

# Every physician matters, each patient counts.

# JOINT PROVIDERSHIP AGREEMENT ("AGREEMENT") FOR LIVE ACTIVITIES

Between The Massachusetts Medical Society ("MMS") And Education Partner ("Joint Provider")

d herein.

# I. Definitions

The Accreditation Council for Continuing Medical Education (ACCME) defines the following terms:

**Employees** - Individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction on how to perform the job.

**Ineligible Company(ies)** - Those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. Examples include advertising, marketing, or communication firms whose clients are ineligible companies, device manufacturers or distributors, pharmaceutical companies or distributors, etc.

Joint Providership – The planning, implementation and evaluation of a CME activity by an accredited provider and one or more nonaccredited entities.

**Owners** – Individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund.

**Relevant Financial Relationships** – An individual's financial relationships of any dollar amount when the educational content that they control is related to the business lines or products of an ineligible company.

#### II. Purpose and Intent of Agreement

The Massachusetts Medical Society (MMS) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The MMS strives to provide quality continuing educational activities that are evidence-based, scientifically accurate, and independent of any commercial influence. The MMS and Joint Provider intend to implement an educational activity that fully meets the *ACCME Accreditation Criteria* and policies, including but not limited to the *ACCME Standards for Integrity and Independence in Accredited Continuing Education*, the American Medical Association (AMA) Core Requirements, the Food and Drug Administration (FDA) Guidance on Industry-Supported Scientific and Educational Activities, and any other CME standards and regulations that MMS deems appropriate and applicable.

#### **MMS and Joint Provider Specific Responsibilities**

Appendix 2 to the Agreement identifies the actions required to complete the activity, and the party responsible for each action. The Joint Provider is required to meet deadlines for the responsibilities as indicated above unless there is agreement by the MMS and the Joint Provider to extend a deadline.

The MMS will review the Activity and proposed content and assess whether they meet the appropriate and applicable CME standards and regulations. The Joint Provider shall comply with MMS's directions, including but not limited to editing the content of the Activity, intended to achieve or maintain compliance with ACCME standards and guidance. If, at any point, the MMS determines in its sole discretion that the Activity or content thereof do not meet the applicable CME standards and regulations or the Joint Provider does not meet required deadlines, the MMS may withdraw its accreditation and terminate this Agreement upon notice to the Joint Provider.

For the sake of clarity, none of the following may be posted, printed, or otherwise deployed until the MMS has reviewed and approved it in writing:

- Marketing materials
- Presentations, handouts, and any other content related to the Activity
- Learner assessments or evaluation tools including pre-tests and post-Activity evaluations
- CME certificate template

In no event may the Joint Provider use any of MMS's name, marks, logos or the like (including those of the *New England Journal of Medicine*, NEJM Group, or other related entity) without MMS's prior written approval in each instance.

The Joint Provider will not allow any other entity to host the same, or substantially similar Activity and/or content developed by the Joint Provider without MMS's prior written approval in each instance.

#### III. Ensure Content is Valid

Accredited providers are accountable to the public for presenting clinical content that supports safe, effective patient care. The MMS and the Joint Provider will develop educational content that actively promote improvements in health care and not proprietary interests of ineligible companies. The MMS and the Joint Provider will cooperate to ensure that patient care recommendations made during CME activities are accurate, reliable, and based on scientific evidence. Clinical care recommendations must be supported by data or information accepted within the profession of medicine. The MMS shall review the Activity and materials to assess compliance with the ACCME's content validity standards and guidelines. The Joint Provider will abide by the MMS's judgment on these matters and will cooperate with MMS requests and directions in this regard. Please refer to Appendix 1, Standard 1 for additional guidance about content validity.

## IV. Prevent Commercial Bias and Marketing in Accredited Continuing Education

Accredited providers must protect learners from commercial bias and marketing in accredited continuing education. All decisions relating to the planning, faculty selection, delivery, and evaluation of accredited continuing education must be made without any influence or involvement from the owners and employees of an ineligible company. The educational activity must be free of marketing or sales of products or service. Faculty must not promote or sell products or services that serve their professional or financial interests during the educational activity. Please refer to Appendix 1, Standard 2 for additional guidance on preventing commercial bias and marketing in accredited continuing education.

#### V. Owners and Employees of Ineligible Companies

Owners and employees of ineligible companies may not have <u>any</u> role where they are in a position to control the content of accredited continuing education, except in the specific situations identified by the ACCME that maintain independence and serve the public interest. The MMS, in its sole discretion, will review and determine whether the circumstances meet the special use cases. The Joint Provider will abide by the MMS's judgment on this matter and will cooperate with MMS requests and directions. Please refer to Appendix 1, Standard 3, item 2 for detailed guidance.

