SOCIAL MEDIA COMPLIANCE GUIDE

December 2023

CME Coalition:
Social Media Compliance Guide

December 2023

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I. Introduction and Purpose

Founded in 2011, the Continuing Medical Education (CME) Coalition (www.cmecoalition.org) is a policy development and advocacy organization composed of and representing continuing education (CE) providers, supporters, and beneficiaries. Representing many of the leading CME providers and supporters in the CE enterprise, our member organizations manage and support the development of healthcare CE programs that impact more than 500,000 physicians, nurses, pharmacists, and other healthcare professionals (HCPs) annually. A significant part of the CME Coalition's role in achieving its mission is developing and disseminating essential policy analyses to its member companies and the community at large.

Over the past two decades, beginning with the launch of Facebook and Twitter (now rebranded as "X"), social media, like the Internet, has emerged as an essential global communication channel for healthcare stakeholders. Simultaneously, numerous questions have arisen over the appropriate use of social media in furtherance of CE activities. Therefore, the Coalition has produced this Compliance Guide in response to the questions it has received. This Compliance

Guide was developed with support from Otsuka America Pharmaceutical, Inc., Medscape, Med-IQ, and the CME Coalition, and the assistance of Dr. Seth B. Whitelaw, President & CEO of Whitelaw Compliance Group, LLC.

While this document is current as dated, the CME Coalition will update and revise it appropriately and indicate applicable dates in future revisions.

II. Overview

A. Scope

This Compliance Guide addresses the use of social media in an educational context. It includes accredited continuing education programs, independent medical education, and non-accredited educational programs. However, it **does not** address (1) activities that are promotional (e.g., that advertise or market a specific manufacturer's product or are otherwise controlled or influenced by a manufacturer) or (2) compliance with general FDA advertising and promotional laws, regulations, or guidance. Moreover, it **does not** address every potential source of guidance. In addition, the Coalition recommends that this Compliance Guide be used in conjunction with its May 2022 *Independent Medical Education (IME) Compliance Guide* as appropriate.

Please note that this document does not represent legal advice. While many topics discussed in this Compliance Guide are well-established policies, principles, and guidance, many scenarios require fact-specific analysis. Therefore, you should read this Compliance Guide with the underlying source materials for further context and contact or retain your legal counsel for specific questions.

B. Sources

The Coalition has drawn upon available guidance from various sources, including but not limited to those provided by the following:

- U.S. Food and Drug Administration (FDA),
- U.S. Federal Trade Commission (FTC),
- Accreditation Council for Continuing Medical Education (ACCME),
- U.K. Prescription Medicines Code of Practice Authority (PMCPA),
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and
- European Federation of Pharmaceutical Industries and Associations (EFPIA).

Section IX of this Compliance Guide provides a comprehensive list of references.

C. Definitions

The table below lists significant terms used throughout this Compliance Guide. It also highlights synonyms (shown in *italics*) and related terms (shown in regular text).

Term	Synonym or Related Term	Meaning
Audience	*Readers*	This term means individuals, groups, or organizations accessing social media content. It is used interchangeably throughout this Guide with "reader."
Education	*Educational Program*	Within this Compliance Guide, "education" refers to providing non-promotional healthcare information to others in a variety of formats. For purposes of this Compliance Guide, the term is interchangeable with "Continuing Education" or "CE." It encompasses various subsets such as accredited continuing education, independent medical education, and non-accredited programs. It also encompasses programs about disease awareness and patient support.
	Accredited Continuing Education	A subset of education that is certified for continuing education credit created by an educational provider that meets the standards of the appropriate accrediting body (e.g., ACCME).
	Independent Medical Education or IME	A subset of education (accredited or non-accredited) supported by a manufacturer grant in which the manufacturer exercises no control, influence, or direction over any aspect of the program, including but not limited to educational design or objectives, faculty, authors, speakers, outcomes, or audience.
	Non-Accredited Education Programs	A subset of education for which no accreditation body has recognized or accredited the content for an HCP or other healthcare stakeholder to receive credit in accordance with applicable state licensing requirements.

