Helping Pharmas Manage Compliance Risks for Speaker Programs

By taking a rigorous and thoughtful approach that pivots around key performance indicators, pharmaceuticals companies can proactively identify and solve noncompliance challenges with speaker programs before they impact the bottom line.
Executive Summary

Among the many promotional and marketing strategies used by pharmaceuticals companies, one of the most widely used and necessary components in the industry is the speaker program event. Pharma companies typically use peer-to-peer speaker programs to promote and educate healthcare professionals (HCPs) about their drug therapies and the diseases their drugs treat. The interactions between HCPs through such events not only affect prescribing patterns but also help HCPs stay up-to-date on the latest molecules, newly approved drug indications, the latest clinical data and safety issues, among many other things.

But over the past few years, speaker program events have become a bone of contention in the industry as they tend to be misused. For example, some programs have provided opportunities for pharma companies to promote “off label” use of their drugs, which is illegal. In such instances, companies have been heavily penalized - and in some cases the resultant fines are estimated to be billions of dollars. As a result, multiple rules and regulations have been enacted by various U.S. government bodies, trade associations, and pharmaceuticals companies themselves, to ensure program compliance.

This white paper examines key rules and regulations surrounding speaker programs and provides an overview of how we believe pharma companies can proactively identify and solve noncompliance challenges before they impact the bottom line.
DECONSTRUCTING SPEAKER PROGRAMS

A speaker program event typically consists of one or more speakers, multiple attendees and the company representative who is responsible for arranging the program venue, topic and speaker.

• **Speakers:** Speakers at such events are typically subject matter experts (SMEs) approved by the company’s internal review organization who have credentials and have undergone speaker training. They can be HCPs (national, regional and/or local key opinion leaders) or non-HCPs (business or best-practice experts). Speakers are paid a fee for service based on fair market value (FMV) determined by their credentials.

• **Attendees:** Attendees are primarily HCPs (prescribers, nurses, technicians, etc.) or non-HCPs (office staff, patients), and their medical specialty must correspond with the topic of the speaker program. Attendees are typically provided a meal at these events as a courtesy for their time.

• **Topic:** Presentation materials used must be compliant and reviewed by the U.S. Food and Drug Administration (FDA). Material can consist of the benefits, safety and usage of the product, or the diseases it treats, or it can be completely unrelated to the product. The speaker must present all the material provided; any modifications made should be approved before the material is presented.
CONSEQUENCES OF NONCOMPLIANCE

During the past nine years, 10 of the world’s major pharmaceuticals companies have been penalized a combined $12.9 billion by the government (see Figure 2) and are now operating under a corporate integrity agreement (CIA) for violating speaker program rules enforced by the Office of Inspector General (OIG). CIAs typically last five years and make corporate officers personally liable for the company’s compliance with stipulations set forth by the CIA. These agreements usually require the following:

- Hire a compliance officer/appoint a compliance committee.
- Develop written standards and policies.
- Implement a comprehensive employee training program.
- Retain an independent review organization to conduct annual reviews.
- Report overpayments, reportable events and ongoing investigations/legal proceedings.
- Provide an implementation report and annual reports to U.S. OIG on the status of the entity’s compliance activities.

A part of the Affordable Care Act (ACA) known as the Physician Payments Sunshine Act covers physician financial transparency reports. This legislation requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals.

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a U.S. industry trade group that represents pharmaceuticals research and biopharmaceuticals companies and advocates for public policies that encourage the discovery of new medicines for patients. They have codified rules concerning interactions with HCPs for the trade group’s members to abide by. (The

Figure 2. Financial Consequences for Noncompliance with a Blockbuster Drug

Penalties levied by the Office of Inspector General on each company during recent years.
peer-to-peer speaker programs are considered a form of interaction with HCPs.)

As mentioned above, companies that have a CIA are also required to hire a compliance officer and/or appoint a compliance committee. These entities must set company policies to prevent inappropriate engagements as well as to preempt any activity that could be perceived as misconduct.

