

INSTRUCTIONS TO JOINT PROVIDERS OF CME ACTIVITIES

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1. OVERVIEW AND TIMELINE

Thank you for your interest in holding a jointly-provided meeting with the American Thoracic Society (ATS). The following document is intended to help guide you through the process and to answer any questions that you or your chapter may have. Please note that phase two of the application and required documents are due to the ATS no less than 4 months prior to the activity. If you are seeking grant support, then we recommend that you submit phase two of the application at least 5 months prior to your activity since you cannot seek commercial support until your activity has received CME designation. Phase two applications received less than four months prior to the activity may not be reviewed for designation.

Important: Under no circumstance may you promote the activity as CME accredited or pending CME accreditation until you have received your certificate of designation from the ATS. Currently, the ATS is only jointly-providing CME activities with ATS Thoracic Society Chapters. The ATS is not jointly-providing CME for external organizations.

Planning Committee Selection and Disclosure Process (Phase One)

Timeframe: 5-9 months prior to activity

Collection and review of Planner disclosures to identify and resolve potential conflicts of interests must be completed prior to the start of the faculty and topic selection for the activity. At this time, chapters are required to:

- Select Course Chair and Planning Committee
- Submit to ATS, through the online application portal (https://www.thoracic.org/form/chapter-cme-application/index.php), a list of planners with contact information
- Work with ATS COI Department to complete an online disclosure form
- The Chair is responsible for ensuring the planning committee discloses in a timely manner
- Once all disclosure forms are complete, the Planning Committee Chair will receive instructions to review and resolve conflicts, if any, for the Planning Committee members.
- The Chair and Chapter Administrator will be notified when the process is complete and you can proceed with selecting topics and speakers.
- Chairs are asked to sign an attestation that the Chapter will comply with ACCME Standards for Commercial Support for their CME activity.
- Indicate if you plan to seek Commercial Support (educational grants or in-kind grants)

Preparation of CME Application (Phase Two)

Timeframe: 4-5 months prior to activity

The completed CME Application should be submitted through the online application portal (https://www.thoracic.org/form/chapter-cme-application/index.php) no less than four months prior to the activity. The application is used to collect information such as:

- Basic Information such as activity title, dates, location and number of credits requested
- List of faculty with contact information which is used to collect financial disclosures
- Needs Assessment
 - Activity summary
 - Statement of Clinical/Scientific Importance
 - Identification of professional practice gaps



- Target audience
- o Educational format
- o References in support of needs assessment
- Learning objectives
- Plan for outcomes assessment (i.e., Pre-test / Post-test questions, follow up survey)
- Budget including potential commercial supporters and exhibitors
- Agenda (<u>Note</u>: If your agenda includes non-accredited educational activities, there must be a 30 minute break between those activities and CME designated activities.)

The Chapter should use the "Faculty Letter" template when confirming with faculty, which outlines key expectations, procedures, and ACCME guidelines. This communication should include the "Teaching by Design Form," which will be a required document in phase three.

ATS will review your application within 10 business days of submission. You will be notified if any additional information or documents are required or receive a certificate of designation once all faculty have properly disclosed and the chair has mitigated any conflicts.

Approval of meeting materials (Phase Three)

Timeframe: Three weeks prior to activity

Chapters must submit required CME documentation that is provided to attendees during the activity for approval at least three weeks prior to the meeting. Required CME documents are:

- CME Information Page
 - o Accreditation statement exactly as it appears on your designation certificate
 - o Course description
 - o Target audience
 - Learning objectives
 - o Planning Committee List
 - Speaker List
- Disclosure to learner of relevant (or no) financial relationships for all individuals in control of content (planners and faculty). ATS will provide the summary once approving phase 2.
- Attribution of sources of commercial support
 - Corporate logos are not allowed
- Acknowledgement of Exhibit Support
- Course and speaker evaluation (please ensure the ability to track who completes the evaluation)
- Post-test or other outcomes assessment
- Fully-executed Letters of Agreement for commercial support (educational grants and in-kind support) signed and dated by all relevant parties
- Teaching by Design forms for each session

Post activity documentation (Phase Four)

