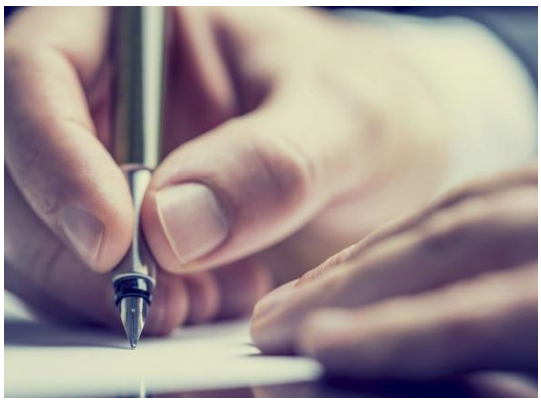
NORTH CAROLINA MEDICAL BOARD

Expert Reviewer Manual



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The purpose of this manual is to describe the North Carolina Medical Board's ("Board") processes, guidelines, and expectations for review of quality of care cases by qualified external expert healthcare providers ("Reviewers"). The Board greatly appreciates your willingness to serve as a Reviewer. You are an important part of the Board's mission to protect the public.

The Role of the Board in Quality of Care Cases

The Board is an agency of the State of North Carolina organized under Chapter 90 of the North Carolina General Statutes and is charged with the responsibility for licensing physicians, physician assistants, anesthesiologist assistants and perfusionists to practice in North Carolina and regulating such practice in the interest of the public health, safety, and welfare. The Board also jointly regulates Nurse Practitioners with the North Carolina Board of Nursing and Clinical Pharmacist Practitioners with the North Carolina Board of Pharmacy.

The Board investigates licensees and assesses applicants in a variety of subject matters areas, one of which is quality of care. A quality of care matter is generally considered to be something that involves care rendered to a patient and it can arise (a) when an applicant applies for licensure in North Carolina and (b) after licensure has been granted in North Carolina. Quality of care matters usually come to the Board's attention in the following ways:

1. A complaint is made to the Board by an individual.

2. A professional liability (malpractice) settlement or verdict is reported to the Board.

3. A change in hospital staff privileges is reported to the Board.

4. An action is taken by another regulatory board or agency and reported to the Board.

When matters such as these are reported to the Board, the Board usually investigates. The first step in the investigative process with quality of care cases involves assembling materials that are relevant to the investigation. These usually include some combination of the following:

1. Complaint, professional liability (malpractice) settlement or verdict report, change in hospital staff privileges report or document reflecting action taken by another regulatory board or agency.

2. Licensee or applicant response and explanation.

3. Relevant treatment records from the applicant or licensee being investigated.

4. Prior, concurrent and subsequent treatment records from other medical providers relating to the care at issue.

5. Other documents relevant to the case (i.e., surgical infection rate statistics, North Carolina Controlled Substance Reporting Service Records, billing records, etc.).

Once these materials are obtained, they are reviewed by members of the Board's Office of Medical Director ("OMD") and Legal Department. At this point, Board staff may determine that the case should be sent for an "external expert review" ("Expert Review") so that a Reviewer can review the case and offer an opinion (usually in written report form) on whether the care provided met the minimum standard or not. A Board

Member may also request an Expert Review. Regardless of who requests the Expert Review or when it is requested, the process is generally the same. Once the Reviewer's report is received, it becomes part of the investigation or licensing file and is reviewed by Board staff and Board Members.

> ***Key Point***
> *Submitting a case for review does not necessarily imply there were departures from the minimum standard.*

The Board usually uses Reviewers in quality of care cases to assist them in determining whether the applicant's or licensee's care was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered. For the purposes of this manual, a Reviewer is generally a healthcare provider who, based on their education, training, skill, and experience, has sufficient knowledge such that Board staff and Board Members can rely on the Reviewer's opinion about the patient care under review.

While the Board has at times used Reviewers with other types of licenses, physicians are used most frequently. Reviewers are generally expected to be in practice and have sufficient credentials at or around the relevant dates of treatment that they are reviewing. For example, a person would not be chosen to review a case where they were in medical school or a resident at the time the relevant treatment was rendered. Generally, Reviewers have the following credentials and experience:

1. A full and unrestricted active North Carolina medical license at or around the dates of treatment at issue in the case.

