

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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**September 2022
A-01-20-00004**

Office of Inspector General

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Report in Brief

Date: September 2022
Report No. A-01-20-00004

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



Why OIG Did This Audit

At the start of the pandemic, the Centers for Disease Control and Prevention 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. COVID-19 is especially dangerous for the more than 1.3 million residents who live in the 15,450 Medicare and Medicaid certified nursing homes nationwide.

Our objective was to determine whether selected Life Care Centers of America (Life Care) 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 surveys. We identified that 6,622 nursing homes had been cited for infection prevention and control program deficiencies as of February 26, 2020, and Medicare.gov indicated that 24 nursing homes were part of the Life Care nursing home chain. We contacted Life Care's corporate office regarding the 24 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 2019 through May 2020.

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

What OIG Found

Selected Life Care nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness. Specifically, 23 of the 24 nursing homes selected had possible deficiencies. Actual deficiencies can only be determined following a thorough investigation by trained surveyors. At 22 nursing homes, we found 35 instances of possible noncompliance with infection prevention and control requirements related to annual reviews of the Infection Prevention and Control Program, training, designation of a qualified infection preventionist, and Quality Assessment and Assurance Committee meetings. We also found at 16 nursing homes 20 instances of possible noncompliance with emergency preparedness requirements related to the annual review of emergency preparedness plans and annual emergency preparedness risk assessments. Life Care officials attributed the possible noncompliance to: (1) leadership turnover, (2) staff turnover, (3) documentation issues (i.e., information was not documented or documentation was either lost or misplaced), (4) staff members who were unfamiliar with requirements (i.e., requirements stipulating that there is no grace period for infection preventionists to complete specialized training and that emergency preparedness plans needed to be reviewed annually), (5) qualified personnel shortage, and (6) challenges related to the COVID-19 public health emergency. We also believe that 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 control requirements, or clarification about the essential components to be integrated in the nursing homes' emergency plans.

What OIG Recommends and CMS Comments

We recommend that CMS instruct SSAs to follow up with the 23 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 concurred with our recommendation and stated that it has contacted the appropriate SSAs to ensure that the 23 nursing homes with possible infection prevention and control and emergency preparedness deficiencies have taken corrective actions in accordance with Federal requirements.

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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 15,450 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, results from survey reports published on the Centers for Medicare and Medicaid Service's (CMS's) Nursing Home Care Compare website indicate that nursing homes are not always in compliance with infection prevention and control requirements. Specifically, according to these reports, 24 Life Care Centers of America (Life Care) nursing homes in 11 States did not always comply with all infection prevention and control requirements, such as following proper hand hygiene, as of February 26, 2020. In March 2021, CMS officials said that the nursing homes had satisfactorily addressed all of the deficiencies identified by these surveys. Our audit focuses on these 24 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 Life Care 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 Mar. 10, 2022.)

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, residents' increased susceptibility to infections, and the significant exposure to

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).

health care-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 includes 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) plan to their SSA no later than 1 year after the date the regulation is issued, at each annual recertification survey, and upon request (phase 2);¹⁰ and
- have the individuals responsible for a 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, while 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 2020.¹¹ 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.¹²

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 QAPI plans are a data-driven and proactive approach to quality improvement. All members of an organization, including residents, are involved in continuously identifying opportunities for improvement. Gaps in systems are addressed through planned interventions with a goal of improving the overall quality of life and quality of care and services delivered to nursing home residents.

¹¹ Memo from the Director of Quality, Safety & Oversight Group at CMS to State Survey Agency Directors, Nov. 22, 2019. (REF: QSO-20-03-NH).

¹² Despite the delay, CMS communicated to nursing homes that they should not wait on the issuance of the interpretive guidance to ensure that they are in compliance with new regulations. (McKnights Long-Term Care News, [With Phase 3 guidance nearing, skilled nursing providers advised ‘don’t wait’ on infection preventionist, other regs](#), Oct. 22, 2021. (Accessed Aug. 26, 2022.))

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 develop strategies to address the risks identified.¹³ 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*. CMS also updated Appendix Z with guidance for "emergency preparedness."¹⁴

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. Standard surveys of nursing homes must occur no later than 15 months after the previous survey.^{15, 16} SSAs cite nursing homes with deficiencies when they do not meet the conditions of participation, including when they do not follow infection prevention and control requirements.

Management and staff at a nursing home are responsible for ensuring the safety and well-being of residents and staff and for complying with Federal, State, and local regulations. They are

¹³ Emerging infectious diseases are those that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range. "NIAID Emerging Infectious Diseases/Pathogens" is available online at <https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens>. (Accessed Mar. 10, 2022.)

¹⁴ Memo From the Director of Quality, Safety & Oversight Group at CMS to State Survey Agency Directors, Mar. 26, 2021 (REF: QSO-21-15-ALL).

¹⁵ The Act §§ 1819(g)(2)(A)(iii)(I) and 1919(g)(2)(A)(iii)(I) and 42 CFR § 488.308(a).

