State of North Carolina

Office of the State Auditor

Beth A. Wood, CPA

Investigations of Medical Providers

North Carolina Medical Board

Performance Audit

January 2023

NC OSA

The Taxpayers' Watchdog

EXECUTIVE SUMMARY

OBJECTIVE

The objective of this audit was to determine whether North Carolina Medical Board (Board) investigations were completed in accordance with state law, Board policies, and regulatory best practices during the period of July 1, 2019, through June 30, 2021. Specifically,

1) Did the Board review all complaints it received against physicians, physician assistants, and other medical providers to determine if they warranted further investigation?
2) Did the Board investigate all complaints in compliance with its policies, state law, and Federation of State Medical Boards'[1] best practices?
3) Was the Board's discipline equitable (no preferential treatment), consistent with other states (not more lenient), and addressed publicly (not handled privately with no public record)?
4) Did the Board report all of its public actions[2] on the Board website and do so in a timely manner?
5) Did the Board complete investigations of medical providers it received complaints against within the six-month timeframe required by state law?
6) Did the Board monitor and enforce disciplinary actions it imposed on medical providers in accordance with regulatory best practices?

If not, identify the impact and causes.

BACKGROUND

The North Carolina General Assembly established the Board in 1859 "to regulate the practice of medicine and surgery for the **benefit and protection** of the people of North Carolina."[3]

To fulfill the Board's regulatory responsibilities, the Board issues licenses to qualified medical providers,[4] investigates complaints against providers, and disciplines providers who violate the North Carolina Medical Practice Act.[5]

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1 The Federation of State Medical Boards represents all state medical boards within the United States and promotes best practices that add to their effectiveness.

2 Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension.

3 North Carolina General Statutes (N.C.G.S.) § 90-2(a). (emphasis added)

4 Medical providers licensed and regulated by the North Carolina Medical Board include: (1) medical doctors, (2) doctors of osteopathic medicine, (3) physician assistants, (4) certified clinical perfusionists, and (5) anesthesiologist assistants. According to the Board, licensed providers totaled 57,275 as of December 31, 2021.

5 Chapter 90, Article 1 of the North Carolina General Statutes. This is the law that governs the practice of medicine in the state of North Carolina. The Board refers to this law as the North Carolina Medical Practice Act.

EXECUTIVE SUMMARY (CONTINUED)

State law[6] requires the Board to complete investigations within **six** months or deliver the provider a written explanation of the circumstances and reasons for extending the investigation.

SCOPE LIMITATION

Auditors encountered a **scope limitation**,[7] as defined by *Government Auditing Standards*.

As a result of the scope limitation, auditors were **unable** to test **all** 4,432 Board investigations[8] that occurred during the period July 1, 2019, through June 30, 2021.

This occurred because the Board **denied auditors access** to its investigative database, ThoughtSpan, citing state law,[9] which states that all information related to Board investigations is to remain confidential and not subject to release except in limited circumstances. Instead, the Board provided heavily redacted documents in response to auditor requests. As a result,

- Items 1 – 4 of the audit objective could not be audited at all.

- Items 5 – 6 of the audit objective were limited to Board investigations that resulted in public actions.[10]

Consequently, auditors could not obtain sufficient, appropriate evidence to determine whether Board investigations were completed in accordance with Board policies, state laws, and regulatory best practices. **(See Objective, Scope, and Methodology section and Finding 1 for further discussion).**

KEY FINDINGS

A **scope limitation** resulted in auditors not able to determine whether Board investigations during the period of July 1, 2019, through June 30, 2021, were completed in accordance with state law, Board policies, and regulatory best practices.

However, despite the scope limitation, auditors were able to perform limited audit procedures on Board investigations that resulted in public actions.[11] Auditors determined that:

- The Board did not complete investigations of providers it received complaints[12] against within the six-month timeframe required by state law.

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6 N.C.G.S. § 90-14(l).

7 Defined by *Government Auditing Standards* as restrictions on access to records, government officials, or other individuals needed to conduct the engagement.

8 This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.

9 N.C.G.S. § 90-16(c).

10 Board public actions accounted for 218 of 4,432 (5%) Board investigations closed during July 1, 2019, through June 30, 2021.

11 Ibid.

12 Complaints include all potential sources of investigations, such as: (1) complaints from the public, (2) actions by other state medical boards, (3) reports from providers, and (4) malpractice insurance claims.

EXECUTIVE SUMMARY (CONCLUDED)

- The Board did not monitor and enforce all disciplinary actions it imposed on medical providers.

KEY RECOMMENDATIONS

- The Board should allow the Office of the State Auditor unrestricted access to all records and supporting documentation necessary to conduct an audit in accordance with state law[13] and professional auditing standards.
- The North Carolina General Assembly should consider inserting clarifying language or specifically exempting the Office of the State Auditor from state law[14] that restricts access to medical board records.
- The Board should complete all investigations of medical providers within the six-month timeframe required by state law.
- The Board should redesign its investigative process so that investigations are completed within the six-month timeframe required by law.
- The Board should monitor and enforce disciplinary actions against medical providers for the maximum protection of public health and safety.
- The Board should create policies and procedures that outline how monitoring and enforcement of disciplinary actions should be performed. Specifically, policies and procedures should include details on: (1) how often and how much monitoring and enforcement to perform, (2) how to track and document monitoring and enforcement activities, and (3) how to determine when stricter monitoring and enforcement is necessary.

[13] Chapter 147, Article 5A of the North Carolina General Statutes.
[14] N.C.G.S. § 90-16(c).

STATE OF NORTH CAROLINA

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AUDITOR'S TRANSMITTAL

The Honorable Roy Cooper, Governor
Members of the North Carolina General Assembly
R. David Henderson, Chief Executive Officer

Ladies and Gentlemen:

We are pleased to submit this performance audit report titled *Investigation of Medical Providers*. The objective of this audit was to determine whether North Carolina Medical Board investigations were completed in accordance with state law, Board policies, and regulatory best practices during the period of July 1, 2019, through June 30, 2021. If not, identify the impact and causes.

The North Carolina Medical Board's Chief Executive Officer, David Henderson, reviewed a draft copy of this report. His written comments are included starting on page 33.

This audit was conducted in accordance with Chapter 147, Article 5A of the *North Carolina General Statutes*.

We appreciate the courtesy and cooperation received from management and the employees of the North Carolina Medical Board during our audit.

Respectfully submitted,

Beth A. Wood

Beth A. Wood, CPA
State Auditor

Beth A. Wood, CPA
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 the power to summon people to produce records and to answer questions under oath.


THE GREAT SEAL OF THE STATE OF NORTH CAROLINA
MAY 20, 1775
APRIL 12, 1776
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BACKGROUND

The North Carolina General Assembly established the North Carolina Medical Board (Board) in 1859 "to regulate the practice of medicine and surgery for the **benefit and protection** of the people of North Carolina."[15] The Board consists of 13 members, including 11 appointed by the Governor and two appointed by the General Assembly upon the recommendations of the Speaker and President Pro Tempore. Eight of the 13 members are **licensed physicians**, one is a **licensed physician assistant**, one is an approved **nurse practitioner**, and three are **members of the public** with no financial or professional interest in a health service or profession. All Board members serve three-year terms with a term limit of two consecutive terms on the Board.[16]

To fulfill the Board's regulatory responsibilities, the Board issues licenses to qualified medical providers,[17] investigates complaints against providers, and disciplines providers that violate the North Carolina Medical Practice Act.[18]

Board's Investigative Process

The Board initiates an investigation when it receives a complaint against a provider. A complaint can come from various sources, including a patient of the provider, another medical provider (such as a hospital), or the general public. Examples of complaints include substandard medical care, inappropriate or excessive prescribing of medication, unprofessional or unethical conduct, and sexual assault or misconduct.

An investigation may consist of interviewing the provider, interviewing the patient(s) relevant to the complaint, and requesting and reviewing relevant medical records. After medical and legal reviews are completed, Board staff submits a recommendation for action to the Board. State law[19] requires the Board to complete investigations within six months or deliver the provider written explanation of the circumstances and reasons for extending the investigation.

[15] North Carolina General Statutes (N.C.G.S.) § 90-2(a). (emphasis added)
[16] https://www.ncmedboard.org/about-the-board.
[17] Medical providers licensed and regulated by the North Carolina Medical Board include: (1) medical doctors, (2) doctors of osteopathic medicine, (3) physician assistants, (4) certified clinical perfusionists, and (5) anesthesiologist assistants. According to the Board, licensed providers totaled 57,275 as of December 31, 2021.
[18] Chapter 90, Article 1 of the North Carolina General Statutes. This is the law that governs the practice of medicine in the state of North Carolina. The Board refers to this law as the North Carolina Medical Practice Act.
[19] N.C.G.S. § 90-14(l).

The Board has three main categories of Board Actions: Accept as Information, Private Actions, and Public Actions. See **Table 1** below.

Table 1 – Types of Board Actions

Type of Action	Description
Accept as Information (AAI)	The Board finds no violation of the Medical Practice Act. The case is closed and kept on file in the provider's confidential permanent file.
Private Actions	The Board does not find a violation of the Medical Practice Act that warrants public action, but it is nonetheless concerned about some aspect of the provider's conduct or performance. Private action is taken such as: • Letter of Concern.[20] • Remedial Continuing Medical Education (CME) course. • Request that the provider attend a confidential interview to discuss their conduct with members of the Board. • Issue a Non-Practice Agreement.[21] The Private Action is kept on file in the provider's confidential permanent file.
Public Actions	The Board determines there was a violation of the Medical Practice Act that requires an adverse action. These actions can include: • Letter of concern. • Non-Practice Agreement. • Formal reprimand. • Fine. • License restriction (such as a prohibition on prescribing certain medications). • License suspension or revocation. The Public Action is kept on file in the provider's confidential permanent file and posted to the Board's public website.

The Board **does not** receive state appropriations and is **funded entirely** by **license application and renewal fees**. As of December 31, 2021, there were 57,275 medical professionals licensed through the Board.[22]

[20] If the Board lacks sufficient evidence to determine that the provider violated the Medical Practice Act but it still has concerns about the provider's care or conduct, it can issue a Letter of Concern.

[21] Non-Practice Agreements (NPA) are private or public agreements between the Board and the provider whereby the provider agrees not to practice medicine until authorized to do so by the Board. The Board issues an NPA when it believes there may be an immediate risk to patient safety and it needs time to determine the extent of the risk and consider disciplinary action against the provider.

[22] North Carolina Medical Board 2021 Annual Report.

Key terms discussed in this report include:

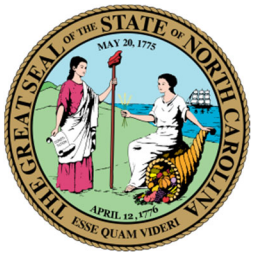
Medical Practice Act – Chapter 90, Article 1 of the North Carolina General Statutes. This is the law that governs the practice of medicine in the state of North Carolina. Various parts of this law establish the Board's powers and duties, requirements for licensure, and disciplinary authority. The Board refers to this law as the North Carolina Medical Practice Act.[23]

Non-Practice Agreements – Non-Practice Agreements (NPA) are private or public agreements between the Board and the provider whereby the provider agrees not to practice medicine until authorized to do so by the Board. The Board issues an NPA when it believes there may be an immediate risk to patient safety and it needs time to determine the extent of the risk and consider disciplinary action against the provider.

Systems discussed in this report include:

ThoughtSpan – the Board's electronic database that keeps all records of complaints, investigations, and Board actions.

[23] https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/laws.



OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether North Carolina Medical Board (Board) investigations were completed in accordance with state law, Board policies, and regulatory best practices during the period of July 1, 2019, through June 30, 2021. Specifically,

1) Did the Board review all complaints it received against physicians, physician assistants, and other medical providers to determine if they warranted further investigation?
2) Did the Board investigate all complaints in compliance with its policies, state law, and Federation of State Medical Boards'[24] best practices?
3) Was the Board's discipline equitable (no preferential treatment), consistent with other states (not more lenient), and addressed publicly (not handled privately with no public record)?
4) Did the Board report all of its public actions[25] on the Board website and do so in a timely manner?
5) Did the Board complete investigations of medical providers it received complaints against within the six-month timeframe required by state law?
6) Did the Board monitor and enforce disciplinary actions it imposed on medical providers in accordance with regulatory best practices?

If not, identify the impact and causes.

[24] The Federation of State Medical Boards represents all state medical boards within the United States and promotes best practices that add to their effectiveness.

[25] Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension.

SCOPE LIMITATION: Auditors encountered a **scope limitation**,[26] as defined by *Government Auditing Standards*.

As a result of the scope limitation, auditors were **unable** to test **all** 4,432 Board investigations[27] that were closed during the period July 1, 2019, through June 30, 2021.

This occurred because the Board **denied auditors access** to its investigative database, ThoughtSpan, citing state law,[28] which states that all information related to Board investigations is to remain confidential and not subject to release except in limited circumstances. The Board did provide some documentation in response to auditor requests; however, the documents were so heavily redacted they provided no useful information for the audit. Specifically,

For private Board actions and accept as information (AAI) actions,[29] the Board **redacted** information critical for conducting the audit, such as the name of the medical provider with the complaint and the provider's license number.

For public Board actions, the Board included the name of the medical provider with the complaint and the provider's license number. However, the Board **redacted** information that limited auditor review of medical records, interview notes, and recommendations of disciplinary actions taken by the Board.

As a result, auditors were **unable** to test Board investigations that resulted in private actions (including private Non-Practice Agreements),[30] and **any** AAI actions.

According to Board management, there were **4,432** total investigations closed during the period July 1, 2019, through June 30, 2021.[31] These investigations included an unknown number of private and AAI actions that auditors were **unable to identify or test due to the scope limitation**.

There were **218** Board investigations that resulted in public actions.[32] Tests of these investigations were **limited** to determining whether the Board: (1) completed investigations within the six-month timeframe required by state law, and (2) monitored and enforced disciplinary actions it imposed on medical providers in accordance with regulatory best practices.

Consequently, auditors could not obtain sufficient, appropriate evidence to determine whether Board investigations were completed in accordance with Board policies, state laws, and regulatory best practices. **(See Finding 1 for further discussion)**

[26] Defined by *Government Auditing Standards* as restrictions on access to records, government officials, or other individuals needed to conduct the engagement.

[27] This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.

[28] N.C.G.S. § 90-16(c).

[29] An "accept as information" action occurs when the Board finds no violation of the Medical Practice Act. The case is closed and kept on file in the provider's confidential permanent file.

[30] NPAs are private or public agreements between the Board and the provider whereby the provider agrees not to practice medicine until authorized to do so by the Board. The Board issues an NPA when it believes there may be an immediate risk to patient safety and it needs time to determine the extent of the risk and consider disciplinary action against the provider.

[31] This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.

[32] According to information available on the North Carolina Medical Board website.

Audit procedures included:

- Review of state laws relevant to the Board and Board investigations of Medical providers, including the timeliness of investigations.
- Review of Board investigative policies and procedures.
- Review of regulatory program best practices, including the Federation of State Medical Boards guidance for investigating complaints and enforcing disciplinary actions.
- Interviews of Board management and staff.
- Review of public actions on the Board website and the available documentation of the related Board investigations.

To determine whether the Board completed investigations within the six-month timeframe required by state law, auditors:

- Obtained available records and supporting documentation for 85 of 218 (39%) of the Board investigations completed that resulted in **public** actions. Auditors originally planned to test all 218 investigations that resulted in public Board action. However, the Board did not provide the necessary documentation for 132 (61%) of the 218 investigations.

- Calculated the timeliness of the 85 investigations by comparing the date when the Board notified the provider that it had begun an investigation and the date the Board charged the provider with a violation of North Carolina Medical Practice Act. If the Board was automatically notified of a potential violation, such as an out of state action or malpractice claim, the date the Board opened the case was used as the starting date.[33]

To determine whether the Board monitored and enforced disciplinary actions it imposed on medical providers in accordance with regulatory best practices, auditors:

- Obtained available records and supporting documentation for 96 of 212[34] (45%) of the Board investigations that resulted in **public** actions subject to monitoring and enforcement. Auditors originally planned to test all 212 public disciplinary actions subject to monitoring and enforcement. However, the Board did not provide the necessary documentation for 116 (55%) in a timely manner[35] due to delays caused by the Board redacting the documents.

[33] The Board receives automated notifications of some potential violations from the Federation of State Medical Boards and from malpractice insurance payout information.

[34] The population of 212 investigations are part of the same population of 218 investigations for timeliness described above. However, only 212 of the 218 investigations were subject to the Board's monitoring and enforcement. Six of the investigations that resulted in public actions during the audit scope resulted in a formal reprimand or a letter of concern. Therefore, they were not subject to the Board's monitoring and enforcement and were not included in the population of investigations to determine whether the Board monitored and enforced its disciplinary actions.

[35] After 2.5 months had passed since auditors initially requested documentation, the Board had provided less than half of what was requested and would not commit to a definite date by which the remaining would be provided. To prevent further delays, auditors concluded on what had been received.

- Reviewed available Board documentation reflecting monitoring and enforcement of disciplinary actions. For example, if the Board suspended a provider's license, taking steps after the suspension (such as calling previous employers, attempting to make an appointment, or sending an investigator to an office) to help ensure that the provider is not continuing to practice.

As previously stated, according to Board management, there were 4,432 total Board investigations closed during the period July 1, 2019, through June 30, 2021. Auditors were unable to include 4,214[36] in this audit due to the audit's **scope limitation**.

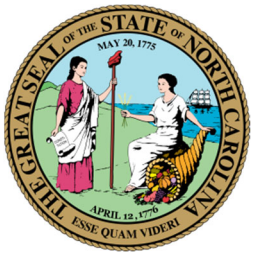
Whenever sampling was used, auditors applied a non-statistical approach. Therefore, test results could not be projected to the population. This approach was determined to adequately support audit conclusions.

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. Except as described in the section titled **SCOPE LIMITATION** on page 5, we believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[36] Total population of investigations closed during audit scope minus population of Board investigations resulting in public actions closed during audit scope (4,432 – 218 = 4,214).



RESULTS AND CONCLUSIONS

Due to a **scope limitation**,[37] auditors could not determine whether North Carolina Medical Board (Board) investigations during the period of July 1, 2019, through June 30, 2021, were completed in accordance with state law, Board policies, and regulatory best practices.

The Board's process for investigating all complaints against medical providers could not be audited in accordance with professional auditing standards.[38] Those standards require auditors to obtain sufficient, appropriate evidence to support their findings and conclusions. **The Board denied auditors access** to the investigative records and supporting documentation necessary to obtain such evidence. Specifically, the Board: (1) prevented auditors from reviewing any of the Board's private actions, and (2) limited what auditors could review for the Board's public actions.

As a result, legislators and the public have no way to know how well the Board's investigative process protected North Carolinians from harm, such as malpractice and inappropriate behavior such as sexual assault.

However, despite the **scope limitation**, auditors were able to perform limited audit procedures on Board investigations that resulted in public actions.[39] Auditors determined that:

- The Board did not complete investigations of providers it received complaints[40] against within the six-month timeframe required by state law.[41]

- The Board did not monitor and enforce all disciplinary actions it imposed on medical providers.

As a result, there was an increased risk that medical providers whose actions posed a threat to patient safety could continue serving patients.

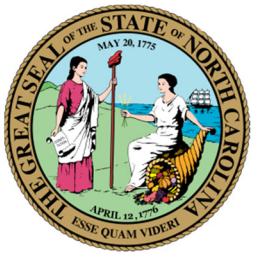
[37] Defined by *Government Auditing Standards* as restrictions on access to records, government officials, or other individuals needed to conduct the engagement.

[38] N.C.G.S. § 147-64.6(c)(1) requires the Office of the State Auditor to conduct audits in accordance with generally accepted auditing standards. These standards, known as *Government Auditing Standards*, are issued by the United States Government Accountability Office.

[39] Board public actions accounted for 218 of 4,432 (5%) Board investigations closed during July 1, 2019, through June 30, 2021.

[40] Complaints include all potential sources of investigations, such as: (1) complaints from the public, (2) actions by other state medical boards, (3) reports from providers, and (4) malpractice insurance claims.

[41] N.C.G.S. § 90-14(l) requires the Board to complete investigations no later than six months from the date of first communication from the Board to the provider regarding a complaint or investigation, unless the Board delivers the provider a written explanation of the circumstances and reasons for extending the investigation.



FINDINGS, RECOMMENDATIONS, AND RESPONSES

1. LIMITED ABILITY TO AUDIT MEDICAL BOARD'S INVESTIGATIVE PROCESS

The North Carolina Medical Board (Board) denied auditors access to investigative records and supporting documentation needed to obtain sufficient, appropriate evidence and perform the audit in accordance with professional standards.[42] Those standards require auditors to obtain sufficient, appropriate evidence to support their findings and conclusions. Specifically, the Board: (1) prevented auditors from reviewing any of the Board's private actions, and (2) limited what auditors could review for the Board's public actions.

As a result, legislators and the public have no way to know whether or how well the Board's investigative process protected North Carolina citizens from harm, including malpractice and inappropriate behavior such as sexual assault.

The Board denied auditors access to investigative records, citing state law,[43] which states that all information related to Board investigations is to remain confidential, and not subject to release except in limited circumstances. However, an **audit** is **essential** for providing an independent, objective assessment of the Board's performance to legislators and the public.

Board Denied Access to Investigative Records

The Board's process for investigating all complaints against physicians, physician assistants, and other medical providers[44] cannot be audited in accordance with professional auditing standards. Specifically, the Board denied auditors unrestricted access to its investigative database, ThoughtSpan.

The Board discussed with auditors the possibility of providing access to ThoughtSpan if auditors acted as the Board's consultant. However, entering into a consulting agreement such as this would have violated auditor independence[45] as required by professional auditing standards and state law.[46]

Instead, for a limited number of auditor requests, the Board provided heavily redacted documents.

Examples of information redacted by the Board included:

- Name of the medical provider.
- License Number and Contact Information for the provider.
- Investigation Case Number.
- All medical records and interview notes used by the Board during its investigations.
- Dates of review by various Board staff members.
- Evidence of action taken by Board staff, such as a recommendation for disciplinary action.

[42] N.C.G.S. § 147-64.6(c)(1) requires the Office of the State Auditor conduct audits in accordance with generally accepted auditing standards. These standards, known as *Government Auditing Standards*, are issued by the United States Government Accountability Office.

[43] N.C.G.S. § 90-16(c).

[44] Medical providers licensed and regulated by the Board include: (1) medical doctors, (2) doctors of osteopathic medicine, (3) physician assistants, (4) certified clinical perfusionists, and (5) anesthesiologist assistants.

[45] For example, by creating unacceptable self-review and management participation threats as defined by paragraph 3.30 of *Government Auditing Standards*.

[46] N.C.G.S. § 147-64.8.

Consequently, auditors were limited to using the Board's website to identify only the investigations that led to public actions,[47] a total of 218 investigations[48] during the period July 1, 2019, through June 30, 2021.

However, according to Board management, there were 4,432 total investigations closed from July 1, 2019, through June 30, 2021.[49] According to the Board, this total included the investigations that led to public actions listed on the Board's website and private and "accept as information" actions.[50] These private and "accept as information" actions (possibly 4,214), along with most of the supporting documentation for the 218 public actions, could not be audited.

