

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SIX OF EIGHT HOME HEALTH AGENCY
PROVIDERS HAD INFECTION CONTROL
POLICIES AND PROCEDURES THAT
COMPLIED WITH CMS REQUIREMENTS AND
FOLLOWED CMS COVID-19 GUIDANCE TO
SAFEGUARD MEDICARE BENEFICIARIES,
CAREGIVERS, AND STAFF DURING THE
COVID-19 PANDEMIC**

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Office of Inspector General

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Report in Brief

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



Why OIG Did This Audit

Medicare beneficiaries receiving home health services may be at a high risk of developing severe illness from COVID-19. Home health agencies (HHAs) must comply with the Centers for Medicare & Medicaid Services' (CMS's) infection prevention and control requirements and follow CMS guidance by having policies and procedures to protect HHA staff, Medicare beneficiaries, and caregivers during the pandemic.

Our objective was to determine whether eight selected HHAs had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic.

How OIG Did This Audit

Our audit covered the infection prevention and control policies and procedures for eight HHA providers. We reviewed each HHA provider's policies and procedures to determine whether they include: (1) guidance for following standards of practice, (2) a coordinated agencywide infection control program, and (3) infection control education for HHA staff, Medicare beneficiaries, and caregivers. We also determined whether the HHA providers' policies and procedures followed CMS COVID-19 guidance for: (1) screening patients, (2) screening staff, and (3) treating patients with known or suspected COVID-19.

Six of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements and Followed CMS COVID-19 Guidance To Safeguard Medicare Beneficiaries, Caregivers, and Staff During the COVID-19 Pandemic

What OIG Found

Six of the eight selected HHA providers had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic. However, one HHA provider did not comply with CMS requirements or follow CMS COVID-19 guidance. Specifically, this HHA provider's infection control policies and procedures did not: (1) require staff to follow one of the standard precautions to prevent the transmission of infections and communicable diseases, (2) include documentation of surveillance methods used for identifying and tracking infections and improvement activities to prevent infection, (3) include COVID-19 screening protocols for staff in accordance with CMS guidance, and (4) include information about how to care for patients with known or suspected COVID-19 in accordance with CMS guidance. In addition, this provider and another HHA provider's COVID-19 screening protocols for patients were not consistent with CMS guidance. As a result, the patients and staff at these two HHA providers were at an increased risk of infection. We did not determine whether these HHA providers had infection prevention and control issues related to the implementation of the policies and procedures. However, State survey agencies identified issues with implementation at several of these HHA providers, as indicated by infection prevention and control deficiencies found during surveys conducted in 2019 and 2020.

What OIG Recommends and CMS Comments

We recommend that CMS develop and share with the HHA industry information on COVID-19 infection prevention and control best practices that HHA providers can use to comply with CMS requirements and follow CMS guidance.

CMS concurred with our recommendation. CMS stated that it has provided education and outreach to HHAs on CMS quality and safety standards to support their infection prevention and control efforts. CMS also stated that it will continue to share information on best practices with the HHA industry.

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INTRODUCTION

WHY WE DID THIS AUDIT

Medicare covers home health services for the elderly and for people with disabilities. Medicare beneficiaries who receive home health services often have underlying medical conditions. COVID-19 is especially dangerous for such individuals. Additionally, because home health agency (HHA) staff see several patients in their homes each week, the staff's risk of exposure to COVID-19 increases. This also increases the risk that they expose their patients and their patients' caregivers, such as family members, friends, or neighbors, to the virus. Because home health patients are vulnerable and the risk of exposure to COVID-19 is high, it is critical that HHA providers comply with the Centers for Medicare & Medicaid Services' (CMS's) infection prevention and control requirements and COVID-19 guidance by having policies and procedures to protect HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic.

OBJECTIVE

Our objective was to determine whether eight selected HHA providers had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic.