¹⁶ 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).

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 stop its spread, CMS issued many guidance memoranda during the COVID-19 PHE. These included, among other things, requiring nursing homes to: (1) prohibit visits from family and friends (except in 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.

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 (NHSN). Nursing homes were required to report on a weekly basis beginning May 17, 2020.¹⁷ CMS published on its website the information reported to NHSN by nursing homes.¹⁸

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 December 26, 2021, by 15,447 nursing homes.^{19, 20}

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
942,849	900,190	1,843,039	141,514	2,230	143,744

¹⁷ 85 Fed. Reg. 27627 (May 8, 2020).

¹⁸ [COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data \(cms.gov\)](https://www.cms.gov/medicare/coverage/eligibility/2022-01-01-eligibility-changes). (Accessed Mar. 10, 2022.)

¹⁹ 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 predated the effective date of the interim final rule; it was left to the discretion of the nursing homes whether to report historical data. As a result, these data could include figures lower than actual figures for COVID-19 cases and COVID-19-related deaths if nursing homes chose not to report the historical data.

²⁰ We removed the COVID-19 cases and related deaths reported by the 24 nursing homes in our audit from these numbers and reported them separately.

Residents and staff at the 24 selected nursing homes were severely impacted by COVID-19. Many of these residents and staff contracted COVID-19—and 293 of these individuals 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 December 26, 2021.

Table 2: COVID-19 Cases and COVID-19-Related Deaths at 24 Nursing Homes*

Confirmed and Suspected COVID-19 Cases			COVID-19-Related Deaths		
Residents	Staff	Total	Residents	Staff	Total
1,994	1,479	3,473	291	2	293
* These numbers include case and death counts reported directly to OIG by the 24 nursing homes through May 31, 2020, and case and death counts reported to CDC and CMS from June 1, 2020, through December 26, 2021. Life Care was unable to provide OIG with suspected COVID-19 cases. Therefore, the data reported directly to OIG by the 24 nursing homes through May 31, 2020, only includes confirmed COVID-19 cases.					

Life Care Centers of America

Life Care is the country’s largest privately held nursing home company with annual revenue of approximately \$3 billion, according to an estimate by Forbes.²¹ Life Care’s headquarters is in Cleveland, Tennessee, and it operates or manages more than 200 skilled nursing, rehabilitation, Alzheimer’s, and senior living campuses in 28 states.²²

At the beginning of the COVID-19 pandemic, news articles indicated two Life Care nursing homes potentially did not comply with regulations pertaining to reporting respiratory infections to appropriate health authorities.²³

HOW WE CONDUCTED THIS AUDIT

As of February 26, 2020, there were 15,450 Medicare and Medicaid certified nursing homes in the United States. We analyzed SSA survey data on Medicare.gov for the most recent standard surveys and the previous 12 months of complaint surveys.²⁴ Based on that analysis, we

²¹ Forbes.com, [Life Care Centers of America](#). (Accessed Mar. 10, 2022.)

²² See Appendix C for the number of Life Care facilities by State.

²³ The Washington Post, [Washington nursing home with deadly coronavirus cluster failed to flag illnesses, federal inspectors find](#), Mar. 23, 2020. (Accessed Mar. 10, 2022.) CBS Boston, [Littleton Assisted Living Facility Considered ‘Hot Spot’ for Coronavirus](#), Apr. 2, 2020. (Accessed Mar. 10, 2022.)

²⁴ A complaint survey is conducted based on a substantial allegation of noncompliance. A substantial allegation of noncompliance is a complaint that would, if noncompliance is found to be present, adversely affect the health and

determined that 6,622 nursing homes (approximately 43 percent) had been cited for IPCP deficiencies related to: (1) not providing and implementing an infection prevention and control program (5,977 nursing homes), (2) not developing and implementing policies and procedures for flu and pneumonia vaccinations (232 nursing homes), or (3) both (413 nursing homes). Medicare.gov indicated that 24 of the 6,622 nursing homes were part of the Life Care nursing home chain. The deficiencies included:

- staff members did not wear appropriate personal protective equipment (PPE) while in the rooms of residents who were in isolation,
- staff and residents used improper hand hygiene,
- a nursing home failed to vaccinate eligible residents with the pneumococcal vaccines as indicated by the facility's policy and current CDC guidelines, and
- a staff member failed to ensure that the glucometer used to test blood glucose levels was properly cleansed between testing for two residents.

We contacted Life Care's corporate office regarding the 24 nursing homes and requested that officials 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 infection preventionist positions, quality assessment and assurance committees (QAACs), 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 emergency preparedness. CMS officials informed us that actual deficiencies are to be cited onsite following a thorough investigation by trained Federal, State, and contractual surveyors to determine compliance with the Federal requirements for participation (i.e., 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.

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.

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).