Resulted in No Ability to Know Whether Board Investigations Were Protecting the Public

Since the Board process for investigating complaints could not be audited, legislators and the public have no assurance that the Board's investigations of physicians, physician assistants, and other medical providers[51] were protecting North Carolinians as required by state law.

The North Carolina Medical Practice Act[52] states that the Board's purpose is to "regulate the practice of medicine and surgery for the **benefit and protection** of the people of North Carolina."[53] Without an independent audit of the Board's investigations, the legislature and public have no assurance that:

- *Complaints were not missed*: Did the Board review all complaints it received against physicians, physician assistants, and other medical providers to determine if they warranted further investigation?

- *Investigations were conducted properly*: Did the Board investigate all complaints in compliance with its policies, state law, and Federation of State Medical Boards'[54] best practices?

- *Discipline was equitable and consistent*: Was the Board's discipline equitable (no preferential treatment), consistent with other states (not more lenient), and addressed publicly (not handled privately with no public record)?

- *Actions were publicly reported*: Did the Board report all of its public actions on the Board website and do so in a timely manner?

[47] Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension.
[48] Excludes certain public actions that were non-disciplinary or that did not have an investigation, such as "full relief of consent order obligations" and "licensure denial."
[49] This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.
[50] An "accept as information" action occurs when the Board finds no violation of the Medical Practice Act. The case is closed and kept on file in the provider's confidential permanent file.
[51] Medical providers licensed and regulated by the Board include: (1) medical doctors, (2) doctors of osteopathic medicine, (3) physician assistants, (4) certified clinical perfusionists, and (5) anesthesiologist assistants.
[52] Chapter 90, Article 1 of the North Carolina General Statutes. The Board refers to this law as the North Carolina Medical Practice Act.
[53] N.C.G.S § 90-2(a).
[54] The Federation of State Medical Boards represents all state medical boards within the United States and promotes best practices that add to their effectiveness.

In North Carolina, recent news articles illustrated why legislators and the public need assurance that the Board's investigations are protecting the public. For example:

- In June 2021, a surgeon was arrested and charged with multiple counts of indecent exposure.[55] Because the surgeon complied with the conditions of a deferred prosecution,[56] the charges were dismissed in December 2021. Even so, the Board never took any public action against him during that time, such as a Non-Practice Agreement or Letter of Concern, allowing the surgeon to continue practicing for **seven** months.

- In November 2020, a physician was arrested and indicted for sexually assaulting a patient. His license was allowed to expire five months after his arrest, but the Board has taken no public actions against him as of June 2022.[57] As a result, there was increased risk to patient safety while the physician was allowed to continue serving patients for **five** months.

- In March 2021, a physician was convicted of assaulting a female. Despite having been previously reprimanded by the Board for similar behavior in 2016, the Board did not take public action against the physician until August 2021.[58] As a result, there was an increased risk to patient safety while the physician was allowed to continue serving patients.

Auditors also found examples of providers licensed to practice in North Carolina that were disciplined by other state medical boards. The North Carolina Medical Practice Act grants the Board the power to discipline providers that were disciplined in other states to help protect North Carolinians, known as reciprocal actions. However, the Board delayed or took no public reciprocal actions against these providers. For example:

- In December 2018, the Kentucky Medical Board took disciplinary action against a physician licensed to practice in North Carolina for a quality-of-care issue that resulted in a malpractice payment. Seven other states, including Georgia, took reciprocal action. The Board took no reciprocal public action as of June 2022.
- In May 2021, the South Carolina Board of Medical Examiners took disciplinary action against a physician licensed to practice in North Carolina who chose to relinquish his South Carolina medical license in lieu of an investigation for an unspecified complaint. The Board took no reciprocal public action as of June 2022, allowing the physician to practice in North Carolina.

- In June 2021, the Virginia Board of Medicine took disciplinary action against a physician licensed to practice in North Carolina based on the quality of care given to a patient. The Board did not take public action against the physician until January 2022.

[55] https://www.wral.com/duke-heart-surgeon-placed-on-leave-after-an-indecent-exposure-charge/19821551/
[56] Deferred prosecution required the surgeon to complete a psychiatric assessment and treatment and for all alleged victims to be notified.
[57] https://abc11.com/nc-med-board-healthgradescom-ncdhhs-doctor-records-health-provider-record/10443303/.
[58] https://morganton.com/news/local/crime-and-courts/doctor-faces-lawsuits-alleging-sexual-misconduct/article_503175f0-d609-11eb-aedc-0b9ec8b82dce.html.

Additionally, a February 2021 audit[59] from the Office of the State Auditor found a number of providers continued to serve Medicaid beneficiaries and receive payment from the state despite adverse actions from the Board, such as license suspensions or revocations, that should have prevented them from doing so.

Recent audits of medical boards in other states have highlighted problems that could exist in North Carolina. For example:

- A 2020 report[60] from the Georgia Department of Audits & Accounts determined that the Georgia Composite Medical Board issued fewer public disciplinary actions than other states and did not ensure investigations progressed in a timely manner.

- A 2016 report[61] from the Office of the Washington State Auditor determined that Washington's two medical boards did not know how effective their disciplinary activities were, and one of the boards did not investigate all of the complaints it received.

However, since the Board limited auditor access to investigations in North Carolina, legislators and the public have no assurance that these problems do not also exist in North Carolina.

Caused by State Law Restricting Access to Investigative Records

The Board denied auditors access to investigative records, citing state law,[62] which states that all information related to Board investigations is to remain confidential, and not subject to release except in limited circumstances.

However, N.C.G.S. § 147-64.7(a)(1) states:

> The Auditor and the Auditor's authorized representatives shall have ready access to persons and may examine and copy all books, records, reports, vouchers, correspondence, files, personnel files, investments, and any other documentation of any State agency.[63]

State law[64] also provides that all the information obtained and used by the Office of the State Auditor (OSA) during an audit is **confidential**. Therefore, the information requested by OSA for this audit would have remained confidential.

Additionally, state law[65] requires the State Auditor to maintain independence in the performance of her duties. Except as provided by law, **no state agency or board** may limit the scope of an audit undertaken by the State Auditor.

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59 https://www.auditor.nc.gov/documents/reports/performance/per-2020-4445.
60 https://www.audits.ga.gov/PAO/19-14_GCMB.html.
61 https://portal.sao.wa.gov/ReportSearch/Home/ViewReportFile?arn=1017904&isFinding=false&sp=false.
62 N.C.G.S. § 90-16(c).
63 N.C.G.S. § 147-64.4.(4) defines a state agency as "Any department, political subdivision, institution, board, commission, committee, division, bureau, officer, official or any other entity for which the State has oversight responsibility, including but not limited to, any university, mental or specialty hospital, community college, or clerk of court."
64 N.C.G.S. § 147-64.6(d) and N.C.G.S. § 147-64.7(d).
65 N.C.G.S. § 147-64.8.

Without ready access to documentation, OSA cannot fulfill its statutory duty of **"determining that the authorized activities or programs effectively serve the intent and purpose of the General Assembly and, if applicable, federal law and regulation."**[66]

Access to medical board records by state audit organizations is not unprecedented. Other states have less restrictive laws. For example:

- Maryland state auditors have access to inspect the records of any state government unit, person, or other body receiving state funds, including those that are confidential by law.[67]
- Georgia state auditors are granted unrestricted access to all records at all state agencies, including confidential records, except where the law expressly states otherwise.[68]

Auditing in Government is Essential to Provide Accountability

Auditing government activities and programs is necessary to provide accountability to legislators, oversight bodies, those charged with governance, and the public. The Government Accountability Office states:[69]

> … Legislators, oversight bodies, those charged with governance, and the public need to know whether (1) **management and officials manage government resources and use their authority properly and in compliance with laws and regulations**; (2) government programs are achieving their objectives and desired outcomes; and (3) government services are provided effectively, efficiently, economically, ethically, and equitably.
>
> Government auditing is essential in providing accountability to legislators, oversight bodies, those charged with governance, and the public. [Professional audit] engagements provide an independent, objective, nonpartisan assessment of the stewardship, performance, or cost of government policies, programs, or operations. …
>
> Auditors should design the methodology to obtain sufficient, appropriate evidence that provides a reasonable basis for findings and conclusions based on the audit objectives. …

RECOMMENDATIONS

The Board should allow the Office of the State Auditor unrestricted access to all records and supporting documentation necessary to conduct an audit in accordance with state law and professional auditing standards.

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[66] N.C.G.S. § 147-64.6(b)(5).
[67] Md. Code Ann., State Government § 2-1223.
[68] O.C.G.A. § 50-6-29 (2010).
[69] Paragraphs 1.03, 1.05, and 8.06, *Government Auditing Standards*. (emphasis added)

The North Carolina General Assembly should consider inserting clarifying language or specifically exempting the Office of the State Auditor from state laws that restrict access to medical board records.

AGENCY RESPONSE

See page 35 for the Board's response to this finding.

NOTE TO THE READER FOR FINDINGS 2 AND 3

This audit's objective was to determine whether North Carolina Medical Board (Board) investigations were completed in accordance with state law, Board policies, and regulatory best practices during the period of July 1, 2019, through June 30, 2021. Specifically,

1) Did the Board review all complaints it received against physicians, physician assistants, and other medical providers to determine if they warranted further investigation?
2) Did the Board investigate all complaints in compliance with its policies, state law, and Federation of State Medical Boards'[70] best practices?
3) Was the Board's discipline equitable (no preferential treatment), consistent with other states (not more lenient), and addressed publicly (not handled privately with no public record)?
4) Did the Board report all of its public actions[71] on the Board website and do so in a timely manner?
5) Did the Board complete investigations of medical providers it received complaints against within the six-month timeframe required by state law?
6) Did the Board monitor and enforce disciplinary actions it imposed on medical providers in accordance with regulatory best practices?

However, as explained in the Objective, Scope, and Methodology section and Finding 1 of this report, the Board **denied auditors access** to its investigative database. Instead, the Board provided heavily redacted documents in response to auditor requests. This resulted in a **scope limitation**[72] as defined by *Government Auditing Standards*. Specifically,

- Items 1–4 of the audit objective could not be audited at all.
- Items 5–6 of the audit objective were limited to Board investigations that resulted in public actions.[73]
    - Board investigations that resulted in public actions accounted for 218 of 4,432 (5%) Board investigations closed during the audit period.

Auditors' results and conclusions for Items 5–6 are detailed in Findings 2 and 3 that follow.

[70] The Federation of State Medical Boards represents all state medical boards within the United States and promotes best practices that add to their effectiveness.
[71] Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension.
[72] Defined by *Government Auditing Standards* as restrictions on access to records, government officials, or other individuals needed to conduct the engagement.
[73] Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension or revocation.

2. UNTIMELY INVESTIGATIONS INCREASED RISK TO PATIENT SAFETY

The North Carolina Medical Board (Board) did not complete investigations of medical providers it received complaints[74] against that resulted in public action[75] in a timely manner. As a result, medical providers who were eventually disciplined by the Board for complaints such as malpractice, negligence, and sexual misconduct, were allowed to continue serving patients while their investigations continued past six months, increasing risks to patient safety.

The Board did not complete investigations within six months because the Board's investigative process was not designed to do so.

However, state law[76] requires the Board to complete investigations within six months or provide a written explanation to the provider as to why the investigation must continue.

Board Investigations Not Completed in a Timely Manner

The Board did not complete investigations of providers it received complaints against that resulted in public action in a timely manner.