BACKGROUND

The Medicare Program and Home Health Services

The Medicare program, established by Title XVIII of the Social Security Act, provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

HHA services are covered for the elderly and people with disabilities under Medicare Parts A and B. These services, provided under a plan of care that is established and periodically reviewed by a physician, must be furnished by, or under arrangement with, an HHA provider that participates in the Medicare or Medicaid programs. HHA services provided by a visiting HHA worker in the beneficiary's home may include, but are not limited to, skilled nursing care, physical therapy, speech-language pathology, and occupational therapy.

Medicare Requirements for Infection Control at Home Health Agencies

HHA providers must meet certain conditions of participation (CoPs) to participate in the Medicare and Medicaid programs, including meeting infection prevention and control standards. Federal regulations (42 CFR § 484.70) state:

[T]he HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases. (a) The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases. (b) The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include: (1) A method for identifying infectious and communicable disease problems; and (2) a plan for the appropriate actions that are expected to result in improvement and disease prevention. (c) The HHA must provide infection control education to staff, patients, and caregiver(s).

Survey and Certification of Home Health Agencies

CMS is responsible for overseeing compliance with Medicare health and safety standards. CMS delegates a variety of tasks related to this oversight to the State survey agencies (the Social Security Act § 1864). One of these tasks is to conduct investigations and fact-finding surveys to determine how well health care providers, including HHA providers, comply with their applicable CoPs. Standard surveys of HHA providers must occur no later than 36 months after the previous survey. The State survey agencies cite HHA providers with deficiencies when they do not meet the CoPs, including not following infection prevention and control requirements.

CMS and CDC Guidance During the COVID-19 Pandemic

On March 10, 2020, CMS issued a State Survey Directors' Letter (CMS Letter) to provide HHA providers with guidance on minimizing the transmission of COVID-19.¹ The CMS Letter stated that HHA providers should monitor the health status of patients and staff in the home care setting for signs or symptoms of COVID-19.² CMS also recommended that HHA providers monitor the Centers for Disease Control and Prevention (CDC) website for information and

¹ The CMS Letter is titled: *Guidance for Infection Control and Prevention Concerning [COVID-19] in [HHA providers] and Religious Nonmedical Healthcare Institutions (RNHCIs)* (QSO-20-18-HHA). This CMS Letter was revised on April 23, 2020, to include guidance for RNHCIs. Available online at <https://www.cms.gov/files/document/qso-20-18-hha-revised.pdf>.

² State survey agencies conducted surveys and investigated complaints during the COVID-19 pandemic. State survey agencies assessed whether HHA providers were following COVID-19 infection control guidance, including whether they screened patients and staff for COVID-19 and tracked patient and staff COVID-19 infections.

resources and follow CDC's *Interim Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs) and Asymptomatic Close Contacts of Confirmed Cases at Their Home or Non-Home Residential Settings* for information on recommended personal protective equipment (PPE) when treating patients with known or suspected COVID-19.

Medicare Home Health Claims With COVID-19 Diagnosis Codes

There are approximately 11,100 HHA providers participating in the Medicare program. During 2020, 4,854 HHA providers submitted 79,131 Medicare claims with a COVID-19 principal diagnosis code for 54,849 beneficiaries from 54 States and U.S. Territories. Appendix B contains a table showing the number of HHA claims containing a COVID-19 diagnosis code by State for calendar year 2020.

HOW WE CONDUCTED THIS AUDIT

Our audit covered the infection prevention and control policies and procedures for eight HHA providers.³ We selected three of the largest HHA providers in the country, and we judgmentally selected five HHA providers that were cited for infection prevention and control deficiencies during surveys conducted in 2019 and 2020 for review.⁴ We had the eight HHA providers complete a questionnaire on their infection prevention and control programs and COVID-19 responses and provide us with their infection control policies and procedures. We reviewed each HHA provider's questionnaire responses and policies and procedures to determine whether they include: (1) guidance for following standards of practice, including all standard precautions; (2) a coordinated agencywide program for the surveillance, identification, prevention, control, and investigation of infections and communicable diseases; and (3) infection control education for HHA staff, Medicare beneficiaries, and caregivers. We also determined whether the HHA providers developed additional infection control measures in accordance with CMS guidance in response to the COVID-19 pandemic. Specifically, we determined whether each HHA provider's policies and procedures included guidance for: (1) screening patients, (2) screening staff, and (3) treating patients with known or suspected COVID-19 in accordance with CMS guidance.

