

Speaker Program Work Instructions

Guiding Principles

Company-sponsored promotional speaker programs are an effective means of educating and informing Healthcare Professionals (HCPs) about the benefits, risks, and appropriate use of our products. However, if not conducted properly, these programs could expose the company to substantial risk. While programs could expose a company to substantial risk if not conducted properly, Sunovion conducts our programs ethically and in a manner we are proud to stand behind. You are accountable for meeting this standard by knowing, understanding and following these Guiding Principles.

1. **We do not pay customers for prescriptions and are not using speaker programs or speaker contracts to do so.**
 - a. **Outside of our industry, speaker programs are highly scrutinized and are often viewed with great skepticism.** Rather than viewing speaker programs as informational presentations in conjunction with incidental meals, the public (including the media and the government) may perceive these programs as a way for a company to reward high prescribers with dinners and drinks or speaker honoraria—a “quid pro quo” if not conducted properly. That is not the reality of how we run our speaker programs, and we must be confident our actions do not present any misperception about our programs.

Be aware of how often you’re using any speaker—and how often we’re paying them honoraria. Ensure that we are providing “fair market value” honoraria for the services they provide: informative, engaging, and educational presentations by professional speakers. For example, humdrum speakers are not a good use of resources and may appear to be “sham” business arrangements. In particular, be aware of how you use your targets as speakers—think of how that looks to a skeptical public. Remember, there should never be any connection (real or perceived) between a speaker’s prescribing and our use of them as a speaker.

- b. **Speaker programs are promotional programs which provide information about the benefits, risks, and appropriate use of our products.** Choose the best speaker that is available—one who can present the data clearly and in a compliant manner. Conduct your programs professionally. You want a well-attended program (at least 3 HCPs, but ideally much more) with an engaged audience (customers who RSVP themselves are more likely to attend; customers who are new to the data will be more engaged). Be mindful of your venue and whether the space is conducive to educational learning (i.e., a private room). Meals are incidental to the presentation and must be modest (\$125 or less per HCP for off-site dinners); limit alcohol consumption. Avoid high-profile venues where, even if we are within our spending limits, we may attract unwanted media

attention or give the wrong impression. These are not social events for you or your customers; they are educational programs, and everyone should treat them as such. Also be conscious about how often your customers attend programs and their level of engagement during the programs. Be aware that Compliance or Marketing may limit how many times a speaker may present or that a customer may attend due to business- or compliance-related concerns.

2. We do not market our products outside of their approved labeling—and speaker programs are no exception.

a. We must be confident that we only have appropriate attendees at our programs, and that we have sufficient information about them to meet our reporting obligations.

Appropriate attendees are those who actively treat patients for our approved indication(s). (For an explanation of who may or may not be an appropriate attendee, see Appendix A.) Our content may be interesting to other people, but it is not worth the risk that the government would consider educating such a person as off-label marketing. We must also ensure that we can document that our attendees are appropriate and be able to accurately identify them for Sunshine Act reporting. Therefore, we often require RSVPs (so we can pre-screen and plan the venue/meal appropriately), and allow walk-ins on a limited basis. (See Appendix B for our walk-in policy.) We also require everyone to sign in, certify they are appropriate attendees, and provide us with information (e.g., medical license or NPI number) allowing us to identify them for reporting purposes. Ultimately, you are accountable for ensuring all your attendees are appropriate and there for the right reasons.

b. Speaker presentations are company-approved promotional presentations and anything presented or any statements made by the speaker are directly attributable to Sunovion. Speaker decks are company-approved, and they must be presented in their entirety, without skipping slides or modifying the presentation, and by presenting a fair balance of the risks and benefits (including discussing the Important Safety Information (ISI) slides at the end). If you suspect that the speaker is not in compliance, we ask that you report your concern by contacting your manager and Compliance or noting any potential issues on your speaker program monitoring form (Compliance Checklist)—otherwise you can be held accountable for the speaker's actions. Attendees may ask questions—but those questions may not be prompted by anything you say. Speakers may then answer those questions, but with restrictions. (For more details on that, see Appendix C.) No additional content other than the company-approved presentation slides may be presented by either you or the speaker.