FINDINGS

Selected Life Care nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness.²⁵ Specifically, 23 of the 24 nursing homes had possible deficiencies, and 20 of these nursing homes had more than 1 possible deficiency.²⁶ At 22 nursing homes, we found 35 instances of possible noncompliance with infection prevention and control requirements related to:

- the nursing homes' annual reviews of their IPCPs,
- training,
- designations of a qualified infection preventionist, and
- QAAC meetings.

We also found at 16 nursing homes 20 instances of possible noncompliance with emergency preparedness requirements related to the annual review of emergency preparedness plans and annual emergency preparedness risk assessments.

Life Care officials attributed the areas of possible noncompliance we identified to: (1) leadership turnover, (2) staff turnover, (3) documentation issues (i.e., information was not documented or documentation was either lost or misplaced), (4) staff members who were unfamiliar with requirements (i.e., requirements stipulating that there is no grace period for infection preventionists to complete specialized training and that emergency preparedness plans needed to be reviewed annually), (5) qualified personnel shortage, and (6) challenges related to the COVID-19 PHE. Life Care officials also said that they have taken actions to correct all possible identified deficiencies.²⁷

In addition, we believe that 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

²⁵ 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., 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.

²⁶ Of the 23 nursing homes with possible deficiencies, 15 had infection prevention and control and emergency preparedness deficiencies, 7 had only infection prevention and control deficiencies, and 1 had only emergency preparedness deficiencies.

²⁷ Life Care officials informed us that the corrective actions apply to all nursing homes that are part of the Life Care chain, not just the 24 nursing homes identified in this audit.

new, phase 3 infection control requirements, or clarification about the essential components to be integrated in the nursing homes' emergency plans.²⁸

As a result of the possible deficiencies we identified, 23 of the 24 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 LIFE CARE NURSING HOMES MAY NOT HAVE COMPLIED WITH INFECTION PREVENTION AND CONTROL REQUIREMENTS

We found that 22 of the 24 nursing homes covered by our audit had at least 1 possible deficiency related to infection prevention and control, and 10 of the 22 nursing homes had more than 1 possible deficiency, totaling 35 possible deficiencies. Appendix D summarizes the areas of possible infection prevention and control noncompliance. These possible deficiencies were related to: (1) annual reviews of the IPCPs, (2) training, (3) designations of an infection preventionist who met Federal regulations, and (4) QAAC meetings.

Nursing Homes May Not Have Reviewed 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 nursing homes up to date on current infection prevention and control best practices.²⁹

Of the 24 nursing homes we reviewed, 17 had possible deficiencies related to conducting annual reviews of their IPCPs.³⁰ Specifically, we found that 17 nursing homes may not have complied with the Federal requirement to review the IPCP at least annually because they did not provide documentation, such as a signed and dated annual review and approval document.

As a result of our audit, Life Care officials said that they have taken multiple corrective actions to ensure that each Life Care nursing home conducts an annual review of their IPCPs. Life Care officials stated that they established a corporate calendar for annual reviews of their IPCP and implemented a system to alert their nursing homes when an IPCP needs to be reviewed. Life Care officials stated that they created an online portal that serves as a centralized repository of facility documents that can be reviewed at the regional, divisional, and corporate levels. Each

²⁸ CMS made training materials related to the new interpretive guidance available to the SSAs on June 28, 2022. On June 29, 2022, CMS informed OIG that they issued the phase 3 interpretive guidance.

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

³⁰ Among the 17 nursing homes, there were a total of 17 possible deficiencies related to the annual review of their IPCPs.

nursing home is required to submit documents related to their IPCP plan to the portal. Life Care officials also stated that they are conducting monthly training webinars for staff regarding IPCPs. Finally, Life Care officials said that Life Care’s compliance department conducts monthly calls with each division vice president to discuss the status of IPCP plans at their facilities.³¹

Nursing Homes May Not Have Maintained an Effective Training Program for Infection Control

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.³² A nursing home must include, as part of its infection prevention and control program, mandatory training that includes the written standards, policies, and procedures for the program.

Of the 24 nursing homes that we reviewed, 8 had possible deficiencies related to infection control training.³³ We determined that each of 24 nursing homes developed and implemented a training program for new and existing staff. However, eight nursing homes may not have complied with the requirement to maintain an effective training program for staff because these nursing homes possibly did not ensure that their staff took their required infection control training classes.

Life Care said that a total of 147 employees at 8 of the 24 nursing homes we reviewed tested positive for COVID-19 during our audit period. For these 147 employees, we reviewed the portion of Life Care’s training program related specifically to infection control. The eight nursing homes determined the amount and types of training necessary and assigned the specific training classes to its staff. These nursing homes assigned the 147 employees to a total of 1,271 mandatory classes specifically related to infection control. All of these classes were assigned during our 17-month audit period. Although all of the 1,271 classes were mandatory, Life Care did not provide evidence, such as training certificates or sign-in sheets, to indicate that employees completed 851 (67 percent) of the classes. Of the 147 employees, Life Care provided evidence that only 23 (16 percent) of the employees completed all classes. However, 68 (46 percent) of the remaining employees possibly did not complete any classes and 56

³¹ Life Care officials said that the corrective actions they took for each possible deficiency noted in this report applied to all Life Care nursing homes in each of the 28 States in which they operate.

