

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CERTAIN NURSING HOMES MAY NOT
HAVE COMPLIED WITH FEDERAL
REQUIREMENTS FOR INFECTION
PREVENTION AND CONTROL AND
EMERGENCY PREPAREDNESS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Christi A. Grimm
Inspector General

July 2022
A-01-20-00005

Office of Inspector General

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Report in Brief

Date: July 2022

Report No. A-01-20-00005

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



Why OIG Did This Audit

The Centers for Disease Control and Prevention indicates that individuals who are aged 65 and older or nursing home residents are at a higher risk for severe illness from COVID-19. In addition, 8 out of 10 COVID-19 deaths reported in the United States in 2020 were adults aged 65 and older. COVID-19 is especially dangerous for the more than 1.3 million residents who live in the 15,446 Medicare and Medicaid certified nursing homes nationwide.

Our objective was to determine whether selected nursing homes complied with Federal requirements for infection prevention and control and emergency preparedness.

How OIG Did This Audit

We analyzed State survey agency (SSA) data on Medicare.gov for the most recent standard surveys and the previous 12 months of complaint reports. We identified 6,830 nursing homes that were cited for infection prevention and control program deficiencies, and Medicare.gov indicated that 39 nursing homes had not provided a plan of correction for the deficiencies as of March 26, 2020. We contacted the 39 nursing homes and requested that they provide us with infection prevention and control and emergency preparedness program documents that were in effect from January 1, 2019, through May 31, 2020.

Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness

What OIG Found

Selected nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness. Specifically, 28 of the 39 nursing homes had possible deficiencies. We found 48 instances at 25 nursing homes of possible noncompliance with infection prevention and control requirements and 18 instances at 18 nursing homes of possible noncompliance with emergency preparedness requirements related to all-hazards risk assessments and strategies to address emerging infectious diseases. The nursing homes attributed the possible noncompliance to: (1) nursing home inadequate internal controls, (2) nursing home inadequate management oversight, (3) nursing home administrative and leadership changes, (4) inadequate communication and training from the Centers for Medicare & Medicaid Services (CMS), and (5) inconsistent and confusing regulations.

What OIG Recommends and CMS Comments

We recommend that CMS: (1) instruct SSAs to follow up with the 28 nursing homes that we have identified with potential infection prevention and control and emergency preparedness deficiencies to ensure that they have taken corrective actions; (2) issue updated phase 3 interpretive guidance as soon as feasible; (3) provide training to SSAs on the updated phase 3 interpretive guidance as soon as feasible; and (4) consider updating the regulation to make clear that nursing homes must include emerging infectious diseases as a risk on their facility- and community-based all-hazards risk assessments.

CMS concurred with our first three recommendations and described corrective actions it had taken or planned to take, such as ensuring that SSAs follow up with the nursing homes, issuing phase 3 interpretive guidance, and providing training related to the phase 3 interpretive guidance. CMS stated that it had intended to release the phase 3 interpretive guidance during the second quarter of 2020. However, prior to issuing the guidance, the COVID-19 public health emergency (PHE) was declared, and CMS immediately redirected resources to address patient safety needs related to the PHE. Regarding our fourth recommendation, CMS stated that it would consider this recommendation in future rulemaking and that it has taken considerable steps to make clear that nursing homes should include emerging infectious diseases as an identified risk on their facility- and community-based all-hazards risk assessments.

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INTRODUCTION

WHY WE DID THIS AUDIT

At the start of the pandemic, the Centers for Disease Control and Prevention (CDC) indicated that individuals who are aged 65 and older or nursing home residents are at a higher risk for severe illness from COVID-19. In addition, 8 out of 10 COVID-19 deaths reported in the United States in 2020 were adults aged 65 and older.¹ COVID-19 is especially dangerous for the more than 1.3 million residents who live in the 15,446 Medicare and Medicaid certified nursing homes nationwide.

In order to minimize exposure to and transmission of COVID-19, it is critical that nursing homes strictly adhere to Federal requirements for proper infection prevention and control practices. However, the Centers for Medicare & Medicaid Services (CMS) reported, through State survey agency (SSA) survey reports published on Medicare.gov, that nursing homes do not always adhere to these requirements. Specifically, according to these reports, 39 nursing homes in 10 States did not always comply with all infection prevention and control requirements, such as following proper hand hygiene, and had not provided a plan of correction for the infection prevention and control deficiencies as of March 26, 2020. In March 2021, CMS officials said that the nursing homes had satisfactorily addressed all deficiencies identified by these surveys. Our audit focuses on these 39 nursing homes.

COVID-19 has created extraordinary challenges for the delivery of health care and human services. As the oversight agency for the Department of Health and Human Services (HHS), the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.²

OBJECTIVE

Our objective was to determine whether the selected nursing homes complied with Federal requirements for infection prevention and control and emergency preparedness.

BACKGROUND

Medicare and Medicaid Coverage of Nursing Homes

The Medicare and Medicaid programs cover care in nursing homes for eligible residents. Sections 1819 and 1919 of the Social Security Act (the Act) establish requirements for CMS and

¹ "COVID-19 Mortality Overview," available online at <https://www.cdc.gov/nchs/covid19/mortality-overview.htm>. (Accessed July 13, 2021.)

² OIG's COVID-19 response strategic plan and information about its oversight activities can be accessed at [HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG](#).

States to perform surveys of nursing homes to determine whether they meet Federal participation requirements.³

CMS Revised Emergency Preparedness and Infection Control Requirements

After a review of guidance developed by several agencies—including the Food and Drug Administration, CDC, and Health Resources and Services Administration—and a review of the existing Medicare emergency preparedness requirements for providers and suppliers, CMS found that the existing emergency preparedness regulatory requirements were not comprehensive enough to address the complexities of emergencies. As a result, CMS issued a proposed rule in December 2013 that would establish national emergency preparedness requirements for providers and suppliers that participate in Medicare and Medicaid to ensure that they adequately plan for natural and man-made disasters.⁴ CMS acknowledged in the final rule, issued in September 2016, that the United States faced several new and emerging diseases, such as Middle East Respiratory Syndrome, Ebola, and Enterovirus D68.⁵

In the September 2016 national emergency preparedness final rule, CMS stated that finalizing the rule was an important part of improving the national response to any infectious disease threats and that if a nursing home does not have an emergency preparedness plan in place prior to an emergency, it could encounter difficulties providing continuity of care for its residents.⁶

In 2015, CMS issued another proposed rule that included revisions to infection prevention and control requirements that nursing homes must meet to participate in the Medicare and Medicaid programs.⁷ These revisions resulted from CMS's comprehensive review of the then current regulations to: (1) improve the quality of life, care, and services in long-term care facilities and (2) optimize resident safety. The proposed changes took a multifaceted approach to reducing health care associated infections and unnecessary hospitalizations. The final rule, issued in October 2016, stated that infection prevention and control is a critical issue for nursing home residents because of the high number of health care associated infections, the residents' increased susceptibility to infections, and the significant exposure to health care

³ For Medicare and Medicaid, these statutory participation and survey requirements are implemented at 42 CFR, part 483, subpart B, and 42 CFR, part 488, subpart E, respectively.