³ Our review was limited to policies and procedures documented by the HHA providers selected for review. We did not determine how those policies and procedures were implemented.

⁴ Seven of the eight selected HHA providers submitted Medicare claims containing a principal diagnosis code for COVID-19 in 2020. Additionally, the five judgmentally selected HHA providers were cited for various reasons including failure to: (1) follow standard precautions; (2) properly document infections and resolution; (3) provide or document infection prevention and control education; and (4) document or maintain an infection surveillance program. Two of these five HHA providers were cited for immediate jeopardy for failing to properly prevent infections and ensure the health and safety of patients. Immediate jeopardy means a situation in which the provider's or supplier's noncompliance with one or more Medicare requirements, CoPs, or conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient (42 CFR § 488.1).

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

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Six of the eight selected HHA providers had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic. However, one HHA provider did not have infection control policies and procedures that complied with CMS requirements or followed CMS COVID-19 guidance. Specifically, this HHA provider's infection control policies and procedures did not:

- require staff to follow one of the standard precautions to prevent the transmission of infections and communicable diseases,
- include documentation of surveillance methods used for identifying and tracking infections and improvement activities to prevent infection,
- include COVID-19 screening protocols for staff in accordance with CMS guidance, and
- include information about how to care for patients with known or suspected COVID-19 in accordance with CMS guidance.

In addition, this provider and another HHA provider's COVID-19 screening protocols for patients were not consistent with CMS guidance. As a result, the patients and staff associated with the two HHA providers were at an increased risk of infection.

We did not determine whether these HHA providers had infection prevention and control issues related to the implementation of the policies and procedures. However, State survey agencies identified issues with implementation at several of these HHA providers, as indicated by infection prevention and control deficiencies found during surveys conducted in 2019 and 2020.⁵

⁵ These previous deficiencies were sometimes the result of HHA staff failing to properly implement provider policies and procedures. For example, one of these HHA providers was cited with an infection prevention deficiency because staff did not follow CMS and agency policy for proper hand hygiene while caring for patients. Therefore, while the policy was in place, the HHA provider did not ensure that the staff followed it to prevent infection. Our review of the State survey agencies' infection prevention and control deficiencies was limited to the five judgmentally selected HHA providers.

SEVEN OF EIGHT HOME HEALTH AGENCY PROVIDERS HAD INFECTION PREVENTION AND CONTROL POLICIES AND PROCEDURES THAT COMPLIED WITH CMS REQUIREMENTS

Seven of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements for Infection Prevention

HHA providers must maintain and document an infection control program with the goals of prevention and control of infections and communicable diseases (42 CFR § 484.70). HHA providers must follow accepted standards of practice, including the use of standard precautions, to prevent infection and disease (42 CFR § 484.70 (a)). HHA providers must follow six standard precautions during any episode of patient care. The standard precautions include hand hygiene, environmental cleaning and disinfection, injection and medication safety, appropriate use of PPE, minimizing potential exposures, and reprocessing of reusable medical equipment between each patient when soiled. The HHA providers must have written infection prevention policies and procedures that are widely available and based on current standards of practice (*Medicare State Operations Manual (SOM)*, Appendix B—Guidance to Surveyors: Home Health Agencies).

We determined that seven of the eight HHA providers had policies and procedures that instructed staff to follow standards of practice, including the use of all standard precautions.⁶ These HHA providers had policies for proper hand hygiene, environmental cleaning and disinfection, injection and medication safety, appropriate use of PPE, minimizing potential exposures, and reprocessing of reusable medical equipment. However, one HHA provider's infection control policies and procedures did not include guidelines for safe injection practices. The HHA provider stated that injection and medication safety was not applicable to the infection control program.⁷ The HHA provider also did not respond to our requests for further explanation on why injection and medication safety was not applicable or documented in its infection control policies and procedures.