³² This requirement had an implementation date of Nov. 28, 2019.

³³ Among the eight nursing homes, there were a total of eight possible deficiencies related to infection prevention and control training.

(38 percent) of the remaining employees completed some classes.³⁴ Because Life Care could not provide evidence that a high number of employees completed their mandatory infection prevention and control related trainings, the eight nursing homes possibly did not comply with the Federal requirement to maintain an effective training program.³⁵

As a result of our audit, Life Care officials said that Life Care has taken multiple corrective actions to ensure that Life Care nursing homes maintain an infection control training program. The compliance department now sends out course completion reports to other departments as part of an enhanced focus on education. The nursing homes are encouraged to discuss mandatory training in staff meetings and QAAC meetings. Executive directors, in coordination with the regional and divisional team, are encouraged to evaluate the logistics and availability of learning stations to enhance compliance with training opportunities.³⁶ Life Care officials also said that they are consulting with their information technology department to explore options, such as training dashboards, that would allow each facility to monitor its training completion status. Finally, Life Care officials said that the compliance department conducts monthly calls with each division vice president to discuss the course completion percentage for mandatory training.

Nursing Homes May Not Have Designated an Infection Preventionist Who Met Federal Requirements

A nursing home must designate one or more individuals as the infection preventionist(s) responsible for the nursing home's IPCP. An infection preventionist 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.³⁷ In addition, CMS

³⁴ Further analysis identified that the 124 employees did not complete 62 percent of their assigned trainings in 2019 and did not complete 71 percent of their assigned trainings in 2020. (Sixty-eight employees did not complete any class and 56 employees completed some classes in 2020). Life Care did not provide evidence, such as training certificates or sign-in sheets, for 62 percent of the assigned trainings in 2019 and 71 percent of the assigned trainings in 2020.

³⁵ We are not suggesting that these employees contracted COVID-19 as a result of the possibility that they did not complete all mandatory training classes.

³⁶ Many of Life Care's staff members do not work on a computer as part of their duties and must use one that is designated for training. Therefore, Life Care set up designated computer kiosks (i.e., learning stations) for staff to complete required training.

³⁷ 81 Fed. Reg. 68810 (Oct. 4, 2016).

collaborated with CDC to develop a free, online training course on infection prevention and control for nursing home staff. Topics of the training course ranged from hand washing to infection preventionist responsibilities and included the facility infection preventionist program overview.³⁸

Of the 24 nursing homes we reviewed, 5 had possible deficiencies related to designating an infection preventionist who met Federal requirements.³⁹ Specifically, we found that three 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, and two nursing homes may not have complied with the Federal requirement to designate at least one individual as an infection preventionist during a portion of the time from November 28, 2019, through May 31, 2020.^{40, 41}

As a result of our audit, Life Care officials said that they have taken multiple corrective actions to ensure that Life Care nursing homes designate an infection preventionist who meets Federal requirements. Life Care officials stated they appointed a corporate director to track the appointment of all infection preventionists across the company to ensure that those positions are filled promptly and that backup infection preventionists are in place. In addition, the corporate director ensures that infection preventionists and their backups provide proof of specialized training completion. Life Care officials also stated that the corporate director each month conducts a 6-hour orientation for all new infection preventionists. All infection preventionists must attend at least one orientation and may repeat the orientation as many times as desired. Finally, Life Care officials said they created a new “IP Corner” on the company’s intranet that provides educational resources and guidance and allows infection preventionists to post questions.

³⁸ CMS and CDC offer a specialized online class called Nursing Home Infection Preventionist Training, available at <https://www.cdc.gov/longtermcare/training.html>. (Accessed Mar. 10, 2022.) However, nursing home staff have the option to complete specialized infection prevention and control training offered by other sources.

³⁹ Among the five nursing homes, there were a total of five possible deficiencies related to designating an infection preventionist who met Federal requirements.

⁴⁰ CMS required nursing homes to designate an infection preventionist who met Federal requirements by Nov. 28, 2019.

⁴¹ We did not receive supporting documentation, such as a certificate of completion of specialized infection prevention and control training, for the three nursing homes to support that the infection preventionists completed their specialized training by Nov. 28, 2019. We did not receive supporting documentation for the two nursing homes to support that they had designated an infection preventionist who met Federal requirements.

