NC Department of Health and Human Services
Division of Health Service Regulation
Oversight of Nursing Homes

Raleigh, NC

Performance Audit Report

December 2024

UNBIASED. IMPACTFUL. IRREFUTABLE.

A Department of the State of North Carolina

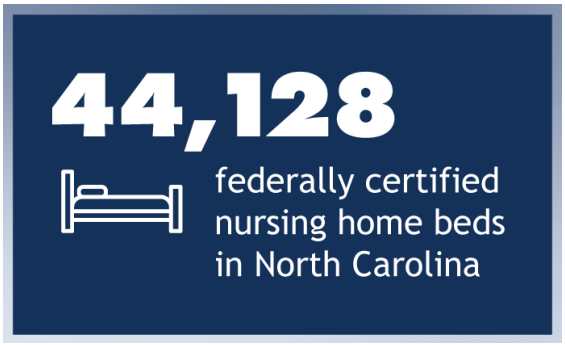
Jessica N. Holmes, J.D., State Auditor

NCOSA Office of the State Auditor

Executive Summary

The Office of the State Auditor has completed a performance audit in accordance with Chapter 147, Article 5A of the North Carolina General Statutes concerning the oversight of nursing homes by the North Carolina Department of Health and Human Services (Department).

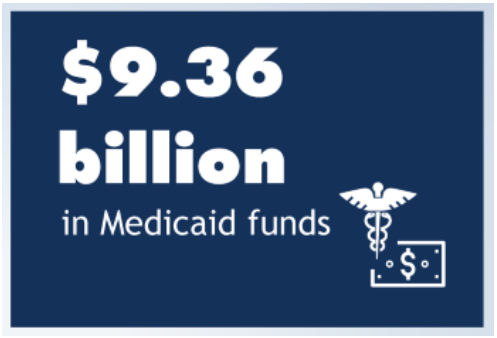
The Department's mission is to improve the health, safety, and well-being of all North Carolinians. The Department helps provide specific services to special populations including individuals who are deaf, blind, developmentally disabled, mentally ill, economically disadvantaged, or seniors.



Medicare and Medicaid programs cover care in nursing homes for eligible beneficiaries in need of nursing services, specialized rehabilitation services, medically related social services, pharmaceutical services, and dietary services.

Federal regulations[1] require participating nursing homes to meet certain specified requirements that include quality of care, nursing services, and infection control (federal participation requirements). Federal regulations[2] also establish requirements for the federal Centers for Medicare and Medicaid Services (CMS) and for North Carolina to inspect nursing homes and investigate complaints to determine whether they meet federal participation requirements.

In North Carolina, the Department's Division of Health Service Regulation (Division) is responsible for the oversight of all nursing homes.[3] The Division's oversight responsibilities include initial licensing,[4] annual inspections and license renewals, complaint investigations, and follow-up of cited deficiencies.[5]



As of December 2023, there were 425 federally certified nursing homes in North Carolina with a total of **44,128 beds**. From January 1, 2019, through December 31, 2023, the nursing homes received **$9.36 billion** in Medicaid funds.

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1 42 CFR part 483, subpart B.
2 42 CFR part 488, subpart E.
3 Both those that participate in Medicare and Medicaid and those that do not. Nursing homes that do not participate in Medicare or Medicaid are known as Licensed-Only Facilities.
4 Licensing and license renewals were not included in the scope of this audit.
5 Deficiencies can be cited from both inspections and complaint investigations.

Objective:

The objective of this performance audit was to determine whether the Division:

- **Inspected** nursing homes in accordance with timeliness requirements prescribed by federal regulations.
- **Investigated** nursing home complaints in accordance with timeliness requirements prescribed by state law.
- **Verified** the correction of identified deficiencies in accordance with federal requirements.

Findings:

- The Division did not conduct **timely inspections**[6] of nursing homes during the period of March 1, 2021, through December 31, 2023.[7]
- The Division did not **complete investigations** of nursing home complaints within the timeframe prescribed by state law during the period of January 1, 2019, through December 31, 2023.[8]
- The Division did not **always verify** the correction of nursing home deficiencies identified during inspections of nursing homes during the period of January 1, 2019, through June 30, 2022.[9]

Accordingly, nursing home residents were at risk of conditions that could have threatened their health and safety.

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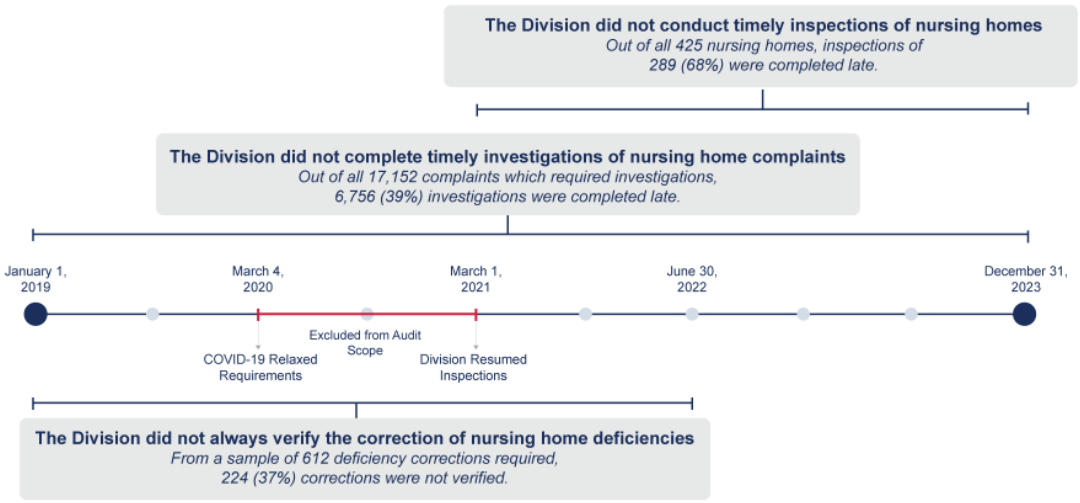
6 Inspections are identified as 'surveys' in federal regulations.

7 In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes from March 4, 2020, through August 17, 2020. Specifically, CMS prescribed that states may resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so." The Division resumed routine inspections on March 1, 2021. **Due to the relaxed timeliness requirements due to COVID-19, inspections prior to March 1, 2021, were not included in this analysis. However, see Additional Consideration 1 for further discussion regarding inspections during the COVID-19 pandemic.**

8 In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes and most investigations of nursing home complaints from March 4, 2020, through August 17, 2020. Specifically, CMS prescribed that states may resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so." The Division resumed routine inspections on March 1, 2021. The period March 4, 2020, through March 1, 2021, was excluded from auditor investigative timeliness calculations.

9 During the audit, the scope period was extended to include January 1, 2019, through December 31, 2023, for inspections and investigations. The scope was not extended for the verification of the correction of deficiencies. Extending the scope in this area would have required a substantial amount of additional time and resources to complete detailed testing.



Recommendations:

1. The Division should inspect all nursing homes in a timely manner, in accordance with all federal regulations and laws.
2. The Division should seek necessary resources from the General Assembly to clear its backlog of overdue inspections and to ensure completion of inspections in accordance with mandated federal regulations and laws.
3. The Division should **initiate** and **complete** all complaint investigations within the timeframes prescribed by state law.
4. The Division should complete a formal analysis identifying the resources necessary to comply with investigative timeframes prescribed by state law. Based on the analysis, the Division should seek sufficient appropriation from the General Assembly to allow it to comply with state law. Alternatively, the Division should seek clarification from the General Assembly as to the Division's responsibilities for investigative timeliness.
5. The Division should verify that deficiencies are corrected in accordance with federal requirements.
6. Division management should develop and implement procedures to ensure that Division staff verify that deficiencies are corrected and that their conclusions are documented.

Additional Considerations:

Division management should consider developing a comprehensive plan for potential future pandemics or other crises to ensure inspections and other safety related activities continue to better protect and care for nursing home residents during those times.

Division management should consider establishing a policy increasing the unpredictability of annual inspections of nursing home facilities that protects the health and safety of nursing home residents. This gives the Division greater ability to obtain valid information because it increases the probability that Division staff will observe conditions and care practices that are typically present.

Division management should consider establishing a policy on the frequency with which it conducts inspections of licensed-only nursing home facilities. The policy should establish an inspection frequency that protects the health and safety of nursing home residents.

North Carolina Office of the State Auditor
Jessica N. Holmes, J.D., State Auditor

Auditor's Transmittal

The Honorable Roy Cooper, Governor
Members of the North Carolina General Assembly
Kody Kinsley, Secretary, Department of Health and Human Services
Mark Benton, Chief Deputy Secretary for Health
Mark Payne, Director, Division of Health Service Regulation

Ladies and Gentlemen:

The Office of the State Auditor has completed a performance audit in accordance with Chapter 147, Article 5A of the North Carolina General Statutes concerning the oversight of nursing homes by the North Carolina Department of Health and Human Services. I hereby submit the corresponding performance audit report titled *Oversight of Nursing Homes*.

The audit objective was to determine whether the Department of Health and Human Services' Division of Health Service Regulation:

1) Inspected nursing homes in accordance with timeliness requirements prescribed by federal regulations.

2) Investigated nursing home complaints in accordance with timeliness requirements prescribed by state law.

3) Verified the correction of identified deficiencies in accordance with federal requirements.

The Secretary of the Department of Health and Human Services has received and reviewed a draft copy of this report, and the Department's written comments are included in the report beginning on page 34. The Secretary and his Department have been forthcoming, reflective, and solutions-oriented throughout this process.

Respectfully submitted,

Jessica N. Holmes, J.D.
State Auditor

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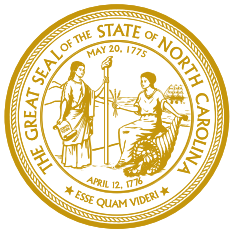
Chapter 147, Article 5A of the North Carolina General Statutes gives the Auditor broad powers to examine all books, records, files, papers, documents, and financial affairs of every state agency and any organization that receives public funding. The Auditor also has subpoena power to compel individuals and entities to produce records and to answer questions under oath.


THE GREAT SEAL OF THE STATE OF NORTH CAROLINA
MAY 20, 1775
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Background

Nursing Homes:

Nursing homes are facilities for residents needing ongoing medical supervision, nursing care, and/or rehabilitation. A nursing home is a home for chronic or convalescent residents, who, on admission, are not as a rule, acutely ill and who do not usually require special facilities such as an operating room, X-ray facilities, laboratory facilities, and obstetrical facilities.

Nursing homes are facilities for residents needing ongoing medical supervision, nursing care, and/or rehabilitation.

The North Carolina Department of Health and Human Services' **Division of Health Service Regulation** is responsible for oversight of all nursing homes in the state.

A nursing home provides care for persons requiring nursing care and continuing medical supervision. These persons have ailments for which medical and nursing care are needed but not necessarily general hospital care.

Medicare and Medicaid programs cover care in nursing homes for eligible beneficiaries in need of nursing services, specialized rehabilitation services, medically related social services, pharmaceutical services, and dietary services. Federal regulations[10] require nursing homes that participate in the Medicare and Medicaid programs to meet certain specified requirements that include quality of care, nursing services, and infection control (federal participation requirements). Federal regulations[11] also establish requirements for the federal Centers for Medicare and Medicaid Services (CMS) and for North Carolina to inspect nursing homes and investigate complaints to determine whether they meet federal participation requirements.

In addition to federal regulations, state law[12] establishes rules and oversight responsibilities of nursing homes in North Carolina.

In North Carolina, the Department of Health and Human Services' (Department) Division of Health Service Regulation (Division) is responsible for the oversight of all nursing homes.[13] The Division's oversight responsibilities include initial licensing,[14] annual inspections and license renewals, complaint investigations, and follow-up of cited deficiencies.[15]

The Division is required to conduct standard inspections of each nursing home in North Carolina at least once every 15 months.

Inspections of Nursing Homes:

The Division is required to conduct standard inspections (also referred to as surveys) to determine whether nursing homes are complying with federal participation requirements.

Inspections include the review of the following areas: resident rights; the right to be free from abuse, neglect, and exploitation; admission, transfer, and discharge rights; resident

[10] 42 CFR part 483, subpart B.
[11] 42 CFR part 488, subpart E.
[12] Chapter 131E, Article 6 of the North Carolina General Statutes.
[13] Both those that participate in Medicare and Medicaid and those that do not. Nursing homes that do not participate in Medicare or Medicaid are known as Licensed-Only Facilities.
[14] Licensing and license renewals were not included in the scope of this audit.
[15] Deficiencies can be cited from both inspections and complaint investigations.

assessments; comprehensive resident centered care plans; quality of life; quality of care; physician services; nursing services; behavioral health services; pharmacy services; laboratory, radiology, and other diagnostic services; dental services; food and nutrition services; specialized rehabilitative services; administration; quality assurance and performance improvement; infection control; physical environment; training requirements; and emergency preparedness.

Federal regulations require that nursing home inspections must be conducted at least once every 15 months.[16]

Complaint Investigations:

The Division is also required to review and investigate all nursing home complaints, including complaints involving allegations of improper care or treatment that could result in the citation of a deficiency in a federal regulation.

Depending on the severity of the complaint, the Division must investigate the complaint during either a standard inspection or a complaint investigation. Federal requirements[17] provide that the Division initiate a complaint investigation from within two business days or up to 15 months after receipt, at the time of the next inspection. **State law**[18] requires that complaint investigations are completed no later than 60 days after receipt of the complaint. According to the federal requirements,[19] "If a State's time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State's timeframes."

The Division is responsible for investigating complaints made against nursing homes in North Carolina.

State law requires those investigations to be completed **within 60 days.**

Whenever a nursing home is cited during an inspection or an investigation, the Division is required to **verify** that each deficiency is corrected.

Deficiencies and Follow-Up for Verification of Correction:

Deficiencies are cited against nursing homes when Division **inspections** or **investigations** conclude that there were one or more violations of federal participation requirements[20] designed to protect the health and safety of residents.