⁴ 78 Fed. Reg. 79082, 79084 (Dec. 27, 2013).

⁵ 81 Fed. Reg. 63860, 63862 (Sept. 16, 2016).

⁶ 81 Fed. Reg. 63862, 63863 (Sept. 16, 2016).

⁷ 80 Fed. Reg. 42167 (July 16, 2015).

associated infections residents face.⁸ The final rule phased in new infection prevention and control regulations over a 3-year period.⁹

In the final rule, CMS required nursing homes to, among other things:

- have a broad effective infection prevention and control program (IPCP) that included a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents and staff (phase 1);
- provide their Quality Assurance and Performance Improvement (QAPI) plans to their SSA not later than 1 year after the date the regulation is issued, at each annual recertification survey, and upon request (phase 2); and
- have the individual(s) responsible for the nursing home’s IPCP complete specialized training in infection prevention and control (phase 3).

The regulations in phase 1 had an implementation date of November 28, 2016, regulations in phase 2 had an implementation date of November 28, 2017, and regulations in phase 3 had an implementation date of November 28, 2019. CMS informed SSAs on November 22, 2019, that although the phase 3 requirements would be effective November 28, 2019, CMS would not release interpretive guidance and training for these requirements until the second quarter of calendar year 2020.¹⁰ The guidance was not issued during the second quarter of calendar year 2020. CMS stated that the COVID-19 public health emergency (PHE) contributed to the delay in issuing the phase 3 interpretive guidance.

Requirements for Infection Control and Emergency Preparedness

Nursing homes are required to operate and provide services in compliance with all Federal, State, and local laws, regulations, and codes, as well as accepted professional standards and principles (42 CFR § 483.70). Federal regulations on infection control (42 CFR § 483.80) require nursing homes to establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. In addition, Federal regulations on emergency preparedness (42 CFR § 483.73) include specific requirements for nursing homes’ emergency preparedness plans, such as requirements that facilities complete a facility-based and community-based all-hazards (including emerging infectious diseases) risk assessment and

⁸ 81 Fed. Reg. 68688, 68808 (Oct. 4, 2016).

⁹ CMS chose to implement the requirements over a “phase-in” period to allow for appropriate clarification and education for facilities, surveyors, and other stakeholders.

¹⁰ Nov. 22, 2019, memo from the Director of Quality, Safety & Oversight Group at CMS to the State Survey Agency Directors (REF: QSO-20-03-NH).

develop strategies to address the risks identified.¹¹ CMS informed SSA directors in February 2019 that it was updating and adding emerging infectious diseases to the current definition of all-hazards approach in Appendix Z of the *State Operations Manual*.

Responsibilities for Infection Prevention and Emergency Preparedness

The Act mandates the establishment of minimum health and safety standards that must be met by providers participating in the Medicare and Medicaid programs. CMS is responsible for overseeing health care provider compliance with Medicare and Medicaid health and safety standards. CMS delegates a variety of tasks related to this oversight to the SSAs (the Act § 1864). One of these tasks is to conduct investigations and fact-finding surveys to determine whether health care providers, including nursing homes, comply with their applicable conditions of participation (CoPs). Standard surveys of nursing homes must occur no later than 15 months after the previous survey.^{12, 13} SSAs are also responsible for conducting a complaint survey if a complaint alleging noncompliance with CoPs is substantiated. Such a survey can happen at any time, regardless of standard survey intervals. SSAs cite nursing homes with deficiencies when they do not meet the CoPs, including when they do not follow infection prevention and control requirements.

Management and staff at a nursing home are ultimately responsible for ensuring the safety and well-being of residents and staff and for complying with Federal, State, and local regulations. They are responsible for ensuring that the nursing home develops, maintains, and implements infection prevention and control and emergency preparedness programs.

Additional CMS Guidance

To keep COVID-19 out of nursing homes and to stop its spread, CMS issued many guidance memoranda during the COVID-19 PHE. These included, among other things, requiring nursing homes to: (1) limit visits from family and friends to certain situations, such as end of life; (2) cease group activities and communal dining; (3) screen residents and others (including staff, vendors, and visitors) entering the nursing home for respiratory illness symptoms; and (4) test residents and staff for COVID-19. See Appendix B for a list of CMS memoranda issued during the pandemic.

¹¹ Emerging infectious diseases are those that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range. “Emerging Infectious Diseases” is available online at <https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens>. (Accessed Jan. 20, 2022.)

¹² Social Security Act §§ 1819(g)(2)(A)(iii)(I) and 1919(g)(2)(A)(iii)(I) and 42 CFR § 488.308(a).

¹³ A standard survey is a periodic, resident-centered inspection that gathers information about the quality of service furnished in a facility to determine compliance with the requirements of participation (42 CFR § 488.301).

COVID-19 Reporting Requirements for Nursing Homes

CMS issued an interim final rule on May 8, 2020, that required nursing homes to report, among other things, the number of confirmed and suspected COVID-19 cases and COVID-19-related deaths among residents and staff to CDC’s National Healthcare Safety Network on a weekly basis beginning on May 17, 2020. CMS published on its website the information it received from nursing homes.

Table 1 contains the total number of residents and staff with confirmed and suspected COVID-19 cases and COVID-19-related deaths reported to CDC and CMS through October 17, 2021, by 15,425 nursing homes.^{14, 15}

Table 1: COVID-19 Cases and COVID-19-Related Deaths

Confirmed and Suspected COVID-19 Cases			COVID-19-Related Deaths		
Residents	Staff	Total	Residents	Staff	Total
906,409	855,145	1,761,554	138,305	2,140	140,445

Residents and staff at the 39 selected nursing homes were severely impacted by COVID-19. Many of these residents and staff contracted COVID-19—and 360 died. Table 2 includes the number of residents and staff with confirmed and suspected COVID-19 cases and COVID-19-related deaths reported to OIG by the selected nursing homes through October 17, 2021.

Table 2: COVID-19 Cases and COVID-19-Related Deaths at 39 Nursing Homes*

Confirmed and Suspected COVID-19 Cases			COVID-19-Related Deaths		
Residents	Staff	Total	Residents	Staff	Total
2,039	1,471	3,510	357	3	360
* These numbers include case and death counts reported directly to OIG by the 39 nursing homes through March 31, 2021, and case and death counts reported to CDC and CMS from April 1, 2021, through October 17, 2021.					

¹⁴ Nursing homes were required to begin reporting these data as of May 17, 2020. However, there was no requirement for them to report data that predate the effective date of the interim final rule; it was left to the discretion of the nursing homes whether to report the historical data. As a result, these data could be lower than the actual COVID-19 cases and COVID-19-related deaths if nursing homes chose to not report the historical data.

¹⁵ We removed the COVID-19 cases and related deaths reported by the 39 nursing homes in our audit from these numbers and reported them separately.