Term	Synonym or Related Term	Meaning
Education Provider		An individual or entity that provides educational programs.
Manufacturer		An entity whose primary business is manufacturing, selling, marketing, or distributing a drug, device, biological, or medical supply used by or on patients.
Posters		Posters are individuals and organizations that place information (i.e., content) on social media platforms.
Posts	*Posted Content* *Social Media Content* *User-Generated Content (UGC)*	These terms are used interchangeably to refer to information (i.e., content) placed on social media platforms.
Promotion		As distinguished from education, promotion involves providing information that advertises or markets a specific manufacturer's product or is otherwise controlled or influenced by a manufacturer.
Social Media	*Social Media Platforms*	Social Media means websites and applications that enable individuals and organizations to create and share content and interact with each other. Common examples include but are not limited to Twitter (rebranded as "X"), LinkedIn, Facebook, Instagram, Snapchat, TikTok, and YouTube.

Term	Synonym or Related Term	Meaning
		The terms "social media" and "social media platforms" are interchangeable.
Unaffiliated	Unaffiliated Content Unaffiliated Third Parties Unaffiliated Posters	"Unaffiliated" refers to content, third parties, or posters that are not officially attached or connected to the originator(s) of the educational program or materials.

III. General Principles

A. Social Media Definition

Although most people intuitively know what social media is when they see it, defining it is not straightforward. Some well-known examples include Twitter (rebranded as "X"), LinkedIn, Facebook, Instagram, Snapchat, TikTok, and YouTube.

While sometimes referred to as social media platforms, these websites and applications have two attributes in common. First, they allow users (i.e., subscribers or members) to create and share content. Second, they allow users to interact with each other. Thus, at its heart, social media is a communication channel.

B. Potential Social Media Use Cases

As a communications channel, social media has several use applications for CE. For example, a major use of social media is to communicate the availability of educational programs to an audience of potential educational consumers (i.e., attendees). Depending on the content and objectives of the program, prospective attendees can include healthcare professionals (HCPs) (most common) or the public (less common). Moreover, education providers can also use social media to gauge interest in a particular educational topic or identify potential facility members.

Other potential uses of social media involve communicating information on "disease awareness" or industry patient support information to the public.[1] However, because of the ability of the readers to interact amongst themselves, education providers and manufacturers should exercise care when communicating via social media, as outlined in greater detail below.

[1] Beyond the use cases discussed in this Compliance Guide, social media can be used for product promotion, clinical trial recruitment, and highlighting professional profiles and job openings. These use cases are out-of-scope for this Compliance Guide and are not addressed.

Social media is primarily a communications channel that has recently begun serving as a delivery platform for CE program content (i.e., where the program content resides). Historically, the substantive CE content, especially for programs directed to HCPs, has been provided separately through an automated learning management system (LMS), as a face-to-face (i.e., live) event or virtual event using of digital videoconference platforms such as Zoom or Microsoft Teams.

C. Maintaining Independence and Integrity

Regardless of how social media is utilized in an educational context, education providers and manufacturers should ask the following question:

> ***Based on the facts and circumstances, will the use of social media undermine the independence and integrity of the educational program, either directly, indirectly, explicitly, or implicitly?***

If the answer to this question is **yes**, then education providers and manufacturers should consider alternatives to mitigate potential legal and compliance risks.

D. General Compliance Controls in a Broader Context

Maintaining independence and integrity also requires education providers and manufacturers using social media to consider a broader context than just those requirements expressly applicable to social media. For example, education providers and manufacturers must remember the cardinal tenet that social media posts, regardless of their purpose, must be "truthful and not misleading."

Moreover, the use of social media has become ubiquitous and presents unique risks in the healthcare environment. Therefore, education providers and manufacturers are encouraged to incorporate general compliance controls for using social media in their operations.

For example, the Coalition recommends establishing new or revising existing policies and procedures to incorporate this guidance and other applicable requirements. However, because there is no single uniform set of requirements governing social media use, the Coalition urges organizations to take a holistic approach and draw on appropriate and practical specific controls regardless of their source.

Moreover, organizations should train staff members about any internal requirements adopted by the organization. This training should provide context on why these requirements exist and explain their application.

Finally, because social media continues to evolve, education providers and manufacturers should establish mechanisms to stay abreast of new or updated requirements and guidance.