2. ABMS or AOA board certification at or around the dates of treatment at issue in the case.

3. Engaged in the same or similar area of practice, or performed the same or similar procedure, at or around the dates of treatment at issue in the case.

The main question that the Board has to answer in a quality of care case is whether the care at issue was within or below the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered with respect to diagnosis, treatment, and documentation. The Board relies on Reviewers to assist them in making this determination. In order to conduct an Expert Review, Reviewers are provided with what is referred to as a "Review Package" that contains all relevant materials for any given case. Depending on the specifics of the case, the Review Package may include all or some of the investigative case files reviewed by Board Members and Board staff. Reviewers are also provided with an Expert Reviewer Worksheet to assist them in creating their report and a cover letter to identify any specific issues to address. If you believe that additional information is needed to render an opinion outside of what is sent to you in a Review Package, do not hesitate to ask us and we will endeavor to obtain that information. You should not complete your report and render an opinion unless you can do so with the materials provided in the Review Package (and any outside reference materials you may review) within a reasonable degree of medical certainty.

To assist you in the process of establishing an adequate foundation for your opinion, you may refer to, and we ask that you include in your written report, a copy of all specific reference materials that you utilize in connection with your review, such as peer-reviewed journal articles, recognized specialty society guidelines, textbook articles, and other relevant medical literature.

The Board is not looking for a specific result in any given case prior to sending a case out for Expert Review. The Board is concerned that your opinion (whatever it may be) is correct, that you have competently

reviewed the case and provided a credible, detailed and explanatory opinion that you can comfortably defend. You should recognize that submitting a case for Expert Review does not necessarily imply there was a departure from the minimum standard. Your opinion should be based on your knowledge of the accepted minimum standard, using your education, training, experience, and knowledge. It is important to recognize that, as a Reviewer for the Board, you are neither an advocate for the Board nor an advocate for the licensee or applicant being investigated.

Standards for Board Regulatory Action

The Board has authority to take action against North Carolina applicants and licensees regardless of their physical practice location for violations of the laws and rules governing the practice of medicine in North Carolina. This authority extends to out of state North Carolina telemedicine practitioners providing care to patients located in North Carolina. It also extends to practitioners relating to care provided outside of North Carolina. This authority generally includes the power to place on probation with or without conditions, impose limitations and conditions on, publicly reprimand, assess monetary redress, issue public letters of concern, mandate free medical services, require satisfactory completion of treatment programs or remedial or educational training, fine, deny, annul, suspend, or revoke a license, or other authority to practice medicine.

Your determination of whether the treatment under review was within the minimum standard will help the Board determine what action to take. The Board may take action in quality of care cases for any of the following reasons:

- Unprofessional conduct including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, or the ethics of the medical profession, irrespective of whether or not a patient is injured thereby, or the committing of any act contrary to honesty, justice, or good morals, whether the same is committed in the course of practice or otherwise, and whether committed within or outside of North Carolina.

- Lack of professional competence to practice medicine with a reasonable degree of skill and safety for patients or failing to maintain acceptable standards of one or more areas of professional practice. In this connection the Board may consider repeated acts of failure to properly treat a patient.

If you are reviewing care provided by a resident (physician in training), physician assistant, anesthesiology assistant, nurse practitioner, or perfusionist, you should know that failure to meet the acceptable and prevailing minimum standard when delegating care to others, supervising care by others or collaborating with others to provide care may also be grounds for the Board to take action against the delegating, supervising or collaborating provider.

If you are reviewing a case that involves experimental or nontraditional medicine, you should know that the Board may not take action against an applicant or licensee in any manner, solely because the practice uses a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practice unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.

Reviewer Assignment

Board staff identify potential Reviewers and contact them to determine if they are available, have sufficient expertise or experience to review a case, and if any conflict of interest exists. Because medicine is an ever-

changing profession, Reviewers must have experience with, or knowledge of the treatment or procedure involved during the timeframe of the issues in question. If, after accepting a case for review, you find that your education, experience, or background makes you not suited to review the case, or other commitments preclude you from meeting the completion deadline, or for any reason you need to be excused from the case (for example to avoid a potential conflict of interest), immediately notify Board staff.