Timeframe: due 45 days after activity

- Attendance summary in Excel format
 - broken down by physicians and non-physicians *(you must collect information which can be used to distinguish physicians from non-physicians)
 - Must contain name as it should appear on Certificate and email address
- Sign in sheets or registration report



- Reconciled budget with all receipts and invoices
- Fully-executed Letters of agreement for commercial support received not previously provided
- Exhibitor list
- Final Attendee kit and handouts
 - o CME Information page
 - o Disclosure to Learners
 - Sources of Corporate Support
- Chair Disclosure Attestation Form if there were any last-minute speaker changes
- Summary of course and speaker evaluations (Excel format preferred or link to results if collected online). Course and speaker evaluations are required to receive CME credit.
- Summary of Pre/Post-Test results (Excel format preferred or link to results if collected online)

ATS will review your final submission within 10 business days. You will be notified if any additional information or documents are required. Once verified as complete, the ATS will send out attendance or CME certificates to the appropriate learners who have also completed the course/speaker evaluation.

2. ONLINE APPLICATION PROCESS

To complete the online application log into https://www.thoracic.org/form/chapter-cme-application/index.php using the log in information that was provided to the Chapter Administrator. Each Chapter is provided with unique log in information for the site.

Phase One: In this phase you will be asked to provide the names and contact information of the Planning Committee and sign off on the acknowledgement section that you agree to comply with the ATS and ACCME policies when planning and hosting your activity. You will also be asked to indicate if you plan on seeking commercial support for this activity (educational grants or in-kind grants). Once this section is complete, save and submit your application.

Phase Two: Once the ATS has reviewed and approved Phase One of your application, Phase Two will be unlocked. In this section you will be asked to complete information about the activity and upload an agenda and budget. You may save your work as you go along, but the application will not be reviewed until you submit your application. Once you submit your application, it will be locked and further editing will not be allowed.

The ATS will review your application within 10 business days of submission. The submitter will be notified once the review is complete. You may be asked to provide additional information or you will receive a certificate of designation. If additional information is requested, the application will be unlocked for editing. When this phase is complete, your meeting will be designated for CME.

Phase Three: Once you have received your certificate of designation, Phase Three of the application will be unlocked. At least three weeks prior to your meeting you are required to upload meeting materials for approval. If not received by the required deadline, CME designation may be rescinded by the ATS.

Phase Four: Forty-five days after your meeting, post activity documentation should be uploaded. Attendance lists must distinguish physicians from non-physicians.

If you need log in information or have questions about completing the application, please contact Kimberly Lawrence (klawrence@thoracic.org) for assistance.



3. POLICIES

A. ACCME Accreditation

The American Thoracic Society is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

B. Use of Accreditation Statement

The ATS will provide you with a certificate of designation once your application has been reviewed and approved. While you can market a program prior to receiving a certificate of CME designation, certain restrictions apply:

- You <u>cannot</u> indicate that an event is CME accredited or that CME accreditation is pending until
 you have received your certificate of designation.
- Faculty names <u>cannot</u> be used on promotional materials until you have received accreditation.
- You <u>cannot</u> seek commercial support until you have received accreditation.

C. ATS CME Mission

- CME Purpose: The purpose of the ATS CME Program is to support the ATS mission of: decreasing
 morbidity and mortality from respiratory disorders on both national and international levels,
 providing a high quality CME program that addresses the professional practice gaps of our
 learners and by facilitating change in learner competence and performance. As stated in our
 motto, "We help the world breathe."
- 2. Content Areas: The content of the ATS CME program focuses on research, clinical, and administrative aspects of Pulmonary, Critical Care and Sleep Medicine.
- 3. Target Audience: The target audience consists of researchers, clinicians, and other health professionals practicing in Pulmonary, Critical Care or Sleep Medicine. The ATS believes that optimal patient care is achieved through an interdisciplinary team approach.
- 4. Types of Activities: The ATS coordinates live courses, manuscript review, enduring materials (e.g. internet, print), journal CME and activities separately and jointly-provided with our Thoracic Society Chapters and other national organizations with missions congruent with our own.
- 5. Expected Results: The ATS CME program is expected to lead to improvement in learner competence or performance. Results are measured with self-report and objective assessments.