The Board conducts investigations of providers when it receives complaints that allege violations of the North Carolina Medical Practice Act.[77] These complaints can include:

- Substandard medical care.
- Inappropriate or excessive prescription of medication.
- Unprofessional or unethical conduct.
- Sexual assault or misconduct.

State law[78] requires the Board to: (1) notify the provider that it has initiated an investigation, and (2) complete the investigation within six months of notification. If the Board must extend the investigation beyond six months, the Board must provide the provider with a written explanation of the circumstances and reasons for doing so.

[74] Complaints include all potential sources of investigations, such as: (1) complaints from the public, (2) actions by other state medical boards, (3) reports from providers, and (4) malpractice insurance claims.

[75] Board public actions accounted for 218 of 4,432 (5%) Board investigations closed during July 1, 2019, through June 30, 2021.

[76] N.C.G.S. § 90-14(l) requires the Board to complete investigations no later than six months from the date of first communication from the Board to the provider regarding a complaint or investigation. When necessary, the statute allows investigations to continue past six months if the Board provides a written explanation to the provider as to why the investigation must continue. However, auditors determined that proper notification occurred for just three investigations, and those three were not considered untimely.

[77] Chapter 90, Article 1 of the North Carolina General Statutes. The Board refers to this law as the North Carolina Medical Practice Act.

[78] N.C.G.S. § 90-14(l).

Auditors tested the timeliness[79] of 85 of 218 (39%)[80] Board investigations that resulted in public actions[81] and were completed during the period July 1, 2019, through June 30, 2021. Auditors found that the Board did not complete 25 of the 85 (29%) investigations within six months as required by state law. See **Table 2** below.

Table 2 – Timeliness of Investigations Resulting in Public Actions (July 1, 2019 – June 30, 2021)

# of Investigations	Time to Completion
1 (1%)	More than 2 Years
6 (7%)	1 to 2 Years
18 (21%)	6 to 12 Months
Total: 25 (29%)	**> 6 Months**

Source: Board records and auditor analysis.

Auditor's Note: Auditor tests **were limited** to investigations that resulted in public actions listed on the Board's website. Auditors were unable to test Board investigations that resulted in private actions or "accept as information" actions[82] because the Board **denied auditors access** to these investigative records and supporting documentation.

According to Board management, there were 4,432 investigations closed during the period July 1, 2019, through June 30, 2021.[83] According to the Board, this total included the investigations that led to public actions listed on the Board's website and private and "accept as information" actions. These private and "accept as information" actions (possibly 4,214) could not be audited **due to the scope limitation.**

Consequently, this audit could not reach a conclusion on the timeliness of these investigations performed by the Board. Therefore, the legislature and public have no assurance of the Board's investigative timeliness for non-public actions and investigations. **(See Finding 1 for further discussion.)**

[79] Timeliness was calculated as the time between the date the Board notified the provider that it had begun an investigation and the date the Board charged the provider with a violation of North Carolina Medical Practice Act. If the Board was automatically notified of a violation, such as an out of state action, the date the case opened was used as the starting date.

[80] Auditors originally planned to test all 218 investigations. However, the Board was unable to provide the necessary documentation for 132 (61%) in a timely manner due to delays caused by the Board redacting the documents. See Finding 1 for more discussion.

[81] Examples of public actions include a letter of concern, formal reprimand, license restriction (such as a prohibition on prescribing certain medications), and license suspension or revocation.

[82] An "accept as information" action occurs when the Board finds no violation of the Medical Practice Act. The case is closed and kept on file in the provider's confidential permanent file.

[83] This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.

Resulted in Increased Risk to Patient Safety

Since the Board's investigations were not timely, medical providers who were eventually disciplined by the Board for complaints such as malpractice, negligence, and sexual misconduct, were allowed to continue serving patients while their investigations continued past the six-month timeframe required by state law, increasing risks to patient safety.

For example, auditors found medical providers that continued to provide care to patients and bill and collect from Medicaid[84] while the Board's investigations continued past six months:

- Provider A – The Board took an additional 11 months to complete an investigation regarding the death of a patient. After the investigation concluded, the Board suspended Provider A's license due to "a departure from, or the failure to conform to the standards of acceptable and prevailing medical practice."

  During these 11 months, Provider A treated 572 patients and billed Medicaid for $443,796.

- Provider B – The Board took an additional 10 months to complete an investigation regarding an inappropriate sexual relationship with a patient. After the investigation concluded, the Board suspended Provider B's license due to a "failure to conform to the ethics of the medical profession."

  During these 10 months, Provider B treated 811 patients and billed Medicaid for $80,825.

- Provider C – The Board took an additional 21 months to complete an investigation regarding excessive prescribing of controlled substances. The Board's independent reviewer criticized Provider C's patient care, including prescribing certain medications "on a chronic basis, without clear justification for their use." After the investigation concluded, the Board suspended Provider C's license.

  During these 21 months, Provider C treated 156 patients and billed Medicaid for $34,955.

In total, auditors found 13 medical providers who treated 4,044 patients and billed Medicaid a total of $2.7 million while the Board's investigations continued past six months.

Caused by Investigative Process Not Designed for Timely Investigations

The Board's investigations were not timely because the Board's investigative process was not designed to complete investigations in accordance with the **six-month timeframe required by state law**.[85]

[84] Auditors were able to access billing records for Medicaid patients of disciplined providers but were unable to do so for patients with private insurance.

[85] N.C.G.S. § 90-14(l).

The Board begins an investigation by notifying the medical provider of the complaint. The investigation may consist of interviewing the provider, interviewing the patient(s) relevant to the complaint, and requesting and reviewing relevant medical records. After medical and legal reviews, Board staff submits a recommendation for action to the Board. The Board decides whether to charge the provider with a violation of the North Carolina Medical Practice Act, such as malpractice, negligence, or sexual misconduct.

When the investigative process was designed, Board management did not establish deadlines for the investigative process based on the six-month timeframe required by state law.

For example, the Board gave medical providers over four months to respond to complaints before issuing subpoenas.[86] However, state regulation **allowed for no more than 45 days** for providers to respond, **plus a one-time 30-day extension** for good cause.[87]

Additionally, the Board allowed medical providers to respond to requests from investigators (such as interview requests) within a "reasonable" period of time.[88] State regulation required providers to submit to an interview within **30 days of a request**, plus a one-time **15-day extension** for good cause.[89]

The Board's current design of its investigative process does not ensure investigations are completed in a timely manner.

State Law Required Timely Completion of Investigations

State law required the Board to investigate complaints in a timely manner.

> N.C.G.S. § 90-14(l) provides:
>
> The Board shall complete **any** investigation initiated pursuant to this section **no longer than six months** from the date of the first communication required under subsection (i) of this section, unless the Board provides to the licensee a written explanation of the circumstances and reasons for extending the investigation. (emphasis added)

RECOMMENDATIONS

The Board should complete all investigations of medical providers within the six-month timeframe as required by state law.

The Board should redesign its investigative process so that investigations are completed within the six-month timeframe required by law.

AGENCY RESPONSE

See page 37 for the Board's response to this finding.

[86] Follow-up letters are sent every 45 days after the initial notification. After the third follow-up letter a subpoena is issued for the information.
[87] 21 N.C. Admin Code 32N.0107(b).
[88] "Reasonable" was defined by the Board as "discretionary based on a number of factors" and therefore was determined on a case-by-case basis by individual investigators.
[89] 21 N.C. Admin Code 32N.0107(d).

3. LACK OF MONITORING AND ENFORCEMENT OF DISCIPLINARY ACTIONS INCREASED RISK TO PATIENT SAFETY

The North Carolina Medical Board (Board) did not monitor and enforce all its disciplinary actions imposed on medical providers for reasons such as malpractice or misconduct. As a result, there was an increased risk that medical providers, whose actions posed a threat to patient safety, could continue serving patients without detection by the Board.

The Board monitored and enforced some disciplinary actions it imposed and not others because: (1) the Board did not have a standard or formalized policy in place that outlined how monitoring and enforcement of disciplinary actions should be performed, and (2) the Board stated that the monitoring and enforcement of disciplinary actions is not a legal requirement.

However, best practices identified by the National State Auditors Association state the Board should track, follow-up, and enforce its disciplinary actions to protect public health and safety and determine whether additional enforcement action is needed.

Lack of Monitoring and Enforcement of Disciplinary Actions

The Board did not monitor and enforce all its disciplinary actions imposed on medical providers.

The Board imposes disciplinary action on medical providers when a Board investigation concludes that the medical provider committed **negligence, malpractice, misconduct**, or some other violation of the North Carolina Medical Practice Act.[90] Disciplinary actions can include the medical provider's license being:

- Limited (such as a prohibition to perform certain procedures or prescribe certain medications).
- Suspended.
- Revoked.

Auditors tested the Board's monitoring and enforcement of 96 of 212 (45%)[91] public disciplinary actions imposed during the period July 1, 2019, through June 30, 2021 that were subject to monitoring and enforcement.[92] Auditors found that the Board did not monitor and enforce **54 of 96 (56%)** public disciplinary actions it imposed.

[90] Chapter 90, Article 1 of the North Carolina General Statutes. This is the law that governs the practice of medicine in the state of North Carolina. The Board refers to this law as the North Carolina Medical Practice Act.

[91] Auditors originally planned to test all 212 public disciplinary actions subject to monitoring and enforcement. However, the Board was unable to provide the necessary documentation for 116 (55%) in a timely manner due to delays caused by the Board redacting the documents. See Finding 1 for more discussion.

[92] The population of 212 investigations are part of the same population of 218 investigations for timeliness described in Finding 2. However, only 212 of the 218 investigations were subject to the Board's monitoring and enforcement. Six of the investigations that resulted in public actions during the audit scope resulted in a formal reprimand or a letter of concern. Therefore, they were not subject to the Board's monitoring and enforcement and were not included in the population of investigations to determine whether the Board monitored and enforced its disciplinary actions.

Of the 54 disciplinary actions:

- 42 (78%) were medical providers who had their license suspended, revoked, or inactivated.[93]

- 12 (22%) were medical providers who had limitations[94] placed on their license.

Auditor's Note: Auditor tests **were limited** to Board investigations that resulted in public disciplinary actions listed on the Board's website. Auditors were unable to test Board investigations that resulted in private actions or "accept as information" actions[95] because the Board **denied auditors access** to these investigative records and supporting documentation.

According to Board management, there were 4,432 investigations closed during the period July 1, 2019, through June 30, 2021.[96] According to the Board, this total included the investigations that led to public actions listed on the Board's website and private and "accept as information" actions. These private and "accept as information" actions (possibly 4,214) could not be audited **due to the scope limitation.**

Consequently, this audit cannot conclude on the monitoring and enforcement of disciplinary actions from these investigations. Therefore, the legislature and public have no assurance that the Board compels compliance. **(See Finding 1 for further discussion.)**

Resulted in Increased Risk to Patient Safety

As a result, there was an increased risk that medical providers whose actions posed a threat to patient safety could continue serving patients.

For example, the Board did not monitor and enforce disciplinary actions on the following providers despite the risk posed to patient safety:

- Provider A – The Board prohibited Provider A from treating patients after finding evidence that his treatment of two pregnant patients "failed to conform to the standards of acceptable and prevailing medical practice." One patient and her newborn were subsequently hospitalized with multiple complications. Additionally, Provider A admitted he had failed to conform to previous license limitations from 2015.

  Auditors determined that as of June 2022, Provider A continued to maintain a website advertising his medical practice, including a recent patient testimonial and an active phone number.

[93] Includes providers with Non-Practice Agreements (NPAs). NPAs are private or public agreements between the Board and the provider whereby the provider agrees not to practice medicine until authorized to do so by the Board. The Board issues an NPA when it believes there may an immediate risk to patient safety and it needs time to determine the extent of the risk and consider disciplinary action against the provider.

