ACCME Process for Handling Complaints Regarding ACCME Accredited Providers

Revised August 2017

A. Complaint Status and Statute of Limitation

1. Complaints are written notifications to the Accreditation Council for Continuing Medical Education (“ACCME”) by a third party which claim that an ACCME accredited Provider (a “Provider”) is not in compliance with ACCME Rules (defined herein as ACCME Policies, Standards for Commercial Support, Essential Areas and Elements and accreditation criteria required by the ACCME) with regard to one or more of its activities (“Complaint”).

2. To receive status as a Complaint, the written Complaint must identify the accredited Provider (“Provider”), identify the CME activity in question if applicable, and confirm the name, US Postal Service address and contact information of the person making the submission (“Complainant”).

3. A Complaint may a) refer to single activities/series, or b) the Provider’s entire program of CME.

4. The statute of limitation of the length of time during which an accredited Provider must be accountable for any Complaint received by the ACCME is twelve (12) months from the date a live activity ended, or in the case of a series, twelve months from the date of the session which is in question. Providers are accountable for an Enduring Material during the period of time it is being offered for CME, and twelve (12) months thereafter.

5. ACCME may initiate a Complaint against an accredited Provider.

B. Procedure for Complaint Review and Provider Response

1. ACCME will review the Complaint to determine whether it relates to the manner in which the Provider complies with the ACCME’s Rules.

2. If the Complaint does not relate to the Provider’s compliance with ACCME Rules, the Complainant will be advised of ACCME’s position and the Complaint process will be closed.

3. If the ACCME determines that the Complaint relates to the Provider’s compliance with ACCME Rules, then ACCME will send a letter which identifies the alleged non-compliance to the Provider (“Notice of Complaint”). The Notice of Complaint from ACCME may include a request for documents or data from the Provider. ACCME will attach a redacted copy of the Complaint to the Notice of Complaint. The identity of the Complainant will be deleted from the Complaint. To the extent feasible, ACCME will not disclose the identity of the Complainant during the Complaint process, but the identity of a Complainant may be evident due to the circumstances of the Complaint, and the Complainant’s identity may be revealed in a legal proceeding.

4. For complaints related to ACCME’s content validity policies, the accredited provider will be asked to 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. If, upon receipt of the materials, the ACCME determines that an objective content review of the activity is necessary to determine compliance, the ACCME will seek independent content reviews by at least two (2) clinicians with relevant content expertise who have completed ACCME’s disclosure and conflict of interest process and for whom all conflicts have been resolved and documented. The provider will pay any costs related to the review of the activity beyond the first $500. The provider has the option to obtain its own independent content review, the results of which may be submitted
to the ACCME at the time of the notice of complaint or within 30 days of a notice of noncompliance. ACCME staff will perform an analysis of the independent reviews submitted and will present this information to a committee or subcommittee of the ACCME Board of Directors.

5. The Provider shall either admit the allegations of the Complaint or provide a written rebuttal and any information requested by ACCME within forty-five (45) days of receipt of the Notice of Complaint. The Provider's failure to provide information requested by ACCME within the forty-five (45) day time limit may contribute to a finding of noncompliance. The Provider will be informed in writing that a change of status to Nonaccreditation may occur if the Provider has failed to respond to the request for information in the manner stipulated by ACCME.

C. ACCME Findings and Decisions

1. The Provider will be found in Compliance or Not in Compliance for that activity. The completed process and the findings will be kept confidential by ACCME, with the exception of ACCME’s response to a lawful subpoena or other legal process; provided, however, that ACCME reserves the right to make public the noncompliance issue without naming the Provider which was in noncompliance.

