

# **A Position Paper on Letters of Agreement for Commercial Support Grants in Support of Continuing Medical Education Activities: The Accredited Provider's Position**

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## **Introduction**

Accredited providers of Continuing Medical Education activities have a responsibility to ensure that activities they certify for credit meet the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME). Compliance with the Standards for Commercial Support of Continuing Medical Education is an integral part of the process. One of the key factors related to the use of commercial support is the execution of a Letter of Agreement (LOA) between the Accredited Provider and the Commercial Interest (grantor) providing funding to support the activity. The purpose of the LOA is to document the independence of the Accredited Provider from any control of the commercial interest in the development and conduct of the educational activity.

Accredited providers have encountered numerous versions of Letters of Agreement produced by various pharmaceutical and device companies that, although well intentioned, have caused great consternation and legal concerns for the providers. In fact, some of the clauses that have been included in these letters have actually violated the intended purpose of the LOA. This document addresses the ACCME requirements for Letters of Agreement (LOAs) and those elements found in some industry developed LOAs that have caused problems for accredited providers.

Fully executed Letters of Agreement are required as they:

- Document the independence of the Accredited Provider from the Commercial Interest
- Establish the terms and conditions under which the grant will be provided
- Demonstrate compliance with enforceable standards of the ACCME
- Assure that the provider can develop CME activities without control or influence of the commercial interest.

The ACCME Standards for Commercial Support state in Elements 3.4, 3.5 and 3.6:

- 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.
- 3.5 The written agreement must specify the commercial interest that is the source of commercial support.
- 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider. Although the educational partner must be referenced, there is no requirement that the educational partner also be a party to the signed document. In fact, any agreement with an educational partner should be with the accredited provider and not with the commercial interest. To do otherwise assumes a contractual relationship between the educational partner and the commercial interest and could in turn violate 3.1 and 3.3 of the Standards.

The Letter of Agreement should reference that all parties will adhere to the ACCME Standards for Commercial Support. It is not necessary to replicate all of the language found within the Standards.

Accredited providers recognize that other codes and guidelines are applicable to both industry and Accredited Providers in regard to the educational grant process including:

- FDA Regulations, specifically the 1997 Guidance Document
- PhRMA Code on Interactions with Healthcare Professionals
- AdvaMed Code of Ethics on Interactions with Health Care Professionals
- AMA Ethical Opinions 8.061 (Gifts to Physicians from Industry) and 9.011 (Ethical Issues in CME)
- HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers 2003
- Fraud and Abuse Laws and Regulations

Accredited providers in recognizing these issues have found that often other clauses are incorporated into LOAs that create problems that are not consistent with the intent of the Standards for Commercial Support and are outside the boundaries of the relationship between the Provider (grantee) and commercial interest (grantor). Following is a list of issues and clauses that are problematic for accredited providers and an explanation of the rationale as to why these are problematic.

### **LOA's as Grants vs. Contracts**

Many have discussed whether a LOA creates a business relationship. In distinguishing a grant vs. a contract, essentially both are a type of "business relationship," but with different responsibilities.

- A **contract** involves an offer by one party and acceptance by another party creating an obligation to do or not to do something, for consideration, creating a legally binding agreement. Or put another way, an obligation for one party to provide specified goods or services in exchange for payment from the other party.

- A **grant** is a funding mechanism where there is no substantial involvement by the funding party in the performance of the supported activities. Or put another way, to bestow something on another without compensation.

For further clarification of these terms see the following definition of terms provided in the NIH website:

- **Contract** -- An award instrument establishing a binding legal procurement relationship between <grantor> and a recipient obligating the latter to furnish a product or service defined in detail by <grantor> and binding the <grantor> to pay for it.
- **Grant** -- Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the <grantor> anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Thus for CME purposes, the LOA for Commercial Support must not be considered a “contract” in order to comply with the ACCME Standards for Commercial Support.

### **Electronic acceptance and signature**

In many cases, the person who actually submits the on-line grant request is a staff person who does not have signature authority for the Accredited Provider. Thus, they do not have the authority to click on the acceptance trigger. While electronic signature may be the technological solution for rapid submission and acceptance, it can and often does create a legal quandary for many Accredited Providers. In addition, some systems require that the individual who clicks the “submit icon” agrees to an anonymous set of terms and conditions without benefit of review. Finally, some systems do not provide the ability to have a printed copy with the electronic signature for the Provider’s records. ACCME requires such documentation be present in the file.

### **Choice of Law or Choice of Venue clauses**

While it is understandable that this clause is necessary for the “normal” legal contract, it becomes questionable when one considers the intent of the LOA. The LOA should not be considered a business contract in the normal sense, but rather a document that establishes the independence of an accredited provider from the influence or control of the commercial interest. Its purpose is not to establish a “business relationship,” but rather to document the terms and conditions of the awarding of a grant that will permit the recipient to develop an educational activity for physicians and possibly other health care professionals that will be entirely independent of the commercial interest.

Furthermore, the requirement of choice of law or venue becomes problematic for many academic providers and some hospitals which may be agencies of the state in which they are located. Thus, they are prohibited from accepting a state of venue or state of law other than their own. An option some may have is to “remain silent” and remove all clauses related to choice of law or choice of venue. However, this can cause delays and even the rejection of the LOA by the commercial interest.