[94] License limitations are specific restrictions imposed on a provider's ability to practice (e.g. required to have a chaperone present when examining female patients).

[95] An "accept as information" action occurs when the Board finds no violation of the Medical Practice Act. The case is closed and kept on file in the provider's confidential permanent file.

[96] This information was provided by the Board and could not be verified due to auditor's lack of access to Board files.

- Provider B – The Board restricted Provider B's ability to practice spine surgery after finding evidence that three patients had received "wrong-level [spinal] fusion procedures" resulting in one patient receiving a malpractice insurance payout.

  Provider B was ordered to have a co-surgeon present for at least 20 spine surgeries. After the order was issued, Provider B's attorney notified the Board that he would no longer perform spinal surgeries. The Board did not independently verify to ensure Provider B stopped performing spinal surgeries.

- Provider C – The Board prohibited Provider C from practicing pain management and ordered him to "close his pain management practices as soon as possible and no later than June 1, 2021." The Board investigated Provider C after receiving a report that he was in the top 2% of opioid prescribers in North Carolina, eventually determining that he "frequently increases patients' opioid doses rapidly without documenting specific treatment goals."

  The Board was unable to provide auditors with documentation to support whether the Board monitored and enforced its prohibition against Provider C. However, auditors determined that as of June 2022, Provider C continued to maintain an active website advertising his pain management practice.

Auditors also found medical providers with public disciplinary actions who were enrolled providers in Medicaid.[97] These medical providers continued to provide care to Medicaid patients and bill Medicaid despite imposed disciplinary actions that prohibited them from doing so. For example:

- Provider D – The Board prohibited Provider D from administering anesthesia or supervising its administration for over seven months due to an investigation into a patient's death. However, during these seven months, Provider D administered anesthesia 339 times and billed Medicaid for $63,379.

- Provider E – The Board inactivated a physician's license after receiving a complaint that during a "follow-up visit to check her thyroid function, [Provider E] inappropriately touched Patient A's left breast." However, after his license was inactivated, Provider E treated 50 patients and billed Medicaid for $62,618.

Caused by the Board's Lack of a Monitoring and Enforcement Policy

The Board monitored and enforced some disciplinary actions it imposed and not others because the Board did not have a standard or formalized policy in place that outlined how monitoring and enforcement of disciplinary actions should be performed. The Board did not have a policy that detailed:

- The frequency and extent of monitoring and enforcement.
- How to track and document monitoring and enforcement activities.
- How to determine when stricter monitoring and enforcement is necessary.

[97] Auditors were able to access billing records for Medicaid patients of disciplined providers but were unable to do so for patients with private insurance.

Instead, the Board stated that it frequently relied on the public, other medical providers, and the attorneys of the disciplined medical provider to submit complaints or provide notification when a disciplined medical provider violated the Board's imposed disciplinary actions.

Also Caused by the Board's Position that Monitoring and Enforcement of Disciplinary Actions is Not Required

Additionally, the Board monitored and enforced some disciplinary actions it imposed and not others because the Board stated it was **not legally required** to monitor and enforce disciplinary actions. For example, the Board stated the Medical Practice Act does not explicitly require the Board to monitor and enforce disciplinary actions.

But the Board's statement is **contradictory** to what they actually did, because the Board **did** monitor and enforce **some** disciplinary actions it imposed. Though, based on auditor tests, it appeared that the Board's monitoring and enforcement activities were limited to "less severe" disciplinary actions. For example, the Board was **consistent** in ensuring medical providers completed continuing education requirements. However, auditors found the Board **rarely** monitored to ensure that medical providers with suspended licenses were not continuing to provide care to patients.

There is no explicit legal requirement for the Board to monitor and enforce the disciplinary actions it imposes. However, the Federation of State Medical Boards[98] (FSMB) recommends that to ensure that malpractice or misconduct is corrected, the Board should assess itself by asking, "Does the status quo provide **maximum potential for protection of the public interest?"**[99] [emphasis added]

Further, in 2020, the Board formally updated its motto to "The **safety of the people** is the highest law."[100] [emphasis added]

Based on the Board's lack of monitoring and enforcement of disciplinary actions, the maximum potential for protection of the public interest and safety of the people has not yet been achieved.

Best Practices Recommend Monitoring and Enforcement of Disciplinary Actions

Best practices identified by the National State Auditors Association (NSAA) state that the Board, as a regulatory agency, should monitor and enforce the disciplinary actions it imposes to ensure the medical providers comply or stop operating. Specifically, the NSAA recommends that regulatory agencies like the Board should:

> [ ]Track and flag [medical providers] that have not come into compliance after problems or violations were identified, including those operating without a license or permit. ...
>
> [ ]Follow-up as needed (i.e. through written reports, the inspection process, special investigations, etc.) to determine whether the [problem or violation] has been corrected or whether additional enforcement action is needed.

[98] The Federation of State Medical Boards represents all state medical boards within the United States and promotes best practices that add to their effectiveness.

[99] Federation of State Medical Boards, *Guidelines for the Structure and Function of a State Medical Board and Osteopathic Board*, April 2018, pages 1-2.

[100] https://www.ncmedboard.org/images/uploads/disciplinary_reports/NCMB_Annual_Report_2020_web.pdf.

> [ ]Track and oversee the enforcement actions taken to ensure that they are being addressed appropriately and that things don't slip through the cracks.[101]

RECOMMENDATIONS

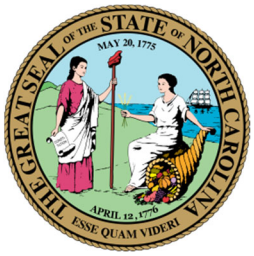
The Board should monitor and enforce disciplinary actions against medical providers for the maximum protection of public health and safety.

The Board should create policies and procedures that outline how monitoring and enforcement of disciplinary actions should be performed. Specifically, policies and procedures should include details on: (1) how often and how much monitoring and enforcement to perform, (2) how to track and document monitoring and enforcement activities, and (3) how to determine when stricter monitoring and enforcement is necessary.

AGENCY RESPONSE

See page 42 for the Board's response to this finding.

[101] National State Auditors Association, *Carrying Out a State Regulatory Program*, 2004.



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 the 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 North Carolina Medical Board (Board) made numerous **inaccurate** and **potentially misleading** statements. To ensure the availability of complete and accurate information, OSA offers the following clarifications for the **most significant inaccuracies**.

Board's Response to Finding #1: Limited Ability to Audit Board's Investigative Process

In its response to this finding, the Board made several **inaccurate** and **potentially misleading** statements.

FIRST, the Board stated:

> OSA's request for changes to the law to allow unfettered access to NCMB records ignores federal law that otherwise prohibits OSA's access to private health information.

This is not true. Federal law does not prohibit OSA's access to private health information. OSA is allowed access to private health information during our audits on a regular basis. For example, OSA performs annual audits of Medicaid at the Department of Health and Human Services (DHHS). OSA enters into business associate agreements with DHHS that, in addition to state law,[1] maintain confidentiality and protect health information in accordance with federal law.

Additionally, in its response, the Board continually mentioned that it was prohibited from "**releasing**" investigative case files and private health information of patients. To be clear, OSA asked for **access** to the Board's information, not for it to be "**released**." Granting auditors read-only **access** of the Board's investigative database to be reviewed onsite at the Board's offices would have allowed OSA to complete all audit objectives.

SECOND, the Board stated:

> In an effort to timely and fully provide OSA the requested confidential information OSA sought, NCMB offered to designate OSA as a consultant, as it does with subject matter experts who need access to protected information. NCMB's consultant agreements include provisions that ensure that confidentiality is maintained. OSA declined to follow the legally authorized pathway to gain the information.

[1] N.C.G.S. § 147-64.6(d) and N.C.G.S. § 147-64.7(d).

This is **misleading**. While the Board did discuss the possibility of providing access to this information if auditors acted as the Board's consultant, OSA never received an agreement or framework for an agreement in writing. **However**, as the report clearly states, entering into a consulting agreement such as this would have **violated auditor independence[2] as required by professional auditing standards and state law**.[3] Therefore, acting as the Board's consultant was not a legally authorized pathway or feasible option.

As mentioned above, a legitimate legally authorized pathway would have been to enter a business associate agreement with OSA as DHHS does. This agreement would have included a provision that ensured confidentiality was maintained and could have included the stipulation that access to the Board's investigative database would be "read-only" and only available at the Board offices.

Ultimately, the Board is arguing to maintain the confidentiality of its investigative records and supporting documentation. As the Board states, that includes anonymous complainant information, attorney-client privileged communications, medical records, prescription histories, expert reviews, and identifying patient information.

However, the Board's investigative records and supporting documentation would **remain confidential** with OSA. As stated in this audit report, state law[4] also provides that all the information obtained and used by OSA during an audit is **confidential**. Specifically,

- N.C.G.S. § 147-64.6(d). states "audit work papers and related supportive material are confidential."
- N.C.G.S. § 147-64.7(d). states "The production of documents or information…does not constitute a waiver or an impairment of the attorney-client privilege."

In its response, the Board also stated how it strives to be transparent and that it voluntarily publishes an annual report detailing statistical information about its investigative and disciplinary processes. To be clear, everything the Board publishes is **self-reported**. There is **no assurance** that what is included in the Board's annual report is **accurate** or **complete**.

Without access to the Board's investigative records, an **independent** and **objective assessment** of the Board's performance cannot be completed. Therefore, **legislators** and the **public** have **no** way to know whether or how well the Board's investigative process protected North Carolina citizens from harm, including malpractice and inappropriate behavior such as sexual assault.

As such, this audit recommends the North Carolina General Assembly should consider inserting claryifying language or specifically exempting the Office of the State Auditor from state laws that restrict access to medical board records.

[2] For example, by creating unacceptable self-review and management participation threats as defined by paragraph 3.30 of *Government Auditing Standards*.
[3] N.C.G.S. § 147-64.8.
[4] N.C.G.S. § 147-64.6(d) and N.C.G.S. § 147-64.7(d).

As stated in this audit report, access to medical board records by state audit organizations is not unprecedented. Other states have less restrictive laws. For example:

- Maryland state auditors have access to inspect the records of any state government unit, person, or other body receiving state funds, including those that are confidential by law.[5]
- Georgia state auditors are granted unrestricted access to all records at all state agencies, including confidential records, except where the law expressly states otherwise.[6]

Again, to be clear, OSA asked for **access** to the information. OSA did not ask for the Board's information to be "**released**." Granting auditors read-only **access** to the Board's investigative database to be reviewed onsite at the Board's offices would have allowed OSA to complete all audit objectives.

Board's Response to Finding #2: Untimely Investigations Increased Risk to Patient Safety

In its response to this finding, the Department made several **inaccurate** and **potentially misleading** statements.

FIRST, the Board stated:

> OSA mistakenly states that North Carolina law requires investigations to conclude within six months. In fact, no such time limit exists. NCMB is merely obligated to notify a licensee under review that the investigation has extended beyond six months.

This response **misleads the reader** to believe that state law does not require investigations to be completed in six months, and the Board is only *merely* required to notify a licensee under review that the investigation will extend beyond six months.

This is not true. State law clearly requires the Board to complete investigations **within six months** OR provide a written explanation to the licensee as to why the investigation must continue.

> N.C.G.S. § 90-14(l) provides:
>
> The Board shall complete **any** investigation initiated pursuant to this section **no longer than six months** from the date of the first communication required under subsection (i) of this section, unless the Board provides to the licensee a written explanation of the circumstances and reasons for extending the investigation. [emphasis added]

As the report clearly states, the Board's investigative process was not designed to complete investigations within six months.

[5] Md. Code Ann., State Government § 2-1223.
[6] O.C.G.A. § 50-6-29 (2010).