3. You are responsible and accountable for every aspect of your programs—and for making ethical decisions all along the way. While these Work Instructions include specific rules, you may encounter situations that are not specifically addressed by them. In those situations, these

principles should be your guide, but the over-riding concept is that we must be ethical in all of our business practices. At the end of the day, you have to be able to defend the integrity of your speaker programs. If you have any questions or want to talk anything out, contact your manager or Compliance. You also have to ensure that your Compliance Checklist is accurate and complete—your signature certifies this.

Additional Guidance

1. We currently allow three main types of speaker programs. Off-site (or venue-based) speaker programs typically occur in private rooms at restaurants. On-site (or in-office) programs typically occur in offices, hospitals, or other institutional settings. We also conduct web-based programs (including National Broadcasts) that can occur in either off-site or on-site locations.
2. Each speaker program must have at least 3 HCP customer attendees (not including the speaker). (This does not apply to National Broadcasts or web-based programs.) Having fewer than 3 HCP attendees is a poor use of our financial resources. Further, low attendance may lead to a less formal and unstructured presentation that is not useful or otherwise non-compliant (even off-label). If you're waiting around for the speaker or for a third attendee, you may serve drinks or appetizers—but no meal or presentation until everyone is there. If at any point you determine that you will not have 3 HCP attendees, you must tell your attendees that company policy requires that the program be cancelled. (For on-site programs, if you have less than 3 HCP attendees, you may conduct a detail, but the speaker should not be in the room.) Contact your speaker program vendor to arrange cancellation.
3. Submit your speaker program request well in advance of your planned date. For off-site programs, once your program has been accepted, confirm 5 HCP registrations within 8 calendar days of a venue-based program or it will be automatically cancelled. This helps set you up for success by making it more likely you will have at least 3 attendees and allowing time to plan the meal and venue appropriately. For more details, see the associated Speaker Program Work Instructions Logistics document. You may never provide any compensation, services, gifts, or honoraria of any amount or value to the speaker or program attendees. Examples would include payment of parking or transportation to a program or babysitting. You may however drive the speaker to a program if necessary.
4. You should not spend more than \$125 per HCP at an off-site speaker program (\$75 for off-site lunchtime programs; \$25 for each attendee (including non-HCP staff) for on-site and web-based programs). This is a maximum; it is not a spending goal. The budget includes food, beverage, tax, tip, and any food and beverage minimum (but not room rental or A/V fees). You are responsible for ensuring that the cost-per-attendee cap is not exceeded—and that includes reviewing the receipt at the end of the program.
5. The company limits the number of programs any one HCP may attend to ensure we can defend the value of the education being provided at each program. Based upon the number of slide

decks we have, it's hard to justify our customer having to hear the same presentation repeated more than a certain number of times. Lastly, we don't want our customers to see our programs as "free rides" or raise any potential anti-kickback concerns.

6. You may not arrange for a speaker to speak exclusively to their own colleagues or practice(s). A speaker may not present at the physical location where they work or sometimes work. If a speaker is presenting off-site, the audience must include attendees from other locations not associated with the location where the speaker works. Similarly, speakers can present to groups from the same physician network or group as long as the audience includes attendees from multiple locations. This guidance encourages a formal, professional presentation to an objective audience. It also avoids misperceptions that we are sponsoring an office get-together or paying an HCP to share their knowledge with colleagues—something they should be doing in any case without our involvement. If you think you have a situation that merits an exception, e.g., a large hospital network, contact Compliance.
7. You may not organize an off-site speaker program solely for a single, specific practice or institution. These may be perceived to be sponsorships of celebrations or office parties. (See also #6 above—and contact Compliance if you have any questions.)
8. Maintain a good balance of Sunovion attendees to HCP attendees. An ideal ratio is no more than one Sunovion employee for every two HCP customer attendees. This prevents the perception that a program is a one-on-one meal with your customers. The program lead should take first priority for attendance of all Sunovion personnel.
9. Special state laws: If a speaker program is taking place in Minnesota or Vermont, you should be familiar with state-specific restrictions on speaker programs and refer any questions to your manager or Compliance.