Nursing Homes May Not Have Conducted Quarterly Quality Assessment and Assurance Committee Meetings With All Key Members

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)).⁴² A QAAC must consist of a minimum of: (1) the director of nursing services; (2) the medical director or a designee; (3) at least three other members of the facility's staff, at least one of whom must be the administrator, owner, a board member, or another individual in a leadership role; and (4) the infection preventionist (42 CFR § 483.75(g)(1)).⁴³

Effective QAPI programs are critical to improving the quality of life, care, and services delivered in facilities, according to CMS.⁴⁴ Section 6102 of the Affordable Care Act required the establishment and implementation of a QAPI program for nursing homes. Therefore, CMS has required that nursing homes develop, implement, and maintain an effective, comprehensive, and data-driven QAPI program that focuses on systems of care, outcomes, and services for residents and staff. A QAAC reports to the governing body regarding its activities,⁴⁵ including implementation of the QAPI program, and the governing body has the ultimate responsibility to ensure that the QAPI program is defined, implemented, and maintained.⁴⁶

Of the 24 nursing homes we reviewed, 5 had possible deficiencies related to conducting QAAC meetings at least quarterly with all key members.⁴⁷ Specifically, we found that two nursing homes may not have complied with the Federal requirements to conduct a QAAC meeting with the medical director or their designee at least quarterly, and three nursing homes may not have complied with the Federal requirement to conduct a QAAC meeting with the infection preventionist at least quarterly.⁴⁸

⁴² CMS required at least quarterly meetings of QAAC with phase 3 of implementation on Nov. 28, 2019.

⁴³ 81 Fed. Reg. 68688 (Oct. 4, 2016).

⁴⁴ 81 Fed. Reg. 68804 (Oct. 4, 2016).

⁴⁵ 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 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)).

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

⁴⁷ Among the five nursing homes, there were a total of five possible deficiencies related to conducting QAAC meetings at least quarterly with all key members.

⁴⁸ We did not receive supporting documentation, such as QAAC meeting notes or sign-in sheets, to show evidence that the key members attended QAAC meetings at least quarterly.

As a result of our audit, Life Care officials said that they have taken multiple corrective actions to ensure that Life Care nursing homes conduct QAAC meetings at least quarterly with all key members. Life Care requires that each nursing home submit the documents related to their QAAC Program to an online portal. Life Care officials also stated that their Compliance Department conducts monthly calls with each division vice president to discuss the status of their facilities' QAAC Programs. Finally, Life Care officials said that they conducted additional QAAC training for executive directors and directors of nursing.

SELECTED NURSING HOMES MAY NOT HAVE COMPLIED WITH EMERGENCY PREPAREDNESS REQUIREMENTS

We found that 16 of the 24 nursing homes had at least 1 possible deficiency related to emergency preparedness. Four of the 16 nursing homes had more than 1 possible deficiency, for a total of 20 possible deficiencies. Appendix E summarizes the areas of possible emergency preparedness noncompliance. These possible deficiencies related to annual review of the emergency preparedness plans and annual emergency preparedness risk assessments.

Nursing Homes May Not Have Reviewed and Updated Emergency Preparedness Plans Annually

Nursing homes must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually (42 CFR § 483.73(a)).

Of the 24 nursing homes that we reviewed, 8 had possible deficiencies related to reviewing or updating their emergency preparedness plans.⁴⁹ Specifically, we found that seven nursing homes may not have complied with the Federal requirement to review their emergency preparedness plan at least annually because they did not provide documentation, such as a signed and dated annual review document.⁵⁰ One nursing home may not have complied with the Federal requirement to update its emergency preparedness plan at least annually; this nursing home had not made any updates to its emergency preparedness plan since 2016, including any updates in response to COVID-19.⁵¹

As a result of our audit, Life Care officials said that they have taken multiple corrective actions to ensure that Life Care nursing homes review and update their emergency preparedness plans.

⁴⁹ Among the eight nursing homes, there were a total of eight possible deficiencies related to reviewing or updating their emergency preparedness plans.

⁵⁰ To comply with this Federal requirement, Life Care officials stated that the individual nursing homes prepare an "Annual Review Sheet" and management officials, such as an executive director, sign and date the document after they have reviewed the annual plan in its entirety.

⁵¹ Of the remaining 23 nursing homes we reviewed, 19 nursing homes updated their emergency preparedness plans in response to COVID-19.

Life Care officials stated that they established a corporate calendar for annual reviews of their emergency preparedness plan and implemented a system to alert their nursing homes when the emergency preparedness plan needs to be reviewed. Life Care now requires each nursing home to submit a signed and dated annual review sheet to the portal. In addition, Life Care officials stated that they provided emergency preparedness plan training to divisional and regional staff and to applicable facility leaders. Life Care officials also said that the compliance department conducts monthly calls with each division vice president to discuss the status of the emergency preparedness plan at their facilities.

Nursing Homes May Not Have Completed Annual Emergency Preparedness Risk Assessments

Nursing homes' emergency preparedness plans must be based on and include a documented, facility-based and community-based risk assessment, utilizing an "all-hazards approach" (42 CFR § 483.73(a)(1)).

Of the 24 nursing homes we reviewed, 12 had possible deficiencies related to all-hazards risk assessments.⁵² Specifically, we found that these 12 nursing homes may not have complied with the Federal requirement to document an annual facility-based and community-based risk assessment that uses an all-hazards approach.

As a result of our audit, Life Care officials said that they have taken multiple corrective actions to ensure that Life Care nursing homes complete their all-hazards risk assessments. Life Care officials stated that the nursing homes are required to submit their risk assessment documents to the portal. In addition, Life Care's compliance department conducts monthly calls with each division vice president to discuss the status of the emergency preparedness documents at their nursing homes.