HOW WE CONDUCTED THIS AUDIT

As of March 26, 2020, there were 15,446 Medicare and Medicaid certified nursing homes. We analyzed SSA survey data on Medicare.gov for the most recent standard surveys and the previous 12 months of complaint surveys.¹⁶ Based on that analysis, we determined that 6,830 nursing homes (approximately 44 percent) had been cited for IPCP deficiencies related to: (1) not providing and implementing an infection prevention and control program (6,169 nursing homes), (2) not developing and implementing policies and procedures for flu and pneumonia vaccinations (243 nursing homes), or (3) both (418 nursing homes). Medicare.gov indicated that 39 of the 6,830 nursing homes had not provided a plan of correction for the infection prevention and control deficiencies to the SSAs as of March 26, 2020. The deficiencies included:

- failure of surveillance program to identify and prevent the spread of possible communicable diseases or infections,
- improper hand hygiene among staff and residents,
- failure to disinfect shared equipment between uses, and
- improper care and storage of a resident's nebulizer mask and tubing that was attached to the nebulizer machine.

We contacted the 39 nursing homes and requested that they provide us with documentation related to infection prevention and control and emergency preparedness program policies and procedures that were in effect from January 1, 2019, through May 31, 2020. This documentation included, but was not limited to, the nursing homes' IPCP policies and procedures, information regarding the infection preventionist position, quality assessment and assurance committees (QAAC), training, all-hazards risk assessments, and emergency preparedness policies and procedures. We reviewed these documents to determine whether the nursing homes complied with Federal requirements for infection prevention and control and infection-control-related emergency preparedness. CMS officials informed us that actual deficiencies are cited onsite following a thorough investigation by trained Federal, State, and contractual surveyors to determine compliance with the Federal requirements for participation (i.e., the minimum health and safety standards). Therefore, we defer to trained surveyors who may conduct a followup review at the selected nursing homes to determine whether a deficiency exists for each condition identified in this report.

¹⁶ A complaint survey is conducted based on a substantial allegation of noncompliance. A substantial allegation of noncompliance is a complaint that would, if found to be present, adversely affect the health and safety of residents and raises doubts as to a provider's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements (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

Selected nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness.¹⁷ Specifically, 28 of the 39 nursing homes had possible deficiencies,¹⁸ and 18 of these nursing homes had more than 1 possible deficiency. We found 48 instances at 25 nursing homes of possible noncompliance with infection prevention and control requirements related to:

- the designation of a qualified infection preventionist,
- the occurrence of QAAC meetings,
- infection preventionist attendance at QAAC meetings,
- policies and procedures regarding reporting possible incidents of communicable diseases and infections,
- the nursing homes' annual reviews of their IPCPs, and
- training.

We also found 18 instances at 18 nursing homes of possible noncompliance with emergency preparedness requirements related to all-hazards risk assessments and strategies to address emerging infectious diseases.

Nursing home officials attributed the areas of possible noncompliance we identified to: (1) inadequate internal controls, (2) inadequate management oversight, (3) administrative and leadership changes, (4) inadequate CMS communication and training, and (5) inconsistent and

¹⁷ CMS officials informed us that actual deficiencies are cited onsite following a thorough investigation by trained Federal, State, and contractual surveyors to determine compliance with the Federal requirements for participation (i.e., the minimum health and safety standards). Therefore, we will defer to the trained surveyors who may conduct a followup review at the selected nursing homes to determine whether a deficiency exists for each condition identified in this report.

¹⁸ Of the 28 nursing homes with possible deficiencies, 15 had infection prevention and control and emergency preparedness deficiencies; 10 had only infection prevention and control deficiencies; and 3 had only emergency preparedness deficiencies.

confusing regulations. In addition, we believe many of the conditions noted in our report occurred because CMS did not provide nursing homes with communication and training related to complying with the new phase 3 infection requirements or clarification about the essential components to be integrated in the nursing homes' emergency plans.

As a result of the possible deficiencies, 28 of the 39 nursing homes we audited may have increased the risk of health and safety issues, including emerging infectious disease threats, for their residents and staff.

SELECTED NURSING HOMES MAY NOT HAVE COMPLIED WITH INFECTION PREVENTION AND CONTROL REQUIREMENTS

We found that 25 of the 39 nursing homes had at least 1 possible deficiency related to infection prevention and control, and 14 of the 25 nursing homes had more than 1 possible deficiency totaling 48 possible deficiencies. Appendix C summarizes the areas of possible infection prevention and control noncompliance. These possible deficiencies were related to: (1) the designation of an infection preventionist who met Federal regulations, (2) conducting QAAC meetings at least quarterly, (3) infection preventionist attendance at the QAAC meetings, (4) policies and procedures regarding reporting possible incidents of communicable diseases and infections, (5) annual review of the IPCP, and (6) training.

Nursing Homes Did Not Designate an Infection Preventionist Who Met Federal Requirements

A nursing home must designate one or more individuals as the infection preventionist who is responsible for the nursing home's IPCP. This person must, among other things, have completed specialized training in infection prevention and control (42 CFR § 483.80(b)).

In the final rule dated October 4, 2016, CMS discussed the importance of nursing homes having a designated individual responsible for a nursing home's infection prevention and control program. CMS said that nursing homes should ensure coverage whenever the designated infection preventionist is unavailable. Therefore, CMS allows nursing homes the flexibility to designate more than one individual to be responsible for the IPCP.¹⁹

In addition, CMS collaborated with the CDC to develop a free online training course on infection prevention and control for nursing home staff.²⁰

¹⁹ 81 Fed. Reg. 68810 (Oct. 4, 2016).

²⁰ CMS and CDC offer a specialized online class called "Infection Prevention and Control Training for Nursing Home Staff in the Long-Term Care Setting" at <https://www.cdc.gov/longtermcare/training.html>. (Accessed July 13, 2021.) However, nursing home staff have the option to complete specialized infection prevention and control training from other sources.

Of the 39 nursing homes that we reviewed, 12 had possible deficiencies related to designating an infection preventionist who met Federal requirements.²¹ Specifically, we found that six nursing homes may not have complied with the Federal requirement to ensure that the designated infection preventionist completed specialized training by the implementation date of the Federal requirement. We also found that six nursing homes were unable to provide documentation, such as a certificate of completion of specialized infection prevention and control training, to support that the designated infection preventionist had met the Federal requirement of completing specialized training.^{22, 23}

Nursing Homes Did Not Conduct Quarterly Quality Assessment and Assurance Committee Meetings

A nursing home's QAAC must meet at least quarterly and as needed to coordinate and evaluate activities under the quality assurance and performance improvement program (42 CFR § 483.75(g)(2)(i)).²⁴

Effective QAPI programs are critical to improving the quality of life, care, and services delivered in facilities, according to CMS.²⁵ Section 6102 of the Affordable Care Act required the establishment and implementation of a QAPI program for nursing homes. Therefore, CMS has required nursing homes to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on systems of care, outcomes, and services for residents and staff. The QAAC reports to the governing body regarding its activities,²⁶ including implementation of the QAPI program, and the governing body has ultimate responsibility to ensure that the QAPI program is defined, implemented, and maintained.²⁷

²¹ Among the 12 nursing homes, there were a total of 12 deficiencies related to designating an infection preventionist who met Federal requirements.

²² CMS required nursing homes to designate an infection preventionist who met Federal requirements by Nov. 28, 2019.