D. ACCME Standards for Integrity and Independence in Accredited Continuing Education

As an ACCME accredited provider of CME ATS is committed to meeting ACCME disclosure requirements.

All CME activities must be planned and implemented in accordance with the ACCME requirements and Standards for Integrity and Independence in Accredited Continuing Education. Please refer to the ACCME website for further information: Accreditation Criteria | ACCME

1. Conflict of Interest: Collection, Review and Resolution of Disclosures for All Individuals in Control of Content

Collection:

All individuals in a position to control content of this activity are required to disclose all financial relationships with any ineligible companies, as defined by the ACCME for themselves that occurred in the last 24 months to the ATS. According to the ACCME definition, an ineligible company is any entity



whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

The ACCME does not consider providers of clinical service directly to patients to be an ineligible company - unless the provider of clinical service is owned, or controlled by, an ACCME-defined ineligible company.

An ineligible company is not eligible for ACCME accreditation. **Ineligible** companies cannot be accredited providers and cannot be joint providers. Here is a list of organization types that are considered ineligible:

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers

Within the context of this definition and limitation, the ACCME considers the following types of organizations to be **eligible** for accreditation and free to control the content of CME:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs that do not sell proprietary products
- Electronic health records companies
- Government or military agencies
- Group medical practices
- Health law firms
- Health profession membership organizations
- Hospitals or healthcare delivery systems
- Infusion centers
- Insurance or managed care companies
- Nursing homes
- Pharmacies that do not manufacture proprietary compounds
- Publishing or education companies
- Rehabilitation centers
- Schools of medicine or health science universities
- Software or game developers

"'Relevant' financial relationships" are financial relationships in any amount occurring within the past 24 months that create a conflict of interest. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.



Anyone who does not disclose all relevant financial relationships is disqualified from being a planning committee member or a teacher in a CME Activity. All conflicts of interests must be mitigated prior to the activity.

An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Collection of disclosures is handled by ATS COI Department and all individuals in control of content must complete an online disclosure.

Review:

The Planning Committee Chair is responsible for reviewing and mitigating conflicts of interests, if any, prior to the start of the activity. The ATS COI Department will provide Chairs with instructions on how to complete the online review and resolution process and can provide guidance with questions.

Disclosure to learner:

Disclosure of relevant (or no) financial relationships for all individuals in control of content to learners CME events must made available to all learners in writing prior to the activity. ATS with provide the Chapter Administrator with a summary of disclosures collected. This summary must be provided to all attendees.

2. Commercial Support of CME Activities

Grants from Ineligible companies:

The ACCME has strict guidelines on commercial support of CME activities. ATS will deny any application for CME joint providership if commercial support has been solicited prior to receiving CME designation.

Chapters are responsible for applying for grants (educational and in-kind). Letters of Agreement are required and must be signed by the Chapter, an ATS representative and the grantor prior to the start date of the activity.

Commercial Support for a CME activity is financial, or <u>in-kind</u>, contributions given by an ineligible company, which is used to pay all or part of the costs of a CME activity. The definition of roles and requirements when commercial support is received are outlined in the <u>Standards for Integrity and Independence in Accredited Continuing Education | ACCME</u>

Exhibit Support is not considered Commercial support.

Receipt and Disbursement of Commercial Support:

Chapters may apply for grants only after they have received official designation from the ATS. Chapters are responsible for the application, reconciliation and maintenance of grant files. Chapters that receive grant support are responsible for grant reconciliation within 60 days of their activity. Chapters are also required to provide the ATS National Office with a complete set of activity files within 45 days of their activity.



Support from eligible companies:

Chapters may solicit support from sources such as government agencies or foundations that are not-ineligible companies as defined by the ACCME.

Exhibit Support:

Chapters may solicit exhibit support from both eligible and non- ineligible companies. You should not seek exhibit support until you have received CME designation.

If your exhibitor is not an ineligible company as defined by ACCME, you may solicit funds beyond your normal exhibit fee.

If your exhibitor is an ineligible company as defined by ACCME, you may not solicit funds beyond your normal exhibit fee.