Timely Review Completion and Report Submission

Because cases referred for review are potentially serious, the Board requests completed review reports be returned within 30 to 45 days. The Board recognizes that case review is a time-consuming process and often Reviewers are busy with their own practice. However, because substandard care poses a potential threat to the public, the Board requests that reviews be completed promptly.

Confidentiality

Reviewers are expected to maintain the confidentiality of all information and materials sent to them by the Board as part of the review process. Reviewers are not permitted to divulge any information about the case with anyone other than Board staff.[1] Reviewers must maintain the confidentiality of the identity of all persons involved, all medical records and any other information included in the Review Package. Reviewers should not contact any Board Member or any of the patients, practitioners or other persons involved or under review. If additional information is needed from any of these sources, the Reviewer should address questions to Board staff. Reviewers are encouraged to perform any literature research necessary to assist them, but should not make any effort to investigate or obtain additional facts of the case further. Posting or discussion of any aspect of a case on social media, even if anonymous or disguised, is not permitted.

Key Point

Reviewers must scrupulously maintain the confidentiality of persons, medical records, and all other information related to case review.

Conflicts of Interest

Objectivity is vital to the integrity of the review process. It is incumbent on Reviewers to conduct their reviews in an impartial manner. To ensure impartiality and the integrity of the review process, Reviewers should not participate in any review in which there is the potential for a conflict of interest. If you have personal knowledge of the individuals involved, you have current or former business relationships, or if you feel you cannot be objective for any reason, do not accept the case. Reviewers should not accept cases under the following circumstances:

Key Point

Reviewers should not participate in any review where there is the potential for conflict of interest.

1. The Reviewer has/had a close personal, professional, or business relationship with the applicant or licensee or their immediate family which would bias, or appear to bias, the Reviewer's judgement.

2. An arrangement exists in which the Reviewer routinely refers patients or receives referrals from the applicant or licensee under review.

3. The Reviewer has treated any of the patients whose care is under review.

[1] Reviewers may, on occasion, consult with professional colleagues regarding general medical aspects of a case they are reviewing, but must maintain the strict confidentiality of the identity of the applicant or licensee and patients under review.

4. The Reviewer's practice competes with that of the applicant or licensee under review.

5. The Reviewer has knowledge of, or information about, the applicant or licensee other than that related to the current investigation, which could bias or appear to bias the Reviewer's judgment about the case under review.

6. The Reviewer has previously formed an opinion about the practice, skills, or character of the applicant or licensee under review which might bias (positively or negatively) the Reviewer's assessment of the present case.

7. The Reviewer practices in the same hospital or practice setting as the applicant or licensee under review.

Consider these issues carefully. Failure to disclose a conflict of interest has serious consequences. If a Reviewer has a conflict of interest, but agrees to review a case, the investigation of the case may be significantly delayed or adversely affected. Reviewers who are unsure whether a possible conflict of interest exists should contact the Board staff they are working with to determine the propriety of a Reviewer's participation in the case.

Key Point
Failure to disclose a conflict of interest has serious consequences.

Civil Immunity
Reviewers for the Board are provided with statutory immunity from civil liability for their good faith service as a Reviewer by North Carolina General Statute § 90-14(f), which provides:

> *(f) A person, partnership, firm, corporation, association, authority, or other entity acting in good faith without fraud or malice shall be immune from civil liability for (i) reporting, investigating, assessing, monitoring, or providing an expert medical opinion to the Board regarding the acts or omissions of a licensee or applicant that violate the provisions of subsection (a) of this section or any other provision of law relating to the fitness of a licensee or applicant to practice medicine and (ii) initiating or conducting proceedings against a licensee or applicant if a complaint is made or action is taken in good faith without fraud or malice. A person shall not be held liable in any civil proceeding for testifying before the Board in good faith and without fraud or malice in any proceeding involving a violation of subsection (a) of this section or any other law relating to the fitness of an applicant or licensee to practice medicine, or for making a recommendation to the Board in the nature of peer review, in good faith and without fraud and malice.*

Your immunity from civil liability does not apply if you conduct an Expert Review with "fraud or malice." Malice in this context means intentionally or recklessly committing a wrongful act in the course of your work for the Board as a Reviewer. If you act in good faith and follow the guidelines in this manual, you will be provided immunity by law. If you disregard these guidelines intentionally or are careless about following them, you may lose it. Discussing a case with any person outside the Board review process is an example of an activity that could result in the loss of immunity for a Reviewer and the denial of the confidentiality protection and due process rights provided by law to the applicant or licensee under review.