²³ Of the six nursing homes that were unable to provide documentation that they designated an infection preventionist who met Federal requirements, three nursing homes were unable to provide documentation that they had designated an infection preventionist, and three nursing homes had designated an infection preventionist but were unable to provide documentation that the infection preventionist had completed specialized training.

²⁴ CMS required at least quarterly meetings of the QAAC with phase 3 of implementation, Nov. 28, 2019.

²⁵ 81 Fed. Reg. 68804 (Oct. 4, 2016).

²⁶ The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility (42 CFR § 483.70(d)(1)). The governing body is responsible and accountable for the QAPI program (42 CFR § 483.75(f)).

²⁷ 42 CFR § 483.75(f) and 80 Fed. Reg. 42212—42214 (July 16, 2015).

Of the 39 nursing homes we reviewed, 7 had possible deficiencies related to conducting QAAC meetings at least quarterly.²⁸ Specifically, we found that one nursing home may not have complied with the Federal requirements to conduct a QAAC meeting at least quarterly, and six nursing homes did not provide documentation, such as agendas or sign-in sheets, to support that they had complied with the Federal requirement.²⁹

Infection Preventionists Did Not Attend Quality Assessment and Assurance Committee Meetings

Infection preventionists must be members of nursing homes' QAAC to ensure that they are active participants in nursing homes' QAPI plan (42 CFR §§ 483.75(g)(1)(iv) and 483.80(c)). Infection preventionists coordination with the QAAC and with QAPI activities is important to the success of the infection control and prevention program.³⁰

Of the 39 nursing homes that we reviewed, 13 had possible deficiencies related to infection preventionists' participation in the QAAC meetings.³¹ Specifically, we found that four nursing homes may not have complied with the Federal requirement to ensure that designated infection preventionists attended QAAC meetings, and nine nursing homes did not provide documentation, such as meeting sign-in sheets, to support that they had complied with the Federal requirement.

Nursing Homes' Reporting Policies Did Not Specify When and to Whom Incidents of Communicable Diseases Should Be Reported

Nursing homes must have written standards, policies, and procedures for the program, which must include an explanation of when and to whom possible incidents of communicable disease or infections should be reported (42 CFR § 483.80). Nursing homes must know how to recognize and contain infectious disease outbreaks and take appropriate steps to contain an outbreak.³²

²⁸ Among the seven nursing homes, there were a total of seven deficiencies related to at least quarterly QAAC meetings.

²⁹ One nursing home was closed; therefore, we did not get any documentation for meetings from that nursing home. The other five nursing homes provided documentation of meetings; however, the documentation did not support that meetings were held at least quarterly. For example, one nursing home provided documentation for meetings held every 4 months, and another nursing home provided documentation for meetings held in August 2019 and March 2020.

³⁰ 80 Fed. Reg. 42214 (July 16, 2015).

³¹ Among the 13 nursing homes, there were a total of 13 deficiencies related to infection preventionist attendance at QAAC meetings.

³² *State Operations Manual*, Appendix PP – Guidance to Surveyors for Long Term Care Facilities (Rev. 173, Nov. 22, 2017, p. 684–685).

Of the 39 nursing homes that we reviewed, 9 had possible deficiencies related to their reporting policies and procedures.³³ Specifically, these nursing homes may not have complied with the Federal requirement to specify in their written standards, policies, and procedures for the program when and to whom possible incidents of communicable diseases or infections should be reported.

Nursing Homes Did Not Review IPCPs Annually

Nursing homes must conduct annual reviews of their IPCPs and update their programs, as necessary (42 CFR § 483.80(f)). CMS stated that an annual update of nursing home IPCPs is important to ensure the effectiveness of the IPCP in order to keep the nursing homes up to date on current infection prevention and control best practices.³⁴

Of the 39 nursing homes that we reviewed, 6 had possible deficiencies related to the annual review of their IPCPs.³⁵ Specifically, we found that one nursing home may not have complied with the Federal requirement to review its IPCP at least annually, and five nursing homes did not provide documentation, such as dated policies and procedures or signed and dated manual annual review and approval documents, to support that they complied with the Federal requirement that the IPCP had been reviewed at least annually.

One Nursing Home Did Not Demonstrate That It Conducted Infection Prevention and Control Training

A nursing home must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles (42 CFR § 483.95). A nursing home must determine the amount and types of training necessary based on a facility assessment. Training topics must include, but are not limited to, infection control.³⁶ A nursing home must include, as part of its infection prevention and control programs, mandatory training that includes the written standards, policies, and procedures for the program.

Of the 39 nursing homes that we reviewed, 1 had a possible deficiency related to infection prevention and control training.³⁷ Specifically, this nursing home did not provide any documentation, such as in-service training sign-in sheets, to support that it complied with the

³³ Among the nine nursing homes, there were a total of nine deficiencies related to policies regarding when and to whom possible incidents of communicable diseases should be reported.

³⁴ 80 Fed. Reg. 42216 (July 16, 2015).

³⁵ Among the six nursing homes, there were a total of six deficiencies related to the annual review of the IPCP.

³⁶ This requirement had an implementation date of Nov. 28, 2019.

³⁷ For this nursing home, there was one deficiency related to infection prevention and control training.

Federal requirement to conduct infection prevention and control training.

SELECTED NURSING HOMES MAY NOT HAVE COMPLIED WITH EMERGENCY PREPAREDNESS REQUIREMENTS

We found that 18 of the 39 nursing homes each had 1 possible deficiency related to emergency preparedness. Appendix D summarizes the areas of emergency preparedness possible noncompliance. These possible deficiencies related to completing a facility-based and community-based risk assessment and strategies to address emerging infectious diseases.

All-Hazards Risk Assessment Did Not Include Emerging Infectious Diseases

Nursing homes must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must be based on a facility- and community-based risk assessments, using an “all-hazards approach” (42 CFR §483.73(a)(1)). In February 2019, CMS updated Appendix Z of the *State Operations Manual* to include emerging infectious diseases to the definition of an all-hazards approach.³⁸

Of the 39 nursing homes that we reviewed, 10 had possible deficiencies related to all-hazards risk assessments.³⁹ Specifically, we found that one nursing home may not have complied with the Federal requirement to complete facility- and community-based risk assessment, and nine nursing homes did not include emerging infectious diseases on their all-hazards risk assessments.⁴⁰

Emergency Plans Did Not Include Strategies To Address Emerging Infectious Diseases

Nursing homes’ emergency preparedness plans must include strategies for addressing emergency events identified by the risk assessment (42 CFR §483.73(a)(2)).

Of the 39 nursing homes that we reviewed, 8 had possible deficiencies related to their emergency plans.⁴¹ Specifically, we found that 8 of the 29 nursing homes that completed a risk assessment and included emerging infectious diseases as a risk on their risk assessments may not have complied with the Federal requirement to include strategies in their emergency plans

³⁸ 84 Fed. Reg. 51732, 51755 (Sept. 30, 2019) and Feb. 19, 2019, memo from the Director of Quality, Safety & Oversight Group at CMS to the State Survey Agency Directors (REF: QSO19-06-ALL).

³⁹ Among the 10 nursing homes, there were a total of 10 deficiencies related to all-hazards risk assessments.