CAUSES OF POSSIBLE NONCOMPLIANCE WITH FEDERAL REQUIREMENTS

Life Care officials provided the following reasons for possibly not complying with Federal requirements for infection prevention and control and emergency preparedness:

- leadership turnover,
- staff turnover,
- documentation issues (i.e., either information was not documented or the documentation was lost or misplaced),

⁵² Among the 12 nursing homes, there were a total of 12 possible deficiencies related to all-hazards risk assessments.

- staff members were unfamiliar with requirements (i.e., requirements stipulating that there is no grace period for infection preventionists to complete specialized training and that emergency preparedness plans needed to be reviewed annually),
- qualified personnel shortage, and
- challenges related to the COVID-19 PHE.

We believe that 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 control requirements, or clarification about the essential components to be integrated in the nursing homes' emergency plans.

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

As a result of 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 instruct SSAs to follow up with the 23 nursing homes that we have identified with possible infection prevention and control and emergency preparedness deficiencies to verify that they have taken corrective actions.⁵³

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our recommendation and described actions that it has taken to address our recommendation. Specifically, CMS stated that it has contacted the appropriate SSAs to ensure that the 23 nursing homes with possible infection prevention and control and emergency preparedness deficiencies have taken corrective actions in accordance with Federal requirements. CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, appear as Appendix F.

We commend CMS for the action it has taken to ensure the safety and quality of care for residents of our Nation's nursing homes. We also included in Appendix B a list of many of the actions that CMS took in response to the PHE.

⁵³ SSAs should prioritize followup activities based on: (1) the level of risk to beneficiaries and (2) in accordance with CMS policies for triaging nursing home complaints and incidents.

OTHER MATTERS

Federal regulations state that nursing facilities must establish an infection prevention and control program that must include, at a minimum, written standards, policies, and procedures for the program. These standards, policies, and procedures must address “[w]hen and to whom possible incidents of communicable disease or infections should be reported” (42 CFR § 483.80(a)(2)(ii)).

We identified seven nursing homes (located in five States) that identified resident cases of COVID-19 during our audit period.⁵⁴ Among these seven, we determined that four nursing homes (located in four States) reported cases of COVID-19 in accordance with their State reporting requirements. However, for the remaining three nursing homes—all located in Massachusetts—we were unable to determine whether the nursing homes reported COVID-19 cases in accordance with the State’s reporting requirements.⁵⁵

Life Care officials said that the three nursing homes in Massachusetts were in daily contact with officials from their local boards of health to discuss COVID-19 cases in the nursing homes. Although Life Care provided us with written statements from two of the three local boards of health confirming this statement, Life Care did not maintain any records of these discussions to support that the cases of COVID-19 were reported in accordance with the State reporting requirements. Life Care officials said that the three nursing homes did not keep contemporaneous records involving any conversations with the local boards of health regarding COVID-19 cases.

Furthermore, we attempted on numerous occasions to directly contact officials at the Massachusetts Department of Public Health and local boards of health (via telephone and email) for independent, third-party verification regarding reported COVID-19 cases for each nursing home. But the officials were unresponsive to our requests.

Life Care officials said they have taken corrective action to ensure that their nursing homes have written standards, policies, and procedures for when and to whom possible incidents of communicable disease or infections should be reported. Life Care officials stated they made significant enhancements to the nursing homes’ reporting controls and processes related to reportable diseases and conditions in 2021. Life Care officials stated that they developed and implemented State-specific policies that include instructions on what possible incidents of communicable disease or infections need to be reported, when they need to be reported, and

⁵⁴ The five States are Florida, Idaho, Indiana, Massachusetts, and Ohio.

⁵⁵ Massachusetts required both suspected and confirmed cases of respiratory infections thought to be due to any novel coronavirus to be reported immediately by telephone to the individual nursing home’s local board of health. If local board of health officials were unavailable, nursing homes were required to contact the Massachusetts Department of Public Health.

to whom. Each policy has links to applicable State criteria and applicable State or local contacts, and the policies are periodically updated as necessary based on any changes implemented by the States. Life Care officials stated that these enhancements apply to all nursing homes in each of the 28 States in which Life Care operates.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

As of February 26, 2020, there were 15,450 Medicare and Medicaid certified nursing homes. SSA data on the Medicare.gov website indicated that 6,622 (approximately 43 percent) of these 15,450 nursing homes had been cited for infection control deficiencies. After further analysis of the data, we found that these deficiencies had occurred at 24 different nursing homes that were part of the Life Care nursing home chain. We contacted Life Care's corporate office regarding the 24 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 or the nursing homes' overall internal control structures. Rather, we limited our review of internal controls to the selected Life Care nursing homes' infection prevention and control policies and procedures and emergency preparedness policies and procedures.