SECOND, the Board stated:

> OSA has no evidence and hence, no reasonable basis, to state that the duration of NCMB investigations put any patients at risk.

This is **not true** and **minimizes the importance** of the auditor's findings. The report clearly includes examples of **medical providers** that **continued** to **provide care** to patients and bill and collect from Medicaid[7] while the Board's investigations continued past six months.

In total, auditors found 13 medical providers who treated 4,044 patients and billed Medicaid a total of $2.7 million while the Board's investigations continued past six months. See page 18 for more details.

Further, there were more than **4,000 Board investigations** that **could not be audited** due to the Board restricting auditor access to Board investigative records and supporting documentation.

THIRD, the Board stated:

> Furthermore, completing certain investigations more rapidly than six months could have the effect of putting patients at risk.

This response attempts to **distract the reader** from the importance of the timeliness of Medical Board investigations. State law allows investigations to extend past six months when appropriate notification and explanation is provided to the medical provider under investigation. As the Medical Board includes in its response, there are reasons certain investigations may require more than six months to complete.

However, there is also a reason state law includes six months as the benchmark for investigative timeliness. As investigations continue on, medical providers who were eventually disciplined by the Board for complaints such as **malpractice**, **negligence**, and **sexual misconduct**, were allowed to continue serving patients while their investigations continued past six months, increasing risks to patient safety.

FOURTH, the Board stated:

> It is also important to note if at any time NCMB has sufficient evidence to show an imminent threat to the public, it has the authority to immediately seek a suspension, preventing the licensee from practicing until the complaint is resolved. However, immediate action may not always be the most effective tool to use. Sometimes NCMB and the licensee will enter into a non-practice agreement, where the licensee agrees not to practice until the matter is resolved. NCMB's top priority is always the protection of the people of North Carolina.

[7] Auditors were able to access billing records for Medicaid patients of disciplined providers but were unable to do so for patients with private insurance.

This response **misleads the reader** to believe that the Board regularly takes action to protect the public until a complaint is resolved. However, as explained in Finding 1 of this report, the Board: (1) prevented auditors from reviewing any of the Board's private actions, and (2) limited what auditors could review for the Board's public actions.

As a result, legislators and the public have no way to know whether or how well the Board protected North Carolina citizens from imminent threats, including malpractice and inappropriate behavior such as sexual assault.

Additionally, as explained in Finding 3 of this report, the Board does not monitor and enforce all of the actions it imposes on medical providers, including those that present imminent threats to the public.

FIFTH, the Board stated:

> Throughout this audit, there was also disagreement about the definition of "investigation," which the MPA does not define. While NCMB did not have a written policy, the standard procedure was for the investigations department to collect information, generally within six months, and then provide that investigative information for review, which includes making a disciplinary recommendation to the Board, which may or may not adopt the recommendation.

It is accurate that there was a disagreement about the definition of "investigation." As the Board's response indicated, the Board's position is that an "investigation" only includes the period of collecting investigative information and that "generally takes six months."

It is the Board's position that an investigation does not include review of the collected information and Board staff making a disciplinary recommendation to the Board, such as:

- Medical review, including by the Board's medical consultants.
- Legal review by the Board's attorneys.
- Requests to collect more information and conduct additional interviews.

However, state law[8] clearly requires the Board to complete investigations **within six months** OR provide a written explanation to the licensee as to why the investigation must continue.

Additionally, how can an investigation conclude if information has only been collected but no review has occurred, and no disciplinary recommendation has been made? Further, how can such an investigation achieve the Board's stated top priority of "the protection of the people of North Carolina"?

Board's Response to Finding #3: Lack of Monitoring and Enforcement of Disciplinary Actions Increased Risk to Patient Safety

In its response to this finding, the Department made several **inaccurate** and **potentially misleading** statements.

[8] N.C.G.S. § 90-14(l).

FIRST, the Board stated:

> OSA inappropriately applied best practices developed by the National State Auditors Association to medical board regulatory actions, without regard to the unique content of medical regulatory actions.

This is **not true.** The Board's response **misleads the reader** to believe that best practices developed to evaluate state regulatory programs should not be applied to the Board, which is a state regulatory program.

To review the Board's monitoring and enforcement of its disciplinary actions, OSA applied best practices identified by the National State Auditors Association (NSAA). The document was developed as a tool for audit organizations and government agencies to use in identifying and evaluating best practices in carrying out a state regulatory program (like the Board). While all organizations have unique aspects, all regulatory programs are nonetheless designed to safeguard the public's health and welfare.

As such, the NSAA best practices document includes what practices are more likely to result in a **well-designed regulatory program** that **safeguards the public's health** and welfare.

SECOND, the Board stated:

> OSA implies that NCMB failed to follow industry best practices for monitoring compliance with regulatory actions and provisions when, in fact, no such standards exist for medical regulatory authorities.
>
> OSA, despite repeated requests by representatives of NCMB, did not investigate or discuss the monitoring programs of any other occupational licensing agencies ("OLA") in North Carolina or any other U.S. jurisdiction.

This is **not true**. This response **misleads the reader** to believe that no industry best practices for monitoring compliance with regulatory actions exist for medical regulatory authorities, and that OSA should have investigated monitoring programs at other occupational licensing agencies.

First, as stated above, it is appropriate to apply the best practices identified by the NSAA to all state regulatory programs and occupational licensing agencies, including medical regulatory authorities such as the Board.

Second, auditors also applied guidance from the Federation of State Medical Board's (FSMB) in this audit.[9] The Federation of State Medical Boards (FSMB) is an organization that supports state medical Boards in licensing, disciplining, and regulating physicians and other healthcare professionals. The FSMB created the guidance document (1) To serve as a guide to those states that may adopt new medical practice acts or may amend existing laws, and (2) To encourage the development and use of consistent standards, language, definitions, and tools by boards responsible for physician and physician assistant regulation.

[9] Federation of State Medical Boards, *Guidelines for the Structure and Function of a State Medical Board and Osteopathic Board*, April 2018, pages 1-2.

In the document, the FSMB recommends that to ensure that malpractice or misconduct is corrected, each individual Board should assess itself by asking, "Does the status quo provide **maximum potential for protection of the public interest?"** [emphasis added]

Without monitoring and enforcing Board disciplinary actions, how would the Board even be able to answer this question?

THIRD, the Board stated:

> OSA did not hire any experts in medical regulation for this audit.

This response **misleads the reader** to believe that experts in medical regulation were necessary to determine whether the Board monitored and enforced disciplinary actions it imposed on medical providers in accordance with regulatory best practices.

In fact, the Board **prevented** OSA from determining if an expert in medical regulation was necessary. As stated in Finding 1, the Board denied OSA unrestricted access to investigative records, preventing auditors from seeing what the records contained. Without seeing what the records contained, OSA could not determine if hiring an expert was necessary, in accordance with professional auditing standards.

Additionally, **monitoring** and **enforcement** is a **universal management function** and **responsibility**, and the frequent subject of performance audits. It is not unique to medical regulatory agencies.

FOURTH, the Board stated:

> OSA has no evidence or reasonable basis to state that NCMB's established system of monitoring compliance put patients at any risk of harm.

This is **not true** and also **minimizes the importance** of the auditor's findings. The report clearly includes examples of instances in which auditors identified the Board did not monitor and enforce disciplinary actions despite the risk posed to patient safety, including examples in which medical providers **continued** to provide care. See pages 21-22 for more information.

Further, there were more than **4,000 Board investigations** that **could not be audited** due to the Board restricting auditors' access to Board investigative records and supporting documentation.

Board's Response: Additional Clarifications

In this section of its response, the Board made an **inaccurate** statement that requires clarification so that readers are not **misled**. The Board stated:

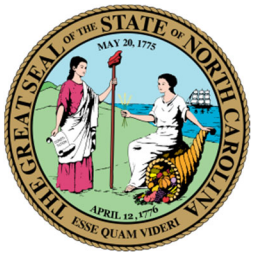
> In its report, OSA references several examples of licensees billing Medicaid for services during periods of suspension covered by disciplinary orders. NCMB repeatedly requested further information and evidence in order that it might investigate these providers for violations of any NCMB disciplinary order. OSA declined to provide any evidence supporting these allegations…

This is **not true**. The Board **never** requested "further information and evidence" for the referenced medical providers, only their names, which OSA provided. This is the information necessary for the Board to follow-up on these specific medical providers with DHHS and conduct an investigation.

Even if the Board had requested "further information and evidence," OSA would have been unable to provide any additional details. The detailed data used for these examples were obtained from DHHS as part of an audit. As previously mentioned, state law[10] provides that all information obtained and used by OSA during an audit is **confidential**. Which is the same point OSA made to the Board when requesting access to the Board investigative records and supporting documentation.

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

[10] N.C.G.S. § 147-64.6(d) and N.C.G.S. § 147-64.7(d).



RESPONSE FROM NORTH CAROLINA MEDICAL BOARD

North Carolina Medical Board
Michaux R. Kilpatrick, MD, PhD: President | Christine M. Khandelwal, DO: President-Elect | Devdutta G. Sangvai, MD, MBA: Secretary/Treasurer

November 30, 2022

The Honorable Beth A. Wood
NC State Auditor
2 S. Salisbury St.
20601 Mail Center Road
Raleigh, NC 27699-0600

Auditor Wood,

Thank you for the opportunity to respond to the Office of the State Auditor's Report on "Investigations of Medical Providers." The North Carolina Medical Board (NCMB) has reviewed the report on the findings and recommendations that resulted from the Performance Audit conducted by the Office of the State Auditor (OSA). NCMB appreciates the work done on behalf of the people of North Carolina as well as the opportunity to make clarifications and corrections to portions of the report that may lead to misunderstandings that compromise the public's trust in NCMB. Our organization is concerned that some of OSA's findings and recommendations misstate the requirements of state law and, as such, essentially find fault with NCMB for complying with its statutory obligations.

Specifically:

- OSA states that NCMB should provide full access to its investigative case files, including private health information of patients. In fact, state law specifically prohibits NCMB from releasing this information and giving OSA unrestricted access would be a direct violation of the statute.

- OSA's request for changes to the law to allow unfettered access to NCMB records ignores federal law that otherwise prohibits OSA's access to private health information.

- OSA mistakenly states that North Carolina law requires investigations to conclude within six months. In fact, no such time limit exists. NCMB is merely obligated to notify a licensee under review that the investigation has extended beyond six months. Our investigations department has already implemented a process that ensures that each licensee is timely notified of an extended investigation.

- OSA fails to recognize that, if there were a six-month requirement without exception, it would seriously impair NCMB's ability to protect the public and afford due process to licensees in its investigations.

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- OSA asserts that NCMB failed to meet agency best practices without any evidence that other state agencies, including state medical boards, have such monitoring practices. NCMB's monitoring program was designed to track licensees who were required to perform an action for the purposes of improving their clinical practice. It was not designed to track individuals who lost a license and indefinitely ensure they are not continuing to practice medicine without a license, which is a crime. NCMB does not have any legal authority to prosecute crimes, as that authority lies with law enforcement.

- OSA agreed during their audit process that they had received no complaints that prompted the audit and that there have been no allegations and there is no evidence that NCMB ever failed to review all complaints, administer discipline in an equitable manner or report all its public actions.

NCMB is always eager to improve its processes and wishes to be accountable to the people of North Carolina. Attached is the complete response to the findings and recommendations, including the multiple steps NCMB has taken to improve any areas of concerns noted by OSA. Furthermore, NCMB will explore additional options, including engaging an independent firm armed with subject-matter experts to perform an audit to examine the questions raised by OSA in its objectives.

If you have any questions regarding our efforts or response, please direct those to Thomas W. Mansfield, Chief Legal Officer, at Thomas.Mansfield@ncmedboard.org.