#### VI. Identify and Mitigate Relevant Financial Relationships

The Joint Provider is required to collect disclosure information from all individuals in control of the Activity's content on their financial interests with ineligible companies. An individual must disclose all financial relationship(s) within the past twenty-four (24) months., Any individual who refuses to provide disclosure information may not participate in the planning or delivery of the Activity. The MMS has the right to review the disclosure information and determine appropriate steps. The Joint Provider will abide by the MMS's judgment in these matters and will cooperate with MMS requests and directions in this regard. Please refer to Appendix 1, Standard 3 for detailed guidance regarding identification and mitigation of relevant financial relationships.

#### VII. Communicate Disclosure of Relationships to Learners

The MMS will create the Disclosure Statement, which includes all relevant financial relationships for the Activity, to the Joint Provider to distribute to the learners prior to the beginning of the Activity.

#### VIII. Appropriate Management of Commercial Support

The MMS or the Joint Provider may seek commercial support for the Activity. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter, the MMS, and the Joint Provider and/or other educational partner(s). The MMS must be a party to the agreement for commercial support and retains the rights to approve the terms of such, even if the support is given directly to the MMS's educational partner or Joint Provider. This agreement must be fully executed by all parties prior to the beginning of the Activity. The MMS shall review the agreement to assure compliance with

various laws, regulations, policies, and procedures, including but not limited to compliance with ACCME policies and guidance.

The MMS must make all decisions regarding the receipt and disbursement of the commercial support. Ineligible companies may not pay directly for any of the expenses related to the education or the learners. Commercial support may be used to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. Commercial support may not be used to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education. Commercial support may also be used to defray or eliminate the cost of the education for all learners.

If the Activity receives commercial support, the MMS will provide a statement to the learners that acknowledges the name(s) of the ineligible company(ies) and the nature of the support including monetary and in-kind. Other sources of financial support will also be disclosed if appropriate. The Joint Provider will abide by the MMS's judgment regarding what support will be acknowledged and will cooperate with MMS requests and directions in this regard. Please refer to Appendix 1, Standard 4 for additional guidance on managing commercial support.

## IX. Appropriate Management of Ancillary Activities Offered in Conjunction with Accredited Continuing Education

The MMS and the Joint Provider will cooperate to ensure that education is separate from marketing by ineligible companies – including advertising, sales, exhibits, and promotion – and from nonaccredited education. Further, the MMS and the Joint Provider will cooperate to ensure that the selling of advertising or exhibit space is a business transaction entirely separate from the acceptance of commercial support for accredited continuing education. Ineligible companies may not provide access to, or distribute, accredited education to learners. The Joint Provider will abide by the MMS's judgment on these matters and will cooperate with MMS requests and directions in this regard.

Learners must be able to easily identify the difference between accredited education and other types of activities. MMS will provide direction to the Joint Provider for a-c:

- a. Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.
- b. Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.
- c. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.

Please refer to Appendix 1, Standard 5 for detailed guidance regarding advertising, sales, exhibits and promotion.

#### X. Data and Reporting Requirements

**Evaluation Data**: If the Joint Provider opts to use a non-MMS evaluation tool, the Joint Provider must first seek MMS's approval of the tool, for which approval shall not be unreasonably withheld. The Joint Provider will submit to the MMS the data or information generated from this Activity on changes in learners' competence, performance and/or patient outcomes and for all other required data on a date specified by the MMS.

**Reporting Requirements:** The Joint Provider will submit to the MMS documentation of financial reconciliation, attendance and any other required reports in a time frame set forth by the MMS.

**Attendance:** For activities where registration is handled by the Joint Provider, the MMS requires an attendance report, including learners' first and last names, full contact information including email address, mailing address, designation (MD, DO, etc.) and AMA PRA Category 1 Credits<sup>™</sup> earned within 2 days following the conclusion of the Activity.

Activity Records: The MMS will maintain final documentation of the Activity planning, evaluation, attendance, and financial information including a complete financial reconciliation for audit purposes for at least six years from the date of the Activity's original release.

The Joint Provider shall upon request provide the MMS with any additional documentation necessary to comply with the ACCME Accreditation Criteria and policies or as otherwise required by any state, federal, or regulatory authority.

#### XI. Payment for Services and Fiscal Responsibilities

The MMS will assess a non-refundable application fee of \$500.00 which is payable with the Activity Planning and supporting documents. The Joint Providership fee in the amount of \$\_\_\_\_\_\_ is due within 30 days of invoice date. The MMS will invoice the Joint Provider for both fees. If you have any questions, contact <a href="mailto:CEcompliance@mms.org">CEcompliance@mms.org</a>.