⁴⁰ During the exit conference, CMS officials said that they would expect an SSA to cite a nursing home for a deficiency if the nursing home did not include emerging infectious diseases on its all-hazards risk assessment. CMS added that it cannot state that the SSAs **must** (emphasis added) cite a deficiency because the regulations do not state that the risk assessment **must** (emphasis added) include emerging infectious diseases.

⁴¹ Among the eight nursing homes, there were a total of eight deficiencies related to emerging infectious disease strategies.

to address emerging infectious diseases.

CAUSES OF POSSIBLE NONCOMPLIANCE WITH FEDERAL REQUIREMENTS

Officials from the 28 nursing homes provided the following reasons for potentially not complying with Federal requirements for infection prevention and control and infection-control-related emergency preparedness:

- nursing home internal controls were inadequate,
- nursing home management oversight was lacking,
- nursing home administrative and leadership positions experienced changes,
- inadequate CMS communication and training, and
- inconsistent and confusing regulations.⁴²

We also believe that the lack of interpretive guidance could have contributed to the number of infection prevention and control possible deficiencies.

SELECTED NURSING HOMES MAY HAVE INCREASED THE RISK OF INFECTIONS TO RESIDENTS AND STAFF

As a result of the potential infection prevention and control and emergency preparedness deficiencies, selected nursing homes may have an increased risk for health and safety issues, including emerging infectious disease threats for residents and staff.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

⁴² Title 42 CFR § 483.73(a)(1) states that nursing homes **must** (emphasis added) develop an emergency plan that is based on a facility-based and community-based risk assessment utilizing an all-hazards approach, including missing residents. A February 2019 memo from CMS to SSA directors informed them that it was updating Appendix Z of the *State Operations Manual* to reflect changes to add emerging infectious diseases to the current definition of all-hazards approach. The February 2020 revision of Appendix Z of the *State Operations Manual* states that planning for using an all-hazards approach **should** (emphasis added) also include emerging infectious disease threats.

- instruct SSAs to follow up with the 28 nursing homes that we have identified with possible infection prevention and control and emergency preparedness deficiencies to verify that they have taken corrective actions,⁴³
- issue the updated phase 3 interpretive guidance as soon as feasible,⁴⁴
- provide training to SSAs on the updated, phase 3 interpretive guidance as soon as feasible,⁴⁵ and
- consider updating the regulation to make clear that nursing homes must include emerging infectious diseases as a risk on their facility- and community-based all-hazards risk assessments.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first three recommendations. Regarding our fourth recommendation, CMS stated that it would consider this recommendation in future rulemaking. Summaries of CMS’s comments and our responses are provided below.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS’s comments, excluding the technical comments, appear as Appendix E.

INTRODUCTORY COMMENTS

CMS Comments

In its introductory comments on this report, CMS stated that it takes seriously its role in improving the safety and quality of care in the Nation’s nursing homes and that it is leading the Biden-Harris Administration’s new efforts to increase accountability for nursing homes. The Administration has laid out 21 initiatives spread across 5 key, strategic goals. One goal is to ensure pandemic and emergency preparedness in nursing homes and carry forward lessons learned during COVID-19. These initiatives were developed with extensive input from advocates, industry experts, nursing home workers, and nursing home residents and their loved ones. CMS said it is considering a wide range of methods to accomplish this important work.

CMS further stated that since the beginning of COVID-19 it has taken numerous actions to further strengthen infection prevention and control in nursing homes. CMS also stated that focused infection control surveys had been conducted at more than 99 percent of nursing

⁴³ SSAs should prioritize followup activities: (1) based upon the level of risk to beneficiaries and (2) in accordance with CMS policies for triaging nursing home complaints and incidents.

⁴⁴ CMS provided comments to the OIG draft report on May 18, 2022. On June 29, 2022, CMS informed OIG that they issued the phase 3 interpretive guidance.

⁴⁵ CMS made training materials related to the new interpretive guidance available to the SSAs on June 28, 2022.

homes as of July 2020 and that it now requires that SSAs conduct annual, focused infection control surveys at 20 percent of nursing homes.

CMS added that it uses data submitted by nursing homes to improve oversight and inform the public. This data includes things such as COVID-19 testing, cases, and mortality for residents and staff; nursing home staff and resident COVID-19 vaccination; and weekend nurse staffing levels.

Office of Inspector General Response

We commend CMS for the action it has and plans to take in order to ensure the safety and quality of care for residents of our Nation’s nursing homes. We included examples in the report of actions that CMS took such as: (1) limiting visits to certain situations, such as end of life, (2) ceasing group activities and communal dining, (3) screening residents and others entering the nursing home for respiratory illness symptoms, and (4) testing residents and staff for COVID-19. We also included in Appendix B a list of many of the actions that CMS took in response to the PHE.

COMMENTS ON RECOMMENDATIONS

CMS Comments

CMS concurred with our first three recommendations and described actions that it has taken or plans to take to address our recommendations. CMS stated that it will: (1) ensure that SSAs follow up with the 28 nursing homes to verify that they have taken corrective actions, (2) issue the phase 3 interpretive guidance, and (3) provide training as soon as feasible. CMS stated that it had intended to release the phase 3 interpretive guidance during the second quarter of 2020. However, prior to issuing the guidance, the COVID-19 PHE was declared, and CMS immediately redirected resources to address patient safety needs related to the PHE. Regarding our fourth recommendation, CMS stated that it would consider this recommendation in future rulemaking. CMS further stated that it has taken considerable steps to make clear that nursing homes should include emerging infectious diseases as an identified risk on their facility- and community-based, all-hazards risk assessments.

Office of Inspector General Response

Regarding our fourth recommendation, OIG believes that the regulation should be strengthened to require the inclusion of emerging infectious diseases as an identified risk on their facility- and community-based all-hazards risk assessments. Although CMS addresses the inclusion of emerging infectious diseases as a risk in its *State Operations Manual*, Appendix Z, “Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance,” the manual states that planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. The word “should” could be inferred by nursing homes to mean that the inclusion of emerging infectious diseases is not a requirement but rather a

recommendation.

OTHER MATTERS

Nursing homes typically struggle with staffing shortages and turnover, which only became worse during the COVID-19 PHE. For example, one of the nursing homes in our audit had shortages that led it to require staff who received positive COVID-19 tests while at work to complete their shifts.⁴⁶ When asked about the rationale for this, nursing home officials stated that the extreme staffing shortage made it necessary in order to ensure the safety of the residents. They also stated that all employees donned full PPE for their entire shifts. Additionally, 34 of the 39 nursing homes that we reviewed reported to OIG that between January 1, 2019, and April 30, 2021, they had average monthly staff turnover rates ranging from a low of 1 percent to a high of 20 percent.⁴⁷ One nursing home reported a 154 percent staff turnover during 2020. Nursing homes also often had turnover in ownership and key senior management positions. Nursing homes reported to us:

- 4 changes in ownership (4 nursing homes reported changes in ownership 1 time each from January 1, 2019, through April 30, 2021),
- 49 changes in administrators (24 nursing homes reported changes in administrators between 1 and 5 times from January 1, 2019, through April 30, 2021), and
- 56 changes in the infection preventionist position (21 nursing homes reported changes in the position between 1 and 6 times from January 1, 2019, through April 30, 2021).

