Checklist for Life Sciences Organizations

Engaging Key Opinion Leaders and Healthcare Professionals

Pharmaceutical, medical device, medtech, and other life sciences organizations engage providers (e.g., physicians, advanced practice providers, etc.) and other ancillary services and non-clinical personnel (i.e., nurses, administrators, etc.) to help develop new medications and devices via various interactions (i.e., speaker programs, consulting, advisory boards, etc.). To manage and mitigate the regulatory and reputational risks associated with payments to these key opinion leaders (KOLs) and healthcare professionals (HCPs), a life sciences company should evaluate certain items prior to engagement and payment for the services. PYA's KOL and HCP Checklist serves as a guide to assist life sciences organizations in evaluating both the payment to and the process for engaging KOLs and HCPs. Depending on an organization's specific facts and circumstances, additional considerations may be important to analyze and subsequently add to this general guide, which is not intended to be all inclusive.

If the answers to the following questions are "No," further consideration may be required.

Engagement Process	Yes	No
Does the organization have a pre-approval process prior to engagement for services provided by KOLs/HCPs?	☐	☐
Service Definition		
Are the required qualifications (e.g., education, expertise, etc.) for the position and/or specific services well defined and documented?	☐	☐
Does the nature of the duties to be performed (including the separation of clinical, instructional, and administrative functions) require a KOL/HCP, and are they clearly outlined?	☐	☐
Is the expected time or burden associated with the requested services clearly defined (i.e., what topics and materials need to be prepared, what are the audience size and demographic, will the service be conducted virtually or in person, etc.)?	☐	☐
Have budgets been developed and approval from the respective parties involved been obtained for various KOL/HCP activities (i.e., speaker programs, consulting, advisory boards, peer-to-peer presentations, etc.)?	☐	☐
Documentation of Need		
Has documentation been developed and maintained to support the following:		
Does an identifiable business need to engage a KOL/HCP to provide the proposed services exist (i.e., how it meets an essential need of the company such as providing advice on drug development or clinical trials, presenting scientific or real-world information, consulting on patient needs, etc.)?	☐	☐
Are the proposed services provided by the KOL/HCP related to the company's business and/or clinical plans and strategies?	☐	☐
Does the arrangement contribute to the company's profits and/or development of a product or service excluding income from proscribed referrals?	☐	☐
Are the number of, or hours required from KOLs/HCPs needed to fulfill an organization's service, appropriate?	☐	☐
Are the national, regional, and local economic conditions appropriate for the proposed arrangement?	☐	☐
Are the qualifications and time demanded to perform the services adequate?	☐	☐
Have the expected outcomes and benefits to the organization from the services been identified?	☐	☐
Is the need for KOLs/HCPs based on scientific/medical expertise, reputation, knowledge, and experience in a particular therapeutic area, and are there no other internal or other available resources to fulfill the need?	☐	☐
Are safeguards in place to ensure the company receives real value from the KOL/HCP services and those services are actually performed (e.g., written agreement, meeting minutes, performance evaluation, etc.)?	☐	☐
Is the arrangement periodically reviewed to ensure a legitimate and necessary business need for the service continues?	☐	☐

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Fair Market Value Considerations	Yes	No
Has the organization assessed whether compensation is consistent with fair market value?	☐	☐
Is the KOL/HCP compensation structure based on objective considerations (i.e., established set of criteria via a pre-determined tiered or stratified model)?	☐	☐
Is the compensation structure applied uniformly for requested services (e.g., speaker programs, consulting, advisory boards, etc.)?	☐	☐
Does a process exist for evaluating scenarios where the circumstances may warrant paying a KOL/HCP an amount outside of the predetermined level based on specific facts and circumstances and therefore qualify as an exception?	☐	☐
Is the process used infrequently? If exceptions to predetermined levels occur frequently, such levels may need to be evaluated to minimize the need for exceptions.	☐	☐

Considerations for Specific Interactions	Yes	No
Speaker Program Factors[1]		
Is the information available only through the speaker program?	☐	☐
Is the event held in a location that is conducive to learning?	☐	☐
Have there been new developments related to the pharmaceutical or medical device?	☐	☐
Is this the first time the KOL/HCP has presented as a speaker for the product or device?	☐	☐
Is the KOL/HCP selected to participate in the speaker program based on factors unrelated to current or future sales targets or anticipated prescription volumes?	☐	☐
Is the KOL/HCP presenting to a new audience (e.g., one that has not previously attended the same program or one that excludes family members, friends, or others)?	☐	☐
Is the information presented relevant to the selected audience?	☐	☐
Does the organization distinguish speaker program activities from continuing medical education activities?	☐	☐
Does the organization monitor speaker programs for compliance with regulatory requirements (i.e., FDA)?	☐	☐
Advisory Board (Ad Board)[1]		
Is the compensation structure for KOL/HCP participation in an Ad Board consistent with the market (e.g., per meeting, annual retainer, etc.)?	☐	☐
Has the format of Ad Board participation been considered (e.g., in-person, virtual, hybrid)?	☐	☐
Are the expectations required of Ad Board KOLs/HCPs well defined and documented?	☐	☐
Are the responsibilities requested of Ad Board KOLs/HCPs consistent with a product's life cycle stage (e.g., clinical trial design input may be more appropriate early while medical education program review may be a later focus)?	☐	☐

Considerations for Specific Interactions (continued)	Yes	No
Consulting[1]		
Are KOLs/HCPs selected based on the qualifications or experience needed and not solely on recommendations from interested parties (e.g., sales and marketing representatives, business unit operators, etc.)?	☐	☐
Do the individuals who select KOLs/HCPs for consulting services have the expertise to do so (i.e., they discern that the KOLs/HCPs meet the criteria needed)?	☐	☐
Can the organization demonstrate use of a KOL/HCP's expertise, and is it documented?	☐	☐
Other		
Does the organization have a policy for compensating KOLs/HCPs for travel and preparation time specific to an identified service? Is it consistent with fair market value and reasonably similar to other organizations of like type?	☐	☐
Does the organization have a policy for use of prescriber or other real-world data/evidence?	☐	☐
Does the organization conduct training at regular intervals for company representatives who interact with HCPs/KOLs specific to applicable regulatory requirements and industry codes of practice?	☐	☐
Does the organization periodically (e.g., annually) monitor executed agreements with KOLs/HCPs to ensure the terms of the agreements are fulfilled and if not, that they are brought into compliance and/or terminated?	☐	☐
Are relevant decision-makers (i.e., compliance, legal, etc.) involved in the contract review process?	☐	☐

PYA can help your organization by evaluating the payment to and process for engaging key opinion leaders and healthcare professionals to mitigate regulatory risk. Contact PYA at (800) 270-9629.

1 These factors are intended to be illustrative and may not be all inclusive with respect to applicable considerations.