Standard of Care
Although a case submitted for Expert Review by the Board may originate as a malpractice lawsuit, it is

important to understand that the law for evaluating the care in a malpractice lawsuit is different from the law relating to a quality of care case for the Board. Specifically, in most cases the Board asks that you assess whether the care is within or below the minimum statewide standard for North Carolina. You should not evaluate the case based on what you may consider your personal standard of care, but rather on what a reasonably prudent healthcare provider in North Carolina would do under the same or similar circumstances. In this regard, it is appropriate to consider or comment on the circumstances under which the care was provided. For example, care provided at a small rural hospital with limited resources might not be the same as that available at a large academic facility with access to additional resources.

What to Write in Your Report

You will be provided with an Expert Reviewer Worksheet for your case review. A sample worksheet with a sample review is included at the end of this manual. Although not mandatory, use of the Expert Reviewer Worksheet is encouraged.

Generally, your report should provide a summary of the care at issue, explain what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required for the diagnosis, treatment, and documentation that you reviewed for a patient and why that standard was either met or not met. It is not sufficient to say, "I would have done it differently . . .", "I would not have done this . . . " or "the preferred approach to this problem is . . . " You should state what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required, whether the care you reviewed met that standard, and why the care did or did not meet that standard.

You may find that the care was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered. If that is the case, do not hesitate to say so. However, if you believe that the care was below the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered, you should focus on explaining how, why, and to what degree the care provided fell below the minimum standard. If your opinion is that some aspects of the care were within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered and some aspects were below that standard, please explain that in detail.

Here are some specific things to consider when you review a case and write your report:

1. A summary of the care provided should be described in your report. You are welcome to provide a chronology of care if that assists you in writing your report.

2. If you find conflicting, confusing, or contradictory information from various sources in your review, please identify them and explain how that impacts your review.

3. If it is not possible to determine whether the minimum standard of care was met, based on the information provided for review, you should indicate this. If you believe additional information or material might allow you to form an opinion, you should contact Board staff to determine if this additional information is available. You should not attempt to obtain any additional information about the case on your own.

4. The Board expects the Reviewer to be familiar with relevant published guidelines and references and, if used to assist in the review, to cite those guidelines and references and provide copies of them. Providing this information will assist the Board in reviewing the report.

5. On occasion, the Board may be interested in your review of a specific limited period of time in a

patient's care. For example, the Board may want the care of a patient reviewed only for the time following completion of remedial CME. In these cases, you will receive specific instructions with a defined period of time to restrict your review. The documents provided to you may include the patient's entire medical record. However, under these circumstances you should limit your review to the time period specified. If you have any questions in this regard, do not hesitate to contact Board staff for additional information.

6. You may also include additional comments or statements regarding other concerns including, if relevant, a discussion of extenuating factors or issues, even if they are not the focus of the case. There also may be ethical or professionalism lapses that you feel contribute to the issues of the case under review. These concerns should also be included in your report. Any issues you believe require further investigation by the Board or possibly by another reviewer in another specialty should also be mentioned, but in a separate communication to Board staff (i.e., email or telephone call).

7. Cultural competency. Not all cultural competency issues relate to foreign languages or cultures. Cultural competency encompasses gender, gender orientation, socioeconomic status, faith, profession, disability, and age, as well as race and ethnicity. Reviewers for the Board should be sensitive to, and be respectful of, all diverse patient communities. The Board will not tolerate culturally biased comments, observations, or statements in reviews submitted to the Board.

8. Disparaging, inflammatory, or frivolous remarks must be avoided and should never be contained in your report.

The Board will rely, to a substantial extent, on your report to determine what action, if any, to take. Based on consideration of all investigative information available, including your report, the Board may choose to take no action, attempt remediation, or take various types of public action or deny a license application. If public action or application denial are not pursued, the Board may use your report to provide guidance to the licensee or applicant regarding ongoing care and future practice changes that are expected. It is therefore critical that your report be thorough, detailed, and supported by a discussion of the case materials you have reviewed.