We performed our audit from June 2020 through June 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 Life Care's corporate office regarding the 24 nursing homes and requested documentation related to their infection prevention and control and emergency preparedness plans;
- reviewed documentation provided by Life Care to determine whether it has programs for infection prevention and control and emergency preparedness in accordance with Federal requirements; and
- discussed the results of the audit with Life Care officials and 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	Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes https://www.cms.gov/files/document/qso-20-29-nh.pdf
May 2020	<i>Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes</i> (version 26 issued March 2022) https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf
May 14, 2020	<i>Trump Administration Announces Call for Nominations for Nursing Home Commission</i> https://www.cms.gov/newsroom/press-releases/trump-administration-announces-call-nominations-nursing-home-commission
May 18, 2020	<i>Trump Administration Issues Guidance to Ensure States Have a Plan in Place to Safely Reopen Nursing Homes</i> https://www.cms.gov/newsroom/press-releases/trump-administration-issues-guidance-ensure-states-have-plan-place-safely-reopen-nursing-homes
June 1, 2020	<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) https://www.cms.gov/files/document/qso-20-31-all-revised.pdf CMS also issued a letter to governors: https://www.cms.gov/files/document/6120-letter-governors.pdf
June 19, 2020	<i>CMS Announces Membership of Independent Coronavirus Commission on Safety and Quality in Nursing Homes</i> https://www.cms.gov/newsroom/press-releases/cms-announces-membership-independent-coronavirus-commission-safety-and-quality-nursing-homes
June 23, 2020	<i>CMS released revised guidance for nursing home visitation during the COVID-19 Public Health Emergency</i> (revised March 10, 2021) https://www.cms.gov/files/document/covid-visitation-nursing-home-residents.pdf

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	<i>Biden-Harris Administration Takes Additional Action to Protect America's Nursing Home Residents From COVID-19</i> https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19
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APPENDIX C: NUMBER OF LIFE CARE FACILITIES BY STATE AS OF MARCH 2022

State	Number of Life Care Facilities
Arizona	10
California	10
Colorado	22
Florida	21
Georgia	3
Hawaii	4
Idaho	8
Indiana	15
Kansas	7
Kentucky	3
Massachusetts	15
Michigan	3
Missouri	10
Nebraska	2
Nevada	3
New Mexico	1
North Carolina	2
Ohio	4
Oregon	3
Pennsylvania	1
Rhode Island	2
South Carolina	3
Tennessee	29
Texas	8
Utah	2
Virginia	1
Washington	15
Wyoming	3
Total	210

**APPENDIX D: AREAS OF INFECTION PREVENTION AND CONTROL POSSIBLE
NONCOMPLIANCE AT 22 OF 24 NURSING HOMES**

Nursing Home	Failed to Review IPCP Annually	Employees Not Adequately Trained in Infection Prevention and Control	Did Not Designate an IP Who Met Federal Requirements	Did Not Conduct Quarterly QAAC Meetings With All Key Members	Total
1	-	1	1	1	3
2	1	-	-	-	1
3	1	-	-	1	2
4	-	-	-	-	0
5	1	-	-	-	1
6	1	-	-	-	1
7	-	-	-	-	0
8	1	-	1	-	2
9	1	-	1	-	2
10	1	-	-	-	1
11	-	1	-	-	1
12	1	-	-	-	1
13	1	1	1	1	4
14	1	-	-	1	2
15	1	-	-	1	2
16	1	1	-	-	2
17	1	-	1	-	2
18	1	-	-	-	1
19	1	-	-	-	1
20	-	1	-	-	1
21	1	-	-	-	1
22	-	1	-	-	1
23	1	1	-	-	2
24	-	1	-	-	1
Totals	17	8	5	5	35

**APPENDIX E: AREAS OF EMERGENCY PREPAREDNESS POSSIBLE
NONCOMPLIANCE AT 16 OF 24 NURSING HOMES**

Nursing Home	Failed to Review EP Plan Annually	Failed to Complete EP Risk Assessment Annually	Total
1	-	-	0
2	-	-	0
3	-	-	0
4	-	-	0
5	1	1	2
6	1	-	1
7	1	1	2
8	-	-	0
9	1	-	1
10	1	-	1
11	-	-	0
12	1	1	2
13	1	-	1
14	-	1	1
15	1	1	2
16	-	1	1
17	-	1	1
18	-	1	1
19	-	-	0
20	-	1	1
21	-	1	1
22	-	1	1
23	-	-	0
24	-	1	1
Totals	8	12	20

APPENDIX F: CMS COMMENTS



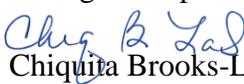
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: August 18, 2022

TO: Gregory Demske
Acting Principal Deputy Inspector General

FROM: 
Chiquita Brooks-LaSure
Administrator

SUBJECT: Office of Inspector General Draft Report: Certain Life Care Nursing Homes May Not Have Complied with Federal Requirements for Infection Prevention and Control and Emergency Preparedness, A-01-20-00004

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, and 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.^{1,2} 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 required to comply with CMS quality and safety standards, including those relating to infection prevention and control and emergency preparedness. CMS shares management 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.