Seven of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements for Infection Control

HHA providers must maintain coordinated agencywide programs for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that are an integral part of the HHA provider's QAPI program (42 CFR § 484.70 (b)). Infection control programs must include methods for identifying infectious and communicable disease problems and plans for the appropriate actions that are expected to result in improvement and

⁶ Three of the five judgmentally selected HHA providers were cited by State survey agencies in 2019 for infection prevention deficiencies. However, the HHA providers' policies and procedures that we reviewed complied with CMS requirements for infection prevention.

⁷ The HHA provider indicated that the standard precaution for reprocessing of reusable medical equipment between each patient when soiled was also not applicable to its infection control program. However, the HHA provider's infection control policies included guidelines for cleaning and reusing medical equipment.

disease prevention (42 CFR § 484.70 (b) (1-2)). Actions that facilitate improvement and disease prevention may include changing policies and procedures to improve care and educating patients, caregivers, and HHA staff to prevent infections (SOM, Appendix B—Guidance to Surveyors: Home Health Agencies).

We found that seven of the eight HHA providers' policies and procedures included a coordinated agencywide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases.⁸ These HHA providers had documentation of the methods they used to identify and track infections. However, we determined that one of the HHA providers did not provide documentation or information on its surveillance methods for identifying and tracking infections. This HHA provider was also cited by the State survey agency in 2019 for failure to maintain a coordinated agencywide program for surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that was part of its quality assessment and QAPI program. The HHA provider's infection control policy included requirements for staff to report infections and take appropriate performance-improvement actions. However, the HHA provider did not respond to our requests for additional information on how it tracks and analyzes infection data or evidence that it implements performance-improvement actions as part of its QAPI program.

Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements for Infection Control Education

HHA providers must provide infection control education to staff, patients, and caregiver(s) (42 CFR § 484.70 (c)). HHA providers must provide education at orientation, annually, and as needed to meet the staff's learning needs to: provide adequate care; identify infection signs and symptoms; identify routes of infection transmission; appropriately disinfect, sanitize, and transport equipment and devices used for patient care; and use proper medical waste disposal techniques. Such education must include instructions on how to implement current infection prevention and treatment practices in the home setting (SOM, Appendix B).

All eight HHA providers had policies and procedures requiring staff to receive education at orientation, annually, and as needed to meet their learning needs.⁹ The HHA providers documented a variety of education methods for staff, patients, and caregivers including online learning course schedules, onsite supervision checklists, written policies and procedures, and informational handouts for patients and caregivers. The HHA providers informed us that they track staff training requirements through attendance records and personnel files.

⁸ Two of the five judgmentally selected HHA providers were cited by State survey agencies in 2019 for infection control deficiencies. Furthermore, only one of these HHA provider's policies and procedures that we reviewed complied with CMS requirements for infection control.

⁹ One of the five judgmentally selected HHA providers was cited by the State survey agency in 2020 for an infection control education deficiency. However, the HHA provider's policies and procedures that we reviewed complied with CMS requirements for infection control education.

SIX OF EIGHT HOME HEALTH AGENCY PROVIDERS HAD INFECTION CONTROL POLICIES AND PROCEDURES THAT FOLLOWED CMS COVID-19 GUIDANCE

Seven of the Eight HHA Providers Had Infection Control Policies and Procedures That Followed CMS Guidance for Screening Staff for COVID-19

HHA staff with signs and symptoms of a respiratory infection should not report to work. Staff that develop signs and symptoms during work, should immediately stop, inform the clinical manager, and self-isolate at home. Clinical managers should obtain information from the staff about recent contact with individuals and equipment for contact tracing to identify patients and staff who may also have been exposed (CMS Letter).