What Happens to Your Report When You Send It to The Board

Once your completed report is returned to the Board, it will be reviewed by Board staff to ensure that the report contains all the essential elements needed for an expert opinion and that all the questions in the Expert Reviewer Worksheet are answered. If clarification or more information is needed, you may be sent follow-up "Addendum" questions to answer. Once the report is complete, Board staff will make recommendations based on your report and it will then go to the Board for review. Ultimately, the Board determines how to proceed with the case. The Board has considerable discretion and may take one of the following actions:

- Accept as information. The Board may close the case or issue a license without further action. This usually happens in cases where the care is found to be within the minimum standard.

- Private Action. The Board frequently uses Interim and Private Letters of Concern in cases where the Board has concerns about the care provided, but the concerns do not rise to the level of public action or denial of licensure. These letters are a confidential communication between the Board and the applicant or licensee and may request that topic specific CME or other remediation be done. The Board may rely on the information from your report to advise the applicant or licensee of

specific concerns and recommend corrective action. These private actions become part of the applicant's or licensee's permanent internal Board record. Although the Board may share this information with other state medical boards and other regulatory agencies, these letters are not available to the public in most situations.

- Formal Charges or Denial of Licensure. In the event that your report establishes grounds for initiating formal disciplinary action or denying a license application and the Board elects to proceed, the Board may file public disciplinary charges or deny an application.

Reviewer's Involvement in the Hearing Process
Part of being a Reviewer means agreeing in advance to be available to testify at a deposition and a hearing if necessary. Less than 5% of all cases sent for Expert Review result in a Reviewer testifying at a deposition and a hearing.

If a disciplinary or denial hearing is scheduled, then your report will likely be shared with the applicant or licensee whose care you reviewed, and you may be asked to testify at a deposition and a hearing. If that happens, you will be contacted in advance by a Board attorney who will work with you to schedule mutually convenient dates and times to discuss the case, conduct your deposition and, if needed, prepare you for hearing testimony. If you have questions at any time about the status of the case, you may call the Board staff person assigned to the case.

Payment
You will receive One Hundred and Seventy-Five Dollars ($175.00) per hour for your review of case materials and completion of your report. Time spent for a pre-hearing deposition, preparing to testify at a hearing, and testifying at a hearing is reimbursed as outlined in the fee schedule attached at the end of this manual. Discuss any concerns you have about compensation with Board staff before accepting the case for review.

Conclusion
The Board is very appreciative of your willingness to review cases for the Board. Your time and effort are highly respected and critical to the Board's mission to regulate the practice of medicine for the benefit and protection of the people of North Carolina.

Frequently Asked Questions

Who will see my report, and can I remain anonymous?
The Board maintains the confidentiality of reports submitted by Reviewers to the extent allowed by law. Should the case proceed to a stage where a disciplinary or denial hearing is scheduled, the applicant or licensee and their legal representative (if they have one) will be provided with a copy of your report and you may be asked to testify at a deposition and a hearing. Be aware that once a case proceeds to a hearing, your report may become a public record.

What is expected if I am asked to provide expert testimony?
- Be truthful.
- Be prepared. Review the case documents and your report before the hearing and deposition.
- If the opinions you express at a hearing are inconsistent in any way with those you expressed in your written review or deposition, explain how and why your opinion has changed.
- Listen to the questions and answer responsively and honestly. Don't be argumentative or non-responsive.
- Work with the Board attorney before testifying.
- Dress professionally and maintain a professional demeanor.

Can I be sued for serving as a case reviewer for the Medical Board?
North Carolina General Statute § 90-14(f) provides civil immunity for Reviewers when their review is provided in good faith and without fraud or malice.

What should I include in my report?
When you write your report, you should provide a summary of the care at issue, explain what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required for the diagnosis, treatment, and documentation that you reviewed and why that standard was either met or not met. It is not sufficient to say, "I would have done it differently . . .", "I would not have done this . . . " or "the preferred approach to this problem is . . . " Generally, you should state what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required, whether the care you reviewed met that standard, and why the care did or did not meet that standard.

Can I do research while reviewing a case and preparing my report?
Yes, you may consult peer-reviewed journal articles, medical texts, and other relevant reference materials. Please identify any references used in your review and provide copies of all such references. You should not discuss the case specifics with other physicians, Board members, or anyone else; although reviewers may, on occasion, consult with professional colleagues regarding general aspects relating to a case they are reviewing. As always, you must maintain the strict confidentiality of the identity of the healthcare providers and patients under review and scrupulously protect the confidentiality of those involved.