The Division determines the deficiency rating of each deficiency based on the severity[21] and scope[22] of the

[16] 42 CFR § 488.308(a).
[17] CMS State Operations Manual § 5075.9.
[18] N.C.G.S. § 131E-124.
[19] CMS State Operations Manual § 5010.
[20] 42 CFR part 483, subpart B.
[21] Severity is the degree of or potential for resident harm and ranges from immediate jeopardy to resident health or safety to no actual harm with potential for minimal harm.
[22] Scope is the number of residents affected or pervasiveness of the deficiency and ranges from widespread to isolated.

deficiency. Nursing homes are required to submit plans of correction for most deficiencies cited[23] for the Division's review and approval.[24]

Federal requirements[25] state that the Division must verify the correction of identified deficiencies through obtaining evidence of correction[26] from the nursing home or conducting an onsite revisit of the nursing home.[27]

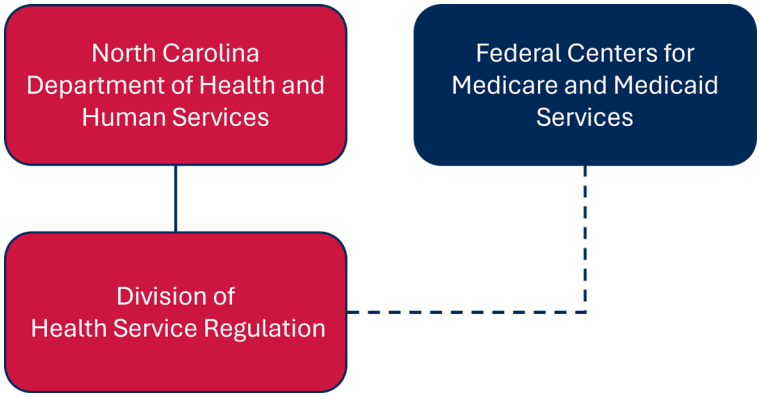
The Division uses the Automated Survey Processing Environment (ASPEN) System to record these inspections of nursing homes. As Division staff conduct inspections and investigations, they identify deficiencies using the Quality Indicator Survey (QIS)[28] process then record on tablets and upload the results into ASPEN. Similarly, when Division staff conduct follow-up reviews of identified deficiencies, they upload the results of those reviews into ASPEN.

As of December 2023, there were 425 federally certified nursing homes in North Carolina with a total of **44,128 beds**. From January 1, 2019, through December 31, 2023, the nursing homes received **$9.36 billion** in Medicaid funds.

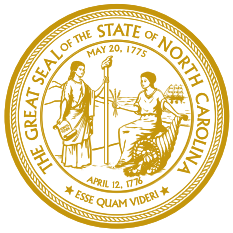
Responsible parties discussed in this report include:

North Carolina Department of Health and Human Services' Division of Health Service Regulation (Division) – The Division oversees medical, mental health and adult care facilities, emergency medical services, and local jails. While nursing homes are ultimately responsible for ensuring the health and safety of residents, the Division also ensures that people who receive care in these facilities are safe and receive appropriate care through its regulatory oversight.

Centers for Medicare & Medicaid Services (CMS) – CMS is a federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS is responsible for providing guidance and oversight to all states in the oversight of the state's operation and oversight of participating nursing homes. The Division is contracted with CMS to inspect and investigate nursing homes to ensure compliance with federal requirements.



[23] Nursing homes are not required to submit a plan of correction for deficiencies cited as Severity – no actual harm with potential for minimal harm and Scope – isolated.
[24] CMS State Operations Manual, Chapter 7.
[25] CMS State Operations Manual § 7300.3.
[26] Examples of evidence of correction included sign-in sheets of those attending in-service training and interviews with training participants.
[27] The method in which the correction of deficiencies may be verified (obtaining evidence vs. onsite revisit) is determined by the scope and severity of the deficiency. Per CMS State Operations Manual § 7317.2, an onsite revisit is required when a facility's beginning survey finds deficiencies that constitute substandard quality of care, harm, or immediate jeopardy.
[28] QIS is a computer-based, long-term care inspection process used to determine whether nursing homes meet federal requirements.



Findings and Recommendations

1. Division Inspections of Nursing Homes Were Not Timely

The Department of Health and Human Services' Division of Health Service Regulation (Division) did not conduct timely inspections[29] of nursing homes during the period March 1, 2021, through December 31, 2023.[30]

As a result, nursing home residents were at risk of conditions that could have threatened their health and safety.

According to Division management, the Division's annual inspections were late because of challenges brought on by the COVID-19 pandemic, including concerns about the health and safety of Division staff, high vacancy rates, and staff turnover.

Federal regulations[31] and federal law[32] required the Division to inspect nursing homes timely.

Division Did Not Conduct Inspections Timely

The Division did not conduct timely inspections of nursing homes during the period March 1, 2021, through December 31, 2023.

Federal regulations[33] required nursing homes to be inspected no later than 15 months after the date of the last inspection. Additionally, federal law[34] required higher-risk[35] nursing homes to be inspected no less than once every six months.

In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes from March 4, 2020, through August 17, 2020. CMS prescribed that states may resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so."

CMS also prescribed that when states resumed inspections on a regular basis, they were to do so by establishing new intervals based on each facility's next inspection, not based on the last inspection that was conducted prior to the COVID-19 pandemic. For example, if the Division scheduled an inspection for a nursing home in April 2020 and was unable to conduct it

In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes from March 4, 2020, through August 17, 2020. CMS prescribed that states could resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so."

The Division resumed routine inspections on March 1, 2021.

[29] Inspections are identified as 'surveys' in federal regulations.

[30] In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes from March 4, 2020, through August 17, 2020. Specifically, CMS prescribed that states may resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so." The Division resumed routine inspections on March 1, 2021. **Due to the relaxed timeliness requirements due to COVID-19, inspections prior to March 1, 2021, were not included in this analysis. However, see Additional Consideration 1 for further discussion regarding inspections during the COVID-19 pandemic.**

[31] 42 CFR § 488.308.

[32] 42 U.S.C. § 1395i-3(f)(8) and 42 U.S.C. § 1396r(f)(10).

[33] 42 CFR § 488.308.

[34] 42 U.S.C. § 1395i-3(f)(8) and 42 U.S.C. § 1396r(f)(10).

[35] Higher-risk nursing homes were those the Division designated as "Special Focus Facilities" and had histories of serious quality issues. Special Focus Facilities are subject to stricter oversight by the Division.

because of the COVID-19 pandemic, but now conducts that inspection in August 2021, the next annual inspection would be due by the end of October 2022 (i.e., 15 months from completion of the August 2021 inspection).

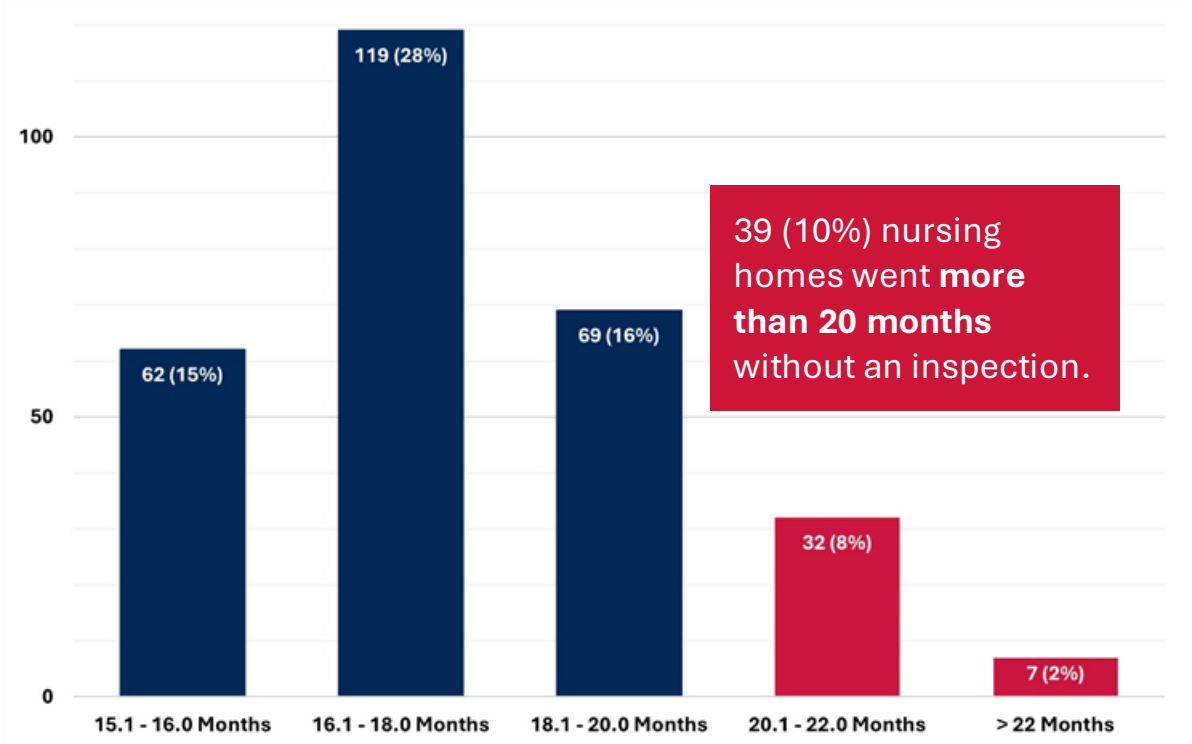
The Division resumed routine inspections on March 1, 2021.

Auditors determined that inspections for 289 (68%) nursing homes were **late.**

Auditors obtained inspection data for all 425 nursing homes in North Carolina[36] inspected from March 1, 2021, through December 31, 2023, and calculated the time between inspections for each nursing home.

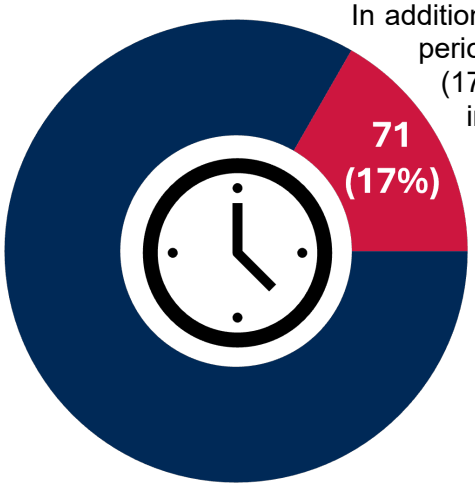
Auditors determined that **inspections for 289 of 425 (68%) nursing homes were late,** exceeding the 15-month limit between inspections. Not only did the Division not inspect 289 of 425 (68%) nursing homes in accordance with the 15-month federal requirement, but 39 (10%) nursing homes were not inspected for more than 20 months since the last inspection. See Chart 1, below:

Chart 1: Timeliness of Nursing Home Inspections



Source: Auditor analysis of Division data.

[36] Excluded ten nursing homes that were not certified to receive Medicare and/or Medicaid payments.



In addition to the inspections that were completed late during the audit period, auditors also determined that, as of December 31, 2023, 71 (17%) nursing homes were already overdue for their **next** inspection.

As of December 31, 2023, 71 (17%) nursing homes were already overdue for their next inspection.

Additionally, auditors determined that six of nine (67%) inspections at higher-risk[37] nursing homes were late, exceeding the six-month limit between inspections with a range of 6.1 to 7.3 months.

Inspections for six of nine (67%) higher-risk nursing homes were late.

Resulted in Risk to Resident Health and Safety

Because the Division's inspections were late, nursing home residents were at risk of conditions that could have threatened their health and safety.

The goal of inspections is to assess how well the nursing home complied with applicable laws and regulations affecting the quality of care provided.[38] Late inspections can allow poor quality of care to go undetected and uncorrected for longer periods of time. For example,

Nursing Home A, which had 160 beds, was inspected in July 2021. However, the next inspection was not initiated until February 2023, nearly 20 months later. When the Division inspected Nursing Home A, inspectors identified three deficiencies, including one Immediate Jeopardy.[39] Specifically,

Nursing Home A went **20 months** without an inspection. After the Division completed the late inspection, it cited the nursing home for abuse, neglect, and failure to treat pressure ulcers.

[37] Higher-risk nursing homes were those the Division designated as "Special Focus Facilities" and had histories of serious quality issues. Special Focus Facilities are subject to stricter oversight by the Division.
[38] https://info.ncdhhs.gov/dhsr/nhlcs/lthfines.html.
[39] Immediate Jeopardy is defined as noncompliance by the facility leads to injury, harm, impairment, or death of one or more residents. 42 CFR § 489.3.

***Immediate Jeopardy[40] due to abuse and neglect**:* Immediate Jeopardy started on November 14, 2022, and lasted until the inspection in February 2023. A resident suffered an open wound and abrasions to her foot during transport in a wheelchair when staff did not stop pushing the wheelchair after the resident explained that her foot was caught under the footrest and was being dragged. In the Division's inspection report, the resident was quoted as saying "I was telling him to stop. I was telling him I was in pain, but he never said anything and kept pushing me forward." A second staff member stopped the transport stating that the resident's foot was bleeding badly. It took a month for the resident's wounds to heal.

***Failed to treat pressure ulcers**:* A resident was not treated for a previously identified pressure ulcer by nursing home staff. The resident received no treatment for the pressure ulcer until the day she was sent to the hospital because the pressure ulcer had severely worsened.

Immediate Jeopardy is defined as noncompliance by a nursing home that leads to **injury, harm, impairment, or death** of one or more residents.

Nursing Home B, which had 120 beds, was inspected in April 2021. However, the next inspection was not initiated until January 2023, more than 21 months later. When the Division inspected Nursing Home B, inspectors identified a total of 11 deficiencies, including failing to treat residents with dignity, not handling medications as required, and not reporting injuries of unknown origin to the Division. For example:

***Lack of dignity**:* Inspectors found two residents that had not been treated with dignity when their call bells were not answered for more than an hour. One resident needed help pulling up her pants but was not provided assistance for more than an hour. The second resident waited between 45-60 minutes for a drink. The residents reported that the staff made them feel bad for asking for assistance.

***Lack of handling medications appropriately**:* Inspectors found medications on the medication carts that had expired in November 2022, were unlabeled from the pharmacy, and one that required refrigeration and had expired in October 2022.

Nursing Home B went **21 months** without an inspection. Once the inspection was completed, it cited the nursing home for failing to treat residents with dignity, mishandling medications, and failing to follow the facility's abuse policy.

***Not following abuse policy**:* In August 2022, a resident was sent for an X-ray due to a pain complaint and found to have a fractured right femur. No explanation for the injury was identified. Injuries of unknown origin are required to be reported to the Division within two hours so that an investigation may be conducted to ensure that residents are not being abused or neglected, but the nursing home did not adhere to that requirement.

[40] Immediate Jeopardy is defined as noncompliance by the facility leads to injury, harm, impairment, or death of one or more residents. 42 CFR § 489.3.

Nursing Home C, which had 90 beds, was inspected in June 2021. However, the next inspection was not initiated until February 2023, 21 months later. When the Division inspected Nursing Home C, inspectors identified a total of 22 deficiencies, including problems with quality of care. For example,

Skilled care not consistently provided: Inspectors determined that (1) registered nurses had not been consistently provided for the minimum requirement of eight hours per day since July 2022; and (2) nurse staffing information was not accurate for 22 of 38 days reviewed with fewer staff being provided than reported. Similar deficiencies were found in the previous inspection from June 2021.

