Dear Dr. Kopelow:

Thank you for speaking with us on September 11 and extending the deadline to allow the American Medical Writers Association (AMWA) to comment on ACCME’s proposal for additional features of independence in accredited continuing medical education (CME). AMWA represents 5,600 medical communicators (writers and editors) in North America and around the world, and the ACCME proposal may have implications for many of them.

In this response letter, we have focused on the single ACCME policy proposal that specifically affects medical communicators:

*Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.*

We do not intend our remarks to address issues related to scientific or medical experts who create or present continuing education. They should be considered under a separate policy. Our concern is for medical communicators who work with subject matter experts in the development of promotional or CME materials.

Although we agree in principle with the premise that medical education needs to be independent of commercial bias and that writers should not introduce bias, we found that ambiguities in the proposed ACCME policy statement led us to different opinions about the policy based on our varied interpretations of it. Some clarification will help providers to implement the final policy in the real-world setting.

The intent of the proposed ACCME policy appears to be that those who control the content of promotional materials should not be able to control the content of CME on the same material. Promotional materials are inherently supportive of a specific product or service. A medical communicator who controls promotional content could have the opportunity to introduce bias into similar CME content, and should therefore be excluded from controlling similar CME content.

However, medical communicators rarely have full control of content they develop as freelance writers or editors doing work for hire or as employees of a CME provider. Medical communicators who assist authors may think they are exempt from the proposed ACCME policy because the named authors or clients have final responsibility for the content of most types of medical writing. Therefore, we request clarification: Under the proposed ACCME policy, would...
medical communicators who contribute substantially to—but do not have full control over—their work product be excluded from controlling the content of CME activities?

If so, the underlined text below might clarify this point:

Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content.

On the other hand, if control is to be interpreted strictly, then many writers would be exempt from the proposed policy, which may be what the ACCME intends.

We also request clarification of “promotional materials.” It is our understanding that “promotional materials” refers to materials originally intended for marketing/advertising purposes. If the ACCME agrees with that definition, medical communicators who perform the following non-commercial services on behalf of commercial interests would not be prohibited from controlling the content of CME activities on the same content.

- Helping prepare documents for submission to regulatory bodies (e.g., FDA)
- Helping authors prepare manuscripts (including review articles) for medical journals
- Helping authors prepare abstracts, slides, or poster presentations for medical congresses

If the ACCME agrees, we suggest clarifying the proposed policy as follows:

Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content.

Documents for submission to regulatory bodies, manuscripts (including review articles) for medical journals, and presentations for medical congresses are not considered promotional materials.

Finally, we would like to request clarification surrounding the intent of the medical communicator. A medical communicator may help prepare a document for nonpromotional purposes, which is subsequently repurposed, in whole or in part, for promotional use, by parties outside the control of the writer. Would a medical communicator whose noncommercial work product is repurposed for commercial use be excluded from controlling the content of CME activities?

If not, we suggest inserting the underlined clarification below:

Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content.

Documents for submission to regulatory bodies, manuscripts (including review articles) for medical journals, and presentations for medical congresses are not considered promotional materials. Persons whose noncommercial work product
is subsequently repurposed for commercial use outside of their control are exempt.

In general, we urge the ACCME to consider the implications of its proposal carefully, because such a sweeping prohibition has the potential to unfairly restrict qualified writers and editors from being employed in CME. The comprehensiveness of the policy should be commensurate with the risk it seeks to mitigate.

Again, we thank you for granting us an extension to submit our response for your consideration. We did not have time to obtain endorsement of this response by AMWA’s Board of Directors, which is the voting body. Therefore, please consider this the response of the undersigned only, reflecting our individual perspectives as experienced medical communicators. We appreciate the opportunity to continue to work with you on issues related to medical communicators in CME.

Sincerely,

Sue Hudson
President, AMWA
Principal, Medical Writing Associates

Jim Cozzarin, ELS
Past President, AMWA

Cindy W. Hamilton, PharmD, ELS
President Elect, AMWA
Principal, Hamilton House