# XII. Miscellaneous

The MMS is relying on the accuracy of the Joint Provider's representations in the Planning Document submitted for consideration for AMA PRA Category 1 Credit<sup>TM</sup>. Therefore, if there are any changes to the activity, including but not limited to:

- Addition, deletion, or substitution of faculty;
- Addition, deletion, or substitution of content creators or reviewers;
- The time, date, and/or location of the activity;
- The content of the activity (including the title of a presentation or the whole activity);
- The agenda of the activity; or
- The questions used to evaluate the activity

The Joint Provider must inform the MMS of these changes, and the MMS may choose to withdraw its accreditation and terminate this Agreement immediately upon notice to the Joint Provider. If the Joint Provider does not notify the MMS of any changes in a timely manner, the MMS may choose to withdraw its accreditation and terminate this Agreement immediately upon notice to the Joint Provider.

This Agreement is effective upon execution by both parties (the "Effective Date"). The MMS reserves the right to terminate the Agreement or to rescind AMA PRA Category 1 Credit<sup>™</sup> for failure to meet any of the above requirements that may place them in non-compliance with the ACCME requirements or other state, federal or regulatory authority requirements.

Either party may terminate the Agreement with thirty (30) days written notice to the other party at any time, with or without cause. In the event of termination, the Joint Provider will be responsible for paying the MMS the non-refundable application fee, and the full accreditation fee if the Activity takes place. If the Activity does not take place, the amount due will be pro-rated by the percentage of work that is completed. The MMS reserves the right to immediately terminate the Agreement or to rescind *AMA PRA Category 1 Credit*<sup>™</sup> for failure to meet any of the above requirements that may, in the MMS' discretion, place the MMS in non-compliance with the ACCME requirements or other state, federal or regulatory authority requirements.

While this Agreement remains in place, the MMS may take whatever steps it reasonably believes necessary to maintain compliance with applicable laws, policies, and regulations including but not limited to ACCME accreditation criteria and policies. The Joint Provider will abide by the MMS's judgment on these matters and will immediately cooperate with MMS requests and directions in this regard.

Joint Provider will perform all of its obligations in full compliance with all applicable laws, regulations, standards, policies and guidance, and will indemnify and hold harmless the MMS, its employees, officers and assigns against any damages, cost, or expense, including reasonable attorney's fees, due to any claim by any third party regarding the Activity or the Materials or arising out of any breach by Joint Provider of any term or representation of this Agreement. MMS will give Joint Provider prompt notice of any such claim.

Joint Provider will not disparage or denigrate MMS or its representatives, except that Joint Provider may make truthful statements as part of a Legal Proceeding or if compelled by Court Order or otherwise required by law or ACCME standards. Joint Provider agrees that any information furnished to it by the MMS is a valuable asset of the MMS and will be kept confidential ("Confidential Information"). Joint Provider will use Confidential Information only as permitted by the MMS will take all necessary and proper steps to prevent unauthorized use or disclosure of Confidential Information. For purposes of clarity, the terms of this Joint Provider Agreement and the parties' dealings hereunder shall be considered Confidential Information.

MMS's total aggregate liability for any claims of Joint Provider arising from or related to this Agreement shall not exceed the amounts MMS collected in the prior twelve months from the Joint Provider pursuant to "Payment for Services and Fiscal Responsibilities" above. In no event shall the MMS be liable to Joint Provider or any third party for incidental, exemplary, special, indirect, consequential, or punitive damages including, but not limited to, lost business profits and loss, damage, or destruction of data even if the MMS has been advised of the possibility of the same.

# Appendix 1

#### Standard 1: Ensure Content is Valid

Standard 1 applies to all accredited continuing education.

- 1. All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
- 2. All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to generally accepted standards of experimental design, data collection, analysis, and interpretation.
- 3. Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
- 4. Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

#### Standard 2 – Prevent Commercial Bias and Marketing in Accredited Continuing Education

Standard 2 applies to all accredited continuing education.

- 1. The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.
- 2. Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.
- 3. The accredited provider must not share names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

#### Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships

Standard 3 applies to all accredited continuing education.

- Collect information: Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Disclosure must include:
  - a. The name of the ineligible company with which the person has a financial relationship.
  - b. The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds to not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.
- Exclude owners or employees of ineligible companies: Review the information about financial relationships to identify individuals who are owners or employees of ineligible companies. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion – employees of ineligible companies can participate as planners or faculty in these specific situations:
  - a. When the content of the activity is not related to the business lines or products of their employer/company.
  - b. When the content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
  - c. When they are participating as technicians to teach safe and proper use of medical devices, and do not recommend whether or when a device is used.