Care plans[41] ***not updated***: Inspectors determined care plans had not been reviewed or updated after residents had falls, developed pressure ulcers, or had medication changes. One resident suffered six falls since August 2022 without an update to his care plan. Two residents had orders for a clear liquid diet only, but the actual care plans incorrectly called for a regular diet and a mechanical soft diet with thin liquids.

Care not provided: Inspectors documented that staff had not provided care as ordered by the physician since July 2022 for one resident that needed treatment throughout the day but was only treated once a day. Also, inspectors determined that residents were not being assisted with maintaining good nutrition, grooming, and personal and oral hygiene. One resident did not receive any care from early morning to mid-afternoon when a family member stopped by and found the resident had not been bathed, changed, or gotten out of bed and was soaked in urine. Similar deficiencies were found in the previous inspection from June 2021.

Nursing Home C went **21 months** without an inspection. When the Division completed the late inspection, it cited the nursing home because it did not provide enough nursing staff, did not keep accurate staffing records, did not update resident care plans, and did not properly care for residents.

The COVID-19 Pandemic Resulted in High Vacancy and Turnover Rates

The Division asserts its annual inspections were untimely due to challenges resulting from the COVID-19 pandemic, which included concerns regarding the health and safety of Division staff and higher than normal vacancy rates and staff turnover.

Division management also asserts that, during the audit period, a significant number of staff were unavailable to perform inspections due to COVID-19 illness, or exposure to COVID-19, which at the time necessitated lengthy periods of isolation and quarantine.

Additionally, Division management told auditors that high vacancy rates and staff turnover contributed to untimely inspections.

[41] Care plans are used by nursing homes to identify the quantity and quality of care provided by staff.

According to Division data, the vacancy rates[42] ranged from 4% (four of 99 positions) in July 2021 to 13.3% (14 of 105 positions) in December 2023. Additionally, the Division's turnover rate averaged 17.8%. See Table 1, below:

Table 1 – Turnover Rate

Calendar Year	Turnover Rate[43]
2019	15.6% (15 of 96 positions)
2020	16.4% (16 of 97.5 positions)
2021	16.2% (16 of 99 positions)
2022	23.2% (23 of 99 positions)
2023	17.2% (18 of 102 positions)
Average	**17.8%**

Source: Auditor analysis of Division data.

The U.S. Department of Health and Human Services Office of Inspector General (U.S. DHHS OIG) issued a report[44] in January 2022 that reviewed all states' performance for conducting nursing home inspections.

The U.S. DHHS OIG found that the most common cause cited for not completing inspections within required timeframes was staffing-related issues. Per the U.S. DHHS OIG report, the most common staffing-related description in state corrective action plans centered on the inability to attract and retain surveyors, often due to not being able to offer high enough salaries to compete in local markets.

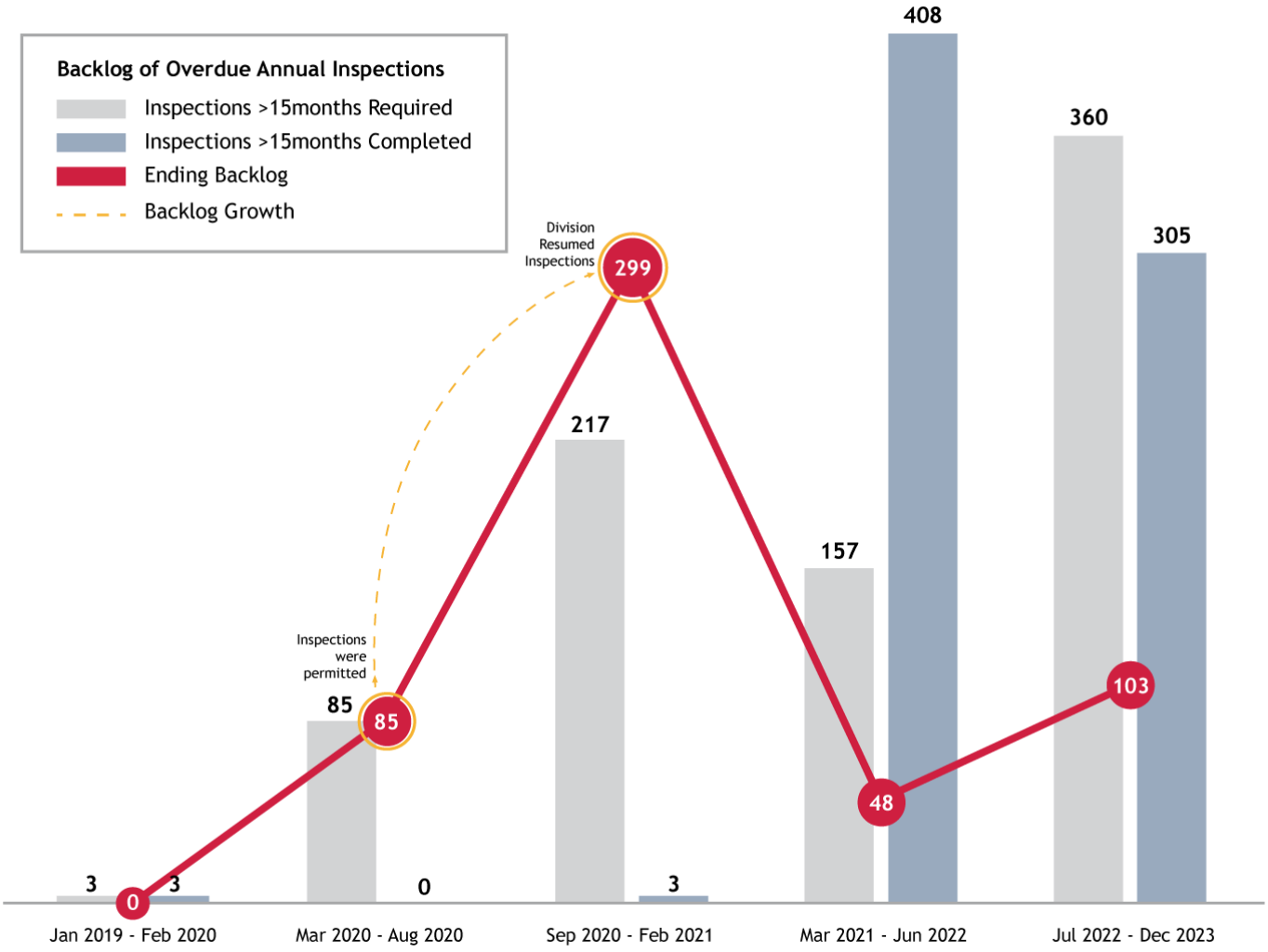
According to Division management, recruiting and retaining qualified personnel to inspect nursing homes has been a longtime challenge due to their inability to offer competitive salaries. The challenges brought on by the COVID-19 pandemic including the health and safety of Division staff, high vacancy rates, and staff turnover all contributed to the Division having a backlog of 103 inspections as of December 2023. See Chart 2, on the following page:

[42] Includes inspectors and investigators (non-management and non-administrative personnel). Auditors determined position numbers and vacancy rates based on organizational charts that were provided by the Division for various dates throughout the audit period.

[43] Includes inspectors and investigators (non-management and non-administrative personnel). Auditors determined position numbers and vacancy rates based on organizational charts that were provided by the Division for various dates throughout the audit period.

[44] https://oig.hhs.gov/oei/reports/OEI-06-19-00460.pdf.

Chart 2 – Backlog of Overdue Annual Inspections



Time Period	Beginning Backlog	Inspections >15 months	Inspections >15 months Completed	Inspections <15 months Completed	Ending Backlog	Inspections per Month
Jan 2019 - Feb 2020	0	3	3	498	0	35.4
March 2020 - Aug 2020	0	85	0	15	85	2.5
Sept 2020 - Feb 2021	85	217	3	3	299	0.8
March 2021 - June 2022	299	157	408	24	48	26.9
July 2022 - Dec 2023	48	360	305	125	103	24.9

Source: Auditor analysis of Division data.

Assuming four inspectors per team that average one inspection per week, the Division would need at least an additional two dedicated teams (eight inspectors) to clear the backlog (103 inspections) by January 31, 2026.

Division was Required to Inspect Each Nursing Home Timely

Federal regulation required the Division to inspect[45] each nursing home at least every 15 months:

> **42 CFR § 488.308 – Survey Frequency**
>
> (a) *Basic period.* The survey agency must conduct a standard survey for each nursing home not later than 15 months after the last day of the previous standard survey.

Additionally, federal law required higher-risk nursing homes called Special Focus Facilities to be inspected at least every six months:

> **42 U.S.C. § 1396r(f)(10)**
>
> (B) Periodic surveys. — Under such program the Secretary shall conduct surveys of each [nursing home] in the [Special Focus Facility] program not less often than once every six months.

Recommendations:

1. The Division should inspect all nursing homes in a timely manner, in accordance with all federal regulations and laws.
2. The Division should seek necessary resources from the General Assembly to clear its backlog of overdue inspections and to ensure completion of inspections in accordance with mandated federal regulations and laws.

[45] Inspections are identified as 'surveys' in federal laws, federal regulations, and CMS guidance.

2. Division Did Not Investigate Nursing Home Complaints Timely

The Department of Health and Human Services' Division of Health Service Regulation (Division) did not complete timely investigations of nursing home complaints.

As a result, nursing home residents were at risk of suffering from delayed corrective action to conditions that could be life-threatening, abusive, and neglectful.

According to Division management, the Division has never been able to implement the timelines required by state law due to the large number of complaints that require investigation and a lack of resources.

State law[46] required the Division to complete complaint investigations no later than 60 days after receipt of the complaint.

Complaint Investigations Were Not Completed Timely

The Division did not complete investigations of nursing home complaints within the timeframe prescribed by state law.

During the period January 1, 2019, through December 31, 2023, the Division received 35,564 nursing home complaints, of which 17,152 required investigations.[47] State law required the Division to complete an investigation of each complaint no later than 60 days from receipt of the complaint.

Auditors tested all 17,152 complaints for timeliness[48] and determined that the Division did not complete an investigation within 60 days for 6,756 of 17,152 (39%) complaints. See Chart 3, on the following page:

Between January 2019 and December 2023, the Division received 17,152 complaints that required investigation.

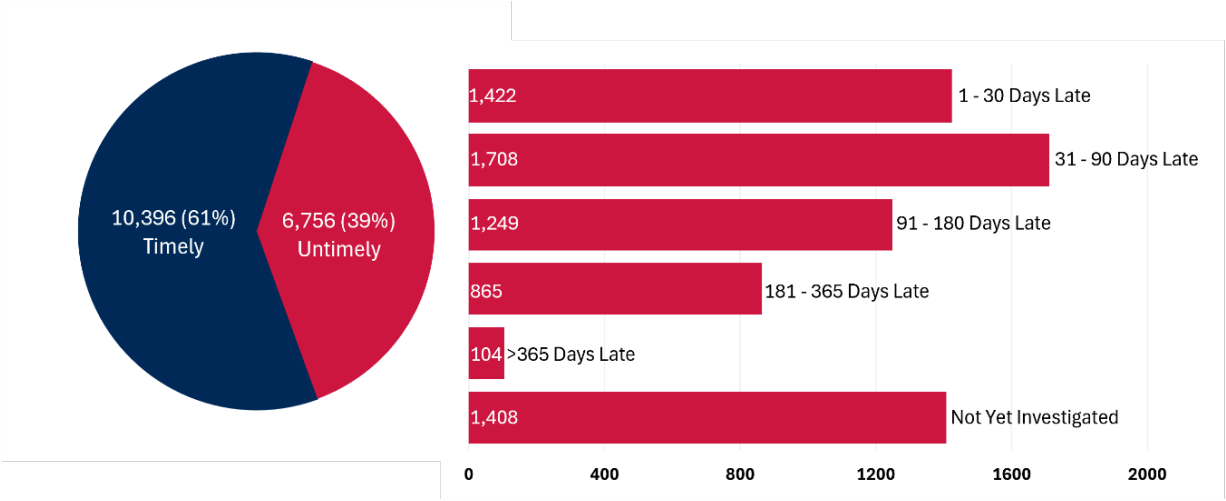
6,756 (39%) of those investigations were **completed late.**

[46] N.C.G.S. § 131E-124(a).

[47] Complaints that did not require investigation were those that the Division triaged as "No Action Necessary" or referred to another agency.

[48] Calculated as the amount of calendar days between the date the complaint was received and the date the complaint investigation was completed.

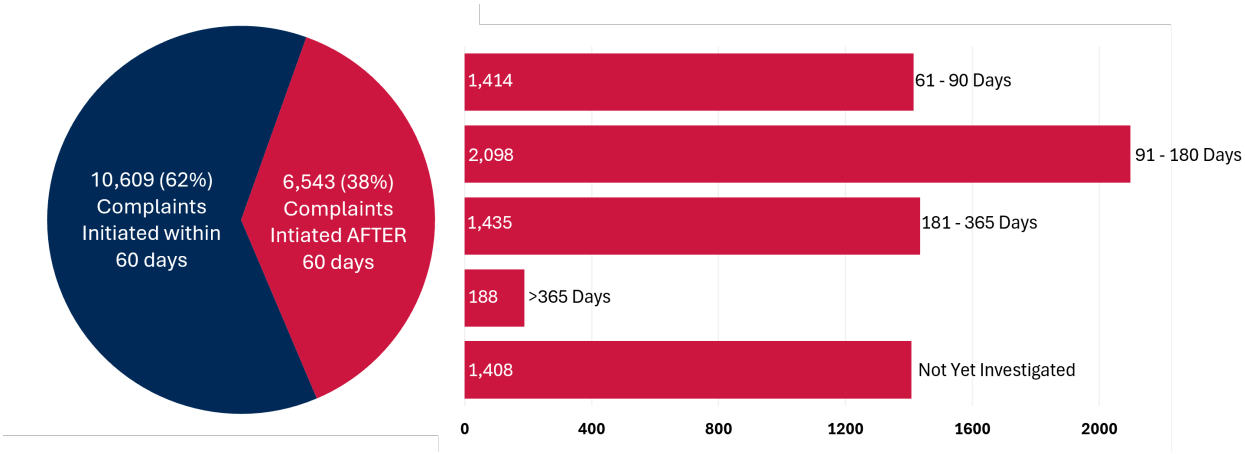
Chart 3: Timeliness of Complaint Investigations[49]



Source: Auditor analysis of Division data.

In addition to not **completing** 6,756 (39%) of its investigations within 60 days, the Division did not **initiate** an investigation within 60 days for 6,543 (38%) of the complaints. See Chart 4, below:

Chart 4: Timeliness of Initiating Complaint Investigations[50]



Source: Auditor analysis of Division data.