What if additional information is needed to form an opinion?
Contact the Board staff who sent you the initial materials to review to request any additional information you need to complete the review.

How long do I have to review the case and complete my report?
You are asked to complete your review as expeditiously as reasonably possible and usually within 30 to 45 days of receipt of case materials. Some cases are voluminous and involve multiple patients and, in those situations, additional time is allocated.

How much time should I spend on medical record review and report completion?
Please contact Board staff if your review process will require more than Three (3) hours per individual patient

medical record or Ten (10) hours in total. Some cases may involve several charts. The Board recognizes these cases are often complex and may require more time to complete. In those situations, you should request additional time from Board staff prior to proceeding.

How much will I be paid?
You will receive One Hundred and Seventy-Five Dollars ($175.00) per hour for your medical record case review and completion of your report. Time spent on a pre-hearing deposition, preparing to testify at a hearing, and testifying at a hearing is reimbursed as outlined in the fee schedule at the end of this manual.

What should I do with the case materials after I have completed my review?
Unless instructed to return the case materials that were sent to you (i.e., original pathology slides), the materials need not be returned to the Board. Due to the sensitive nature of all documents related to the case, please securely destroy all materials once the case has been concluded.

What should I do if medical records or other documents associated with a case are lost or stolen?
Case materials should be maintained in a secure manner as would be expected with any confidential patient information. If materials are stolen, lost, or misplaced, please contact the Board staff person assigned to the case for instructions on how to proceed.

Expert Reviewer Worksheet with Case Example Provided

NORTH CAROLINA MEDICAL BOARD

Expert Reviewer Worksheet

(Please type within this worksheet or attach a separate typed report)

Licensee or Applicant Name:

Patient Name:

Reviewer Name:

Case No.:

PATIENT DOCUMENTATION

It is important that you formulate your opinion(s) within a reasonable degree of medical certainty and that you feel confident that you can defend the same. Please confirm that you have been provided with and reviewed all documentation necessary to formulate your opinion. (**If you need additional documents, please notify Board staff so that they can request what you need and provide you with a copy to review**).

__X_Yes, I have received and reviewed all documents necessary for me to properly formulate my opinion(s).

GUIDELINES, ARTICLES, TEXTBOOKS AND OTHER AUTHORITIES

If you are using any specific guideline, article, textbook or other authority to assist you in formulating your opinion(s) relating to what the minimum standard of acceptable and prevailing medical practice in North Carolina was at the time the care was rendered in this matter, please reference all such authorities, and provide full and complete electronic copies of all such authorities. Please confirm below that you have done this.

_X__Yes, I represent that, if I have utilized any such authorities, they are referenced and attached.

INSTRUCTIONS

When answering the questions below, please explain what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required for the diagnosis, treatment, and documentation that you reviewed for this patient and why that standard was either met or not met. It is not sufficient to say, "I would have done it differently . . .", "I would not have done this . . . " or "the preferred approach to this problem is . . . " You should state what the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered required, whether the care you reviewed met that standard, and why the care did or did not meet that standard.

It is also important to understand that, unless otherwise requested, the Board asks that you assess whether the care is within or below the statewide standard of care for North Carolina. You should not evaluate the case on the basis of what you may consider your personal standard of care, but rather on what a reasonably prudent healthcare provider in North Carolina would do under the same or similar circumstances. In this regard, it is appropriate to consider and comment on the circumstances under which the care was provided. For example, care provided at a small rural hospital with limited resources might not be the same as that available at a large academic facility with more and different resources.

You may find that the provider's care was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered. If that is the case, do not hesitate to say so. However, if you believe that the care was below the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered, you should focus on explaining how, why, and to what degree the care provided fell below. If your opinion is that some aspects of the care were within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered and some aspects were below that standard, please explain that in detail.

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CASE REVIEW

Based on your background and experience and review of the information provided to you, can you form an opinion as to whether the care rendered by the care provider met or was below the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the care was rendered?

_X_ Yes, I can form an opinion.

__ No, I cannot form an opinion. Please explain why:

CASE SUMMARY

Please provide a description of the symptom(s), diagnosis, and course of treatment provided to the patient below.

