



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

The Massachusetts Medical Society (MMS) has a multitiered accreditation process for evaluating a Provider's compliance with the MMS'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 MMS's Rules that arise outside of the accreditation process. MMS reserves the right to amend this Policy at any time. This Policy is subject to regular review.

### **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.

"CAR" means Committee on Accreditation Review .

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

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

"MMS's Accreditation Requirements" means all accreditation requirements made available to Providers by MMS, including those adopted by the ACCME.

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

"Notice of Alleged Noncompliance" means a written notice from the MMS to the Provider explaining why the MMS believes the Provider to be in violation of MMS's Accreditation Requirements.

"Notice of Inquiry" means a written notice from the MMS of a third-party concern which states that a Provider may not be in compliance with MMS's Accreditation Requirements and, to the extent known, which aspects of the Provider's activities or conduct may not comply with MMS's Accreditation Requirements.

"Notice of Noncompliance" means a written notice that includes the following: a statement that the Committee on Accreditation Review (CAR) found the Provider in noncompliance; the 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 MMS accredited provider.

"Reconsideration and Appeal Policy" means the MMS 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 MMS Accreditation Requirements.

## **B. Inquiry Process**

1. MMS will review Third-Party Concerns and MMS-Initiated Concerns that arise outside of the accreditation process.
2. If MMS determines in its sole discretion that a Third-Party Concern or an MMS-Initiated Concern does not relate to a Provider's compliance with MMS's Accreditation Requirements, then the matter will be closed, and MMS will notify in writing any third parties that submitted Third-Party Concerns that it will not open an inquiry.
3. If MMS, in its sole discretion, determines that a Third-Party Concern or an MMS-Initiated Concern merits further review, then MMS 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 MMS-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 MMS. The Notice of Inquiry shall include a copy of this Policy and the Reconsideration and Appeal Policy. MMS will notify in writing any third parties that submitted Third-Party Concerns that it will open an inquiry. MMS 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 MMS in the Notice of Inquiry within twenty-one (21) days of Delivery of such Notice of Inquiry. If MMS 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 MMS a written notice stating that the Provider did/does not comply with one or more of the MMS's Accreditation Requirements identified in said notice, in which case the MMS shall have the right to take any of the actions described in Section C.6 of this Policy; provided, however, that if MMS in its sole discretion believes that the Provider may have violated MMS Accreditation Requirements other than those identified in the Provider's notice, MMS may continue an inquiry.
5. As part of an inquiry related to content validity policies, the Provider shall submit to the MMS, 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 MMS determines that an objective content review of the activity is necessary to determine compliance, the MMS will seek independent content reviews by at least two (2) Independent Reviewers. The Provider will pay all costs related to the review of the activity. The Provider has the option to submit its own independent content review to the MMS within twenty-one (21) days of Delivery of the Notice of Inquiry.
6. MMS, in its sole discretion, shall make a determination regarding compliance or noncompliance of the Provider. If MMS 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 MMS, in its sole discretion, concludes that a Provider is in noncompliance with MMS Accreditation Requirements, MMS shall send the Provider a Notice of Alleged Noncompliance. MMS 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 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 MMS a written notice stating that the Provider did/does not comply with one or more MMS Accreditation Requirements identified in said notice, in which case the MMS shall have the right to take any of the actions described in Section C.6 of this Policy; provided, however, that if MMS in its sole discretion determines that the Provider has violated MMS Accreditation Requirements other than those identified in the Provider's notice, the MMS 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. MMS has the right to submit any materials received from the Provider for independent content review by at least one Independent Reviewer. In addition, the MMS 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. MMS shall review the materials submitted by the Provider as well as any content review reports requested by MMS.
5. If MMS, in its sole discretion, makes a finding of compliance, MMS shall notify the Provider of the finding and the matter will be closed.
6. If MMS, 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 Committee on Accreditation Review. The Committee on Accreditation Review 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 Committee on Accreditation Review makes a finding of compliance, MMS shall notify the Provider of the finding and that the matter will be closed.
  - ii. If the Committee on Accreditation Review makes a finding of noncompliance, MMS shall send the Provider a Notice of Noncompliance. MMS, in its sole discretion, may also take the following actions when it sends the Provider a Notice of Noncompliance:
    - a. MMS 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 Standards for Integrity and Independence 1, 2 or 3.2 (Ensure Content is Valid;) (Prevent Commercial Bias in Marketing in Accredited Continuing Education; and), (exclude owners or employees of ineligible companies, respectively) adopted by the ACCME and implemented by MMS, 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 MMS for MMS's approval or modification prior to providing such Corrective Information to the learners, faculty and planners, and MMS shall have the sole discretion to determine the content of the Corrective Information. In addition, MMS shall have the right to direct that learners, faculty and planners be informed by the Provider that in the opinion of MMS, certain information presented to the learners does not meet the ACCME standards for content validity, and that in MMS's opinion a learner should not rely upon such information.

- b. MMS may require the Provider to submit a monitoring progress report at a time determined by the MMS;
  - c. MMS may declare that a Provider no longer is accredited with commendation; and
  - d. MMS 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, MMS , 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 members of the Committee on Accreditation Review as part of the MMS 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 MMS 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. MMS has the right, in its sole discretion, to grant extensions with respect to any time requirement contained in this Policy.
13. Members of the Committee on Accreditation Review shall not participate in any vote of the Committee on Medical Education 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, MMS 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 MMS , with the exception of MMS's response to a lawful subpoena or other legal process; provided, however, that MMS reserves the right to make public the noncompliance issue without naming the Provider which was in noncompliance; and provided further that MMS shall publish changes to the Provider's accreditation status. The identity and credentials of the Independent Content Reviewers engaged by MMS 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**

MMS 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 MMS, 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 Committee on Accreditation Review.

If a Provider submits documentation of corrective action but the MMS in its sole discretion determines that such action does not demonstrate compliance with MMS Accreditation Requirements, or if a Provider submits a monitoring progress report and the MMS determines in its sole discretion that the actions reported do not show compliance with MMS Accreditation Requirements, then MMS 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 MMS Initiated Concern that identifies a credible allegation against a Provider, as determined in MMS's sole discretion, that poses an immediate danger to patients of learners, MMS shall have the ability to immediately suspend such Provider's accreditation status. In event of such suspension, MMS 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 II of the Reconsideration and Appeal Policy.