[49] In response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) suspended inspections of nursing homes and most investigations of nursing home complaints from March 4, 2020, through August 17, 2020. Specifically, CMS prescribed that states may resume performing inspections "at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so." The Division resumed routine inspections on March 1, 2021. The period March 4, 2020, through March 1, 2021, was excluded from auditor timeliness calculations.

[50] Ibid.

Resulted in Increased Risk to Resident Safety

Because the Division's complaint investigations were not completed timely, nursing home residents were at an increased risk of suffering from delayed corrective action to conditions that could be life-threatening, abusive, and neglectful. For example:

- On March 11, 2022, the Division received a complaint that a nursing home injured a resident by allowing them to slip and fall from a lift when moving them from their bed to a wheelchair. The complaint stated that the resident had to be taken to the hospital and consequently required surgery.

  The Division did not complete an investigation until August 3, 2022, 145 days after the complaint was made, **85 days late**. When the Division completed the investigation, the complaint was **substantiated**, and the nursing home was required to take corrective action.

- On March 10, 2022, the Division received a complaint that a nursing home failed to administer a resident's prescribed seizure medications, which resulted in the resident experiencing a seizure and being sent to the Emergency Room.

  The Division did not complete an investigation until July 20, 2022, 132 days after the complaint was made, **72 days late**. When the Division completed the investigation, the complaint was **substantiated**, and the nursing home was required to take corrective action.

- On October 21, 2021, a nursing home self-reported an incident in which a staff member, assisted by three others, inappropriately restrained a resident while attempting to inject them with medication to treat an infection. According to the nursing home's internal report, the resident had been exhibiting extreme behavioral issues, but the staff member failed to administer the resident's prescribed Ativan[51] and instead resorted to physically restraining the resident.

  The Division did not complete an investigation until March 2, 2022, 132 days after the complaint was made, **72 days late**. When the Division completed the investigation, the complaint was **substantiated**, and the nursing home was required to take corrective action.

The Division **was 72 days late** investigating an allegation that a nursing home restrained a resident inappropriately. When the Division completed the investigation, the allegation was **substantiated.**

Division Management Stated that it Lacks the Resources Needed to Comply with State Law

According to Division management, the Division acknowledges the investigative timelines required by state law. However, the Division has never been able to implement the timelines required by state law due to the large number of complaints that require investigation and a lack of resources.

[51] According to the U.S. Food and Drug Administration, Ativan can be used for the short-term relief of the symptoms of anxiety.

However, Division management stated it had not completed a formal needs analysis to determine the resources needed to comply with state law. Management stated that it conducted an initial needs analysis that indicated that a significant increase in the number of investigators would be required to comply with state law. Due to significance of the potential increase in required investigators, the Division never formalized its analysis for the purpose of requesting that the General Assembly appropriate additional resources.

Division Was Required to Complete Complaint Investigations Within 60 Days

State law required the Division to complete complaint investigations no later than 60 days after receipt of the complaint. Specifically,

> **§ 131E-124. Enforcement and investigation; confidentiality.**
>
> (a) The [Division] shall be responsible for the enforcement of the provisions of this Part. The [Division] shall investigate complaints made to it and reply within a reasonable time, **not to exceed 60 days**, upon receipt of a complaint. *[emphasis added]*

Recommendations:

3. The Division should **initiate** and **complete** all complaint investigations within the timeframes prescribed by state law.

4. The Division should complete a formal analysis identifying the resources necessary to comply with investigative time frames prescribed by state law. Based on the analysis, the Division should seek sufficient appropriation from the General Assembly to allow it to comply with state law. Alternatively, the Division should seek clarification from the General Assembly as to the Division's responsibilities for investigative timeliness.

3. Division Did Not Always Verify Correction of Nursing Home Deficiencies

The Department of Health and Human Services' Division of Health Service Regulation (Division) did not always verify the correction of nursing home deficiencies. As a result, nursing home residents were placed at continued risk of conditions that threatened their health and safety. The Division did not always verify the correction of nursing home deficiencies because Division management did not ensure that Division staff performed required verifications.

Federal requirements[52] state that the Division is required to verify the correction of identified deficiencies.

Division Did Not Always Verify Deficiencies Were Corrected

The Division did not always verify the correction of nursing home deficiencies identified during inspections of nursing homes during the period January 1, 2019, through June 30, 2022.

The Division cites nursing homes when they discover violations of federal requirements designed to protect the health and safety of residents.

The Division cites deficiencies against nursing homes when a Division inspection or investigation concludes that there are one or more violations of federal requirements[53] designed to protect the health and safety of residents.

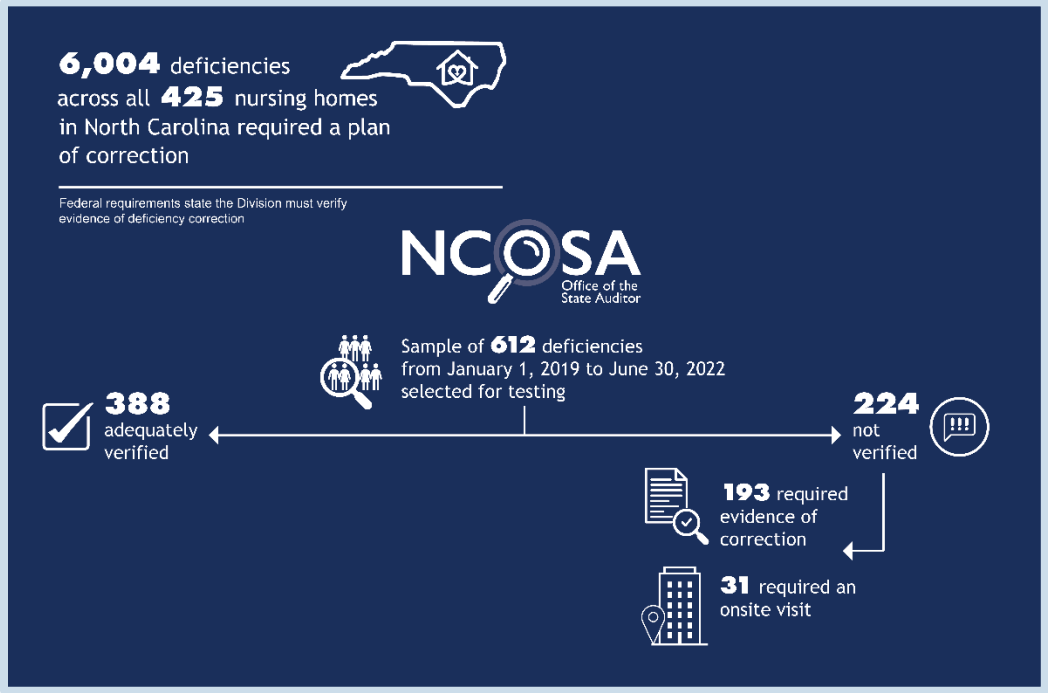
Federal requirements[54] state that the Division must verify the correction of identified deficiencies through obtaining evidence of correction[55] or conducting an onsite revisit.[56]

Auditors obtained a list of deficiencies[57] cited by the Division for all of North Carolina's approximately 425 nursing homes[58] from January 1, 2019, through June 30, 2022. According to CMS data, the Division cited 6,004 deficiencies that required a plan of correction and verification of correction. Auditors judgmentally selected[59] 612 deficiencies[60] cited to determine whether the Division verified correction of the deficiencies.[61]
Auditors analyzed documentation provided by the Division and determined that the Division did not verify the correction of 224 of 612 (37%) deficiencies. Specifically, for these 224

[52] Centers for Medicare & Medicaid Services (CMS) State Operations Manual § 7300.3.
[53] 42 CFR part 483, subpart B.
[54] CMS State Operations Manual § 7300.3.
[55] Examples of evidence of correction included sign-in sheets of those attending in-service training and interviews with training participants.
[56] The method in which the correction of deficiencies may be verified (obtaining evidence vs. onsite revisit) is determined by the scope and severity of the deficiency. Per CMS State Operations Manual § 7317.2, an onsite revisit is required when a facility's beginning survey finds deficiencies that constitute substandard quality of care, harm, or immediate jeopardy.
[57] Obtained from CMS data.
[58] The actual number of nursing homes fluctuated slightly throughout the audit period due to openings, closings, consolidations, etc.
[59] Factors for selection included whether the deficiency was related to a quality of care deficiency tag, and whether the quality of care deficiency tag was cited at the same nursing home more than once. Auditors tested all 612 deficiencies that met these criteria.
[60] Cited from 122 nursing homes.
[61] According to federal requirements, 524 of these deficiencies required the Division to verify correction by obtaining evidence of correction, and 88 required the Division to verify correction by conducting an onsite revisit. The method of verification was determined based on the scope and severity of the deficiency. CMS State Operations Manual § 7317-7317.2.

deficiencies, the Division was unable to provide supporting documentation[62] that it had verified the correction of the deficiencies either by obtaining evidence of correction or conducting an onsite revisit.

Of these 224 deficiencies, the Division was required to verify the correction of 193 (86%) of the deficiencies by obtaining evidence of correction, and 31 (14%) of the deficiencies by conducting an onsite revisit.



Resulted in Risk to Health and Safety of Nursing Home Residents

Because the Division did not always verify the correction of deficiencies, nursing home residents were placed at continued risk of conditions that threatened their health and safety. For example, the Division did not have evidence that it verified the correction of the following deficiencies:

- ***Failed to prevent significant medication errors*:** In March 2022, the Division cited a nursing home for failing to prevent significant medication errors for 9 of 11 residents sampled during the inspection. Residents did not receive multiple medications including insulin for diabetes, heart medication for atrial fibrillation,[63] pain medication for respiratory failure, anti-seizure medication to prevent seizures, and medication to prevent pulmonary embolisms.[64]

[62] Documentation included inspector notes.
[63] According to National Heart, Lung, and Blood Institute (NIH), atrial fibrillation is one of the most common types of irregular heart rhythms.
[64] According to National Heart, Lung, and Blood Institute (NIH), a pulmonary embolism occurs when a blood clot breaks loose, travels to the lungs, and blocks arteries within the lung.

- ***Lack of dignity*:** In February 2022, the Division cited a nursing home for failure to treat residents in a dignified manner. Residents were not provided with incontinence care when requested and were instead wrapped in two or three diapers to extend the time between care. Residents stated that waiting on the incontinence care and wearing multiple diapers made them feel embarrassed, demeaned, and degraded.

- ***Wound care not being provided:*** In July 2020, the Division cited a nursing home for failure to provide pressure ulcer care and failure to assess and monitor pressure ulcers. Specifically, two residents were not provided care for pressure ulcers according to physicians' orders and the facility did not have a wound care nurse to provide care and keep track of residents' wounds. The inspector noted that staff were unclear about who was supposed to be providing care and no documentation could be found for any care having been provided for one of the resident's then-current wound.

Caused by Division Management Not Ensuring Division Verified Correction of Deficiencies and Documented Verification

The Division verifies correction of citations through onsite reviews or desk reviews, depending on the severity of the deficiency.

The Division did not always verify the correction of deficiencies because Division management[65] did not centrally track the deficiencies to ensure that verifications occurred and were documented.

According to Division management, Division Branch Managers[66] are responsible for ensuring that deficiencies are corrected. The Branch Managers, Team Leads (for the inspection and investigation teams), and the Division's Section Chief have weekly meetings that include the prioritization (and re-prioritization) of upcoming inspections, investigations, and verification of correction of deficiencies based on staffing, complaints, and any applicable due dates.[67]

To verify that deficiencies were corrected, Division staff will:

- Perform onsite revisits or desk reviews.[68]
- Obtain, review, and evaluate evidence of correction.[69]
- Document results of their onsite revisit or desk review.[70]

[65] For the purposes of this issue, Division management includes the Division Section Chief and Assistant Section Chief.
[66] Nursing homes are split into three regions across the state based on their geographical location. Survey teams are assigned to each region that are responsible for inspections, investigating complaints, and for verifying deficiencies are corrected. Each region of survey teams is led by a Branch Manager.
[67] Follow-ups to verify whether deficiencies have been corrected are required to be completed within 60 days from the inspection end date. CMS State Operations Manual § 7317.2.
[68] Based on the scope and severity of the deficiency.
[69] Examples of evidence of correction included sign-in sheets of those attending in-service training, interviews with training participants, and interviews with nursing home staff and residents.
[70] The results are uploaded into the Automated Survey Processing Environment System (ASPEN). ASPEN is Centers of Medicare and Medicaid Services (CMS) software used by the Division to collect and manage nursing home federal compliance data, including recertification inspections and complaint investigations.

However, Division management did not have formal procedures in place to track the deficiencies and perform a documented, formal review to ensure the verifications occurred and were documented. Instead, according to Division management, they performed informal, undocumented reviews.

Division management did not have formal procedures in place to track the deficiencies and perform a formal review.

Potential procedures to help ensure verifications occurred and were documented could include:

- Evaluating each deficiency's risk of not being corrected to determine the appropriate selection, scope, and frequency of management review.
- Developing a monitoring plan and schedule based on each deficiency's risk of not being corrected.
- Reviewing Division staff verification that a deficiency was corrected, including that the verification was documented.

According to Division management, the federal Centers for Medicare and Medicaid Services (CMS) does not require the Division to have **supporting documentation**[71] that the correction of deficiencies have been verified. Division management stated that having CMS form 2567B[72] completed is sufficient.

However, the form alone is not sufficient according to federal requirements. Additionally, this is not the first time that the Division was found to lack documentation to support the verification of the correction of deficiencies.

In 2018, the United States Department of Health and Human Services Office of Inspector General (U.S. DHHS OIG) issued an audit[73] of the Division which found that the Division did not always verify the correction of nursing home deficiencies. Specifically, the U.S. DHHS OIG found that the Division **lacked supporting documentation** and Division files contained inadequate inspector notes.

Without performing the procedures above, or ones similar to the above, Division management could not ensure Division staff:

- Maintained documentation supporting verification of deficiencies.
- Verified deficiencies were corrected in accordance with all federal requirements.

[71] Documentation included inspector notes.

[72] CMS Form 2567B is the Post-Certification Revisit Report. This report includes cited deficiencies and includes whether the deficiency was corrected, and the date corrective action was accomplished. It provides no other information or details regarding the deficiency or corrective action.

[73] Department of Health and Human Services Office of Inspector General, *North Carolina Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid*, January 2018.