- 3. Identify relevant financial relationships: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.
- 4. **Mitigate relevant financial relationships:** Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
  - a. Mitigate relationships prior to the individuals assuming their roles. Take steps appropriate to the role of an individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins.
  - b. Document the steps taken to mitigate relevant financial relationships.
- 5. Disclose all relevant financial relationships to learners: Disclosure to learners must include each of the following:
  - a. The names of the individuals with relevant financial relationships
  - b. The names of the ineligible companies with which they have relationships
  - c. The nature of the relationships
  - d. A statement that all relevant financial relationships have been mitigated.

**Identify ineligible companies by their name only.** Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.

**Disclose absence of relevant financial relationships.** Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies.

# Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.

**Exceptions:** Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:

- 1. Accredited education that is non-clinical, such as leadership or communication skills training.
- 2. Accredited education where the learner group is in control of content, such as spontaneous case conversation among peers.
- 3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning from teaching, remediation, or a personal development plan. When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

#### Standard 4 – Manage Commercial Support Appropriately

Standard 4 applies only to accredited continuing education that receives financial or in-kind support from ineligible companies.

- 1. **Decision-making and disbursement:** The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.
  - a. Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
  - b. The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only.
  - c. The accredited provider must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education.
  - d. The accredited provider may use commercial support to defray or eliminate the cost of education for all learners.
- Agreement: The terms, conditions, and purposes of the commercial support must be documented in an agreement between the ineligible company and the accredited provider. The agreement must be executed prior to the start of the accredited education. An accredited provider can sign onto an existing agreement between an accredited provider and a commercial supporter by indicating its acceptance of the terms, conditions, and amount of commercial support it will receive.
- 3. Accountability: The accredited provider must keep a record of the amount or kind of commercial support received and how it was used, and must produce that accounting, upon request, by the accrediting body or by the ineligible company that provided the commercial support.
- 4. Disclosure to learners: The accredited provider must disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the

education. Disclosure must not include the ineligible companies' corporate or product logos, trade names, or product group messages.

#### Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Standard 5 applies only when there is marketing by ineligible companies or nonaccredited education associated with the accredited continuing education.

- 1. Arrangements to allow ineligible companies to market or exhibit in association with accreditation education must not:
  - a. Influence any decisions related to the planning, delivery, and evaluation of the education.
  - b. Interfere with the presentation of the education.
  - c. Be a condition of the provision of financial or in-kind support from ineligible companies for the education.
- 2. The accredited provider must ensure that learners can easily distinguish between accredited education and other activities.
  - a. Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.
  - b. Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.
  - c. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.
  - d. Information distributed about accredited information that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible company.
- 3. Ineligible companies may not provide access to, or distribute, accredited education to learners.

# Appendix 2

Activity Responsibilities/Tasks After JPA is Executed	MMS	Joint Provider	N/A
Prepare references and bibliography for Activity, and revise as necessary for compliance		Х	
Identify and recruit qualified faculty and moderators		Х	
Solicit commercial support (if applicable)		Х	
Ensure all Letters of Agreement are fully executed by all parties and submitted to the MMS prior to the beginning of the activity, (if applicable)	X	Х	
Solicit exhibitors (live for conferences; virtual for webinars)		Х	
Exhibits: If virtual, submit link to exhibit hall to MMS for review and approval within 3-5 business days prior to the activity.			
Develop all marketing materials and submit to MMS for approval before distribution		Х	
Develop, and revise as necessary, an activity evaluation and submit to MMS for approval.	X	Х	
Collect and submit all faculty presentations and content and submit to MMS for review by the due date on page one		X	
Work with planners and faculty to communicate revisions to content and submit final content for approval to MMS			
Distribute Disclosure Statement and Commercial Support Statement (if applicable) to learners prior to the beginning of the activity.	x		
Distribute CME Certificates and Certificates of Attendance to learners	Х		
Collect registration fees from attendees		Х	
Provide complete attendance list per the Reporting Requirements outline (MD, DO, etc.) within 1-2 days following activity		Х	
Provide evaluation data or information generated from this Activity about changes in learners' competence, performance and/or patient outcomes		Х	
Prepare and submit actual income and expenses using the MMS CME Activity Financial Report – Budget/Actual		Х	

For:	Massachusetts Medical Society
Print Name:	
Title:	
Signature:	
Date:	
For:	Joint Provider Name
Print Name:	
Title:	
Signature:	
Date:	
	Attestation:

# □ I have read the ACCME Standards for Integrity and Independence in Accredited Continuing Education and will abide by them.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_