IDENTIFYING NONCOMPLIANCE

Our solution proposed in Figure 3 not only helps to identify cases of noncompliance but will also help a pharma company to more efficiently manage speaker programs, in turn making them more effective. It will also enable the company to identify the gaps in its compliance systems and processes - and help it define the guidelines required to close them.

Our process involves, initially, defining or identifying the various metrics or key performance indicators (KPIs). These KPIs would be based on the relevant laws, regulations, policies, standards, procedures or contractual obligations to which the organization must conform. These include the CIA, the Sunshine Act, the PhRMA code on interactions with HCPs, and the pharma company’s own internal regulations and guidelines, among others.

Some of the compliance areas covered are the following:

- **Transparency of speaker payments**: All expenses paid to speakers and other “transfers of value” (i.e., meals) can be tracked for each individual speaker in a calendar year. This can be tied to the type of program (lunch/dinner/teleconference), the number of times each speaker presented, the number of attendees, whether the program took place or not (to...
According to a company’s CIA, it must submit annual plans that identify the business needs for various publication activities (including speaker programs) and the estimated numbers of such activities.

- **Excessive value of company-provided meals**: This would satisfy transparency and PhRMA guidelines, which stipulate that each meal should be of nominal value and is provided as a courtesy. Importantly, it should not be used to influence an attendee or a speaker.

- **Signed contract confirmation**: For every speaker program, a statement of work (SOW) or contract must be signed between the speaker and the organization that details the speaker’s fee-for-service, expenses, topic to be covered, etc.

- **Approved specialty monitoring**: To prevent the promotion of off-label use of its drugs, companies must ensure that attendees are appropriate to the topic presented. The approved specialty is usually determined by FDA parameters covered in the speaker program.

- **RSVPs**: To ensure that the event has a minimum number of attendees apart from the speakers and reps, speaker programs are required to have a minimum number of RSVPs a few hours prior to the event. The minimum number may vary based on the event type.

- **Annual plan monitoring**: According to a company’s CIA, it must submit annual plans that identify the business needs for various publication activities (including speaker programs) and the estimated numbers of such activities. The plans also identify the budgeted amounts to be spent on such activities. Speaker bureau size, number of programs and amount spent on programs are tracked.

- **Meal consumption**: Companies are allowed to provide a nominal meal as a courtesy to the attendees and speakers for participating in a speaker program. They will set limits on frequency of meals consumed by attendees to avoid the perception of the meal serving as a kickback. In addition, reporting on the meals consumed will be utilized for transparency of payments and transfer of value to HCPs (attendees and speakers).

- **Food and beverage management**: When speaker programs are held in a physician’s office, the meals provided are intended for only those individuals who attend the speaker program. HCPs at the physician’s office not
attending the speaker program are not permitted to receive food intended for attendees (i.e., distribution of leftovers is not permitted). So, the amount of food ordered should not exceed the requirements for the number of actual attendees or other parameters set forth by the company, such as RSVPs.

• **Speaker bureau management**: Companies can track the frequency of speaker utilization (national/regional/local key opinion leader (KOL) and non-KOL), average attendance size per speaker, attendee mix per speaker (doctor, physician’s assistant, etc.), speakers with expiring contracts, etc.

• **Presentation decks management**: Companies can track the frequency of utilization, average number of attendees per topic, average attendee mix (doctor, physician’s assistant, etc.), expiring topics, etc.

• **Attendee summary**: Companies can track the number of attendees by program type (in-office, out-of-office or teleconference), attendee category, etc.

• **Speaker program costs summary**: Speaker program-related expenses can be tracked for better budget management. Expenses can be categorized into expense types, such as speaker expenses (honoraria, travel, meals, etc.), pass-through costs (A/V costs, room rentals, management fees, etc.) and catering. These expenses can also be viewed by program type.
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