Federal Requirements state that the Division Must Verify the Correction of Nursing Home Deficiencies

Federal requirements state that the Division is required to verify the correction of identified deficiencies through obtaining evidence of correction[74] or conducting an onsite revisit. Specifically, CMS State Operations Manual states: *[emphasis added]*

> **CMS State Operations Manual § 7300.3**
>
> With the exception of an initial survey for reasonable assurance, if the initial survey of the prospective provider finds that the noncompliance is such that the deficiencies fall at levels D, E, or F (without a finding of substandard quality of care) on the scope and severity scale, the State survey agency may opt to **accept evidence of correction** to confirm substantial compliance in lieu of an onsite revisit; however, the State survey agency always has the discretion to **conduct an onsite revisit** to determine if corrections have been made. If the noncompliance falls at level F (with a finding of substandard quality of care), or any level higher than level F, the option to accept evidence of correction in lieu of an onsite revisit does not apply. In this case, an onsite revisit is necessary to determine substantial compliance after the facility submits an acceptable plan of correction.
>
> **CMS State Operations Manual § 7317.1**
>
> While the plan of correction serves as the facility's allegation of compliance in nonimmediate jeopardy cases, substantial compliance cannot be certified and any remedies imposed cannot be lifted until facility compliance has been verified.

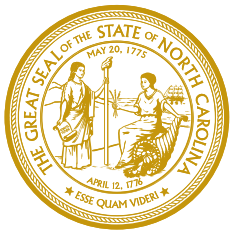
Additionally, **the CMS State Operations Manual § 7317.2** lists examples of **acceptable evidence** of a nursing home's correction of a deficiency, which include invoices verifying purchases or repairs, sign-in sheets verifying attendance of staff at in-service training, or interviews with more than one training participant about training.

Recommendations:

5. The Division should verify that deficiencies are corrected in accordance with federal requirements.

6. Division management should develop and implement procedures to ensure that Division staff verify that deficiencies are corrected and that their conclusions are documented.

[74] Examples of evidence of correction included sign-in sheets of those attending in-service training, interviews with training participants, and interviews with nursing home staff and residents.

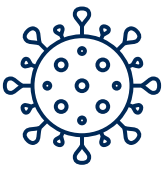


Additional Considerations

During the course of an audit, the Office of the State Auditor may uncover potential issues that are outside of the specific audit objectives. Below are three such issues.

1. Division Should Consider Developing a Plan to Respond To Pandemics And Other Times Of Crisis

Department of Health and Human Services' Division of Health Service Regulation (Division) management should consider developing a comprehensive plan for how it would respond to pandemics or other crises to allow inspections and other activities to continue to ensure nursing home residents are safe during those times.



Auditors acknowledge that there will be significant resource limitations during times of crisis. However, the Division should consider establishing a risk-based methodology for ensuring that nursing homes with a history of health and safety compliance issues are inspected during these times, even when there are limited resources and no specific federal compliance requirement to do so.

96% of all nursing homes went more than 15 months without an inspection during the pandemic.

69% of all nursing homes went **more than two years**.

Inspections are typically conducted on an annual basis. But federal requirements for inspection timeliness were relaxed due to the COVID-19 pandemic.

However, not performing inspections left nursing home residents at risk of conditions that could have threatened their health and safety.

Auditors found that 410 of 425 (96%) nursing homes were not inspected for more than 15 months during the COVID-19 pandemic.[75] In fact, 292 (69%) nursing homes went more than two years between inspections.

Additionally, auditors determined that 3 of 9 (33%) inspections at higher-risk[76] nursing homes were late, exceeding the six-month limit between inspections with a range of 6.3 to 7.6 months.[77]

Untimely inspections can allow poor quality of care to go undetected and uncorrected for longer periods of time. For example,

Nursing Home D, which had 151 beds, was inspected in August 2019, but the next inspection was not initiated until February 2022, over two years and five months later. When the Division inspected Nursing Home D, inspectors identified a total of 22 deficiencies, including medication errors and a lack of supervision. For example,

[75] Determined by calculating the amount of time between inspections at each nursing home.
[76] Higher-risk nursing homes were those the Division designated as "Special Focus Facilities" and had histories of serious quality issues. Special Focus Facilities are subject to stricter oversight by the Division.
[77] For the period January 2019 through February 2021.

Medications not administered: Inspectors determined that a resident did not receive antibiotics for an eye infection, as prescribed. The resident's eye was still enlarged and red with a swollen lid four weeks later during the inspection. Medication was only provided after the inspectors intervened.

Nursing Home D went **two years and five months** without an inspection. When the Division completed the inspection, it cited the nursing home for not administering medications and not supervising residents.

Lack of supervision: Inspectors found that staff were not supervising residents as necessary for appropriate care. One resident was spotted walking down the middle of a road in only sweatpants and a shirt despite a temperature of 24 degrees. Police returned the resident after he was located at a local service station; the nursing home staff had not been aware that he had left the facility until informed by the police.

Lack of administration: Inspectors found that the nursing home's administration failed to provide oversight and leadership; the nursing home residents were in Immediate Jeopardy[78] for almost three months. Specifically, the administration failed to ensure that residents were free from abuse, to prevent residents from exiting the facility unsupervised, and to provide sufficient staffing to meet the needs of the residents.

Nursing Home E, which had 120 beds, was inspected in December 2019, but the next inspection was not initiated until June 2022, over two years and six months later. When the Division inspected Nursing Home E, inspectors identified a total of 20 deficiencies, including pain management and resident rights. For example:

Lack of pain management: A resident was frequently denied pain medication for a fractured wrist and shoulder. The doctor had prescribed the medication for every 12 hours, as needed, but it was being administered only every 24 hours, leaving the resident in pain throughout the night.

Nursing Home E went **two and a half years** without an inspection. When the Division completed the inspection, it cited the nursing home for leaving a resident in pain through the night, not showering residents regularly, and not maintaining a clean environment.

Lack of self-determination and clean environment: Residents were not regularly assisted with showers; one resident only received three showers over a six-month period. Floors were sticky, and resident living spaces were missing drawers and doors, had leaking toilets, and were "permeated with odors." One resident stated that she had been waiting months for repairs.

Nursing Home F, which had 134 beds, was inspected in March 2019, but the next inspection was not initiated until June 2021, over two years and three months later. When the Division inspected Nursing Home F, inspectors identified a total of 17 deficiencies, including medication errors and insufficient nursing staff. For example,

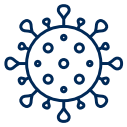
[78] Immediate Jeopardy is defined as noncompliance by the facility leads to injury, harm, impairment, or death of one or more residents. 42 CFR § 489.3.

Medication errors: Inspectors determined that the medication error rate was over 15%, including residents being giving the wrong medication and one resident being given a delayed release medication that was crushed despite instructions requiring the medication to be given only as a whole tablet.

Lack of sufficient nursing staff: Inspectors identified that the facility did not have sufficient nursing staff to meet the needs of incontinence care for the residents. The inspectors documented that one nurse reported that she had been assigned 108 residents during the current shift plus those in the assisted living areas of the facility. Care that was not completed was left for the staff on the next shift to catch up. The inspectors documented that several residents were found to be without care for hours, either needing incontinence care or assistance getting out of bed. Inspectors also attributed the lack of following physician orders for pressure ulcer care to insufficient nursing staff.

Nursing Home F went **two years and three months** without an inspection. When the Division completed the inspection, it cited the nursing home for giving residents the wrong medications and not providing enough nursing staff.

Consideration:



Division management should consider developing a comprehensive plan for potential future pandemics or other crises to ensure inspections and other safety related activities continue to better protect and care for nursing home residents during those times.

2. Division Should Consider Increasing the Unpredictability of Nursing Home Inspections

Department of Health and Human Services' Division of Health Service Regulation (Division) management should consider increasing the unpredictability in how annual inspections of nursing homes are conducted.

The goal of inspections is to assess how well the nursing home complied with applicable laws and regulations affecting the quality of care provided to nursing home residents.[79] Inspections are required to be conducted at least once every 15 months.

Federal requirements state that the Division has the responsibility for keeping inspections (also called "surveys") unannounced and their timing **unpredictable**. Specifically, the Centers for Medicare and Medicaid Services (CMS) State Operations Manual states: *[emphasis added]*

> **CMS State Operations Manual § 7207.2**
>
> To increase the opportunity for unpredictability in standard surveys, the [Division] **should** incorporate the following procedures when planning [nursing home] surveying:
>
> **CMS State Operations Manual § 7207.2.1**
>
> Facilities, within a given **geographical area,** should not be surveyed in the same order as was conducted in the previous standard survey.
>
> **CMS State Operations Manual § 7207.2.2**
>
> When facilities are surveyed, the **time of day**, **day of the week**, and **time of month** should be varied from the time of the previous standard survey.
>
> At least 10 percent of standard health surveys must begin either on the weekend or in the evening/early morning hours before 8 a.m. or after 6 p.m.
>
> Likewise, the **month in which a survey begins** should not, if possible, coincide with the month in which the previous standard survey was conducted.

The CMS State Operations Manual tells the Division that, to increase the unpredictability of inspections, it **should** vary the day of the week, month of the year, time of the month, and geographic order of inspections.

Auditors obtained documentation for all 1,417 inspections for 425 certified[80] nursing home[81] inspections conducted from January 1, 2019, through December 31, 2023, and reviewed to determine whether the inspection was unpredictable in comparison to previous inspections.

[79] https://info.ncdhhs.gov/dhsr/nhlcs/lthfines.html.
[80] Certified as in compliance with 42 CFR Part § 483, Subpart B in order to receive Medicare and/or Medicaid payments as a nursing home.
[81] Excluded 10 nursing homes that were not certified to receive Medicare and/or Medicaid payments.

Auditors found:

- 181 of 1,417 (13%)[82] nursing home inspections began on the weekend.[83]

However,

- 154 (36%) nursing homes had inspections that began on the same **day of the week** for at least **three** consecutive inspections.

- 35 (8%) nursing homes had inspections that began on the same **day of the week** for **four** consecutive inspections. Three nursing homes had **five** consecutive inspections that all started on a Monday.

- 1,032 (73%) nursing home inspections began on a **Monday**. Only 12 (1%) inspections began on a Wednesday (9) or Saturday (3), and no inspections began on a Thursday or Friday.

73% of all inspections began on a **Monday.**

- 181 (43%) nursing homes had inspections that began in the **same month** as the previous inspection. Sixteen (4%) nursing homes had three consecutive inspections that began in the same month.

- 86 (20%) nursing homes were inspected in a **geographically**[84] **predictable**[85] manner, representing 33 counties. In fact, 29 (7%) nursing homes had inspections in the same order for **four** consecutive inspections, representing 13 counties.

When asked about conducting inspections in an unpredictable manner, Division management stated that the Division **(1)** began inspections primarily on Mondays so that staff were not required to work through the weekend which could impact morale, and **(2)** inspection schedule met the minimum requirements for unpredictability if the inspections were not verbally announced.

However, federal requirements[86] state:

> The [Division] has the responsibility for keeping surveys unannounced **and** their timing **unpredictable**. This gives the [Division] doing the surveying **greater ability to obtain valid information** because it increases the probability that the surveys will observe conditions and care practices that are typically present. *[emphasis added]*

[82] The federal 10% requirement is based on inspections conducted during the federal fiscal year (FFY) (October – September). Inspections that began on the weekend by FFY: 2020 (12%), 2021 (10%), 2022 (12%), 2023 (12%).

[83] Requirement is for at least 10% of inspections to begin either on the weekend or in the early morning/evening hours before 8 a.m. or after 6 p.m. Auditors did not have access to the time the inspection began so we tested based on whether the inspection began on the weekend. Inspections that began on the weekend satisfied the 10% requirement without taking into consideration inspections that began before 8 a.m. or after 6 p.m.

[84] The Division did not have procedures or policies for geographical variability; auditors defined it as a county.

[85] Predictable means that the inspections were conducted in the same nursing home order for at least three consecutive recertification inspections.

[86] CMS State Operating Manual § 7207.2.

Without unpredictability, nursing homes may anticipate when Division inspectors will arrive and temporarily adjust conditions and care practices from what is typically present to minimize deficiencies. As a result, nursing home residents may be at risk of suffering from undetected deficiencies in their care.

Consideration:

Division management should consider establishing a policy increasing the unpredictability of annual inspections of nursing homes facilities that protects the health and safety of nursing home residents. This gives the Division greater ability to obtain valid information because it increases the probability that Division staff will observe conditions and care practices that are typically present.

3. Division Should Consider Establishing a Policy on the Frequency of Licensed-Only Nursing Home Facility Inspections

Department of Health and Human Services' Division of Health Service Regulation (Division) management should consider establishing a policy on the frequency with which it conducts inspections of licensed-only nursing home facilities (licensed-only facilities). The policy should establish an inspection frequency that protects the health and safety of nursing home residents.

In North Carolina, there are 10 nursing homes which are operated as licensed-only facilities. Licensed-only facilities do not receive Medicare or Medicaid funding; therefore, the facilities are not required to be certified by federal Centers for Medicare and Medicaid Services (CMS) and are not subject to CMS regulations.

In North Carolina, there are 10 nursing homes that are not regulated by CMS because they do not receive Medicare or Medicaid funding.

These nursing homes are still subject to oversight by the Division.

However, licensed-only facilities are subject to the Division's regulation and oversight in accordance with the state's Nursing Home Licensure Act (Act).[87] While the Act does not require the Division to inspect licensed-only facilities at any particular frequency, the Act's purpose is "to establish [the] **authority** and **duty** for the [Division] to **inspect** and license private nursing homes."[88] *[emphasis added]*

During our audit, we noted[89] that the Division did not regularly inspect licensed-only facilities.[90] However, best practices identified by the National State Auditors Association[91] state that inspections should be frequent enough to provide reasonable safeguards to the public. See Table 2, on the following page:

[87] Chapter 131E, Article 6, Part 1 of the North Carolina General Statutes.
[88] N.C.G.S. § 131E-100(b).
[89] Determined by calculating the amount of time between inspections at each licensed-only nursing home.
[90] Some licensed-only nursing homes were the subject of complaint investigations. However, such investigations are limited in scope and would not ensure the facility was in overall compliance with requirements of the Act.
[91] National State Auditors Association, *Carrying Out a State Regulatory Program*, 2004.

