

Policy Regarding Inquiries and Allegations of Noncompliance that Arise Outside of the Accreditation Process

The North Carolina Medical Society (NCMS) has a multitiered accreditation process for evaluating a Provider's compliance with the NCMS's Rules. As an additional safeguard, this Policy Regarding Inquiries and Allegations of Noncompliance (this "Policy") is implemented in response to concerns about Providers' compliance with NCMS's Rules that arise outside of the accreditation process. This Policy is effective with regards to proceedings for which a Notice of Inquiry or a Notice of Immediate Suspension is sent by NCMS on or after December 11, 2018. NCMS reserves the right to amend this Policy at any time. This Policy is subject to regular review to ensure it continues to support the mission of NCMS.

A. Definitions

"ACCME" means the Accreditation Council for Continuing Medical Education.

"Adverse Action" means a reduction of a Provider's accreditation to Probation or Nonaccreditation.

"ARC" means Accreditation Review Subcommittee.

"Decision Committee" means a committee which consists of members of the Board of Directors of NCMS.

"Delivery" or "Delivered" means the date that NCMS sends a written communication to a Provider via email.

"Independent Reviewer" means a clinician with relevant content expertise who has completed NCMS's disclosure and conflict of interest process and for whom all conflicts have been resolved and documented, as determined by NCMS in its sole discretion.

"NCMS" means the North Carolina Medical Society.

"NCMS Initiated Concern" means a concern identified by NCMS, including without limitation as a result of communications with third parties.

"NCMS Policies" means all policies made available to Providers by NCMS.

"NCMS Rules" means NCMS Policies, Standards for Integrity and Independence in Accredited Continuing Education, and accreditation criteria required by the NCMS and NCMS.

"Notice of Alleged Noncompliance" means a written notice which explains why the Provider is in violation of NCMS's Rules.

"Notice of Inquiry" means a written notice which states that a Provider may not be in compliance with NCMS's Rules and, to the extent known, which aspects of the Provider's activities or conduct may not comply with NCMS's Rules.

“Notice of Noncompliance” means a written notice that includes the following: the Decision Committee found the Provider in noncompliance; corrective action required of the Provider, if any; any Adverse Action or other action described in Section C.6.ii of this Policy; and a statement that if the notice includes an Adverse Action, the Provider has the right to request a reconsideration of the change in accreditation status pursuant to the Reconsideration and Appeal Policy.

“Provider” means an NCMS accredited provider.

“Reconsideration and Appeal Policy” means the NCMS Procedures for Reconsideration and Appeal of Adverse Actions.

“Third-Party Concern” means concerns raised by third parties in writing regarding a Provider’s compliance with NCMS’s Rules.

B. Inquiry Process

1. NCMS will review Third-Party Concerns and NCMS Initiated Concerns that arise outside of the accreditation process.
2. If NCMS determines in its sole discretion that a Third-Party Concern or an NCMS Initiated Concern does not relate to a Provider’s compliance with NCMS’s Rules, then the matter will be closed, and NCMS will notify in writing any third parties that submitted Third-Party Concerns that it will not open an inquiry.
3. If NCMS, in its sole discretion, determines that a Third-Party Concern or an NCMS Initiated Concern merits further review, then NCMS shall send the Provider a Notice of Inquiry, which shall include a redacted copy of any Third-Party Concern, or state that the issue being addressed is an NCMS Initiated Concern. The name of the third party that submitted the Third-Party Concern will be redacted and will not be disclosed to the Provider. The Notice of Inquiry may request that the Provider transmit information to NCMS. The Notice of Inquiry shall include a copy of this Policy and the Reconsideration and Appeal Policy. NCMS will notify in writing any third parties that submitted Third-Party Concerns that it will open an inquiry. NCMS will not communicate further with third parties concerning the status or results of the inquiry other than to inform a third party that a matter has been resolved without indicating the resolution, in keeping with the Confidentiality policy described in Section D below.
4. The Provider shall transmit any information requested by NCMS in the Notice of Inquiry within twenty-one (21) days of Delivery of such Notice of Inquiry. If NCMS requests further information, the Provider shall provide such information within fourteen (14) days of Delivery of such further request. At any time during an inquiry process, the Provider may send NCMS a written notice stating that the Provider did/does not comply with one or more NCMS’s Rules identified in said notice, in which case the NCMS shall have the right to take any of the actions described in Section C.6 of this Policy; provided, however, that if NCMS in its sole discretion believes that the Provider may have violated NCMS’s Rules other than those identified in the Provider’s notice, NCMS may continue an inquiry.
5. As part of an inquiry related to NCMS’s content validity policies, the Provider shall submit to the NCMS, or provide access to, an unaltered set of all CME materials (e.g., audio/video recordings, slides or other content outlines, program book or other handouts) related to the CME activity at issue. If, upon receipt of the materials, the NCMS determines that an objective content review of the activity is necessary to determine compliance, the NCMS will

seek independent content reviews by at least two (2) Independent Reviewers. The Provider will pay any costs related to the review of the activity in excess of an amount which is determined by NCMS in its sole discretion, which amount will be posted on the NCMS website. The Provider has the option to submit its own independent content review to the NCMS within twenty-one (21) days of Delivery of the Notice of Inquiry.