In many instances, the reason why a nursing home was unable to provide documentation to support that it had complied with Federal regulations appeared to be related to turnover. For example, one nursing home was unable to provide documentation that infection prevention and control training had taken place because ownership was new and the new owner did not have access to the prior owner's computer system that maintained training records. In other instances, the administrators who responded to our audit were not employed by the nursing homes during our audit period or were not the administrators throughout the entire audit period; therefore, they were unable to answer certain questions, such as whether the nursing home had designated an infection preventionist at the start of the requirement's implementation date.

⁴⁶ CDC guidance allowed for COVID-19 positive staff to continue working during periods of staff shortages <https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html>. (Accessed Mar. 1, 2022.)

⁴⁷ Of the five remaining nursing homes, two nursing homes closed during our fieldwork, one nursing home had an ownership change during fieldwork and did not have turnover information from the previous owner, one nursing home stated that it did not track staff turnover, and one nursing home did not respond to our request.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

As of March 26, 2020, there were 15,446 Medicare and Medicaid certified nursing homes. SSA data on the Medicare.gov website indicated that 6,830 (approximately 44 percent) of these 15,446 nursing homes had been cited for infection control deficiencies. After further analysis of the data, we found that these deficiencies had been corrected in all but 39 (less than 1 percent) nursing homes that did not have a plan in place to correct the deficiencies as of March 26, 2020. We contacted the 39 nursing homes and requested documentation to determine whether they complied with Federal regulations from January 1, 2019, through May 31, 2020.

We did not assess CMS's or the nursing homes' overall internal control structures. Rather, we limited our review of internal controls to the nursing homes' infection prevention and control policies and procedures and infection-control-related emergency preparedness policies and procedures.

We performed our audit from June 2020 through March 2022.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State requirements;
- corresponded with CMS program officials to gain an understanding of the infection prevention and control and emergency preparedness requirements;
- contacted the 39 nursing homes and requested documentation related to their infection prevention and control and emergency preparedness plans;
- reviewed documentation from nursing homes to determine whether they have programs for infection prevention and control and emergency preparedness in accordance with Federal requirements; and
- discussed the results of the 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: LIST OF CMS PUBLIC HEALTH ACTIONS FOR NURSING HOMES
CONCERNING THE COVID-19 PUBLIC HEALTH EMERGENCY**

Date	Title
February 6, 2020	<i>CMS Prepares Nation’s Healthcare Facilities for Coronavirus Threat</i> https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat
March 4, 2020	<i>CMS Announces Actions to Address Spread of Coronavirus</i> https://www.cms.gov/newsroom/press-releases/cms-announces-actions-address-spread-coronavirus
March 10, 2020	<i>COVID-19 Response News Alert: CMS Issues Key Protective Mask Guidance for Healthcare Workers</i> https://www.cms.gov/newsroom/press-releases/covid-19-response-news-alert-cms-issues-key-protective-mask-guidance-healthcare-workers
March 13, 2020	<i>Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (revised March 10, 2021)</i> https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf
March 20, 2020	<i>Prioritization of Survey Activities (updated March 10, 2021)</i> https://www.cms.gov/files/document/qso-20-20-allpdf.pdf
April 2, 2020	<i>Trump Administration Issues Key Recommendations to Nursing Homes, State and Local Governments</i> https://www.cms.gov/newsroom/press-releases/trump-administration-issues-key-recommendations-nursing-homes-state-and-local-governments
April 19, 2020	<i>Trump Administration Announces New Nursing Homes COVID-19 Transparency Effort</i> https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-nursing-homes-covid-19-transparency-effort
April 30, 2020	<i>CMS Announces Independent Commission to Address Safety and Quality in Nursing Homes</i> https://www.cms.gov/newsroom/press-releases/cms-announces-independent-commission-address-safety-and-quality-nursing-homes

May 6, 2020	<p><i>Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes</i></p> <p>https://www.cms.gov/files/document/gso-20-29-nh.pdf</p>
May 2020	<p><i>Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes</i> (version 26, issued March 2022)</p> <p>https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf</p>
May 14, 2020	<p><i>Trump Administration Announces Call for Nominations for Nursing Home Commission</i></p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-announces-call-nominations-nursing-home-commission</p>
May 18, 2020	<p><i>Trump Administration Issues Guidance to Ensure States Have a Plan in Place to Safely Reopen Nursing Homes</i></p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-issues-guidance-ensure-states-have-plan-place-safely-reopen-nursing-homes</p>
June 1, 2020	<p><i>COVID-19 Survey Activities, CARES Act Funding, Enhanced Enforcement for Infection Control Deficiencies, and Quality Improvement Activities in Nursing Homes</i> (revised January 4, 2021)</p> <p>https://www.cms.gov/files/document/gso-20-31-all-revised.pdf</p> <p>CMS also issued a letter to governors:</p> <p>https://www.cms.gov/files/document/6120-letter-governors.pdf</p>
June 19, 2020	<p><i>CMS Announces Membership of Independent Coronavirus Commission on Safety and Quality in Nursing Homes</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-announces-membership-independent-coronavirus-commission-safety-and-quality-nursing-homes</p>
June 23, 2020	<p><i>CMS released revised guidance for nursing home visitation during the COVID-19 Public Health Emergency</i> (revised March 10, 2021)</p> <p>https://www.cms.gov/files/document/covid-visitation-nursing-home-residents.pdf</p>

June 25, 2020	<p><i>CMS Ends Emergency Blanket Waiver for the Nursing Home Staffing Data Submission Requirement</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-ends-emergency-blanket-waiver-nursing-home-staffing-data-submission-requirement</p>
July 10, 2020	<p><i>CMS Directs Additional Resources to Nursing Homes in COVID-19 Hotspot Areas</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-directs-additional-resources-nursing-homes-covid-19-hotspot-areas</p>
July 14, 2020	<p><i>Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes</i></p> <p>https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html</p>
July 22, 2020	<p><i>Trump Administration Announces New Resources to Protect Nursing Home Residents Against COVID-19</i></p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-resources-protect-nursing-home-residents-against-covid-19</p>
August 17, 2020	<p><i>CMS Announces Resumption of Routine Inspections of All Provider and Suppliers, Issues Updated Enforcement Guidance to States, and Posts Toolkit to Assist Nursing Homes</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-announces-resumption-routine-inspections-all-provider-and-suppliers-issues-updated-enforcement</p>
August 24, 2020	<p><i>CMS Issues Informational Bulletin on Medicaid Reimbursement Strategies to Prevent Spread of COVID-19 in Nursing Facilities</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-issues-informational-bulletin-medicaid-reimbursement-strategies-prevent-spread-covid-19-nursing</p>
August 25, 2020	<p><i>Trump Administration Launches National Training Program to Strengthen Nursing Home Infection Control Practices</i></p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-launches-national-training-program-strengthen-nursing-home-infection-control</p>
August 25, 2020	<p><i>Trump Administration Strengthens COVID-19 Surveillance with New Reporting and Testing Requirements for Nursing Homes, Other Providers</i></p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-strengthens-covid-19-surveillance-new-reporting-and-testing-requirements</p>