Appendix A - Examples of Appropriate Attendees

You are responsible for ensuring each attendee is an appropriate attendee. Appropriate attendees must sign in and certify that they are HCPs who treat patients for your product's approved indication(s).

1. Appropriate attendees include:
 - a. Healthcare professionals directly involved in the treatment of patients for a product's approved indication(s), including treatment team members.
 - i. For example:
 - A podiatrist may care for a schizophrenic patient, but does not treat that patient for schizophrenia and should not attend our Latuda programs.
 - A phlebotomist may be involved in the care of patients with epilepsy, but does not treat patients for epilepsy and should not attend our Aptiom off-site programs.
 - A billing coordinator may work with patients with COPD, but is not involved in the treatment of patients for COPD and should not attend our Brovana programs.
2. Other appropriate attendees are those involved in HCP and patient access to medications for the treatment of patients for our approved indication(s), such as formulary committee members, hospital executives, and pharmacy directors.
3. Inappropriate attendees include: Non-HCP clerical office staff (with an exception for on-site and web-based programs); non-HCP guests (such as family and friends of appropriate attendees or the speaker); HCP colleagues of appropriate attendees or the speaker who are not directly involved in the treatment of patients for your product's approved indication(s).

Appendix B - Walk-In Policy for Off-Site Programs

1. All attendees should pre-register. Pre-registration allows Sunovion to best meet our objectives of (1) determining our attendees are appropriate attendees, (2) confirming Sunovion has sufficient information with which to appropriately track and report spend for an attendee, and (3) making the on-site program registration go as smoothly as possible.
2. Unregistered walk-ins are permitted if the Therapeutic Specialist or Regional Business Manager responsible for the program positively identifies the attendee and:
 - a. Verifies the walk-in attendee is a target, a treatment team member of a target, or an appropriate attendee from a target hospital;

- b. Ensures the walk-in attendee signs in, certifies that they treat patients within the product's approved indication, and provides a Sunovion CID/SID/, NPI, ME, or state license number if applicable;
- c. For HWP programs: Documents all walk-ins by email with an explanation of each walk-in to your manager, Compliance (joseph.wholley@sunovion.com), and your speaker program vendor (sunovion@hwpnj.com); for NeoHealth programs: ensure that walk-ins sign-in appropriately;
- d. Holds themselves accountable for inappropriate attendees.

Appendix C - Addressing Unsolicited Questions

1. All information presented at a program, including answers to questions from attendees, must be "on-label" and consistent with the Package Insert. Speakers may answer only on-label questions during the presentation or formal Q&A session. On-label questions include those about the data presented at the program. Speakers may use their own clinical experiences in responding to on-label questions, but should qualify that their responses are from their own clinical experience and not directly from the product's label.
2. Speakers may respond to unsolicited, off-label questions within an approved indication from an attendee as part of an individual private one-on-one conversation separate from the program after a program concludes. Such questions must not be answered in front of other attendees who did not ask the question. An example of an off-label question about an approved use would be a question about off-label dosing of Latuda for adult patients with schizophrenia or bipolar disorder. If asked such a question, the Speaker should tell the audience that the question involves off-label information and inform the attendee that the two can speak one-on-one after the presentation has concluded.
3. Off-label questions related to unapproved indications should be addressed via a Medical Information Request Form (MIRF) to be completed by the program lead. An example of this would be a question about the use of Aptiom for anything other than epilepsy. An attendee asking such a question can also contact Medical Information directly via the toll-free line at (800) 739-0565 or via email at minfo@sunovion.com.