Sincerely,

R David Henderson

R. David Henderson
Chief Executive Officer

North Carolina Medical Board

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NCMB RESPONSES TO OSA'S KEY FINDINGS

Key Finding

1. *Limited Ability to Audit Medical Board's Investigative Process*

NCMB Response: NCMB agrees OSA had limited ability to audit NCMB's investigative process. It must be noted:

- The organization's refusal to provide unrestricted access to investigative case files OSA requested was not willful, but rather, the necessary result of NCMB following state law.

- While the law prohibits disclosure of investigative information to any person, one exception allows NCMB to share investigative information with consultants. In an effort to timely and fully provide OSA the requested confidential information OSA sought, NCMB offered to designate OSA as a consultant, as it does with subject matter experts who need access to protected information. NCMB's consultant agreements include provisions that ensure that confidentiality is maintained. OSA declined to follow the legally authorized pathway to gain the information.

- While it is certainly within the NC General Assembly's discretion to amend the law, NCMB respectfully observes that these case files are confidential for good reason, including the need to keep patients' sensitive medical information private.

NCMB can only operate within the authority it has been given by the NC General Assembly through the North Carolina Medical Practice Act found in Article 1 of Chapter 90 of the N.C. General Statutes. The Medical Practice Act ("MPA") is clear and states that any investigative information within NCMB's possession is "privileged, confidential and ***not subject to disclosure by subpoena, discovery, or any other means of legal compulsion for release to any person***." N.C. Gen. Stat. § 90-16(c). "Any person" is broad and includes state agencies, like OSA and elected officials.

Much of the investigative information requested by OSA included the private health information of patients, which is regulated under federal law. Protected health information includes the most sensitive information about an individual's health. It not only includes identifiable data like a patient's name, social security number and birthdate, but more importantly a patient's full medical history. It includes diagnoses, treatments, prescriptions, procedures, and private communications with health care providers. Private health information may not only appear in medical records, but also in the contents of complaints received, correspondence, as well as in interviews with patients and health care providers. While OSA may have some discretion in keeping information in its possession confidential, NCMB is not authorized by law to disclose it.

Federal law, specifically HIPAA, recognizes the sensitive nature of these records and has protected them – this private health information between a provider and a patient cannot be shared with anyone unless the patient specifically authorizes it. The law does make an exception for health care providers to release private health information to state licensing boards without patient authorization in order to ensure patient safety.[1] Once that information is passed on to a state licensing board like NCMB, HIPAA is not enforceable against that state agency and hence the importance of North Carolina state law, which maintains that confidentiality under N.C. Gen. Stat. § 90-16(c). Without this law, the information could be subject to subpoenas and used against the patient in cases like personal injury claims, contracts, or divorce proceedings. In addition, there is no applicable federal exception that allows a health care provider to release private health information to non-public health agencies or elected officials, like OSA, without the patient's authorization. Therefore, NCMB should not release it to OSA without either the patient's authorization or the express authorization of law.

NCMB made every effort to follow state and federal regulations and comply with OSA's request to the extent allowed by law. It took great care to redact any privileged and confidential investigative and medical information, which includes anonymous complainant information, attorney-client privileged communications, medical records, prescription histories, expert reviews, and identifying patient information. The time-consuming redaction process involved reviewing each document thoroughly and redacting any confidential information, including the private health information of the people of North Carolina.

Recommendations:

The audit recommends the Medical Board should allow OSA unrestricted access to all records and supporting documentation necessary to conduct an audit in accordance with state law and professional auditing standards. It also suggests that the North Carolina General Assembly should consider inserting clarifying language or specifically exempting OSA from state laws that restrict access to medical board records.

NCMB Response: As mentioned above, the law does not allow NCMB to provide OSA with unrestricted access to all records and supporting documentation necessary to conduct an audit. In terms of changing the law exempting OSA from the restrictions that currently protect NCMB records, that authority lies with the NC General Assembly. It is up to lawmakers to evaluate the importance of confidentiality of investigative information. Of course, state law cannot limit the protections set out in federal law. Beyond federal and state laws protecting a patient's personal health information, there are many other practical reasons the investigative information is confidential and protected, including:

1. Investigative information can involve unsubstantiated allegations that can be harmful to a physician's reputation if made public and could negatively impact the delivery of patient care. N.C. Gen. Stat. § 90-16(c) serves to not only protect the public's private health information, but also serves to protect licensees in the spirit of "innocent until proven guilty." If an investigation results in insufficient evidence of a violation of the MPA, the licensee's reputation remains intact and continuity of care for patients is maintained without disruption of care due to NCMB's investigation.

[1] See 45 CFR 164.512(d).

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2. Confidential protection secures investigative files involving the disclosure of a patient's private health information. Details of a patient's past, present or future physical or mental health conditions are intimate and can be stigmatizing, including diagnoses for sexually transmitted diseases or psychiatric disorders, opiate and narcotic prescriptions, fertility treatments, history of sexual abuse and trauma and many other details that are only shared with a health care provider with an expectation of confidentiality.

3. If patients were aware that their private health information could be shared with elected officials and non-health related state agencies, it could not only have a chilling effect on their willingness to seek treatment with providers but also any willingness to file a complaint about the care they have received.

4. Article 5A of Chapter 147 of the General Statutes regarding the Auditor does not provide adequate protection of confidential information received by OSA. Thus, if the General Assembly were to amend Article 1 of Chapter 90, not inconsistent with federal law, it would be necessary to prevent the redisclosure of sensitive confidential investigative information.

The disclosure of this information is extremely sensitive and should not be taken lightly without thorough and thoughtful consideration for all the implications of disclosure. Ultimately, if the NC General Assembly wants to grant the State Auditor, or non-health related agencies, unlimited, unrestricted, and unregulated access to NCMB investigative information, including private health information of patients of North Carolina, then it should pass a law that clearly and expressly authorizes that access in a way that is in harmony with federal law and guarantees that OSA will maintain confidentiality of that information.

NCMB understands some of OSA's concerns, especially whether every complaint is investigated and whether those investigations follow best practices. While NCMB must maintain confidentially of its investigative information, it does strive to be transparent to the extent allowed by law. It voluntary publishes on its website an annual report detailing statistical information about its investigative and disciplinary processes. These reports include the number of cases opened and closed each year, the types of allegations, and the types of action taken, including the number of private letters of concern issued. NCMB understands this reporting may not be sufficient to ensure that each complaint is being investigated and is therefore willing to work with the NC General Assembly to provide any additional oversight, but only to the extent that oversight does not negatively impact the delivery of care and does not compromise a patient's private health information. NCMB will also explore additional options, like hiring consultants, including experts in medical regulation, to provide evaluations of the objectives OSA sought to investigate while ensuring compliance with N.C. Gen. Stat. § 90-16(c).

Key Finding

2. *Untimely Investigations Increased Risk to Patient Safety*

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NCMB Response: NCMB does not agree with the representation of this finding for the following reasons:

- OSA indicates that NCMB failed to meet a statutory obligation to complete medical board investigations within six months when no such obligation exists. N.C. Gen. Stat. § 90-14(l) permits investigations to exceed six months, as long as licensees are notified in writing that the investigation is ongoing. NCMB acknowledges that it did not provide the required notification in writing in every case.

- OSA has no evidence and hence, no reasonable basis, to state that the duration of NCMB investigations put any patients at risk. OSA assured NCMB that the audit was not conducted in response to any complaints or allegations from the public.

- Furthermore, completing certain investigations more rapidly than six months could have the effect of putting patients at risk.

N.C. Gen. Stat. § 90-14(l) in its entirety states:

> *The Board shall complete any investigation initiated pursuant to this section no later than six months from the date of first communication required under section (i) of this section,* ***unless the Board provides to the licensee a written explanation of the circumstances and reasons for extending the investigation****.*

NCMB's investigations are the process of collecting ***sufficient*** evidence to permit a valid determination of whether the Medical Practice Act (MPA) has been violated. The process varies depending on the underlying allegations, but it can involve collecting, organizing and reviewing medical records, NC Controlled Substances Reporting System prescription records, legal documents from malpractice lawsuits, text messages, phone records, and emails. It can also involve interviewing a variety of witnesses, such as patients, employees, pharmacists, and law enforcement officers, many of whom may not be easily identified, located or willing to submit to an interview. There may also be the need to obtain cooperation from out-of-state licensing boards, hospitals, other state agencies, law enforcement organizations and state or federal attorneys to obtain evidence. Finally, drug tests, mental health evaluations, and clinical competency evaluations of licensees may be necessary to complete the investigation and allow NCMB members to evaluate all the relevant information.

NCMB investigates almost 3,000 cases a year with a range of allegations involving communication issues, medical records issues, sexual misconduct with patients, quality of care, and substance use. Before taking any action, NCMB must have ***sufficient, credible, and reliable*** evidence that a violation of the MPA has occurred. Without sufficient evidence, any action taken will not withstand judicial scrutiny. While most investigations conclude within six months, there are exceptions where additional time is necessary to properly conduct a thorough investigation. In those situations, the law only requires NCMB to provide a written notice to the licensees explaining the reason the investigation is extending beyond six months.

At all times during this audit, OSA strictly focused on whether licensees received that formal written notice when an investigation extended beyond six months. OSA did not examine the

reasons investigations may be extended or the various ways the status of an investigation may be communicated.

There are several reasons why an investigation may take longer than six months, including:

- NCMB must have sufficient, credible, and reliable evidence in order to withstand judicial scrutiny. Licensees have the opportunity and right to appeal any final disciplinary order in a court of law. An incomplete or inaccurate investigation would not only be a waste of time and resources for patients and licensees, but also waste the resources of the court and would detrimentally impact the practice of medicine in the state.

- Investigations may be augmented by subsequent complaints that result in additional investigations. In the report, OSA has incorrectly equated the number of public actions it reviewed with the number of investigations it reviewed. Rather one public action may be the result of multiple investigations. For instance, a suspension might be the result of an investigation for a malpractice settlement, having a sexual relationship with a patient and overprescribing controlled substances. With multiple investigations, there are multiple witnesses and multiple sources of evidence to review, which may extend the original investigation beyond six months.

- Complex cases require extensive resources to obtain and review medical records, interview witnesses, or obtain records from other institutions. These steps require proper notice and sufficient time to fulfill requests. Specifically, NCMB licensees have the due process right to respond within 45 days and a 30-day extension may be granted. It would be a violation of due process for NCMB to deny licensees reasonable time to respond, and it would be imprudent to conclude an investigation without obtaining proper reports or documentation.

- Quality-of-care cases require expert reviews of medical records. This critical step entails collection and organization of, often extensive, medical records. Outside reviewers must have sufficient time to review information, which generally takes at least 45 days. Subsequent reviews may be necessary and may take an additional 45 days. In that event, the initial phase of a quality-of-care case, which includes the collection of the licensee's response, medical records and two expert reviews, will take at least 135 days or approximately 4.5 months. Given that reality, it is likely that limiting the duration of investigations to six months would result in incomplete investigations that put the public at risk.

- Cases involving accusations of sexual misconduct require particular skill and consideration of the circumstances. Often fearing retribution or embarrassment, victims request anonymity and are unwilling to provide testimony. In those cases, rather than dismiss the allegation, NCMB continues its investigation and attempts to find corroborating evidence. A comprehensive investigation of sexual misconduct and gaining trust of a victim takes time and cannot be rushed.

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- There is no statute of limitations, or time limit, on how long a complaint must be filed with NCMB. The older the date of the alleged misconduct, the longer it will take NCMB to locate evidence, including witnesses and records. Imposing a six-month limitation on investigations would effectively create a time-bar on otherwise legitimate complaints and would be especially detrimental to sexual assault victims.