August 26, 2020	<p><i>CMS posts guidance for implementing new testing requirements in nursing homes and labs</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-posts-guidance-implementing-new-testing-requirements-nursing-homes-and-labs</p>
September 16, 2020	<p><i>Independent Nursing Home COVID-19 Commission Findings Validate Unprecedented Federal Response</i></p> <p>https://www.cms.gov/newsroom/press-releases/independent-nursing-home-covid-19-commission-findings-validate-unprecedented-federal-response</p>
September 17, 2020	<p><i>CMS Announces New Guidance for Safe Visitation in Nursing Homes During COVID-19 Public Health Emergency</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-announces-new-guidance-safe-visitation-nursing-homes-during-covid-19-public-health-emergency</p>
September 29, 2020	<p><i>CMS Updates COVID-19 Testing Methodology for Nursing Homes</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes</p>
November 17, 2020	<p><i>CMS Releases Nursing Home COVID-19 Training Data with Urgent Call to Action</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-releases-nursing-home-covid-19-training-data-urgent-call-action</p>
November 18, 2020	<p><i>CMS Urging Nursing Homes to Follow Established COVID Guidelines This Holiday Season</i></p> <p>https://www.cms.gov/newsroom/press-releases/cms-urging-nursing-homes-follow-established-covid-guidelines-holiday-season</p>
August 18, 2021	<p><i>Biden-Harris Administration Takes Additional Action to Protect America's Nursing Home Residents from COVID-19</i></p> <p>https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19</p>

**APPENDIX C: AREAS OF INFECTION PREVENTION
AND CONTROL POSSIBLE NONCOMPLIANCE
AT 25 NURSING HOMES**

Nursing Home	Did Not Designate an Infection Preventionist Who Met Federal Requirements	Did Not Conduct Quarterly QAAC Meetings	IP Did Not Attend QAAC Meetings	P&P Did Not Include When and to Whom Incidents of Communicable Diseases Should Be Reported	Failed to Review IPCP Annually	Did Not Support That They Conducted IPCP Training	Total
2	1	-	-	1	-	-	2
3	1	-	-	-	-	-	1
4	-	-	-	1	-	-	1
5	-	-	1	-	-	-	1
6	1	-	-	1	-	-	2
7	1	-	-	1	1	-	3
8	1	-	1	-	-	-	2
9	-	-	-	1	-	-	1
10	1	1	1	1	1	-	5
11	-	-	1	1	-	-	2
13	1	-	-	-	-	-	1
15	-	-	1	1	1	-	3
16	-	-	-	-	1	-	1
18	1	1	1	-	-	-	3
19	-	-	1	-	-	-	1
20	-	1	1	-	-	-	2
23	-	1	1	-	1	-	3
26	-	1	1	-	-	-	2
27	-	1	1	1	-	-	3
28	1	-	-	-	-	-	1
30	1	-	-	-	-	-	1

Nursing Home	Did Not Designate an Infection Preventionist Who Met Federal Requirements	Did Not Conduct Quarterly QAAC Meetings	IP Did Not Attend QAAC Meetings	P&P Did Not Include When and to Whom Incidents of Communicable Diseases Should Be Reported	Failed to Review IPCP Annually	Did Not Support That They Conducted IPCP Training	Total
31	-	-	-	-	-	1	1
32	1	-	1	-	-	-	2
33	1	1	1	-	-	-	3
37	-	-	-	-	1	-	1
Totals	12	7	13	9	6	1	48

**APPENDIX D: AREAS OF EMERGENCY
PREPAREDNESS POSSIBLE NONCOMPLIANCE
AT 18 NURSING HOMES**

Nursing Home	Did Not Complete an All-Hazards Risk Assessment	All-Hazards Risk Assessment Did Not Include EID	EID Strategies Not Included in Emergency Plans	Total
3	-	1	-	1
8	-	-	1	1
10	-	1	-	1
11	-	-	1	1
15	-	-	1	1
16	-	1	-	1
17	-	-	1	1
18	-	-	1	1
20	-	-	1	1
23	-	-	1	1
26	1	-	-	1
27	-	1	-	1
28	-	1	-	1
32	-	1	-	1
33	-	1	-	1
35	-	1	-	1
37	-	1	-	1
39	-	-	1	1
Totals	1	9	8	18



Administrator

Washington, DC 20201

DATE: May 18, 2022

TO: Gregory Demske
Acting Principal Deputy Inspector General

FROM: Chiquita Brooks-LaSure *Chiquita LaSure*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness, A-01-20-00005

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 takes seriously its role in improving the safety and quality of care in our nation's nursing homes, as such, CMS is leading the Biden-Harris Administration's new efforts to increase accountability for nursing homes. The Administration has laid out 21 initiatives spread across five key strategic goals, including a goal to ensure pandemic and emergency preparedness in nursing homes and carry forward lessons learned during the COVID-19 public health emergency. These initiatives were developed with extensive input from advocates, industry experts, nursing home workers, and most importantly, residents and their loved ones. CMS is considering a wide range of methods to accomplish this important work.

Nursing homes receiving Medicare or Medicaid payments are already required to comply with CMS quality and safety standards, including those relating to infection prevention and control and emergency preparedness. CMS shares responsibility of nursing home oversight with State Survey Agencies (SSAs) who conduct onsite surveys to assess compliance with the Federal 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. Accordingly, when an SSA identifies an issue of non-compliance, the nursing home is cited for a deficiency and is required to correct the issue(s) and demonstrate substantial compliance with all Federal requirements.

Long before the COVID-19 pandemic began, CMS had acted to strengthen emergency preparedness and infection control practices in nursing homes. CMS took pivotal actions in the 2016 final rule, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (81 FR 63860). This rule outlined updates to emergency preparedness requirements for all facilities. The rule's updates highlighted the need for nursing homes to guide emergency preparedness and response within the framework of our national response to COVID-19 and any infectious disease threats. The requirements encouraged providers and suppliers to coordinate their preparedness efforts within their own communities and states as well as across state lines, as necessary, to achieve their goals. The rule also required facilities to perform a risk assessment that uses an all-hazards approach. It further laid out that an all-hazards approach was one that "...focuses on capacities and capabilities that are critical to preparedness for a full

spectrum of emergencies or disasters.”¹ In addition, CMS also outlined specific reform requirements for long-term care facilities in the 2016 final rule, Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities (81 FR 68688), which was the impetus for the requirement that nursing homes develop an infection prevention and control program that includes an antibiotic stewardship program.²

Since the COVID-19 public health emergency declaration in early 2020, CMS has taken a number of actions to further strengthen infection prevention and control within nursing homes. CMS began by issuing guidance to nursing homes encouraging them to take appropriate action to address potential and confirmed COVID-19 cases and mitigate transmission. CMS reiterated the importance of longstanding infection control guidelines, and guidelines on screening processes and the use of personal protective equipment (PPE).