We determined that seven of the eight HHA providers developed policies and procedures that require staff to self-assess symptoms and report symptoms and exposures to management.¹⁰ These HHA providers documented actions for staff to take if they are exposed or experience COVID-19 symptoms, including stopping work, testing for COVID-19, and quarantining at home. These HHA providers also developed guidelines for returning to work after quarantining for COVID-19. These HHA providers had a variety of tools including online reporting systems and questionnaires that require staff to report whether they have any symptoms or were exposed to COVID-19. (See Other Matters for a list of potential best practices for HHA providers during the COVID-19 pandemic.) One of the HHA providers did not develop policies and procedures for staff to self-assess for COVID-19. However, this HHA provider had a policy that required staff to self-quarantine before returning if they traveled outside their work area. This HHA provider did not respond to our requests for additional information on actions taken to safeguard patients and staff during the COVID-19 pandemic.

Seven of the Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Followed CMS Guidance for Treating Patients With Known or Suspected COVID-19

HHA providers should continue to provide appropriate patient care for the severity of a patient's illness and overall clinical condition for the patient with known or suspected COVID-19. HHA providers should limit the number of staff to essential personnel and ensure that supplies are cleaned and disinfected in accordance with environmental infection control guidelines. Hand hygiene should be performed before putting on and after removing PPE using alcohol-based hand sanitizer with greater than 60 percent ethanol or 70 percent isopropanol or washing hands with soap and water for at least 20 seconds. CMS recommends that HHA staff put on PPE outside of the home prior to entry, if possible. PPE should ideally be removed outside of the home and discarded by placing in an external trash can before departing the location (CMS Letter). When treating patients with known or suspected COVID-19, CMS recommends that HHA staff wear all PPE recommended by CDC. CDC recommends that public

¹⁰ We determined that none of the five judgmentally selected HHA providers were cited by State survey agencies for infection prevention and control deficiencies related to CMS guidance for screening staff for COVID-19.

health personnel wear gowns, gloves, eye protection such as goggles or a disposable face shields that cover the front and sides of the face, and respiratory protection such as an N-95 or higher-level respirator or facemask approved by the National Institute for Occupational Safety and Health.¹¹

We found that seven of the eight HHA providers developed policies and procedures for treating patients with known or suspected COVID-19.¹² The seven HHA providers developed education material for cleaning and disinfecting equipment and properly donning and doffing PPE, reusing PPE when supplies were low, and properly disposing of PPE. The HHA providers had charts, diagrams, and instructions to educate staff, patients, and caregivers. One of the eight HHA providers did not develop policies and procedures for treating patients with known or suspected COVID-19. This HHA provider did not update its guidelines for properly using PPE to prevent infection during the COVID-19 pandemic. The HHA provider's policies and procedures focused on helping patients and staff identify COVID-19 symptoms. These policies and procedures also provided general information about steps to take to prevent the spread of the virus, including limiting travel and staying home when possible. The HHA provider did not respond to our requests for additional information on actions taken to safeguard staff, patients, and caregivers during the COVID-19 pandemic.

Six of the Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Followed CMS Guidance for Screening Patients for COVID-19

HHA providers should monitor the health status of patients and staff for signs or symptoms of COVID-19. HHA providers should identify patients at risk for having COVID-19 infections before or immediately upon arrival to the home. HHA staff should screen patients by asking about whether the patient:

- traveled internationally within the last 14 days to countries with sustained community transmission;
- had signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat;
- had contact with someone with or under investigation for COVID-19 or who is ill with respiratory illness within the last 14 days; or

¹¹ CDC guidance, "Interim Infection Control Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs) and Asymptomatic Close Contacts of Confirmed Cases at Their Home or Non-Home Residential Settings Evaluating PUIs Residential" (updated April 10, 2020).

¹² We determined that none of the five judgmentally selected HHA providers were cited by State survey agencies for infection prevention and control deficiencies related to CMS guidance for treating patients with known or suspected COVID-19.

- resided in a community where community-based spread of COVID-19 is occurring.

HHA staff should inform the clinical manager and local and State public health authorities about the presence of a person under investigation for COVID-19 (CMS Letter).