E. ATS Policy on Industry Speakers

CME credit cannot be awarded for an activity where the presentations are made by an employee of an ineligible company. The ATS will only accept the following exception to this exclusion: employees of ineligible companies can participate as planners or faculty when the content of the activity is not related to the business line(s) or product(s) of their employer/company.

In instances where an industry employee is presenting on a topic that is unrelated to the business lines and products of their employer, the ATS will offer CME credit that session. In instances where an industry employee is presenting on a topic that does relate to the business lines and products of their employer, the ATS may offer the session but

- 1. Will not award CME credit for that session.
- Must either hold the session in a separate educational space or have a 30-minute break before
 and after the session to act as a buffer between designated content and non-designated
 content.

F. ATS Honorarium Policy in a CME Activity

The ACCME requires that CME providers such as ATS have written policies and procedures on honoraria. We therefore state our longstanding policy updated to reflect new procedures, effective April 15 2008, to support jointly provided CME activities:

- ATS honoraria are consistent within each event, are reasonable and reflect community standards
- Commercial supporters or any other organization or person may not supplement payments to faculty or course planners.
- Only ATS National or its educational partner in a jointly provided activity can set honoraria amounts and make payments to planners and faculty.
- ATS National expects its educational partner in a jointly provided activity to follow the ATS honorarium policy.

G. ATS Reimbursement Policy in a Chapter CME Activity

Please find below guidelines for reimbursement of expenses related to ATS Chapter meetings as issued by a policy memorandum in June 2015. Reimbursement by the ATS is only provided to those Chapters



the ATS holds funds for. All chapters must adhere to the reimbursement policy regardless if the ATS manages your funds, or the Chapter manages their own bank account.

The ATS reimbursement policies have been designed to be as fair as possible to all those who travel and work on behalf of ATS, while at the same time providing good stewardship for the finances that are used to support our travel and meetings. As always, if you have any questions, please do not hesitate to contact ATS staff, and thank you for your service and contributions to the ATS.

If these guidelines are not followed, adjustments will be made by the Executive Office.

Requests for reimbursement must be completed on the official ATS Travel Expense Reimbursement Report form attached. Once completed, please submit the original signed form to the Chapter Administrator.

- Receipts are required for all expenses of \$25.00 or greater. Please attach to the form.
- Original receipts for airline/train tickets (form labeled "Passenger Receipt") are required for
 each trip made. Reimbursement will be based upon coach airfare rates only. ATS will not be able
 to process your reimbursement report without these receipts.
- All charges must be converted into US Dollars (\$) before submitting your expenses to ATS. Please indicate conversion rate in the space provided on the form.
- ATS does not provide a per diem for business travel. However, you have the option to request reimbursement up to a certain limit for meals actually consumed. Meal guidelines are listed as follows:
 - o Breakfast \$13.00
 - o Lunch \$15.00
 - o Dinner \$42.00
- During 2021, mileage for use of your personal vehicle is reimbursed at the rate of 56¢ (cents) per mile. This amount may be adjusted as IRS regulations change.
- Rental of automobiles will not be permitted. ATS will not reimburse employees or members for any approved rentals which extend beyond the dates of a particular ATS meeting.
- "In-room movie", dry cleaning and laundry charges will not be reimbursed.
- Expense forms for reimbursement are due to the Chapter Administrator no later than 60 days following the Chapter Meeting. Please be prompt.

H. Social Events at Chapter Meetings

Chapters meetings may include a Chapter business meeting or other social events. These portions of the meeting are not eligible for CME credit. There must be safeguards in place ensure that social events or meals at commercially supported activities do not compete or take precedence over educational events. Business meetings and social events should be scheduled so that they do not compete with key educational sessions.

I. Advertisements at Chapter Meetings

The ATS does not allow for advertisements at Chapter CME meetings. In addition, faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education. (see ACCME)



J. Sunshine Act (Open Payments)

Open Payments is a common name for the National Physician Payment Transparency Program. You may also hear it referred to as "The Sunshine Act." It's a section of the Patient Protection and Affordable Care Act of 2010, which is commonly referred to as "ObamaCare."