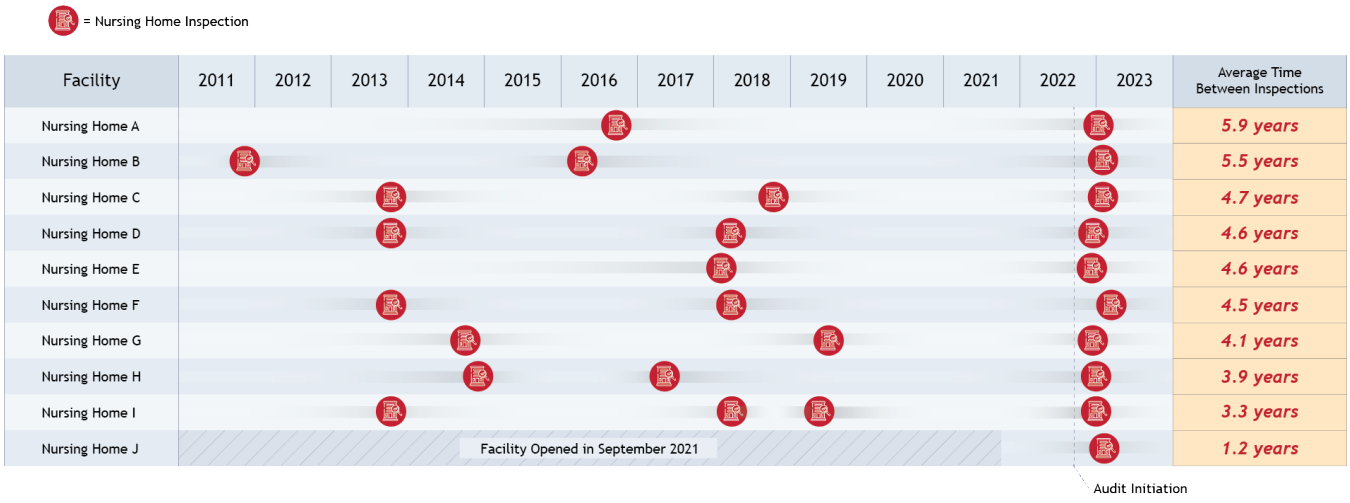
Table 2: Licensed-Only Facility Inspections

Facility	Number of Beds per Facility	Inspections Between March 2011[92] and June 2022	Inspections After June 2022	Average Time Between Inspections
A	90	October 2016	October 2022	5.9 years
B	38	December 2011 May 2016	November 2022	5.5 years
C	173	October 2013 November 2018	November 2022	4.7 years
D	75	October 2013 March 2018	October 2022	4.6 years
E	70	February 2018	September 2022	4.6 years
F	25	October 2013 March 2018	November 2022	4.5 years
G	25	September 2014 June 2019	September 2022	4.1 years
H	58	March 2011 November 2014 April 2017	October 2022	3.9 years
I	60	October 2013 March 2018 May 2019	October 2022	3.3 years
J	36	No Inspections[93]	November 2022	1.2 years
Total Beds	**650**			

Source: Auditor analysis of Division data

After the initiation of our audit,[94] and inquiries regarding the licensed-only facilities, the Division inspected all 10 within three months. See Chart 5, below:

Chart 5: Licensed-Only Facility Inspections



[92] Inspection dates prior to March 2011 were not available.
[93] This licensed-only nursing home opened in September 2021.
[94] Division management was officially notified of our audit engagement on August 3, 2022.

The Division had not conducted any subsequent inspections of the licensed-only facilities as of December 31, 2023.[95]

Without regular inspections, the Division is limited in its ability to know whether the licensed-only facilities are complying with the provisions of the Act or are endangering the health, safety, or welfare of nursing home residents.

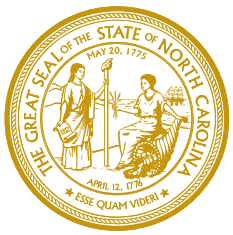
When the Division conducted these inspections after initiation of our audit, Division staff issued citations to the licensed-only facilities. For example, citations were issued for:

- Failing to protect residents from abuse.
- Failing to prevent cognitively impaired residents from wandering out of the facility without supervision.
- Failing to provide emergency preparedness training for staff.

Consideration:

Division management should consider establishing a policy on the frequency with which it conducts inspections of licensed-only nursing home facilities. The policy should establish an inspection frequency that protects the health and safety of nursing home residents.

[95] Based on information available on the Division's website.



Objectives, Scope, and Methodology

The objective of this performance audit was to determine whether the Department of Health and Human Services' Division of Health Service Regulation (Division):

Inspected nursing homes in accordance with timeliness requirements prescribed by federal regulations.

Investigated nursing home complaints in accordance with timeliness requirements prescribed by state law.

Verified the correction of identified deficiencies in accordance with federal requirements.

The audit scope included recertification inspections conducted and investigations of complaints received between January 1, 2019, and December 31, 2023, and included the verification of correction of deficiencies during the period January 1, 2019, through June 30, 2022.[96]

To accomplish the audit objective, auditors:

- Reviewed federal and state laws, federal regulations, and federal requirements relevant to the Division and the Division's inspections and investigations of nursing home facilities.
- Reviewed Division policies and procedures.
- Interviewed Division management and staff.
- Reviewed inspection and investigation results and other documentation of the Division's inspection and investigation procedures.
- Obtained documentation of the dates for all 1,417 (100%) nursing home inspections conducted during the period January 1, 2019, through December 31, 2023. Auditors calculated the number of months between each facility's inspection to determine whether inspections were conducted in accordance with timeliness requirements established by federal regulations.
- Tested all 17,152 (100%) complaints received by the Division during the period January 1, 2019, through December 31, 2023, that required investigation to determine whether the Division completed investigations in accordance with timeliness requirements prescribed by state law.
- Tested 612 of 6,004 (10%) deficiencies cited resulting from Division inspections or complaint investigations during the period January 1, 2019, through June 30, 2022, that required a plan of correction and verification of correction. Auditors analyzed documentation to determine whether deficiencies were verified as corrected in accordance with federal requirements.

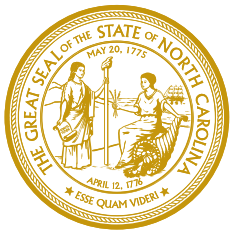
[96] During the audit, the scope period was extended to include January 1, 2019, through December 31, 2023, for inspections and investigations. The scope was not extended for the verification of the correction of deficiencies. Extending the scope in this area would have required a substantial amount of additional time and resources to complete detailed testing.

Whenever sampling was used, auditors applied a risk-based, nonstatistical approach. Therefore, results could not be projected to the population. This approach was determined to adequately support audit conclusions.

Because of the test nature and other inherent limitations of an audit, together with limitations of any system of internal and management controls, this audit would not necessarily disclose all performance weaknesses or lack of compliance.

This audit was designed to identify, for those programs, activities, or functions included within the scope of the audit, deficiencies in internal controls significant to our audit objectives. As a basis for evaluating internal control, auditors applied the internal control guidance contained in professional auditing standards. However, our audit does not provide a basis for rendering an opinion on internal control, and consequently, we have not issued such an opinion.

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.



State Auditor's Response

The Office of the State Auditor (OSA) is required to provide additional explanation when an agency's response could potentially cloud an issue, mislead the reader, or inappropriately minimize the importance of auditor findings.

Generally Accepted Government Auditing Standards state:

> "When the audited entity's comments are inconsistent or in conflict with the findings, conclusions, or recommendations in the draft report, the auditors should evaluate the validity of the audited entity's comments. If the auditors disagree with the comments, they should explain in the report their reasons for disagreement."

In its response, the Department of Health and Human Services (Department) made several inaccurate and misleading statements minimizing issues identified in this audit. OSA offers the following clarifications for the most significant inaccuracies.

> **The Department states that it is an agent for the federal Centers for Medicare & Medicaid Services (CMS) and performs work "at the direction of, and on behalf of CMS."**

This is misleading and misguided because while the Department is subject to CMS' guidance and oversight, the Department is first and foremost an agency of the state of North Carolina. The Department has the authority and duty[97] to provide oversight of nursing homes for the state, North Carolinians, and nursing home residents. Nursing home residents are one of the state's most vulnerable populations and include grandparents, parents, brothers, sisters, and friends who deserve to be provided with quality care in safe and sanitary living conditions.

> **The Department states, "Finding lacks any showing of causal effect and is misleading in implying that the facts underlying the deficiency found would not have occurred. . ."**
>
> **Further, the Department stated that it was takes issue with conclusions that untimely inspections and investigations may increase the risk to the health and safety of nursing home residents.**

This statement is inaccurate because OSA's report does not state that untimely inspections or investigations caused deficiencies to occur. The report states that late inspections and investigations increase the risk that unsafe conditions and other deficiencies (such as poor quality of care) will go undetected and uncorrected for longer periods of time. The Department found and cited nursing homes for unsafe conditions and deficiencies when it actually conducted its inspections and investigations, and required nursing homes to implement corrective actions.

> **The Department disagreed with OSA's conclusion that it did not verify that nursing home deficiencies were corrected and stated that "DHSR did have documentation it had performed the verification and documented that fact in its transmittal of information to CMS via form 2567B which is what is required by CMS."**

This statement is misleading because CMS Form 2567B does not provide documentary evidence of the corrective action. It only cites the deficiencies, indicates whether the deficiency was corrected (by checking a box), and lists the date corrective action was accomplished. It provides no other

[97] Chapter 131E, Article 6, Part 1 of the North Carolina General Statutes.

information or details. Consequently, Department management is limited in its ability to ensure that its staff verified the deficiencies were corrected.

> **The Department made several statements that the audit scope included nursing home inspections that would have been due during the COVID-19 pandemic.**

This is misleading because, after numerous discussions with Department management, OSA acknowledged there was a shift in the focus and responsibilities of the Department because of the COVID-19 pandemic. As such, OSA excluded those periods from the audit scope. OSA excluded all inspections conducted prior to March 1, 2021.[98] OSA also excluded the period[99] in which the Department suspended inspection and investigation activity due to the COVID-19 pandemic from investigation timeliness calculations. Department management knew that these periods were excluded from the audit scope before it wrote its response to OSA's findings.

> **The Department stated that "For the same period [as OSA's audit], CMS concluded that NC met or exceeded all of its annual performance measures—surpassing the performance of most southeastern US states." And since it met CMS standards, that CMS's conclusions differed from OSA's audit conclusions.**

This statement is misleading because CMS's performance measures did not evaluate whether the Department conducted nursing home inspections timely in accordance with federal regulations. OSA's audit did. And it determined that inspections for 289 of 425 (68%) nursing homes were late, exceeding the 15-month limit between inspections.

> **The Department disagreed with OSA's recommendations to complete investigations in accordance with timeliness prescribed by state law and stated that "DHSR prioritizes and conducts complaint investigations per the criteria and within the timeframes established by CMS."**

This statement is misleading because federal requirements prescribed by CMS state that "If a state's time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State's timeframes."[100] Therefore, the Department technically has not complied with either state law or federal requirements.

The General Assembly enacted the more stringent timelines for investigating complaints regarding nursing homes to promote the interests and well-being of the patients in nursing homes.[101] As noted in its response, however, the Department unilaterally decided to ignore the more stringent state law[102] and follow the CMS timeframes.[103] The Department also stated that it has not complied with state law for over 47 years.

The Governor, legislators, and the citizens of North Carolina should consider these clarifications when evaluating the Department's response to this audit.

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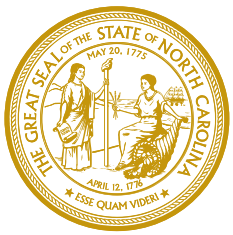
[98] The Department resumed routine inspections on March 1, 2021, after CMS suspended nursing home inspections due to the COVID-19 pandemic.
[99] March 4, 2020, through March 1, 2021.
[100] CMS State Operations Manual § 5010.
[101] N.C.G.S. §§ 131E-115; 131E-124.
[102] N.C.G.S. § 131E-124(a).
[103] CMS State Operations Manual, Chapter 5.



Response From Department of Health and Human Services

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

KODY H. KINSLEY
SECRETARY

October 11, 2024

The Honorable Jessica N. Holmes
State Auditor
Office of the State Auditor
20601 Mail Service Center
Raleigh, NC 27699-0600

Dear Auditor Holmes:

Thank you for providing the North Carolina Department of Health and Human Services (NCDHHS) with the opportunity to respond to your performance audit, titled "North Carolina Department of Health and Human Services Division of Health Services Regulation Oversight of Nursing Homes." The findings in this audit conflict with the federal government's evaluation of our performance during the same time period, it leverages an unprecedented moment in time to assess our efforts, and the findings lack any context or acknowledgement of the resources needed to do this work.

NCDHHS has a long and documented history of improving the health, safety and wellbeing of aged and vulnerable North Carolinians. This work includes expanding Medicaid and strengthening our behavioral health system, as well as our updated Olmstead Plan and the recently released "All Ages, All Stages" blueprint that documents how our state meets the needs of a rapidly aging population. We all have a responsibility to ensure the safety and wellbeing of North Carolina's aged and vulnerable residents, particularly those who reside in a nursing home. Inspecting NC's nursing homes and investigating complaints about care provided in these facilities are regulatory duties we take seriously.

Nursing homes are complex healthcare facilities that provide 24-hour medical care to individuals who are ill or injured, may require oxygen or suctioning, wound management, and may also be in cognitive decline. The task of inspecting and investigating complaints in nursing homes is done by teams of licensed, skilled professionals whose work schedule includes nights, weekends and holidays. These teams are comprised mostly of registered nurses, but also include social workers, pharmacists, dieticians, architects and engineers. Nearly all nursing homes in NC (96%) are federally certified, so NCDHHS performs this important regulatory work at the direction of, and on behalf of, the US Centers for Medicare & Medicaid Services (CMS). This federal agency sets performance standards for all states to meet, including NC, and CMS determines annually whether we met, exceeded or fell short of those measures.

The NCDHHS team assigned to nursing home inspections and investigations has been understaffed and under-resourced for years. Without adequate staff, this team has struggled with

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both a 51% increase in complaints over the past 8 years and an increase in the severity of those complaints. Included in each of the administration's last four recommended budgets were requests for additional staff, higher salaries, and improved benefits for this team. Despite repeated requests, these investments have not been made by the NC General Assembly. Some partial funding for higher salaries and more competitive benefits have been included in enacted budgets, and while helpful, these are insufficient to meet the growing need and to be able to recruit and retain the necessary healthcare personnel in a highly competitive marketplace.

Much of the time period covered in this audit overlaps with the COVID-19 global pandemic. As a result, the audit does not measure performance during routine times. Rather, it judges the timeliness of work during a period of time when the entire healthcare system—including its staff and suppliers—were stressed, responding to evolving information, and working long hours in difficult situations. Even though the federal government suspended routine inspections and the less serious complaint investigations in nursing homes, NCDHHS nursing home staff regrouped, suited up and went onsite to help any nursing home struggling with a COVID-19 outbreak. All told, staff conducted over 1,600 onsite infection control visits during the first year of the COVID-19 pandemic—averaging almost 4 visits per facility that year alone. Even though most of their regulatory work was put on hold, NCDHHS staff continued to visit these facilities and, in doing so, saved countless lives, both patients and staff.