¹ The White House, FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes, February 28, 2022.

² CMS Strategic Plan, August 2022.

Even before the COVID-19 pandemic, CMS had acted to strengthen emergency preparedness and infection prevention and control practices in nursing homes. CMS took pivotal actions toward this goal in the 2016 final rule Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers.³ This rule outlined updates to emergency preparedness requirements for all facilities. The updates from this final rule highlighted the need for nursing homes to guide emergency preparedness and response⁴ using the same framework used in 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.”⁴ In addition, CMS also outlined specific reform requirements for long-term care facilities in the final rule, Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities, which was the impetus for the requirement that nursing homes develop an infection prevention and control program that includes an antibiotic stewardship program.⁵

In February 2019, CMS directed facilities to add emerging infectious diseases to their definition of all-hazard emergency preparedness, and provided appropriate guidance in Appendix Z of the State Operations Manual.^{6,7} Since the beginning of the COVID-19 public health emergency in 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. Through the Quality Improvement Organizations (QIO) CMS also sent federal strike teams comprised of representatives from Centers for Disease Control and Prevention (CDC), CMS, and the Office of the Assistant Secretary for Health to help facilities address COVID-19 challenges related to staffing, personal protective equipment supplies, COVID-19 testing, and infection prevention and control measure implementation. More recently, in June 2022, CMS released the Phase 3 infection control guidance through the memorandum on revised long-term care guidance for surveyors.⁸ In this memo CMS outlines updates made to the State Operations Manual, including to Appendix PP, to, among other things, provide additional guidance for infection prevention and

³ Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 Fed. Reg. 63860, 63862 (Sept. 16, 2016).

⁴ Fed. Reg. 63862.

⁵ Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688 (Oct. 4, 2016).

⁶ QSO-19-06-All Emergency Preparedness - Updates to Appendix Z of the State Operations Manual

⁷ State Operations Manual, Appendix Z - Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance

⁸ QSO-22-19-NH Revised Long-Term Care Surveyor Guidance: Revisions to Surveyor Guidance for Phases 2 & 3, Arbitration Agreement Requirements, Investigating Complaints & Facility Reported Incidents, and the Psychosocial Outcome Severity Guide.

control related deficiencies.⁹ Further, CDC and CMS developed specialized infection preventionist training to include topics such as transmission-based precautions and antibiotic stewardship programs.¹⁰ CMS has held regular calls with stakeholders, nursing home associations, and SSAs to keep them up to date on the latest information to respond to COVID19, and to clarify expectations.

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 CDC and the Assistant Secretary for Preparedness and Response (now the Administration for Strategy Preparedness and Response, ASPR). This tool was informed in part by CMS's experiences on the ground at a Life Care Center nursing home in Kirkland, Washington – the epicenter of the COVID-19 outbreak in that state in early 2020.¹¹ This tool was shared with providers who were encouraged by CMS to use it to self-assess their 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 onset of the COVID-19 public health emergency warranted a more targeted approach for assessing a nursing homes' compliance with infection prevention and control requirements, in November 2021, CMS released a memorandum, *Changes to COVID-19 Survey Activities and Increased Oversight in Nursing Homes*, to help SSAs focus their efforts on identifying concerns for all aspects of quality of care, quality of life, and ensuring health and safety.¹² CMS now requires SSAs to perform annual focused infection control surveys at 20 percent of nursing homes.¹³ 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-19.¹⁴ 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- and Medicaid-certified nursing homes report COVID-19 testing, case, and mortality data for residents and staff to the CDC's National Healthcare Safety Network.¹⁵ 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

⁹ State Operations Manual, Appendix PP - Guidance to Surveyors for LTC Facilities .

¹⁰ CDC Train, Nursing Home Infection Preventionist Training Course.

¹¹ CMS Announces Findings at Kirkland Nursing Homes and New Targeted Plan for Healthcare Facility Inspections in light of COVID-19.

¹² QSO-22-02-All: Changes to COVID-19 Survey Activities and Increased Oversight in Nursing Homes.

¹³ QSO-22-02-All.

¹⁴ QSO-21-08-NLTC: COVID-19 Focused Infection Control Survey Tool for Acute and Continuing Care Providers and Suppliers.

¹⁵ 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.

booster shot data to the website.¹⁶ 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.¹⁷

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 emergency 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 QIO program, CMS assists these targeted 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's responses are below.

OIG Recommendation

Instruct SSAs to follow up with the 23 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 has already contacted the appropriate SSAs to ensure that the 23 nursing homes OIG identified with possible infection prevention and control and emergency preparedness deficiencies have taken corrective actions as appropriate, in line

¹⁶ CMS Makes Nursing Home COVID-19 Booster Vaccination Online Increasing Transparency, CMS News Alert, Feb. 09, 2022.

¹⁷ QSO-22-08-NH: Nursing Home Staff Turnover and Weekend Staffing Levels.

with federal requirements. It is important to note 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 all the federal requirements.