- In cases that are opened as result of a criminal arrests or charges, much of the evidence is held by law enforcement and NCMB may not have access to evidence in the possession of law enforcement until the criminal charges have been resolved. Additionally, NCMB does not want to take any action that could jeopardize the criminal prosecution. Depending on the crime, the venue, as well as the licensee's due process rights, it frequently takes more than six months for the case to go to trial or to be resolved.

- Investigations also hit roadblocks: hospitals will not provide records, agencies will not provide investigative information, witnesses are hard to locate, or licensees cannot respond because they are in prison or in treatment.

All of the reasons above demonstrate that mandating NCMB to complete investigations is six-months would not increase patient safety. It would in fact force the NCMB to stop investigating and allow licensees to continue to practice thereby endangering the public.

It is also important to note if at any time NCMB has sufficient evidence to show an imminent threat to the public, it has the authority to immediately seek a suspension, preventing the licensee from practicing until the complaint is resolved. However, immediate action may not always be the most effective tool to use. Sometimes NCMB and the licensee will enter into a non-practice agreement, where the licensee agrees not to practice until the matter is resolved. NCMB's top priority is always the protection of the people of North Carolina.

Throughout this audit, there was also disagreement about the definition of "investigation," which the MPA does not define. While NCMB did not have a written policy, the standard procedure was for the investigations department to collect information, generally within six months, and then provide that investigative information for review, which includes making a disciplinary recommendation to the Board, which may or may not adopt the recommendation. OSA had a broader interpretation of "investigation," which included both the period of collecting investigative information as well as the period of making a disciplinary determination. However, the law does not require NCMB to make a disciplinary determination or close a case within six months. As a result of this broad interpretation, OSA concluded a number of cases were found to extend beyond six months whereas NCMB had established notice was not required.

The important finding of the audit process was not the timeliness of the investigation, but rather whether NCMB provided the requisite written notice to the licensee that an investigation would extend beyond six months. The notification process was manual and required staff to identify investigations that reached six months, draft a notification letter and send it to the licensee. This manual process only occurred after the investigation had reached the six-month mark. Because the process was manual, there was room for oversight and mistakes were made, but not to the degree as characterized by OSA's report.

North Carolina Medical Board

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It is also important to note that a lack of formal notice in writing does not necessarily mean the licensee was not informed of the status of the investigation. Generally, NCMB and licensees, or their attorneys, communicate regularly about investigations, including when it will be heard before the full Board. There are also many written communications that can occur that do not explicitly specify that the investigation is ongoing, but the written communications certainly indicate that NCMB is still investigating. Nevertheless, going forward, NCMB will be more diligent about ensuring that licensees receive written notification of any investigation extending beyond six months

The NCMB investigation process prioritizes conducting an appropriate investigation and relying on consistent methods for collecting and evaluating information. Looking at NCMB's annual reports, NCMB closed cases within an average of 104 days in 2019; 113 days in 2020; and 127 days in 2021. This means on average, not only was NCMB investigating cases within six months, but it was closing cases within six months. While OSA's audit indicated a seemingly high number of cases requiring greater than six months to investigate, this result was skewed by the most complex cases resulting in public action. When looking at aggregated data from all public and private cases, a vast majority of cases are closed within six months, averaging a little more than four months. Nevertheless, there are cases where the investigation needs to be extended beyond six months and the law clearly allows that extension as long as licensees are provided a written explanation of the circumstances and reasons for the extension.

Recommendation
OSA recommends the Medical Board should complete all investigations of medical providers within the six-month timeframe as required by state law and that it should redesign its investigative process so that investigations are completed within the six-month timeframe required by law.

NCMB Response: As mentioned above, the law allows investigations to extend beyond six months if NCMB provides written notice to the licensee explaining that the investigation is ongoing, and the primary issue of this audit was whether those notices were provided. As of November 2021, all licensees with investigations extending beyond six months are automatically issued a written notice of the investigation extending beyond six months and reasons for the extension. NCMB realized and acknowledged that its prior notification process did not always meet that standard and was already taking steps to improve the process before OSA's initiation of the audit in July 2021. In 2020, NCMB purchased a new software database that would enable it to improve the management of its case files, including tracking the timeline of investigations. The software went live in November 2020 and an automated process for sending notices of extended investigations to the licensees began in November 2021. While there were some technical difficulties, those issues have been resolved and the system has been in place without issue since August 2022. For this reason, we consider this recommendation complete.

Even though NCMB is in compliance with the law, there are other steps NCMB has taken to improve its investigative processes because NCMB aims to continuously improve its operations and processes. For complaint investigations, notice of investigation letters to licensees now include a reference to the rule informing them that failure to respond in a timely manner may be

considered grounds for disciplinary action.[2] Adding this additional language to the notice encourages quicker response times to inquiries and can shorten the time of the investigation.

In addition, NCMB approved its budget in September 2022, which implements some changes to the investigations department. The approved budget included funding for additional personnel, including a Director of Administrative Investigations, who will be responsible for the day-to-day operations of the intake and processing of annual complaints received; a Director of Field Investigations, who will assist the Chief Investigative Officer in managing the day-to-day operations of field investigations; an Out-of-State Field Investigator, who will address investigations commenced based on an action by another state's medical board and serve as liaison to other state medical boards; a Medical Records Manager, who will manage a new medical records section created to organize and improve the review process; four new medical records coordinators, who will organize and handle the expert review process of medical records; and a Complaints Intake Coordinator, who will report to the Administrative Investigations Section Manager (formerly known as the Complaints Section Manager) to assist with the increased volume of complaints, which is projected to exceed 3,300 annually.

Key Finding

3. *Lack of Monitoring and Enforcement of Disciplinary Actions Increased Risk to Patient Safety*

NCMB Response: OSA's opinion is unjustified for the following reasons:

- OSA implies that NCMB failed to follow industry best practices for monitoring compliance with regulatory actions and provisions when, in fact, no such standards exist for medical regulatory authorities. OSA inappropriately applied best practices developed by the National State Auditors Association to medical board regulatory actions, without regard to the unique content of medical regulatory actions. OSA did not hire any experts in medical regulation for this audit.

- OSA, despite repeated requests by representatives of NCMB, did not investigate or discuss the monitoring programs of any other occupational licensing agencies ("OLA") in North Carolina or any other U.S. jurisdiction.

- OSA has no evidence or reasonable basis to state that NCMB's established system of monitoring compliance put patients at any risk of harm. OSA assured NCMB that the audit was not conducted in response to any complaints or allegations from the public.

NCMB consulted with various OLAs in North Carolina, other state medical boards, the Federation of State Medical Boards, and other federal and state agencies with disciplinary authority and determined that no agency has a monitoring program that OSA recommends NCMB should have. All these agencies rely on other means and methods to identify individuals who may be violating orders of revocation or suspension, primarily via complaints and reports from the public.

[2] See 21 NCAC 32 N .0107(b).

The purpose and goal of NCMB's monitoring program is to retrain, reeducate, remediate, and rehabilitate licensees in an effort to improve a licensee's competence and ability to practice medicine in accordance with NCMB's powers and duties outlined in N.C. Gen. Stat. § 90-5.1(a)(8)-(10). Disciplinary actions fall into two categories: requiring a licensee to take an action and prohibiting a licensee from an activity. It was NCMB's standard practice to monitor individuals who were required to take an action, such as completing Continuing Medical Education, having a chaperone, or submitting to an evaluation for the purposes of improving their practice. The audit report identified 54 monitoring cases, with only 8 requiring the licensee to take an action. OSA provided little to no guidance on why the monitoring in these cases was not sufficient and did not offer any guidance, standards, or best practices used by other state licensing boards or other state medical boards to clarify on how any errors might be corrected.

However, a majority of the audit results involved disciplinary actions that required the licensee to refrain from an activity, primarily not practice medicine because their license was suspended or revoked. NCMB can improve its monitoring processes in some of these cases: it can confirm a licensee's employment has been terminated or that a practice has closed after the disciplinary action has been finalized. However, the difficulty lies within continually tracking and surveilling a licensee's activities, especially in their private residences, in other states, and in federal facilities outside NCMB's jurisdiction, which are specific steps that would be required in many cases reviewed for the audit.

Without specifically pointing to any model monitoring programs of other state agencies, OSA has suggested that the "best practice" includes continuously monitoring licensees' websites, former practice addresses, and social media pages to confirm that licensees are not practicing medicine. There may be certain constitutional protections that could prohibit or limit the effectiveness of such monitoring.

Furthermore, the act of practicing medicine without a license in North Carolina is a crime. NCMB does not have the authority to enforce criminal law. It is within the authority of law enforcement to investigate crimes involving the unlicensed practice of medicine and the district attorneys' offices to prosecute those crimes. NCMB assists and cooperates with authorities in such matters, but it is ultimately beyond NCMB's authority to enforce the criminal law prohibiting the unlicensed practice of medicine.

Recommendation

OSA recommends NCMB should monitor and enforce disciplinary actions against medical providers for the maximum protection of public health and safety. NCMB should create policies and procedures that outline how monitoring and enforcement of disciplinary actions should be performed. Specifically, policies and procedures should include details on: (1) how often and how much monitoring and enforcement to perform, (2) how to track and document monitoring and enforcement activities, and (3) how to determine when stricter monitoring and enforcement is necessary.

NCMB Response: While there is no model or guidance that any other agency has such a monitoring program that OSA claims NCMB should have, NCMB strives to become a

progressive nationwide leader in medical regulation. NCMB does acknowledge the absence of formalized policies outlining its monitoring program and those are in process of being developed. In addition, NCMB's Legal Department has taken the following steps to improve monitoring of licensees by:

- Initiating work on a new section on the NCMB website with Compliance FAQs and forms for licensees to complete, including CME approval, supervisor approval, and practice site approval to make the process more efficient.

- Adding more administrative resources to the Compliance Section to tracks compliance with NCMB's disciplinary orders to assist with the increased workload.

- Adding staff to monitor licensee's websites and social media postings for activities that are prohibited.

Additional Clarifications

In its report, OSA references several examples of licensees billing Medicaid for services during periods of suspension covered by disciplinary orders. NCMB repeatedly requested further information and evidence in order that it might investigate these providers for violations of any NCMB disciplinary order. OSA declined to provide any evidence supporting these allegations and as such the NCMB is unable to ascertain whether, (1) the examples are in fact true; (2) NCMB can take disciplinary action against these licensees for violating any disciplinary orders; and (3) whether those individuals committed a crime that should be reported to local law enforcement.

Conclusion

Our vision at NCMB is to be proactive and progressive and we are committed to integrity, excellence, and accountability. We appreciate any opportunity to further that vision and our service to the public. Throughout this audit, NCMB has cooperated with OSA to the maximum extent its technical, statutory, and workforce limitations allowed. We thank OSA for its service to North Carolina, but it is important that we point out clarifications to this report.

State and federal regulations do not authorize NCMB to provide OSA unrestricted access to confidential investigative information, including the private health information of the people of North Carolina. The law also does not require NCMB to complete investigations within six months; it clearly allows investigations to extend beyond six months as long as NCMB keeps the licensee informed. There were issues with the process of providing formal written notice of extensions to licensees, and that process has been corrected.

NCMB has limited practical and effective ways of monitoring suspended licensees and enforcing its orders of suspension and revocation. Licensing boards must rely on law enforcement to enforce and sanction those who engage in the unauthorized practice of a profession. Nevertheless, there are improvements that can be made to ensure that former licensees are not practicing without a license. While NCMB can never prevent a licensee from engaging in

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prohibited behavior, it will continue to be vigilant and assist other agencies in protecting the public to the extent it is able.

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This audit required 3,605.5 hours of auditor effort at an approximate cost of $431,085.