In an effort to focus on controlling the spread of COVID-19, CMS provided SSAs with a streamlined review tool to conduct focused 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). This tool was shared with providers who were encouraged by the agency to use it to self-assess their own ability to prevent the spread of COVID-19. By July 2020, over 99 percent of nursing homes had a focused infection control survey conducted onsite. As the public health emergency continued, the focused infection control survey was revised to incorporate new infection control requirements to address the spread of COVID-19. While the COVID-19 public health emergency warranted a more targeted approach for assessing a nursing homes’ compliance with infection prevention and control requirements, CMS recently released guidance to help SSAs focus their efforts on identifying concerns for all aspects of quality of care, quality of life, and ensuring health and safety. CMS now requires SSAs to perform annual focused infection control surveys at 20 percent of nursing homes.³ CMS also published a toolkit comprised of recommendations and best practices from a variety of frontline health care providers, state governors’ COVID-19 task forces, associations, and other experts that is intended to serve as a catalogue of resources dedicated to addressing the specific challenges facing nursing homes as they combat COVID-19.⁴ CMS continues to review and revise guidance as appropriate.

In addition to the survey process used to verify compliance with Federal requirements, CMS uses data submitted by nursing homes to improve oversight and inform the public. CMS implemented a requirement that Medicare-certified nursing homes report COVID-19 testing, case, and mortality data for residents and staff to the CDC’s National Healthcare Safety Network.⁵ Thereafter, in September of 2021, CMS began posting nursing home staff and resident COVID-19 vaccination data in a user-friendly format on its Nursing Home Care Compare website. Subsequently, in February 2022, CMS began posting staff and resident booster shot data to the

¹ [Medicare and Medicaid Programs; Emergency Preparedness Requirements, 81 Fed. Reg. 63860, 63862 \(Sept. 16, 2016\).](#)

² [Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688 \(Nov. 28, 2016\).](#)

³ [QSO-22-02-All: Changes to COVID-19 Survey Activities and Increased Oversight in Nursing Homes](#)

⁴ [QSO-21-08-NLTC: COVID-19 Focused Infection Control Survey Tool for Acute and Continuing Care Providers and Suppliers](#)

⁵ [QSO-20-26-NH Upcoming Requirements for Notification of Confirmed COVID-19 \(or COVID-19 Persons under Investigation\) Among Residents and Staff in Nursing Homes](#)

website.⁶ To further enhance the information available to consumers, residents, and families and to help support their healthcare decisions and incentivize quality improvement among nursing homes, CMS began posting weekend nurse staffing levels as well as nursing home staff turnover data.⁷

These data are also used in the coordinated effort between CMS and CDC to provide detailed information to state and local health departments and nursing homes to inform infection prevention and control policies and strategies across the country to further support nursing home residents. These data are also used by CMS when it is considering adjusting or introducing new policies. They have informed CMS's national policies as to when to implement, revise, or terminate waivers, and they have allowed CMS to target specific nursing homes for assistance with infection control or vaccine uptake. Specifically, through the work of the Quality Improvement Organization (QIO) program, CMS assists nursing homes in strengthening infection control practices to reduce and prevent transmission of COVID-19.

The QIOs provide educational activities, including frontline training of nursing home staff and management on infection prevention practices to reduce the spread of infection and manage outbreaks effectively, as well as providing individualized training resources based on the nursing homes' specific needs through toolkits, resource materials, guides, webinars, and clinician office hours to provide expert consultation on the particular challenges nursing homes face. CMS collects best practices and lessons learned from each of the QIOs and coordinates the sharing of that information across QIOs nationally for rapid deployment. Additionally, CMS partners with Federal agencies such as the CDC and ASPR, who are the national leaders in disease prevention and control and public health emergency response to ensure coordination of services and alignment of guidance for nursing homes.

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' responses are below.

OIG Recommendation

Instruct SSAs to follow up with the 28 nursing homes that we have identified with possible infection prevention and control and emergency preparedness deficiencies to verify that they have taken corrective actions.

CMS Response

CMS concurs with OIG's recommendation. CMS will ensure that the appropriate SSAs follow up with the 28 nursing homes OIG identified with possible infection prevention and control and emergency preparedness deficiencies to verify that they have taken corrective actions as needed, in line with Federal requirements. It is important to note, however, that when an SSA cites a nursing home with an infection control deficiency, as with any cited deficiency, the nursing home is required to correct the issue and come back into compliance with the Federal requirements. OIG found that less than one percent of nursing homes had not corrected their potential deficiencies at the time of OIG's review.

OIG Recommendation

⁶ [CMS Makes Nursing Home COVID-19 Booster Vaccination Online Increasing Transparency, CMS News Alert, Feb. 09, 2022](#)

⁷ [QSO-22-0-08-NH: Nursing Home Staff Turnover and Weekend Staffing Levels](#)

Issue the updated phase three interpretive guidance as soon as feasible.

CMS Response

CMS concurs with the OIG's recommendation. In November of 2019, CMS expressed its intention to release the phase III guidance.⁸ However, before CMS could implement the guidance, the COVID-19 public health emergency was declared. CMS immediately moved to redirect resources to address immediate needs relating to resident safety. Despite the surveyor guidance not being issued, the requirements were all in effect by November 28, 2019 and facilities were expected to comply with the requirements. CMS continues to prioritize the health and safety of residents, and will release phase three interpretive guidance when feasible.

OIG Recommendation

Provide training to SSAs on the updated phase three interpretive guidance as soon as feasible.

CMS Response

CMS concurs with the OIG's recommendation. In November of 2019, CMS expressed its intention to release phase III guidance along with information on training and implementation of related changes to the Long-Term Care Survey Process.⁹ CMS continues to prioritize the health and safety of residents and will release phase III interpretive guidance and provide training as soon as feasible.

OIG Recommendation

Consider updating the regulation to make clear that nursing homes must include emerging infectious diseases as a risk on their facility- and community-based all-hazards risk assessments.

CMS Response

CMS will consider this recommendation in future rulemaking. CMS has taken considerable steps, as laid out below, to make clear that nursing homes should include emerging infectious diseases as an identified risk on their facility- and community-based all-hazards risk assessments. The Emergency Preparedness Final Rule (81 Fed. Reg. 63860, Sept. 16, 2016) requires facilities to perform a risk assessment that uses an all-hazards approach. It further defines an all-hazards approach as one that "...focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters."

CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program, and specified "emerging infectious diseases" in the definition of "all-hazards" in the interpretive guidance in the State Operations Manual. In light of the COVID-19 pandemic, CMS further updated the emergency preparedness guidance to further expand information on best practices, lessons learned, and planning considerations for emerging infectious disease outbreaks. Specifically, the update noted, "... as emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive emergency preparedness program should include emerging infectious diseases and pandemics during a public health emergency. As part of the comprehensive emergency preparedness program, emerging infectious disease planning should encompass how facilities will plan, coordinate and respond to localized and widespread pandemic, similar to what is occurring with the COVID-19 public health emergency."¹⁰

⁸ [QSO-20-03-NH Updates and Initiatives to Ensure Safety and Quality in Nursing Homes.](#)

⁹ [QSO-20-03-NH Updates and Initiatives to Ensure Safety and Quality in Nursing Homes.](#)

¹⁰ [QSO-21-15-All: Updated Guidance for Emergency Preparedness - Appendix Z of the SOM](#)