The CO*RE/ASAM **Opioid Prescribing:** Safe Practice, Changing Lives

American Society of Addiction Medicine (ASAM)

Agreement to Host Educational Activity and/or Receive an Unrestricted Educational Grant Opioid Prescribing: Safe Practice, Changing Lives

The following agreement is made between the American Society of Addiction Medicine (ASAM),

hereafter, "ASAM," (Section 1.), and _____

hereafter, "Host," (Section 2.) in order to deliver Opioid Prescribing: Safe Practice, Changing Lives,

the free "Educational Activity," as described and acknowledged in Appendix B to be presented at the

time(s) and location(s) outlined below (Section 3.). ASAM and Host enter into this agreement on

_____, and agree to all the terms and conditions outlined in this document

and attached appendices.

Section 1: ASAM and ACCME Accredited Provider Information

American Society of Addiction Medicine 4601 North Park Avenue, Upper Arcade #101 Chevy Chase, MD 20815

Contact: Education Staff | 301-656-3920 | education@asam.org

Tax ID: 31-3177396

Section 2: Host Organization Information

Host Organization Name:	
Contact Person:	
Title:	
Address:	
City, State, Zip Code:	
Phone:	_Fax:
E-mail:	

Section 3: Activity Date(s) and Corresponding Location(s)

Host proposes to organize, promote and execute the following events in order to deliver the Opioid Prescribing Educational Activity:

Date(s) and Time(s)	Venue	Location (City, State)	Expected Completed Learners*
Example: 2/27/2016,	Chicago Hilton	Chicago, IL	100
8:00am – 11:15am			

* "Completed Learners" are defined as people who attend the Educational Activity and submit an evaluation/outcome assessment on-site or electronically for webinar/live webcast learners. This measure is required by CO*RE and the FDA in evaluating the performance of ASAM under the terms of the CO*RE Grant.

Section 4. Educational Grant

ASAM will provide content, speakers and financial support, where needed, in the form of an unrestricted educational grant in the amount of \$______ to the Host to deliver the specified Educational Activity. Host is responsible for the allocation and disbursement of ASAM's grant for the sole purpose of delivering the Educational Activity as outlined below in Section 8. This grant is not intended for Host's general operational support or ordinary and customary business expenses.

Due to CO*RE Grant requirements, the grant cannot cover the cost of food/beverage or snacks.

Some local hosts require little or no money because they collaborate with other institutions which help cover costs for space, A/V, food and beverage, etc. ASAM appreciates this local support which helps conduct more outreach with fewer grant dollars. Some of the following sections should be completed with zeros if the Host has no financial needs and/or is receiving support from other parties.

Section 5. Payment Terms

- 1. ASAM will pay 50% of the total grant amount within 30 days of the execution of this Agreement by both parties.
- 2. The remaining 50% of the total grant will be disbursed within 30 days after ASAM confirms receipt of the evaluation/outcomes and registration lists and any other specified documentation under this agreement.

Full payment of the grant is contingent upon the host organization reaching the expected number of completers outlined in Section 3. above. If the expected number of Completed Learners is not met, the host organization will submit their receipts of their expenses and will be reimbursed for those expenses.

Section 6. Modification or Cancellation

ASAM's grant is contingent on successful completion of the Educational Activity and reaching the expected number of Completed Learners outlined in Section 3. above. If total registration numbers does not equal 20 registrations, ASAM reserves the right to offer the course as webinar only. In the event that both parties agree that the activity will not result in a satifactory number of

Completed Learners, this agreement may be amended to reflect reduced expenses, or may be terminated. In the event of cancellation of the event and termination of the agreement, documentation will be made by Host to ASAM of all expenses incurred as of the date of cancellation. ASAM will reimburse Host for such expenses not to exceed the total grant amount, so Host is made whole. In the event expenses are less than already advanced grant payments, Host agrees to reimburse ASAM for the unexpended balance.

Section 7. Roles and Responsibilities

ASAM is committed to presenting CME activities that promote improvements in the quality of healthcare. ASAM's grant to Host is contingent upon each party to this agreement fulfilling the following roles and responsibilities in planning, promoting, managing and executing the specified Educational Activity:

ASAM	Hosting Chapter/Organization
Sign the Agreement to Host Educational Activity and/or Receive an Unrestricted Educational Grant at least 90 days prior to the desired course date, unless previously discussed.	Sign the Agreement to Host Educational Activity and/or Receive an Unrestricted Educational Grant at least 90 days prior to the desired course date, unless previously discussed.
Arrange for CO*RE-trained national faculty and reimburse all faculty expenses including honorarium, hotel, travel and per diem. Provide Host with event guidelines and specifications to ensure successful Educational Activity.	<i>Make</i> all local meeting arrangements, including AV, webinar capabilities, food & beverage, registration support, moderators, etc. according to ASAM-supplied guidelines and specifications.
Assist with the successful implementation of a live webcast by marketing the live webcast and by providing technical support (eg, use of webinar hardware or software) when needed.	Make the live course available for simultaneous, live webcast. Market the live webcast as an option for those unable to attend the live course. Marketing should target prescribers of ER/LA opioids though non-prescribers are also encouraged to attend.
<i>Provide</i> high-quality Opioid Prescribing Education content developed by CO*RE national faculty members, for a 2 or 3 hour course.	Schedule the Course to ensure maximum visibility, attendance, and Completed Learners. Include in all listings and promotions.
<i>Provide</i> Host with Opioid Prescribing marketing materials, which include suggested language, marketing tips and guidance. ASAM will include Host's event information in its web site, communication vehicles and electronic communications. Review and approve all local marketing materials prior to distribution.	Rigorously <i>market and promote</i> the Course as a free offering to all appropriate prescribers of ER/LA Opioids in accordance with ASAM approved guidelines, acknowledgements and restrictions. While non-prescribers are encouraged to attend, there should be a particular emphasis on marketing to prescribers.
Review and approve budget estimate, advise Host, where appropriate, on prudent management of grant funds, and make timely grant payments and faculty reimbursements.	Develop, manage and monitor budget estimate as outlined in Section 8 to ensure prudent use of grant funds. Disburse grant funds directly to suppliers of goods and services arranged by Host.
<i>Confirm</i> faculty arrangements with Host for on site management. Supply specifications and requirements for registration of all Course attendees to Host.	<i>Manage</i> all on site logistics, attend to faculty needs and manage registration activities according to specifications supplied by ASAM.

ASAM	Hosting Chapter/Organization
Provide AMA PRA Category 1 Credit(s) and CME Certificates upon receipt of completed evaluations/outcome materials. Generate and distribute CME Certificates for all completed learners.	Supply ASAM with a registration list 10 days prior to the event(s) and within 10 days after the event(s) to confirm attendance numbers. Host to collect evaluation/outcome materials from each registrant and ship to ASAM.
<i>Provide</i> Host with sufficient copies of course description & schedule, disclosure listing, CME Credit and e-Learning Center handouts, and evaluation/outcome materials for all registrants plus 10% to accommodate on-site registrants.	<i>Distribute</i> copies of course description & schedule, disclosure listing, and CME credit information and e-Learning Center handouts to distribute registrants on site. Distribute evaluation/outcome materials to session attendees and ensure 100% completion. Provide evaluation/outcome materials collected and reconciliation of all registrants (including on-site registrants) to ASAM within 10 days of the conclusion of the event(s).
Supply host with specifications of registration information to be collected from each registrant for the Educational Activity.	<i>Provide</i> a final registration list categorized by physician(s) and non-physician(s) and include email addresses and other specified information to ASAM within 10 days of the conclusion of the event.
<i>Review and approve</i> additional meeting support if secured by the Host.	If desired, arrange for additional meeting support and unrestricted grant(s) from other sources, e.g. donated meeting space, sponsorship of snacks, etc.
<i>Review and approve</i> additional presenters or faculty to be involved with presenting this Educational Activity.	Arrange for and cover expenses for local course moderator (if necessary) within approved budget.

Section 8. Budget Estimate

ASAM and Host agree to produce the specified Educational Activity based on the estimates outlined in the following budget. List only those costs that will be covered by the ASAM grant amount of \$_____. Some local hosts require little or no money because they collaborate with other institutions who help cover costs. This section or parts of this section should be completed with zeros if the Host has no financial needs and/or is receiving support from other parties.

Host agrees to pay for any additional or unforeseen costs incurred. ASAM will not be liable for any expenses that exceed the terms of the grant, unless mutually agreed to through an addendum to this agreement.

Anticipated Expenses to be Incurred by Host:

Line Item	Unit Cost	# of Units	Description/Comments
Audience Generation (Marketing Expenses, Branding, Licensing, etc.)			
Venue/Rental Costs (Meeting room, Tables, Chairs, etc.) (ASAM recommends classroom or theater style set-up)			
Audio Visual and Webinar Equipment			
Shipping/Postage for Meeting Materials			
Other (provide specifics):			
		Total Budget:	\$

Note: Due to CO*RE grant requirements, the budget cannot included payment for Food/Beverage or Snacks.

Section 9. Whole Agreement

This represents the whole and entire agreement between the parties and supersedes any previous verbal or written agreements regarding this Educational Activity

Agreed:

ASAM Representative:	
Name: Penny S. Mills, MBA	Title: Executive Vice President – CEO, ASAM
Signature:	Date:
Host Representative:	
Name:	Title:
Signature:	Date:

Please complete, scan, and email form to: Education Staff - education@asam.org.

