HHAs, on what specific flexibilities, if any, have been the most or least helpful. While it is challenging to isolate the many compounding factors that affect quality of care and conclude that individual waivers were the sole contributor to changes in patient outcomes, especially given the unique circumstances of the COVID-19 PHE and data limitations during this time, CMS is reviewing waivers as part of larger efforts to ensure health care quality and safety. CMS remains steadfast in its commitment to keeping the HHA community and public informed throughout the COVID-19 PHE.

OIG Recommendation

In collaboration with Administration for Strategic Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE), apply lessons learned from the COVID-19 PHE to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks.

CMS Response

CMS concurs with this recommendation. ASPR TRACIE and CMS have a long history of working together to support providers in responding to emergencies, including emerging infectious diseases, such as COVID-19. CMS has provided education and outreach to HHAs on CMS quality and safety standards to support their infection prevention and control efforts. In addition, CMS has collaborated with ASPR TRACIE on homecare related resources, including a resource on HHA requirements relating to the emergency preparedness rule.[11] This resource was updated in March 2021 to reflect updates from the COVID-19 PHE.

CMS recently published case studies of 30 providers (nursing homes and hospitals) on their responses to challenges during the onset of COVID-19.[12] The study focused on understanding how these providers prepared for and responded to the COVID-19 PHE. The discussions and engagement focused on whether or not the facilities had risk assessments which included emerging infectious diseases prior to the PHE, their input on individual preparedness within their facilities, and discussion on some of the challenges and burdens. The study found that locally developed emergency preparedness plans and staff training were key factors in dealing with the COVID-19 PHE. While this study focused on nursing homes and hospitals, the information gained from the study would apply across provider and supplier types.

CMS will continue to collaborate with ASPR TRACIE and share information based on lessons learned from the COVID-19 PHE with the HHA industry. However, CMS does not provide funding to ASPR TRACIE. While our agencies will continue to collaborate, CMS does not have the authority over ASPR TRACIE work products.

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ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Sarah Hijaz and Shanna Weitz served as the team leaders for this study, and Caitlin Foster served as the lead analyst. Office of Evaluation and Inspections headquarters staff who provided support include Joseph Chiarenzelli, Althea Hosein, Christine Moritz, and Sara Swisher.

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[85] During our contact attempts, we noted that at least 21 nonresponding HHAs had changed their address and 13 had phone connection issues (e.g., disconnected phone line). Challenges accessing these HHAs may at least partially explain our response rate.

[86] We identified 314 HHAs that submitted 2019 Medicare claims in our sample, 225 of which responded to the survey.

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