DESCRIPTION:

The patient is a 70 year old male with a history of hypertension and generalized pruritus secondary to small fiber neuropathy. He presented to Doctor on 1/15/2025 with itching of his arms. The patient has had a diagnosis of small fiber neuropathy for five years which, at the time of the visit in question, he stated caused constant tingling in his hands, legs, and feet as well as intense itching interfering with sleep on both arms and the scalp. He asked Doctor for medication to help treat this issue.

Doctor discussed options for the treatment of generalized pruritus including gabapentin, doxepin, and naltrexone. Gabapentin and doxepin were deemed to be contraindicated for the patient due to an association with suicidal ideation in the distant past. He was therefore prescribed naltrexone 4mg daily at that visit to help with itching.

The patient took his first dose of one 4mg naltrexone pill on the evening of 1/16/2025. Two hours later, the patient states he unconsciously fell out of his bed and awoke with dizziness, and vomiting.

He was seen in the Anytown Emergency Department late in the evening on 1/16/2025. EKG and labs were normal. He was diagnosed with a likely side effect from the naltrexone. He states he experienced seizures for the subsequent 3 days. The complaint alleges that the naltrexone caused his seizures for these three days.

OPINION

PART 1: DIAGNOSIS

Based on your review, was the diagnosis within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered? Please state yes or no.

_X_ Yes, the diagnosis was within the minimum standard of acceptable and prevailing medical practice.

__ No, the diagnosis was below the minimum standard of acceptable and prevailing medical practice.

If your answer is yes, please explain in detail why the diagnosis was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered.

EXPLANATION:

The patient had a long history of previously diagnosed small fiber neuropathy. This resulted in itching on the upper extremities, which had been present for five years. He was diagnosed and treated previously by a neurologist at Anytown Medical Center. The itching that he has experienced has not changed in quality in five years and there is no reason to suspect that there was a cause other than his prior diagnosis. This diagnosis of

small fiber neuropathy is therefore within the minimum standard of acceptable and prevailing medical practice in North Carolina.

If your answer is no, please explain in detail what the correct diagnosis should have been and what a reasonably prudent provider should have done to enable the provider to reach the correct diagnosis at the time it was rendered. If your opinion is that some parts of the diagnosis met the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered and some parts did not, please explain that as well.

EXPLANATION: N/A

PART 2: TREATMENT

Based on your review, was the treatment rendered within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered? Please state yes or no.

__X__Yes, the treatment was within the minimum standard of acceptable and prevailing medical practice.

____No, the treatment was below the minimum standard of acceptable and prevailing medical practice.

If your answer is yes, please explain in detail why the treatment was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered.

EXPLANATION:

Naltrexone is an opioid receptor antagonist. Low dose naltrexone is one available treatment option for refractory pruritus and is within the minimum standard of care in North Carolina to be prescribed. It is considered a safe and effective alternative treatment for patients with severe pruritus. Given the impact that this patient's pruritus had on his life and sleep, naltrexone was an appropriate option.

Typical dosing ranges from 12.5 to 50mg per day. The dose of 4mg that was prescribed is considered a low, but appropriate initial dose. Side effects with naltrexone occur in approximately 11.1-38.5% of patients. The most common adverse effects of naltrexone are nausea, fatigue, dizziness, heartburn, and diarrhea. Syncope is a possible side effect of naltrexone. Seizures, however, are not typical.

There is nothing in the patient's history that makes prescribing naltrexone contraindicated. Side effects are possible with any medication. Given that the patient only took one dose of naltrexone, the events that he had after taking the medication cannot reasonably be attributed to naltrexone given his other medical conditions.

If your answer is no, please explain in detail what course of treatment a reasonably prudent provider should have taken to meet the minimum standard of acceptable and prevailing medical practice in North Carolina at the time care was rendered and why. If your opinion is that some parts of the treatment met the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was rendered and some parts did not, please explain that as well.

EXPLANATION: N/A

PART 3: DOCUMENTATION

Based on your review, was the documentation created and kept in accordance with the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was created? Please state yes or no.

____Yes, the documentation was within the minimum standard of acceptable and prevailing medical practice.

__X__No, the documentation was below the minimum standard of acceptable and prevailing medical practice.

If your answer is yes, please explain in detail why the documentation was within the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was created.