The audit's conclusions about the performance of this NCDHHS team differ vastly from the conclusion made by the federal agency for whom this work is done on their behalf and to whom federal law holds accountable. For the same period, CMS concluded that NC met or exceeded all of its annual performance measures—surpassing the performance of most southeastern US states. NCDHHS requested for CMS to review this report and offer their perspective. That opportunity was twice denied by the Office of the State Auditor. We believe that the federal government would have underscored where and how they redeployed our staff, and they would have also acknowledged that the backlog of routine work—inspections and less serious complaints—would take many months for states like North Carolina to work through.

Performance audits provide useful and helpful information to agencies and their leadership teams. These audits are most helpful when their findings and recommendations can be applied to routine times and routine workloads. COVID-19 was not usual. An understaffed and under-resourced team responded to an unprecedented global pandemic and played an important role in saving countless lives. They also remained diligent in their efforts to work through a sizeable backlog of inspections and complaint investigations—all at the direction and with the blessing of the federal government and the gratitude of many North Carolinians.

The following represents our detailed response to your Audit Findings and Recommendations.

Sincerely,

DocuSigned by:
Mark T. Benton
65A1EF320AD6419...

Mark T. Benton
Chief Deputy Secretary for Health

cc: Kody H. Kinsley, Secretary
Julie Cronin, GC
Jeff Grimes, OIA
S. Mark Payne, DHSR

Audit Findings, Recommendations, and Responses

Background
The Office of the State Auditor (OSA) performance audit period of January 1, 2019, through December 31, 2023, coincides with an unprecedented time of significant challenge for North Carolina and the Division of Health Service Regulation (DHSR) in responding to the COVID-19 pandemic. The Federal COVID-19 Public Health Emergency began on January 31, 2020, and ended on May 11, 2023. (NC's COVID-19 State of Emergency began on March 10, 2020, and was terminated on August 15, 2022.) During the period of March 2020 until early May 2023, there were 3,501,404 reported COVID-19 cases and 29,059 deaths due to COVID-19 in North Carolina.[1]

The audit period was during the COVID-19 global pandemic when DHHS and DHSR's day-to-day work was significantly and negatively impacted. Responding to the COVID-19 pandemic required numerous changes in prioritization of DHSR's nursing home inspections and complaint investigations. In May 2020, the Centers for Medicare and Medicaid Services (CMS) instructed DHSR and other states to complete an on-site focused infection prevention and control inspection of every nursing home in addition to prioritizing the investigation of complaints that alleged potential Immediate Jeopardy or infection control issues. These inspections were a new and significant additional work requirement for DHSR that are not discussed in the Office of the State Auditor report. DHSR conducted on-site focused infection prevention and control surveys of every nursing home in North Carolian prior to June 30, 2020, to prevent the spread of COVID-19 and save lives. During the period of July 1, 2020, through February 29, 2021, DHSR conducted 1,198 on-site focused infection prevention and control inspections at nursing homes in North Carolina. As a result of the change in prioritization, DHSR had a significant backlog of inspections and complaints on March 1, 2021, when it was able to gradually resume conducting standard inspections.

OSA Finding #1: Division Inspections of Nursing Homes Were Not Timely
OSA Recommendations:

1. The Division should inspect all nursing homes in a timely manner, in accordance with federal regulations and laws.
2. The Division should seek necessary resources from the General Assembly to clear its backlog of overdue inspections and to ensure completion of inspections in accordance with mandated federal regulations and laws.

Agency Response: NCDHHS disagrees with the Finding and Recommendations.

Background
NCDHHS' Division of Health Service Regulation's (DHSR) responsibility to inspect nursing homes no later than 15 months after the day of the previous standard survey[2] is based on an agreement between the US Secretary of Health and Human Services (Secretary) and the State of North Carolina's Division of Health Services Regulation, hereinafter referred to as the "1864 Agreement." The US Department of Health and Human Services Secretary delegated authority for the administration of the 1864 Agreement to the Centers for Medicare and Medicaid Services (CMS).[3] DHSR is required to inspect federally certified nursing homes according to federal law or regulation and CMS' requirements and guidance.
The 1864 **Agreement states, in relevant part, that DHSR's inspection of nursing homes "for the purpose of certifying to the Secretary compliance or non-compliance of providers and suppliers of services and**

[1] https://covid19.ncdhhs.gov/dashboard/cases-and-deaths#COVID-19CasesandDeaths-7876
[2] 42 CFR § 488.308
[3] Article I *Definitions and Delegations, Section B of the 1864 Agreement.*

resurveying such entities [shall be] ***at such times and manner as the Secretary may direct . . .*** "[4] *Emphasis added.* This Section of the 1864 Agreement further states that "[t]he application of such conditions, standards, and requirements shall be in accordance with the nationally uniform survey procedures established in the regulations and general instructions."[5] And, Article III *Compliance With Regulations and General Instructions* of the 1864 Agreement specifically states "[t]he State shall comply with such regulations and general instructions as the Secretary may prescribe for the administration of this Agreement."[6]
In addition, Article V *Evaluation*, states that **the Secretary may evaluate the State's performance under the 1864 Agreement and specifies that the performance standards include evaluating that "[s]urveys are planned, scheduled, conducted, and processed timely**."[7]

Analysis
NCDHHS disagrees that DHSR did not conduct timely inspections of nursing homes during the period of March 1, 2021, through December 31, 2023, based on it being contrary to the general instructions provided by CMS and CMS' performance standards during the audit period.[8] **DHSR, in fact, exceeded CMS' performance standards for the period of October 1, 2021 – December 22, 2023**.
This Finding also does not include analysis of the significant additional work performed by DHSR, at the direction of CMS, during the audit period to help protect the health and safety of residents in nursing homes during and subsequent to the COVID-19 pandemic and also fails to take into account the significant backlog of complaints that developed during the pandemic due to the CMS' reprioritization and suspension of some of DHSR's survey work during the audit period.

CMS' General Instructions
DHSR's authority to inspect federally certified nursing homes pursuant to federal law is dependent on the 1864 Agreement and general instructions issued by CMS to state survey agencies. CMS' Center for Clinical Standards and Quality/Quality, Safety & Oversight Group routinely issues memoranda to state survey agencies to provide general instructions which are referred to as a QSO followed by identifying numbers/references. On March 20, 2020, CMS issued QSO-20-20-All, withdrawing authorization for standard surveys of nursing homes and prioritizing investigation of complaints alleging Immediate Jeopardy or infection control concerns, with onsite investigations being performed only when survey staff had the necessary personal protective equipment (PPE) to safely do so.

On January 4, 2021, CMS issued revisions to the general instructions issued in QSO-20-31-All and attached Frequently Asked Questions (FAQs). CMS' answer to Q2 states, in relevant part, that "[p]er QSO-20-35-ALL, States *may* resume performing LTC standard recertification health surveys, and EP and LSC surveys (for all provider types) *at the State's discretion as soon as they have the resources (e.g., staff and/or PPE) to do so.*" (*Emphasis added.*)

Per CMS' general instructions, DHSR was able to gradually resume conducting inspections of nursing homes in March of 2021 to the extent resources were available while prioritizing its investigation of the most serious

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[4] Article II *Functions To Be Performed By The State*, Section A.1.(c) of the 1864 Agreement.
[5] The term "general instructions" is defined in the 1864 Agreement as meaning "operating manuals, related written instructions, and guidelines of general application issued by the Secretary pursuant to the Act and regulations in respect to matters covered by this Agreement." Article I *Definitions and Delegations*, Section A.6.
[6] See also, 42 CFR § 488.26(d) which specifically states that "[t]he State survey agency must use the survey methods, procedures, and forms that are prescribed by CMS."
[7] Article V Evaluation, Sections A and C of the 1864 Agreement. [8] DHSR notes that Chart 2 in OSA's Performance Audit Report reflects that DHSR was timely in conducting inspections during the audit period prior to the COVID-19 State of Emergency (January 2019 – February 2020).
[8] DHSR notes that Chart 2 in OSA's Performance Audit Report reflects that DHSR was timely in conducting inspections during the audit period prior to the COVID-19 State of Emergency (January 2019 – February 2020).

complaints per CMS' instructions. It was not CMS' nor DHSR's expectation that DHSR would be able to inspect all nursing homes (and, investigate the significant backlog of complaints that had accumulated during the prior approximately 12 months) within 15 months of its resumption of inspections. In fact, CMS acknowledged in QSO-22-02-ALL, issued on November 12, 2021, that the "temporary suspension and reprioritization of survey activity nationwide resulted in a backlog of complaint and recertification surveys to be investigated . . . " and stated "[*a*]*t this time*, we believe SAs [State Survey Agencies] should be able to resume recertification surveys on a regular basis, and should do so by establishing new intervals based on each facility's next survey, not based on the last survey that was conducted prior to the COVID-19 PHE." (*Emphasis added.*) This QSO further states that CMS will provide flexibilities for state survey agencies "to work through the current backlog of complaints and recertification surveys that is a direct result of the suspension of certain onsite survey activities in an effort to control the spread of COVID-19."

CMS Performance Standards

Pursuant to the 1864 Agreement, CMS evaluates DHSR's performance inspecting nursing homes. CMS established a State Performance Standards System (SPSS) with specific standards that may be revised annually. In light of CMS withdrawing authorization for state survey agencies to conduct standard surveys of nursing homes and prioritizing complaint investigations of only allegations of an Immediate Jeopardy or infection control, CMS did not establish SPSS measures for federal fiscal year 2021 (October 1, 2020 – September 30, 2021).

CMS did establish SPSS measures for federal fiscal year 2022 (October 1, 2021 – September 30, 2022). CMS' specified that between November 30, 2021[9] and September 30, 2022, State Survey Agencies should reduce the number of past-due standard recertification surveys by at least 50%. DHSR exceeded CMS' nursing home inspection performance measure for federal fiscal year 2022 by achieving a 79% reduction in past-due standard recertification surveys.

CMS also established SPSS measures for federal fiscal year 2023 and measured state survey agency performance completing past-due standard recertification surveys with a goal of a 50% reduction in the number of past due standard recertification surveys as of October 2, 2022, by December 22, 2023. Once again, DHSR exceeded CMS' performance measure for inspecting nursing homes during federal fiscal year 2023 and through December 22, 2023, by achieving a 93% reduction in the past-due standard recertification surveys.

Significant Additional Work Performed by DHSR

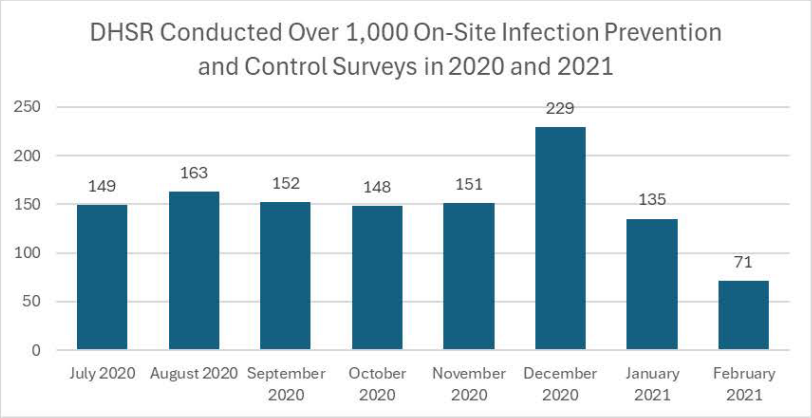
Although CMS prioritized conducting immediate jeopardy complaints and on-site focused infection prevention and control inspections during the COVID-19 pandemic, OSA failed to include on-site focused infection prevention and control inspections as part of its performance audit during the audit period. On May 13, 2020, CMS instructed DHSR to complete an on-site focused infection prevention and control inspection of every nursing home in addition to prioritizing the investigation of complaints that alleged a potential Immediate Jeopardy or infection control issue. DHSR appreciated the importance of this request to help protect the health and safety of residents in nursing homes in our State and staff worked diligently going onsite to nursing homes experiencing a COVID-19 outbreak to perform these surveys.[10] DHSR worked to acquire and distribute PPE to

[9] Footnote 1 to S5 in CMS's State Performance Standards Systems Measures (Fiscal Year 2022) states: "CMS is using November 30, 2021 as the baseline date for this measure rather than October 1, 2021 because of the timing of conversations with States about the survey backlog that occurred around or after October 1, 2021."

[10] Some DHSR's staff were placed on work restrictions by their physician due to health conditions that placed them at high risk for serious illness or death if he/she contracted COVID-19. Others were unable to survey for a period of time due to contracting COVID or being exposed to COVID-19 and having to isolate or quarantine themselves per the Centers for Disease Control guidance which was a requirement for staff entering nursing facilities; and, still others were unable to survey for a period of time due to a family member's serious illness or death. DHSR is thankful and proud of the heroic work of its staff to help protect the health and safety of residents in nursing homes in our State.

its staff. And, prior to July 1, 2020, DHSR conducted on-site focused infection prevention and control surveys of each of the 434 nursing homes in North Carolina.

Beginning July 1, 2020 CMS instructed state survey agencies to conduct an on-site focused infection prevention and control survey within 3-5 business days of receipt of a weekly report provided by CMS identifying a nursing home with three or more new COVID cases or one confirmed resident case in a nursing home that was COVID-free and within two business days if the nursing home was located in a Hotspot County or was a Super Hotspot facility with 30 or more confirmed cases. During the period of July 1, 2020, through February 29, 2021, DHSR conducted 1,198 on-site focused infection prevention and control surveys at nursing homes in North Carolina.



CMS continued to provide DHSR with a weekly report of COVID-19 outbreaks in nursing homes and these on-site focused infection prevention and control surveys continued to be performed through mid-November of 2021.

Complaints

During OSA's audit period from January 1, 2019 – December 31, 2023, the number of complaints received by DHSR about nursing home care increased by almost 18% and facility reported incidents (FRIs) increased 30%. As noted above, on March 20, 2020, CMS prioritized investigation of complaints alleging an Immediate Jeopardy. Immediate Jeopardy and Non-Immediate Jeopardy High made up 32% of the complaints for both 2020 and 2021. Thus, the majority of complaints (68%) for both years were pended for future investigation per CMS' general instructions.

This resulted in a significant backlog of complaints. In QSO-22-02-ALL dated November 12, 2021, CMS issued guidance to state survey agencies to investigate the backlog of complaints and facility reported incidents according to the level of triage. The backlog of complaints triaged as Non-Immediate Jeopardy – Medium and Non-Immediate Jeopardy – Low were investigated as part of the standard inspection which resulted in the standard inspections taking significantly more time to complete than standard inspections performed prior to the COVID-19 pandemic.