6. NCMS, in its sole discretion, shall make a determination regarding compliance or noncompliance of the Provider. If NCMS makes a finding of compliance, the Provider shall be notified of the finding and the matter will be closed.
7. The statute of limitations for initiation of a Notice of Inquiry or a Notice of Alleged Noncompliance is: (a) twelve (12) months from the date a live activity ended, or in the case of a series, twelve (12) months from the date of the session which is in question; or (b) twelve months from the date that an enduring material expires; provided, however, that if a Notice of Inquiry is Delivered within the statute of limitations with respect to a matter, then a Notice of Alleged Noncompliance regarding such matter may be Delivered to a Provider even if it is after the end date set by the statute of limitations, and the proceeding regarding such Notice of Alleged Noncompliance may continue.

C. Process for Allegations of Noncompliance

1. If NCMS, in its sole discretion, concludes that a Provider is in noncompliance with NCMS Rules, NCMS shall send the Provider a Notice of Alleged Noncompliance. NCMS may send a Provider a Notice of Alleged Noncompliance without having conducted an inquiry as described in Section B of this Policy. If the alleged noncompliance relates to a violation of NCMS's content validity policies, the Notice of Alleged Noncompliance shall include copies of any Independent Reviewers' reports which are redacted so as to not disclose the identity of the Independent Reviewers. The redaction will remove the name and details of credentials which may reveal the identity of the Independent Reviewer. The Notice of Alleged Noncompliance shall include a copy of this Policy and the Reconsideration and Appeal Policy.
2. The Provider shall have the right to submit written materials, including, if the Provider desires, an independent content review, which rebut the alleged noncompliance identified in the Notice of Alleged Noncompliance within thirty (30) days of Delivery of the Notice of Alleged Noncompliance. At any time a Provider may send NCMS a written notice stating that the Provider did/does not comply with one or more NCMS's Rules identified in said notice, in which case the NCMS shall have the right to take any of the actions described in Section C.6 of this Policy; provided, however, that if NCMS in its sole discretion determines that the Provider has violated NCMS's Rules other than those identified in the Provider's notice, the NCMS shall send the Provider written notice of such determination and shall continue the process described in this Policy with respect to a Notice of Alleged Noncompliance.
3. NCMS has the right to submit any materials received from the Provider for independent content review by at least one Independent Reviewer. In addition, the NCMS has the right to request one or more individuals and/or committees to review and make recommendations regarding any matters which are being reviewed pursuant to this Policy.
4. NCMS shall review the materials submitted by the Provider as well as any content review reports requested by NCMS.

5. If NCMS, in its sole discretion, makes a finding of compliance, NCMS shall notify the Provider of the finding and the matter will be closed.
6. If NCMS, in its sole discretion, makes a preliminary finding of noncompliance, the preliminary finding of noncompliance and a recommendation for corrective action shall be sent to the Decision Committee. The Decision Committee shall in its sole discretion make a determination as to whether to issue a finding of compliance or noncompliance and what corrective action, if any, shall be required from the Provider in the event of noncompliance, and whether to take an Adverse Action and/or other any other action described in Section C.6.ii below.
 - i. If the Decision Committee makes a finding of compliance, NCMS shall notify the Provider of the finding and that the matter will be closed.
 - ii. If the Decision Committee makes a finding of noncompliance, NCMS shall send the Provider a Notice of Noncompliance. NCMS, in its sole discretion, may also take the following actions when it sends the Provider a Notice of Noncompliance:
 - a. NCMS may require the Provider to submit documentation of corrective action within thirty (30) days of Delivery of the Notice of Noncompliance. If an activity is found to be in noncompliance with the NCMS Standard for Integrity and Independence 1 (Ensure Content is Valid) or Standard for Integrity and Independence 2 (Prevent Commercial Bias in Marketing in Accredited Continuing Education), or Standard for Integrity and Independence 3.2 (exclude owners or employees of ineligible companies) the Provider is required to provide corrective information to the learners, faculty and planners (the "Corrective Information"). The Provider shall submit a copy of the proposed Corrective Information to NCMS for NCMS's approval or modification prior to providing such Corrective Information to the learners, faculty and planners, and NCMS shall have the sole discretion to determine the content of the Corrective Information. In addition, NCMS shall have the right to direct that learners, faculty and planners be informed by the Provider that in the opinion of NCMS, certain information presented to the learners does not meet the NCMS standards for content validity, and that in NCMS's opinion a learner should not rely upon such information.
 - b. NCMS may require the Provider to submit a monitoring progress report at a time determined by the NCMS;
 - c. NCMS may declare that a Provider no longer is accredited with commendation; and
 - d. NCMS may take an Adverse Action, in which case the Provider shall be informed of its right to request a reconsideration pursuant to the Reconsideration and Appeal Policy.
7. If a Provider fails to convert noncompliance to compliance via documentation of corrective action and/or monitoring progress report, NCMS, in its sole discretion, reserves the right to take an Adverse Action, in which case the Provider shall be informed of its right to request a reconsideration pursuant to the Reconsideration and Appeal Policy.
8. If the Provider is found in noncompliance, documents related to the review of such noncompliance (such as the Notice of Inquiry, Notice of Alleged Noncompliance,