Speaker Program Logistics

1. Plan ahead for best results. Program leads must submit a program request at least 4 weeks in advance of your anticipated program date. (For products in a “pilot period” mode, this deadline is 2 weeks in advance; for Brovana/Alvesco, the brands request a 6-week notice.) This is to maximize the chance you will be able to secure the speaker of your choice and give you and other stake-holders time to prepare for a program. Examples of other stakeholders are your RBM, ASD, adjacent territories, the brand team, your speaker program vendor, and Compliance.
 - a. Just because a program request has been submitted does not mean the program is confirmed/booked. This includes programs which you or your RBM may have already discussed with a proposed speaker.
 - b. For Latuda: Submit the request through <http://TS.sunovionspeakersnetwork.com/>
 - c. For Aptiom: Submit the request through <http://epilepsyspeakerrequest.com>
 - d. For Brovana/Alvesco: Contact Donna Rinaldi at NeoHealth (donna.rinaldi@neohealth.com).
2. Attendee HCPs should register for off-site programs no later than 3 hours before the program (Note that pre-registration is not required for on-site or web-based programs; however, for on-site programs, you should always plan for and expect 3 or more HCP attendees.)
 - a. Pre-registration allows Sunovion to best meet our objectives of (1) determining our attendees are appropriate attendees, (2) confirming Sunovion has sufficient information with which to appropriately track and report spend for an attendee, and (3) making the on-site program registration go as smoothly as possible.
 - b. For Latuda: HCPs can register at <http://www.sunovionmeetings.com/> or by calling (866) 801-0824
 - c. For Aptiom: HCPs can register at <http://www.aptiommeetings.com> or by calling (877) 829-1266
 - d. For Brovana/Alvesco: HCPs can register by calling (800) 527-6043 or by faxing a registration form to (201) 288-2307.
 - e. You may register for a program on behalf of an HCP through the TS portals in Section 1 above. But be aware that HCPs are more likely to attend if they register themselves.
 - f. While walk-ins may be accepted under the appropriate circumstances as outlined in the walk-in policy, pre-registration will make the program much easier for you to manage on site. Avoid having walk-ins.

3. Monitor attendee confirmations for off-site programs. As program lead, you must confirm 5 HCP registrations within 8 calendar days of the venue-based program or your program will be automatically cancelled. This helps set you up for success by making it more likely you will have the necessary 3 attendees.
4. You may not spend more than \$125 per HCP at an off-site dinner speaker program (\$75 for off-site lunchtime programs; \$25 for each attendee (including non-HCP staff) for on-site and web-based speaker programs). This is a maximum; it is not a spending goal. The budget per HCP includes food, beverage, tax, tip, and any food and beverage minimum (but not room rental or A/V fees). (For on-site programs you may add \$25 non-HCP and for each Sunovion employee attendee who takes a meal.) You are responsible for ensuring that the cost-per-attendee cap is not exceeded—and that includes reviewing the receipt at the end of the program.
 - a. All off-site program expenses must be direct billed through your speaker program vendor. You must not use your corporate credit card or your own personal money to cover any part of expenses associated with an off-site program. However, for on-site and web-based programs, all meal expenses must be billed through your expense report similar to a lunch-and-learn. Use your corporate credit card to cover the costs of the meal.
 - b. Venues requiring a minimum are not recommended. If a venue requires a food and beverage minimum, your speaker program vendor will inform you as program lead of the condition and ask you to confirm that you understand and agree to the requirement.
 - c. The meals and drinks served at your off-site programs often are controlled by the venue's contract with your speaker program vendor. You do not have authority to override the contract. For example, alcoholic drinks are limited to 2 per attendee and to domestic beer and house wine only. If an attendee wants an alternative beverage, they may pay for it themselves; you may not offer to cover the cost out of your own pocket. But be aware that alcohol consumption can be disruptive to the educational value or perception of the program. We should also be concerned of the safety of our customers during and after the program.
 - d. You can allow attendees to opt out receiving any food and beverage from us (both on-site and off-site). For off-site programs only, opt-out attendees may instead pay for their own food and beverage.