Open Payments is a federal law that requires certain pharmaceutical and device manufacturers to annually report to the secretary of Health and Human Services certain payments or other transfers of value (both direct and indirect) furnished to U.S. licensed physicians and CMS teaching hospitals. Open Payments does not ban any payments but simply requires reporting of payments and transfers of value.

Who are 'Covered Recipients' under Open Payments?

Covered recipients include the following health care professionals who are licensed in the U.S.: medical doctors, doctors of osteopathy, podiatrists, dentists, optometrists, and chiropractors. Fellows are covered recipients. Residents are excluded from reporting.

Other U.S. health care providers such as pharmacists, doctors of pharmacy, scientific researchers with credentials not included above, and medical doctors who are not licensed in the United States are not covered by this law and are excluded from reporting under the provisions of Open Payments.

What types of payments must be reported under Open Payments?

Under Open Payments, all companies must report payments and other transfers of value made to U.S. physicians and teaching hospitals. This includes the cost of meals provided to physicians in any setting, as well as payments made to physicians or teaching hospitals as part of a contracted service such as speaker programs, advisory boards, consulting, and clinical trials.

In addition to meals and payments, companies will also have to report other transfers of value provided to physicians or teaching hospitals, including but not limited to honoraria, consulting fees, educational items, stocks, and grants. Also reportable are expenses covered or reimbursed, such as hotel and travel arrangements. Even if a physician asks the company to donate the funding to a charitable organization, the law states it will still be reported to the physician as the covered recipient.

What information are companies required to report?

- Covered recipient name and business address
- NPI number and specialty
- State professional license #(s) for at least one state
- The amount and date of payment
- Form of Payment
 - o Cash or cash equivalent
 - o In-kind items or services
 - Stock, stock option, ownership interest
 - o Dividend, profit, or other return on investment.
- Nature of such payment (16 categories)
 - o If payment or transfer relates to marketing, education, or research of a drug, device, biological, or medical supply, the related product must also be identified.
- Context: 200 characters

Chapters are responsible for collecting and reporting required information to commercial supporters if you are seeking commercial support.



4. ROLES AND RESPONSIBILTIES

A. Chapters will:

- 1. Be held responsible for the educational aspects of their meeting and event planning /logistics
- 2. Comply with ACCME Standard for Integrity and Independence in Accredited Continuing Education and ATS CME policies
- 3. Complete a CME application within timeframe listed above
- 4. Submit meeting materials for approval for each phase by the designated deadline as outlined above
- 5. Submit post-activity documentation
- 6. Apply for commercial support
- 7. Collect data required for Sunshine Act
- 8. Adhere to all specifications of ATS meeting and event planning

B. ATS will:

- 1. Provide accreditation
- 2. Advertise the meetings on the ATS website and other marketing vehicles
- 3. Collect disclosures
- 4. Provide guidance on mitigating conflicts
- 5. Assist with completing online application and questions about policies
- 6. Review application within 10 days
- 7. Provide designation certificate
- 8. Issue CME certificates to attendees based on attendance information provided



5. TEMPLATES

All templates can be found on the ATS CME Sponsorship webpage.

- A. CME Information Page
- B. Budget
- C. Agenda
- D. CME Calculator
- E. Faculty Letter
- F. Teaching by Design Form
- G. Sources of Commercial & Exhibitor Support
- H. Course and Speaker Evaluation
- I. Pre and Post-Test
- J. Chair Attestation Form
- K. Letter of Agreement for In-Kind Support
- L. Letter of Agreement for Commercial Support (Educational Grant)

6. ATS CONTACTS

Questions about the Application and COI process can be address to:

A. CME (Policies & Application)

Suzette Machado
Associate Director, Education Programs and Accreditation
smachado@thoracic.org
(212) 315-8644

B. Chapter Relations

Kimberly Lawrence
Manager, Diversity and Chapter Relations
klawrence@thoracic.org
(212) 315-8633

C. Ethics and Conflict of Interest Policies

Shane McDermott John Harmon

Senior Director, Ethics & Associate Director, Conflict Professionalism of Interest and Documents

smcdermott@thoracic.org jharmon@thoracic.org

(212) 315-8650 (212) 315-8611