Severity of Findings

In addition to standard inspections requiring more time to complete due to the backlog of complaints that were investigated as part of these inspections, the severity of deficiencies found during these inspections and

investigations increased significantly during OSA's audit period from January 1, 2019 – December 31, 2023, which also resulted in standard surveys requiring more time to document and conduct follow up surveys. From 2019 to 2023, the deficiencies determined to be an immediate jeopardy to resident health or safety or actual harm that is not an immediate jeopardy increased by 132% - from 148 in 2019 to 343 in 2023.

Conclusion

As indicated above, DHSR was able to gradually resume conducting inspections of nursing homes in March of 2021 to the extent resources (staff and PPE) were available while prioritizing:

- Investigating an increased number of complaints that alleged immediate jeopardy or noncompliance causing harm to the residents' mental, physical, and/or psychosocial status,
- Conducting on-site focused infection prevention and control surveys at nursing homes who were experiencing a COVID-19 outbreak, and conducting appropriate action; and,
- Working with nursing homes to resolve and follow up on a significantly higher number of deficiencies that were found to be an immediate jeopardy to resident health or safety or actual harm that is not an immediate jeopardy.

It was not CMS' nor DHSR's expectation that it would be able to inspect all nursing homes (and investigate the backlog of complaints that had accumulated during the prior approximately 12 months) within 15 months of its resumption of inspections.

Given the circumstances and the overwhelming workload facing state survey agencies, CMS provided flexibilities for state survey agencies "to work through the current backlog of complaints and recertification surveys that is a direct result of the suspension of certain onsite survey activities in an effort to control the spread of COVID-19." In fact, DHSR exceeded the performance standards established by CMS for the period of October 1, 2021 – December 22, 2023. Therefore, the Agency disagrees with OSA's Finding #1 that DHSR did not conduct timely inspections of nursing homes during the period of March 1, 2021, through December 31, 2023.

Furthermore, OSA's conclusion that "nursing home residents were at risk of conditions that could have threatened their health and safety" based on its Finding lacks any showing of causal effect and is misleading in implying that the facts underlying the deficiency found would not have occurred, but for the incorrect conclusion that the inspection was untimely.

In response to OSA's Recommendation 2, NCDHHS has made numerous requests for additional resources due to the significant increase in complaints received about nursing homes and the increasing level of severity of deficiencies identified in nursing homes. In fact, each of Governor Cooper's four most recent Recommended Budgets have included additional positions for DHSR to conduct inspections and complaint investigations but to date, no additional positions for the nursing home section have been appropriated by the General Assembly.

OSA Finding #2: Division Did Not Investigate Nursing Home Complaints Timely
OSA Recommendations:

3. The Division should initiate and complete all complaint investigations within the timeframe prescribed by state law.
4. The Division should complete a formal analysis identifying the resources necessary to comply with investigative time frames prescribed by state law. Based on the analysis, the Division should seek sufficient appropriation from the General Assembly to allow it to comply with state law. Alternatively, the Division should seek clarification from the General Assembly as to the Division's responsibilities for

investigative timeliness. seek necessary resources from the General Assembly to clear its backlog of overdue

NCDHHS Response: _NCDHHS agrees that investigations were not completed per state law requirements but disagrees with OSA's Recommendations.

OSA's Finding is based on G.S. §131E-124(a), which was enacted in July of 1977. Since that time, the number of complaints has increased dramatically. Since just 2015, DHSR has had a 51% increase in annual nursing home complaints, from 2,594 in 2015 to 3,917 in 2023. Although this requirement was enacted in July 1977, the General Assembly has not appropriated the additional resources and FTEs for DHSR's Nursing Home Section needed to comply with these timelines.

CMS has established a nationally followed triage and prioritization system for complaints regarding nursing homes. DHSR prioritizes and conducts complaint investigations per the criteria and within the timeframes established by CMS. Although DHSR utilizes and complies with CMS' complaint prioritization system used nationwide, DHSR is unable to meet the timelines to complete investigations of nursing home complaints set forth within this state law and, in fact, has not been able to meet these requirements since enactment of this state law over 47 years ago.

Complaint allegations received by DHSR about care provided by a nursing home are triaged based on the severity and urgency of the allegations per criteria established by CMS and applied nationally to identify and respond to those that appear to pose the greatest potential for harming residents. Depending on the severity and urgency of the complaint allegations, DHSR investigates complaint allegations during either a complaint investigation or a standard inspection. Federal requirements provide that CMS' state survey agencies, including DHSR, initiate a complaint investigation from within three business days after receipt (if the allegation is based on a nursing home's noncompliance that has caused or is likely to cause, serious injury, harm, impairment or death to a resident), fifteen business days after receipt (if the allegation is based on a nursing home's noncompliance that may have caused physical and/or psychosocial harm to the resident), 45 days of receipt, or at the time of the next inspection.

During the COVID-19 pandemic, CMS suspended state survey agencies' investigation of certain complaints and reprioritized work to focus on infection prevention and control and investigating only the most serious complaint allegations. Also, the General Assembly suspended all "DHSR monitoring, inspection, or investigative requirements, except (i) as DHSR deems necessary to avoid serious injury, harm, impairment, or death to employees, residents, or patients of these facilities or (ii) as directed by the Centers for Medicare and Medicaid Services" from May 4 – December 31, 2020.[11]

Although DHSR management stated it had not completed a formal needs analysis to determine the resources needed to comply with subsection (a) of G.S. § 131E-124, DHSR completed an initial analysis of the resources required to have surveyors located across the State to work 24/7/365 as required by the language of this state law to initiate investigations of complaint allegations *immediately* (less than 24 hours), within 24 hour, within 48 hours, or within two weeks in other situations per the requirements of subsection (a1). Given the thousands of nursing home complaints received annually, many of which would be prioritized by state law as needing the investigation to begin "immediately", and that there are 434 nursing homes located across the state, it would require an enormous increase in the number of FTEs to be able to "immediately" (in less than 24 hours) commence an investigation. And then the next most serious level of complaints would be required to commence within 24 hours. Based on the significant increase in the number of surveyors required to meet the

[11] Section 3E.3.(a) of SL 2020-3.

timelines in the statute, DHSR did not formalize its analysis for the purpose of requesting that the General Assembly appropriate even more resources.

OSA's conclusion that "nursing home residents were at risk of suffering from delayed corrective action to conditions that could be life-threatening, abusive, and neglectful" based on its Finding fails to consider DHSR's triage of nursing home complaints and prioritization of investigations based on the CMS criteria applied nationwide, lacks any showing of causal effect, and is misleading.

Without significant additional resources, OSA's Recommendation that DHSR initiate and complete complaint investigations within 60 days per State law does not recognize the impact on meeting CMS's performance standards that would jeopardize federal funding as well as the inability of DHSR to meet this timeline within existing resources.

DHSR will work with legislative staff to determine whether it should complete a formal analysis identifying the resources necessary to comply with investigative time frames prescribed by state law or whether there are needed changes to the legislation given DHSR's requirement to comply with CMS' complaint prioritization system.

OSA Finding #3: Division Did Not Always Verify Correction of Nursing Home Deficiencies
OSA Recommendations:

5. The Division should verify that deficiencies are corrected in accordance with federal requirements.
6. Division management should develop and implement procedures to ensure that Division staff verify that deficiencies are corrected and that their conclusions are documented.

NCDHHS Response: NCDHHS disagrees with OSA's Findings and Recommendations.
DHSR verified that deficiencies were corrected and provided OSA with documentation required by CMS that evidenced DHSR's verification of correction of the deficiency.

Federal requirements state that DHSR must verify the correction of identified deficiencies through obtaining evidence of correction or conducting an onsite revisit. Federal requirements do not include documentation requirements for DHSR's verification beyond the documentation DHSR provided to the auditors, completion of form 2567B. DHSR did have documentation it had performed the verification and documented that fact in its transmittal of information to CMS via form 2567B which is what is required by CMS. The CMS State Operations Manual is silent regarding what documentation DHSR must use, beyond its completion of the Form 2567B.

OSA's reliance on the OIG Audit from 2018 is misplaced.[12] In fact, the OIG Audit found that –

> *For the 100 sampled deficiencies, the State survey agency [DHSR] verified the correction of 96 nursing home deficiencies but did not obtain evidence of correction for the remaining 4 deficiencies.*
> *On the basis of our sample results, we estimated that State survey agency [DHSR] did not verify the correction of nursing home deficiencies in accordance with Federal requirements for 5 percent of the deficiencies identified during surveys in 2015.*

OIG's finding that DHSR did not obtain evidence of the correction of 5% of the deficiencies calls into question OSA's evaluation of DHSR's documentation reportedly based on CMS' general instructions and finding that it failed to verify correction of 37% of the deficiencies. Furthermore, OIG recommended in its 2019 report that CMS improve CMS's guidance to State agencies on verifying nursing homes' correction of deficiencies and

[12] https://oig.hhs.gov/oas/reports/region4/41702500.asp

maintaining documentation to support verification. Likely due in part to the COVID-19 pandemic, CMS has not yet updated its guidance to state survey agencies.

OSA's Finding that DHSR failed to verify that deficiencies were corrected is inaccurate. OSA is really criticizing DHSR's documentation of the verification and holding DHSR to a standard that is not required by CMS. DHSR not only verified the deficiency was corrected, but it also documented its verification in the manner required by CMS.

OSA's conclusion that "nursing home residents may have been placed at continued risk of conditions that threatened their health and safety" based on its Finding lacks any showing of causal effect and is misleading.

OSA Additional Consideration #1: Division Should Consider Developing a Plan to Respond To Pandemics and Other Times of Crisis

NCDHHS Response: DHSR has processes to respond to States of Emergency and must comply with CMS' general instructions in compliance with the 1864 Agreement as it did during the COVID-19 pandemic in helping to ensure the health and safety of nursing home residents. The Division must continue to follow the requirements and guidance of CMS when performing work pursuant to the 1864 Agreement.

The COVID pandemic was unprecedented in modern times and significantly and negatively impacted business and government, including NCDHHS and DHSR.
CMS utilized a risk-based approach in directing state survey agency work during the COVID-19 pandemic. CMS prioritized DHSR's conducting on-site focused infection prevention and control surveys and investigation of most serious complaints and suspended routine work to allow the prioritized work to occur and to mitigate the risk of introducing COVID-19 to facilities in connection with the performance of routine work or work investigating less serious complaints.

The examples cited by OSA in support of its statement that "[u]ntimely inspections can allow poor quality care to go undetected and uncorrected for longer periods of time" lack any showing of causal effect and is misleading based on the fact that the recounted facts may have occurred and gone uncorrected even if inspections were conducted on a routine basis.

OSA Additional Consideration #2: Division Should Consider Increasing the Unpredictability of Nursing Home Inspections

Agency Response: DHSR conducts unannounced inspections of nursing homes in accordance with CMS' general instructions in compliance with the 1864 Agreement and met or exceeded CMS' applicable performance standards.

The "federal requirements" in the CMS State Operations Manual Section 7207 – 7207.5 distinguish between "must" (e.g., at least 10% must begin on the weekend or evening or early morning hours) and "should" in describing the unpredictability of inspections.
DHSR met or exceeded the requirements by beginning at least 10 percent of the standard health surveys (inspections) either on the weekend or in the evening/early morning hours before 8 a.m. or after 6 p.m.
The Division contends that it met the requirements from CMS for unpredictability. While CMS lists other considerations a state survey agency "should" strive to do, these are not required, and several are not practicable considering other requirements. For instance, most, not all, unannounced surveys begin on Monday. Given the requirement that once the survey begins it must continue each consecutive day until completed and given that

most surveys take approximately four onsite days to complete, if surveys were routinely started later in the week, it would require staff to work most weekends instead of some weekends each month. This would negatively impact staff retention, which is already a challenge.

OSA's Consideration is not aligned with CMS' State Operations Manual and does not take into account CMS survey process, significant increase in the number of complaints received (many of which are investigated during these inspections) and deficiencies found during these inspections, and DHSR's current staffing.

OSA Additional Consideration #3: Division Should Consider Establishing a Policy on the Frequency of Licensed-Only Nursing Home Facility Inspections.

Agency Response: DHSR utilizes a risk-based approach for inspecting licensed-only nursing homes that helps to protect the health and safety of nursing home residents.

"Licensed-only" nursing homes are not subject to federal law or CMS regulations and State law does not require inspections of nursing homes nor establish a frequency for inspections.

OSA's reliance on the National State Auditors Association (NSAA) *Carrying Out a State Regulatory Program* is misplaced as it is not referenced in applicable State law. Nonetheless, DHSR maintains that it has conducted periodic inspections with sufficient frequency to provide reasonable safeguards to the public utilizing a risk-based approach as recommended by the NSAA.

There are 10 "licensed-only" nursing homes in North Carolina. Nine of 10 are part of a continuing care retirement community ("CCRC"). Unlike other nursing homes, CCRC's and its nursing homes are primarily funded by resident payments of an entrance fee and monthly fees. CCRC's are generally well-funded and their nursing homes have more staff and less staff turnover than other nursing homes.

NSAA's document points out that complaint handling processes are an important source of information for determining if facilities are operating in compliance with applicable laws and rules. DHSR has a complaint handling process and utilizes it to make risk-based decisions related to inspections and investigations of complaints.

In 2021, the average number of complaints for licensed only nursing homes was 0.8, while the average number for all other nursing homes was 7.4. Thus, a risk analysis based on the number of complaints received each year supports surveying the licensed-only nursing homes less frequently.

Chart 5: *Licensed-Only Facility Inspections* in OSA's Performance Audit Report reflects the inspections conducted at licensed only nursing homes from 2011 – 2023. Below is a corresponding number of complaints received about each licensed-only:

		Number of Complaints Received												
Facility	CCRC	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
A	Y		1					2	1					2
B	Y			1			1					1	1	
C	Y				1					1	2	1		
D	Y	1	1				1		2					1
E	Y	1	1		1								1	
F	Y											2		
G	Y							1					1	1
H	Y						1	4	4			3	1	
I	Y	1					1	1	1			1	1	2
J	N													
Total		3	3	1	2	0	4	8	8	1	2	8	5	6

A comparison of this information with Chart #5 *Licensed-Only Facility Inspections* demonstrates that DHSR has appropriately utilized a risk-based approach in its inspection of licensed-only nursing homes.

DHSR disputes OSA's apparent presumption that surveys of licensed-only nursing homes were conducted in response to its audit. Instead, it was a management decision based on periodic inspections performed on 3-5 year intervals and available resources.

Furthermore, OSA's recommendation to create an inspection frequency appears to be inconsistent with a risk-based approach described in the NSAA guide, as frequency suggests a specified period, without regard to risk.

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