Provider's response, documentation of corrective action, and monitoring progress report) will be placed in the Provider's file and made available to the survey team and ARC reviewer as part of the NCMS reaccreditation process.

9. Any communication to a Provider of an Adverse Action, other than those described in Section E below and F, shall include a statement that the Provider has thirty (30) days from Delivery of the communication to the Provider to request reconsideration under the Reconsideration and Appeal Policy and that the change in accreditation status will not become effective until the end of the thirty (30) day period if the Provider does not ask for reconsideration, or until the end of the process under the Reconsideration and Appeal Policy if the Provider does ask for reconsideration. When a Provider requests a reconsideration on a timely basis, then the Provider shall not be required to perform any corrective action until the completion of the process under the Reconsideration and Appeal Policy.
10. At any point during any process described in this Policy, the NCMS reserves the right to require an immediate full or focused accreditation survey, including a full or focused self-study report and interview.
11. In keeping with best practice, Providers shall afford whistleblower protection to their employee, when/if a Third-Party Concern is submitted by an employee of the Provider.
12. NCMS has the right, in its sole discretion, to grant extensions with respect to any time requirement contained in this Policy.
13. Members of the Decision Committee shall not participate in any vote of the Board of Directors which relates to whether to change the accreditation status of the Provider during the processes described in the Reconsideration and Appeal Policy.

D. Confidentiality

To the extent feasible, NCMS will not disclose the identity of the third party that submitted the Third-Party Concern during the process set forth in this Policy, but such third party's identity may be evident due to the circumstances of the Third-Party Concern, and such third party's identity may be revealed in a legal proceeding. The inquiry process and findings, and the process for allegations of noncompliance and findings will be kept confidential by NCMS, with the exception of NCMS's response to a lawful subpoena or other legal process; provided, however, that NCMS reserves the right to make public the noncompliance issue without naming the Provider which was in noncompliance; and provided further that NCMS shall publish changes to the Provider's accreditation status. The identity and credentials of the Independent Content Reviewers engaged by NCMS as described in this Policy shall not be disclosed to the Provider or to the public.

E. Change in Accreditation Status due to Failure to Respond, Act, or Comply with a Course of Corrective Action or Monitoring Requirement

NCMS shall have the right to take an Adverse Action with respect to a Provider without following any other process described in this Policy if a Provider is determined by NCMS, in its sole discretion, to: have not submitted information required by this Policy within ten (10) days after the prescribed deadline; have not taken action required by this Policy within ten (10) days after the prescribed deadline; have not submitted a monitoring progress report within ten (10) days after the prescribed deadline; and/or have not submitted documentation of corrective action

within ten (10) days after the prescribed deadline. Changes in accreditation status described in this paragraph shall not entitle the Provider to review under the Reconsideration and Appeal Policy and shall not require review by the Decision Committee.

If a Provider submits documentation of corrective action but the NCMS in its sole discretion determines that such action does not demonstrate compliance with NCMS's Rules, or if a Provider submits a monitoring progress report and the NCMS determines in its sole discretion that the actions reported do not show compliance with NCMS's Rules, then NCMS reserves the right in its sole discretion to take an Adverse Action. The Provider shall have the right to request reconsideration under the Reconsideration and Appeal Policy within thirty (30) days from the Delivery of a communication to the Provider of an Adverse Action under the circumstances described in the immediately preceding sentence.

F. Immediate Suspension

In the event of a Third-Party Concern or NCMS Initiated Concern that identifies a credible allegation against a Provider, as determined in NCMS's sole discretion, that poses an immediate danger to patients of learners, NCMS shall have the ability to immediately suspend such Provider's accreditation status. In event of such suspension, NCMS will send a written notice of the suspension to the Provider and advise the Provider that the Provider is entitled to appeal of such determination in accordance with Section B of the Reconsideration and Appeal Policy.