We determined that six of the eight HHA providers developed policies and procedures to screen patients for COVID-19 in accordance with CMS guidance.¹³ These HHA providers' policies and procedures required staff to screen patients via telephone calls prior to the home visit through a series of questions. Screening questions include asking patients about signs and symptoms, recent exposure to someone with or under investigation for COVID-19, and recent travel to areas with a high risk of transmission. These HHA providers had a variety of tools to screen patients including online reporting systems to submit patient answers and document HHA followup actions, checklists, and decision trees to determine how to proceed with caring for the patient. These HHA providers' policies and procedures required COVID-19 infections to be reported to management and tracked.

We determined that the other two HHA providers' patient screening protocols were not consistent with CMS guidance. These two HHA providers had questionnaires to screen patients for COVID-19 symptoms only. These HHA providers' screening tools did not include asking patients about recent exposure to someone with or under investigation for COVID-19 or about recent travel. One HHA provider did not respond to our requests for additional information on actions taken to safeguard patients and staff during the COVID-19 pandemic. The other HHA provider informed us that it used the CMS Letter as a resource for staff. However, the HHA provider did not incorporate the screening questions recommended in the letter into its screening questionnaire.

CONCLUSION

The Medicare beneficiaries and staff associated with the two HHA providers that did not follow CMS requirements and guidance for infection prevention and control were at an increased risk of infection. Since we selected a judgmental sample of HHA providers, we cannot project the results of our audit to HHA providers not included in our sample. However, other HHA providers may or may not have developed additional infection prevention and control policies and procedures consistent with CMS COVID-19 guidance. HHA providers should continue to review and update infection control policies and procedures as needed and ensure HHA staff are following them to reduce the risk of infection. The Other Matters section contains some COVID-19 potential best practices identified as part of our review of the eight selected HHA providers.

¹³ We determined that none of the five judgmentally selected HHA providers were cited by State survey agencies for infection prevention and control deficiencies related to CMS guidance for screening patients for COVID-19.

RECOMMENDATION

We recommend that the Centers for Medicare & Medicaid Services develop and share with the HHA industry information on COVID-19 infection prevention and control best practices that HHA providers can use to comply with CMS requirements and follow CMS guidance.

CMS COMMENTS

CMS concurred with our recommendation. CMS stated that it has provided education and outreach to HHAs on CMS quality and safety standards to support their infection prevention and control efforts. CMS also stated that it will continue to share information on best practices with the HHA industry.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix C.

OTHER MATTERS: POTENTIAL HOME HEALTH AGENCY INFECTION PREVENTION AND CONTROL BEST PRACTICES DURING THE COVID-19 PANDEMIC

As part of our review of the infection prevention and control at the eight selected HHA providers, we assessed the various policies and procedures, reporting tools, and education material that the HHA providers developed in response to the COVID-19 pandemic that were consistent with CMS guidance for screening staff, caring for patients with known or suspected COVID-19, and screening patients. We identified potential best practices to the COVID-19 pandemic that other HHA providers not included in our sample could use to improve their own infection prevention and control programs.

SCREENING STAFF FOR COVID-19

- Seven of the eight HHA providers had policies and procedures that required daily COVID-19 screenings for staff conducted and documented prior to starting the workday to assess for symptoms, possible exposure, and recent travel.
- Seven of the eight HHA providers informed us that they used a variety of methods to instruct staff on the appropriate actions to take if they develop symptoms or are exposed to a person with known or suspected COVID-19. These HHA providers developed policies and procedures, COVID-19 exposure decision trees, and reporting systems to record symptoms and infections and track actions taken by staff and management. These HHA providers required staff to self-isolate immediately and notify the supervisor for exposure tracking. They required staff to remain out of work until they met appropriate return-to-work criteria set by CMS and CDC.

CARING FOR PATIENTS WITH KNOWN OR SUSPECTED COVID-19

- Seven of the eight HHA providers had policies and procedures for using PPE while treating Medicare patients during the COVID-19 pandemic.
- Seven of the eight HHA providers informed us that they used a variety of tools to instruct staff on using PPE properly. These HHA providers developed policies and procedures, PPE flow charts, and diagrams to clarify the appropriate PPE for staff. These policies and procedures included instructions for properly using, reusing, and disposing of PPE and the protocol for PPE when supplies are low.
- Seven of the eight HHA providers informed us that they updated their infection control education for staff, patients, and caregivers to be consistent with the latest guidance from CMS and CDC. These HHA providers informed us that they provided infection control education through onsite supervision, online training, inservices, and posters and handouts for patients and caregivers.