(If unable to scan and email, please fax to: Education Staff, 301-656-3815)

Appendix A: Terms and Conditions

- 1. **Statement of Purpose:** Program is for scientific and educational purposes only and will not promote any company's products, directly or indirectly.
- 2. **Control of Content and Selection of Presenters and Moderators:** ASAM is solely responsible for control of content and selection of faculty presenters. ASAM reserves the right to review and approve other speakers or moderators associated with the Course presentation that may be proposed by Host.
- 3. **Disclosure of Financial Relationships:** ASAM and Host will ensure disclosure to the audience of all financial relationships between a sponsor/supporter and ASAM, the Host, individual speakers, and moderators including (a) sponsor/supporter funding and (b) any significant relationship.
- 4. **Involvement in Content:** There will be no "scripting," emphasis, or influence on content by outside commercial entities.
- 5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path as the educational activity. No product advertisements will be permitted in the program room.
- 6. **Objectivity and Balance:** ASAM will make every effort to ensure that data regarding products (or competing products) are objectively elected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
- 7. **Limitations of Data:** ASAM will ensure, to the extent possible, disclosure of limitations of data, eg, ongoing research, interim analyses, preliminary data, or unsupported opinion.
- 8. **Discussion of Unapproved Uses:** ASAM will require that presenters disclose when a product is not approved in the United States for the use under discussion.
- 9. **Opportunities for Debate:** ASAM and Host will ensure opportunities for questioning or scientific debate.

10. Independence of ASAM in the Use of Contributed Funds:

- a. Funds should be in the form of an independent, unrestricted educational grant made to Host.
- b. All other support associated with this CME activity (eg, distributing brochures, preparing slides) must be given with the full knowledge and approval of ASAM.
- c. No other funds from the commercial company will be paid to the program director, faculty, or others involved with the CME.
- d. ASAM is responsible for the payment of all CO*RE faculty honoraria, travel, accommodation, and expenses.
- e. Additional pass through charges, for example, registrant administration fees, will be reconciled within 30 days of the last activity.

ASAM and Host agree to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education (2006), the FDA Final Guidance on Industry-Supported Scientific and Educational Activities, the AMA regulations regarding the Physician's Recognition Award, the AMA Opinion 8.061: Gifts to Physicians from Industry, and the AMA Opinion 9.011: Continuing Medical Education.

Opioid Prescribing Agreement

Appendix B: Educational Activity Background; Description; Goals and Objectives; CME Information; and Support Acknowledgements

The Collaborative on REMS Education (CO*RE)

On July 9, 2012, the Food and Drug Administration (FDA) approved a Risk Evaluation and Mitigation Strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications.

Founded in June, 2010, the Collaborative on REMS Education (CO*RE), a multidisciplinary collaboration of 10 Partners and three cooperating organizations, has designed a core curriculum based on needs assessment, practice gaps, clinical competencies, learner self-assessment, with shared tools, resources, and outcomes to meet the requirements of the FDA REMS Blueprint.

Opioid Prescribing: Safe Practice, Changing Lives

Description

The **Opioid Prescribing: Safe Practice, Changing Lives** course was developed by nationally renowned experts in the ER/LA opioid field. ASAM's course includes CO*RE-branded material with an additional segment that focuses on addiction medicine. The content is delivered in 2 or 3 hours (not including time for breaks) and the course can easily be incorporated into a lunch or dinner meeting. The Opioid Prescribing course can also be included as one part of a larger program.

Learning Objectives

- Describe appropriate patient assessment for treatment with ER/LA opioid analgesics, evaluating risks and potential benefits of ER/LA therapy as well as possible misuse.
- Apply proper methods to initiate therapy, modify dose, and discontinue use of ER/LA opioid analgesics, applying best practices including accurate dosing and conversion techniques as well as appropriate discontinuation strategies.
- Demonstrate accurate knowledge about how to manage ongoing therapy with ER/LA opioid analgesics and properly use evidence-based tools while assessing for adverse effects.
- Employ methods to counsel patients and caregivers about the safe use of ER/LA opioid analgesics, including proper storage and disposal.
- Review/assess general and product-specific drug information concerning ER/LA opioid analgesics and identifying potential adverse effects of ER/LA opioids.

Continuing Medical Education Credit

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

The American Society of Addiction Medicine designates this live activity for a maximum of **2** AMA PRA **Category 1** Credit(s)[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity

The American Society of Addiction Medicine designates this live activity for a maximum of **3** AMA PRA **Category 1** Credit(s)TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Support Acknowledgements

This educational activity is presented by the American Society of Addiction Medicine (ASAM), a member of the Collaborative on REMS Education (CO*RE), 10 interdisciplinary organizations working together to improve pain management and prevent adverse outcomes. Complete information about CO*RE can be found at <u>www.CORE-REMS.org</u>.

This educational activity is supported by an independent educational grant from the ER/LA Opioid Analgesics REMS Program Companies (RPC). Please see <u>www.er-la-opioidREMS.com</u> for a listing of the member companies.

This activity is intended to be fully compliant with the ER/LA Opioid Analgesics REMS education requirements issued by the U.S. Food & Drug Administration (FDA).