2. The Provider will be notified of the finding. If the finding is Not in Compliance, the noncompliance will be described in a Notice of Noncompliance to the Provider.

   a. If an activity is found to be in Noncompliance with the ACCME Standard for Commercial Support 1 (Independence), Standard for Commercial Support 5 (Content and Format without Commercial Bias), or the Content Validation Value Statements, the accredited provider is required to provide corrective information to the learners, faculty and planners. The provider will submit to the ACCME a report describing the action that was taken and the information that was transmitted. Providers will determine how to communicate the corrective information and are under no obligation to communicate that the activity was found in Noncompliance with ACCME requirements.

   b. If the Provider is found Not in Compliance, documents related to the Complaint review (such as Notice of Complaint, the Complaint, Provider’s response, documentation of corrective action, or monitoring progress report) will be placed in Provider’s file and made available to the survey team and ARC reviewer as part of the ACCME re-accreditation process. In addition, ACCME may also take the following actions in response to a finding of non-compliance:

      i. ACCME may require the Provider to submit documentation of corrective action within thirty (30) days of receipt of the Notice of Noncompliance;

      ii. ACCME may require the Provider to submit a Monitoring Progress Report at a time determined by the ACCME;

      iii. ACCME may change the Provider’s accreditation status to Probation or Nonaccreditation; and

      iv. If the Provider fails to convert Noncompliance to Compliance via documentation of corrective action, monitoring progress report, or other remedial measures, ACCME reserves the right to change the Provider’s accreditation status to Probation or Nonaccreditation

3. At any point in the Complaint process the ACCME reserves the right to require an immediate full or focused accreditation survey, including a full or focused self-study report and interview.
4. When asked for ‘documentation of corrective action’ the Provider will be asked to provide documentation of corrective action to the ACCME within thirty days of receipt of the Notice of Noncompliance, and will be notified that failure to correct the deficiencies may result in an immediate resurvey which may affect the Provider’s accreditation status.

5. If the Monitoring Report adequately describes and documents Compliance it will be accepted. If the Monitoring Report does not adequately describe and/or document Compliance it will NOT be accepted.

6. Regarding Request for Information or Response: Change of status to Probation may automatically occur at 45 days from the time the Provider receives a request for information/response from the ACCME, if the Provider has failed to provide a response or provide the requested information.

7. Regarding Documentation of Corrective Action: Change of status to Probation may automatically occur at 15 days after the due date for the notice set by the ACCME, if the Provider has failed to submit the required documentation of corrective action.

8. Regarding Monitoring Progress Report: Change of status to Probation may automatically occur at 30 days after the due date for the Monitoring Progress Report set by the ACCME, if the Provider has failed to submit the required Monitoring Progress Report. Each instance of a failure by a Provider to respond described in this paragraph shall be a “failure to submit.”

9. Change of status to Nonaccreditation may occur at 30 days from the date a Provider was placed on Probation for failure to submit information or a response, documentation of corrective action or a Monitoring Progress Report if the Provider has still failed to submit the required information and/or documentation. Change of status to Probation or Nonaccreditation for ‘failure to submit’ does not require Board action.

10. ACCME will send a notice to the Provider of a change of status in a manner that confirms receipt (e.g., email, USPS certified mail, FEDEX-type courier).

11. Except for an automatic change in status due to a Provider’s “failure to submit”, a Provider’s compliance must be reviewed by the ACCME’s Accreditation Review Committee and Decision Committee in order to either a) change the Provider’s accreditation status to Probation or Nonaccreditation or b) proceed with a full or focused accreditation survey, including a full or focused self-study report and interview.
Decision Pathway for Review of Complaint Related to Content Validity

1. Complaint is received re accredited provider’s compliance with ACCME’s content validity policy.

2. ACCME releases letter to provider identifying alleged non-compliance and requesting access to unaltered set of all CME materials related to the CME activity*.

3. Is independent content review necessary to determine compliance?
   - No
   - Yes

   4. Yes: ACCME seeks independent content review by at least two (2) clinicians with relevant content expertise who have completed ACCME’s disclosure and conflict of interest process and for whom all conflicts have been resolved and documented.
      - Does content challenge ACCME’s validity expectations?
        - No
        - Yes

      5. Yes: Decision Committee review and action
         - Board review and ratification

The provider is informed in writing of ACCME’s findings. If activity is found to be in noncompliance, the provider is required to provide corrective information to learners, faculty and planners. The provider’s plan for corrective action must meet the spirit and intent of ACCME’s expectations related to its findings. The provider will submit a report to ACCME describing action to be taken and information that will be transmitted.

*Provider is informed that it will be responsible for costs related to the activity review that exceed $500 and that it has the option to obtain its own independent content review, the results of which are to be submitted to the ACCME in response to the notice of complaint or within 30 days of notice of noncompliance.