EXPLANATION: N/A

If your answer is no, please explain in detail what was required to meet the minimum standard of acceptable and prevailing medical practice in North Carolina at the time the documentation was created. If your opinion is that some parts of the documentation met the minimum standard of acceptable and prevailing medical practice in North Carolina at the time it was created and some parts did not, please explain that as well.

EXPLANATION:

There is no documentation of a physical examination of the arms in the visit note on 1/15/2025. The examination section of the note states that "an examination was performed including the right foot and left foot." The note does state that "patient exhibits pruritus", but a more in-depth examination is needed to be done and documented in order to comply with the minimum standard of acceptable and prevailing medical practice in North Carolina in January 2025. Given that a medication was prescribed to treat itching on the upper arms, an examination of the arms should have been performed and documented to see if there were any signs of erythema, scaling, or excoriations. This did not occur and is below the minimum standard for documentation.

Additionally, the minimum standard of acceptable and prevailing medical practice in North Carolina in January 2025 required documenting a discussion regarding the side effects of naltrexone. There is no mention of this in any of the documentation by Dr. Doe and that is below the minimum standard for documentation.

The remaining documentation is sufficiently detailed and within the minimum standard of acceptable and prevailing medical practice in North Carolina in January 2025.

2/1/2025	2.5	
Date of Review	Number of Hours	Signature of Expert Reviewer

North Carolina Medical Board
Reviewer Fee Schedule

Thank you for agreeing to review this matter for the North Carolina Medical Board ("Board") and prepare an expert report. Although unlikely, you may also be asked to testify at a deposition and a hearing to support and explain your expert opinion.

The Board appreciates your assistance and wants you to know that professional participation in the regulatory process is essential to protecting the public. The fees paid to you come from license application and renewal fees from applicants and licensees.

The Board pays the following fees/expenses for expert review and deposition and hearing testimony.

- **Medical Record Review, Document Review, Telephone Calls, and Authoring Expert Reports**
  - One Hundred and Seventy-Five Dollars ($175.00) per hour for medical record review, document review, telephone calls with Board staff and your time spent authoring expert reports.
  - If it appears that your review of this matter will take more than Three (3) hours per chart or Ten (10) hours of your total time, please contact the person who sent you the medical records at the Board before proceeding any further with your review to discuss how much additional time you estimate it will take you to complete your review and author an expert report(s).

- **Deposition Testimony**
  - One Hundred and Seventy-Five Dollars ($175.00) per hour for all time spent preparing for your deposition. This includes medical record review, document review, telephone calls and in-person meetings with Board attorneys and other staff.
  - Two Hundred and Fifty Dollars ($250.00) per hour for actual time spent testifying in deposition. This includes a minimum payment to you of Seven Hundred and Fifty Dollars ($750.00) (i.e., you will be paid Seven Hundred and Fifty Dollars ($750.00) if your total time spent being deposed is less than Three (3) hours).

- **Hearing Testimony**
  - One Hundred and Seventy-Five Dollars ($175.00) per hour for all time spent preparing for your hearing testimony. This includes medical record review, document review and telephone calls and in-person meetings with Board attorneys and other staff.
  - Three Hundred Dollars ($300.00) per hour for actual time spent waiting at a hearing site to be called to testify and testifying at a hearing. This includes a minimum payment to you of One Thousand Two Hundred Dollars ($1,200.00) (i.e., you will be paid One Thousand Two

Hundred Dollars ($1,200.00) if your total time spent waiting to be called and testifying is less than Four (4) hours).

- **Mileage, Travel Time, Food & Lodging**
  - The Board will pay you for all travel in your own vehicle at the current Internal Revenue Service mileage reimbursement rate in effect on the date of travel. In addition, the Board will pay you One Hundred and Twenty-Five Dollars ($125.00) per hour for travel time to and from a meeting site, deposition site or hearing site (or hotel site if you are arriving the day before a hearing).
  - The Board will pay for meals associated with your deposition and hearing testimony. The cost of any single meal shall not exceed Thirty Dollars ($30.00). Alcoholic beverages and meals for others are not reimbursable.
  - The Board will make and pay for any lodging reservations you may require. In the event you want to make your own lodging reservations, you will need to have this approved in advance by a member of the Board staff.