SCREENING PATIENTS FOR COVID-19

- Six of the eight HHA providers had policies and procedures that require COVID-19 screening for patients and caregivers to assess for symptoms, possible exposure, and recent travel. These policies and procedures required patients to be screened via a telephone call prior to the HHA visit, if possible. These HHA providers' screening tools included online reporting systems, questionnaires, and checklists.
- Six of the eight HHA providers informed us that they use a variety of tools to document patient screening. These HHA providers developed policies and procedures, COVID-19 exposure decision trees, and reporting systems to record symptoms and infections and track actions taken by staff to safeguard the patient. These HHA providers used patient exposure decision trees and guidance to clarify the appropriate actions staff should take if patients report symptoms or are exposed to a person with known or suspected COVID-19.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

Our audit covered the infection prevention and control policies and procedures for eight HHA providers. We selected three of the largest HHA providers in the country, and we judgmentally selected five HHA providers that were cited for infection prevention and control deficiencies during surveys conducted in 2019 and 2020 for review.¹⁴ We had the eight HHA providers complete a questionnaire on their infection prevention and control programs and COVID-19 responses and provide us with their infection control policies and procedures. We reviewed each HHA provider's questionnaire responses and policies and procedures to determine whether they include: (1) guidance for following standards of practice, including all standard precautions; (2) a coordinated agencywide program for the surveillance, identification, prevention, control, and investigation of infections and communicable diseases; and (3) infection control education for staff and patients. We also reviewed the HHA providers' questionnaire responses and supporting documentation to determine whether they implemented additional infection control measures in accordance with CMS guidance in response to the COVID-19 pandemic. Specifically, we determined whether each HHA provider's policies and procedures include guidance for: (1) screening patients, (2) screening staff, and (3) treating patients with known or suspected COVID-19.

We determined that a review of CMS's internal controls was not significant to accomplishing our audit objective.

We conducted our audit from October 2020 to August 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;

¹⁴ Seven of the eight selected HHA providers submitted Medicare claims containing a principal diagnosis code for COVID-19 in 2020. Additionally, these five judgmentally selected HHA providers were cited for various reasons including failure to: (1) follow standard precautions, (2) properly document infections and resolution, (3) provide or document infection prevention and control education, and (4) document or maintain an infection surveillance program. Two of these five HHA providers were cited for immediate jeopardy for failing to properly prevent infections and ensure the health and safety of patients. Immediate jeopardy means a situation in which the provider or supplier's noncompliance with one or more Medicare requirements, CoPs, or conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient (42 CFR § 488.1).

- met with CMS program officials to gain an understanding of Medicare requirements and guidance for infection prevention and control at HHA providers during the COVID-19 pandemic;
- obtained from CMS's National Claims History file 79,131 HHA claims containing a principal diagnosis code for COVID-19 for calendar year 2020;
- identified 53 HHA providers that were cited for infection control deficiencies during State surveys conducted in 2019 and 2020;
- identified the HHA providers with the largest market share in the country in 2019;
- judgmentally selected three of the largest HHA providers in the country and five HHA providers that were cited for infection control deficiencies in 2019 and 2020;
- developed a questionnaire to obtain information from the selected HHA providers on their infection prevention, infection control, infection control education, and COVID-19 policies and procedures;
- reviewed the HHA providers' responses to our questionnaire on infection prevention and control, infection control education, and COVID-19 response;
- reviewed selected HHA providers' infection prevention and control policies and procedures to determine whether they complied with CMS requirements;
- reviewed selected HHA providers' COVID-19 policies and procedures to determine whether they complied with CMS guidance; and
- discussed the results of our audit with CMS officials.