### **Indemnification clauses**

The requirement of “indemnification” presumes that a business relationship exists between the accredited provider and the commercial interest. Of even more concern, it assumes that there is a client or agency relationship in which the accredited provider is the purveyor of services for the commercial interest and, in this role, should “protect” the commercial interest in the event of wrongdoing on the part of the accredited provider. It is hard to understand how an organization that is required to act entirely independently of the commercial interest could place that entity in jeopardy. If that logic were to be continued, any entity or individual could be considered to be responsible for the actions of the many service and research organizations that are funded through the receipt of grants and donations. The concept of “independence” defies this rationale. Indemnification clauses have no real place in grant agreements as the parties are not acting as each others agents or employees.

### **Arbitration clauses**

The same argument against indemnification clauses holds for arbitration clauses. These are clauses meant for contracts where the intent of the contract is to document the responsibilities of each party to each other. In addition, for many providers, arbitration clauses are dictated by state law. Thus including arbitration clauses is ineffective and often cause a stumbling block to signing an agreement.

### **Cancellation clauses**

The funding is provided to the Accredited Provider as a grant, not as fee for service. When clauses are inserted that “reserve the right of the company to withdraw funding at any time and without advance notice” one must wonder about the rationale for such a clause. Other than the inability of the accredited provider to fulfill the “terms and conditions” of developing and conducting the educational activity, what other reason would there be for funding to be withdrawn? Cancellation clauses appear to provide complete control to a commercial interest to discontinue funding for any reason it may deem appropriate, something that absolutely contraindicates independence of the accredited provider.

### **Confidentiality issues/Release of Attendees Names**

Confidentiality clauses have no place in Letters of Agreement. The concept of such a clause reinforces the perception of an agency relationship between the commercial interest and the accredited provider. A confidentiality clause presupposes that “confidential” information will be shared with the accredited provider. What purpose would this serve, other than something for which the development of an independent medical education activity is not intended? In fact, the concept of “confidentiality” is in complete opposition to the requirements of transparency, openness, and providing all information to allow the participant to come to his or her own conclusions.

Most academic institutions are bound by the Berkley Amendment or FRPA which is the Family Right to Privacy Act that governs most institutions of higher education. CME attendee records or list of attendees cannot be released to anyone other than official requests and those usually must be approved or agreed to by the individual (such as licensing boards or other such audits). In fact, attendee information should never be released to the commercial interest. To do so would most assuredly lead to questions related to the purpose or intent of the activity. If this

information is shared with the commercial interest it would be difficult if not impossible to make a convincing argument that the activity was not conducted for the purpose of marketing a product.

### **Business Code of Conduct inclusions**

It is inappropriate to ask the provider to agree to or attest to a company's business code of conduct. These codes govern the industry and business and have no bearing on the accredited provider. The inclusion of such a requirement does not reinforce independence, but rather helps to establish a client or agency relationship since it would be quite appropriate to have an agency attest to such a requirement as it is acting at the behest of the commercial interest.

### **After the fact requests and requirements**

After an LOA is signed, it is inappropriate for the commercial interest to request or require an accredited provider to additionally use a specific template or 3<sup>rd</sup> party organization for evaluation or to perform some task not addressed in the LOA. Requests of this nature violate the Standards for Commercial Support and are not the purview of the grantor.

### **Clauses restricting or requiring content or speakers**

Clauses that make requirements of, or restrict, the accredited provider in any way in the development or conduct of the activity violate the intent of the LOA as well as Standard 1.1 of the Standards for Commercial Support, that of assuring the activity is developed and conducted independently of the commercial interest. Issues such as fair balance, disclosure, identification and resolution of conflict of interest are basic to the development of proper educational activities. These terms do not have to be included (or repeated) in the LOA". There should be no language permitting the commercial interest any involvement in the development or conduct of the activity in any way, nor should there be language permitting "limited technical assistance by Grantor in preparing audiovisual or graphical materials". It is especially violative when this language includes the term, "at the request of the faculty member". There should be no discussion at any time between the faculty and the commercial interest as this may raise serious concerns about "inappropriate influence".

Clauses that require a "right of review" also violate the letter and the intent of the Standards. The accuracy of the content is not the responsibility of the commercial interest, but rather the responsibility of the Accredited Provider.

### **Clauses related to electronic formats**

Such clauses will be construed as violating the independence of the Provider in "the selection of educational methods" and as such violate SCS1.1 (c ) and (e). Any wording requiring the Provider to preserve information for future use infers that the commercial interest is controlling the use of the material. This same thinking is applicable when wording appears that requires the specific manner in which material should be preserved or posted.

### **Clauses related to distribution of Enduring Materials**

Clauses regarding distribution or non-distribution of enduring materials to certain groups or types of groups are clearly a violation of independence and are not appropriate in

LOAs. Providers are not an agency of commercial supporter and should be able to distribute enduring materials to whomever they wish.

### **Use of funds**

The Accredited Provider is solely responsible to determine the disposition and disbursement of all funds, including those secured as commercial support (3.1) Inclusion of any clauses requiring adherence to policies of the commercial interest pertaining to honoraria amounts, reimbursement of expenses, use of “preferred vendors for services” are all inappropriate and violative of the Standards. The ACCME and AMA have established guidelines to which the Accredited Provider must adhere.

### **Summary**

Letters of Agreement are required in order to clearly demonstrate the independence of the Accredited Provider from the commercial interest (grantor). The purpose of the LOA is to establish the terms and conditions of the grant. The purpose is not to establish any sort of “business relationship” with the commercial interest. Any language that infers such a relationship exists is contrary to the intent of the Standards for Commercial Support and should be removed.

As a matter of principle and compliance accredited providers will sign LOAs that do not suggest legal issues or business practices that will place them in non-compliance with the requirements of the ACCME. To include other issues and clauses creates a situation that is often untenable for the provider for reasons outside the boundaries of the compliance issues to which all must adhere.