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

APPENDIX B: MEDICARE HOME HEALTH CLAIMS WITH A COVID-19 DIAGNOSIS CODE BY STATE

State	Number of Medicare HHA Claims With COVID-19 Diagnosis*
Florida	5,973
Texas	5,487
New York	4,925
California	4,443
Illinois	3,982
Pennsylvania	3,320
New Jersey	3,004
Georgia	2,992
Michigan	2,884
Mississippi	2,826
Massachusetts	2,684
Louisiana	2,375
Alabama	2,215
South Carolina	2,194
Tennessee	2,163
North Carolina	2,062
Virginia	2,051
Maryland	1,981
Ohio	1,974
Missouri	1,830
Oklahoma	1,684
Indiana	1,675
Wisconsin	1,391
Connecticut	1,301
Arizona	1,180
Iowa	1,044
Kentucky	967
Minnesota	957
Kansas	843
Arkansas	787
Nebraska	617
Idaho	580
Colorado	567
Washington	553
Utah	529
Nevada	525
Delaware	405
South Dakota	274

State	Number of Medicare HHA Claims With COVID-19 Diagnosis
New Mexico	269
North Dakota	240
Rhode Island	216
West Virginia	209
New Hampshire	191
Oregon	157
Montana	154
Maine	121
Wyoming	112
District of Columbia	97
Vermont	50
Alaska	38
Hawaii	24
Puerto Rico	5
Guam	3
Virgin Islands	1
Total	79,131
* We obtained these data from CMS's National Claims History file. We identified 79,131 HHA claims containing a principal diagnosis code for COVID-19 for calendar year 2020.	



APPENDIX C: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DATE: September 14, 2021

TO: Amy Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: Six of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements and Followed CMS COVID-19 Guidance To Safeguard Medicare Beneficiaries, Caregivers, and Staff During the COVID-19 Pandemic, (A-01-20-00508)

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 protecting beneficiaries in the home care setting from the spread of infectious diseases.

Home Health Agencies (HHAs) receiving Medicare or Medicaid payments are required to comply with CMS quality and safety standards, including those relating to infection prevention and control. CMS shares responsibility of HHA oversight with State Survey Agencies (SSAs) who conduct onsite surveys to assess compliance with CMS requirements and investigate facility complaints. SSAs serve as the front-line responders to address health and safety concerns raised by residents, their families, and facility staff.

Since the COVID-19 public health emergency declaration in early 2020, CMS has taken a number of actions to address COVID-19 within HHAs. 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). CMS also instructed SSAs to prioritize surveys related to complaints in which the beneficiary was in immediate jeopardy of harm. In addition, CMS provided surveyors a streamlined review tool to conduct targeted infection control surveys of providers identified through collaboration with the Centers for Disease Control and Prevention (CDC) and the Assistant Secretary for Preparedness and Response (ASPR). When onsite survey activity was warranted, SSA's used the tool to assess HHA infection control practices. CMS also shared the infection control survey tool with HHAs to use as a voluntary self-assessment to review their own compliance with federal infection control requirements. As the public health emergency continues, the infection control survey has been revised, most recently in December 2020, to incorporate new infection control requirements to address the spread of COVID-19.

In addition to the survey process used to enforce CMS policies, CMS has provided education and outreach to HHAs on CMS quality and safety standards to support their infection prevention and control efforts. For example, in 2016, CMS released targeted infection control training for providers through the Medicare Learning Network. CMS also held Open Door Forum calls specific to HHAs since 2016 and added additional COVID-19 calls during the pandemic, which continue to date. CMS meets quarterly 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 (QSEP) provides current trainings on various CMS survey and certification requirements. These trainings are used by surveyors but are also free of charge and available to the public by choosing the "public access" link on QSEP.

OIG's recommendation and CMS's response is below.

OIG Recommendation

Develop and share with the HHA industry information on COVID-19 infection prevention and control best practices that HHA providers can use to comply with CMS requirements and follow CMS guidance.

CMS Response

CMS concurs with this recommendation. CMS has provided education and outreach to HHAs on CMS quality and safety standards to support their infection prevention and control efforts. CMS will continue to share information on best practices with the HHA industry.