IV. Developing Social Media Content

A. Ownership & Responsibility

A crucial aspect of social media platforms is that non-industry third parties own and operate the underlying platforms. Consequently, general social media platforms, like LinkedIn or Facebook, are designed to accommodate wide audiences and industries, beyond just healthcare. Moreover, while some platforms allow education providers and manufacturers to control content access and use of personally identifiable information to a degree, the extent of that ability is ultimately controlled by the platform's owners. Therefore, education providers and manufacturers should not assume platform owners know, understand, or abide by the requirements for disseminating healthcare-related posts or collecting personally identifiable information (i.e., data), including healthcare information.

Because they do not own the platforms, educator providers and manufacturers must understand the platform's Terms of Use and other applicable conditions (e.g., posting requirements, collection, and use of personally identifiable data). Furthermore, because educational providers and manufacturers do not "own" or control the platforms, these terms and conditions are subject to change with or without notice. Therefore, it is incumbent upon education providers and manufacturers to monitor these terms and conditions periodically for changes impacting their ability to control the use and access of posted content. Thus, it is insufficient to review these terms or conditions only when first utilizing a platform.

B. Platform Selection

1. Know Your Audience

Education providers and manufacturers need to consider their audience when selecting the appropriate social media platform(s) to use. This consideration includes both intended and unintended recipients.

Most major social media platforms are structured to reach or interact with the public (i.e., open channels). However, if information is intended only for HCPs and not the public in general, posters should explore whether it is possible to create restricted groups or forums (i.e., closed channels). Moreover, education providers and manufacturers should determine who controls admittance to closed channels and create criteria to evaluate the status of admittees.

2. Character Limitations

In many cases, social media platforms restrict the amount of information contained in a single post. These restrictions often are expressed in terms of character limitations. Perhaps the most recognizable are X's, formerly known as Twitter, limits. A single X post can be no more than 280 characters, increased from the initial limit of 140 characters.

These limitations pose significant contextual challenges for education providers and manufacturers. These challenges are particularly acute when providing essential risk/benefit

information[2] or demonstrating that an educational program is not simply disguised advertising, marketing, or promotion of a manufacturer's product.[3]

From a regulatory perspective, in 2014, the FDA provided draft industry guidance when working with character-limited platforms. The draft guidance sets out four considerations when communicating risk information using social media:

1. Risk information should be presented with benefit information for each social media post.

2. For character-limited platforms, risk information, at a minimum, should highlight the most serious risks. For example, the post should highlight all risk concepts contained in a boxed warning or risks to particular patient groups.

3. For each individual post, there should be a hyperlink directly to a complete discussion of a product's risk information. However, the FDA does not object to using URL-shortening programs to address inherent character limitations.

4. The prominence of risk information should be comparable to the prominence of benefit information.

Moreover, the use of commonly recognized linguistic symbols (e.g., ampersands), punctation marks, and scientific abbreviations are appropriate when confronting character limits.

Thus, when selecting which social media platform to use, education providers and manufacturers should consider whether the platform's design provides sufficient space to convey the message any posts with appropriate context. For example, whether both risks and benefits can be communicated (e.g., fair balance). Organizations posting on social media also need to ensure that any space limitations will permit the inclusion of other essential information such as disclosures or disclaimers (see Section IV.C below).

3. Privacy Protections & Practices

By their nature, social media platforms can collect, or facilitate the collection, of various types of personally identifiable information. At minimum, social media platforms collect and maintain some level of personal information about their account holders, which is essential to authenticate accounts and bill for platform access (i.e., subscriptions).

However, the extent of the information collected varies by platform and geography. Nevertheless, given the sensitive nature of collected personal data, especially those related to healthcare, education providers and manufacturers should carefully evaluate the platform's privacy policies and practices, including:

[2] *See* U.S. FOOD & DRUG ADMIN, GUIDANCE FOR INDUSTRY INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS – PRESENTING RISK AND BENEFIT INFORMATION FOR PRESCRIPTION DRUGS & MEDICAL DEVICES. DRAFT GUIDANCE, 3-4 (June 2014).
[3] *See* CME COALITION, INDEPENDENT MEDICAL EDUCATION COMPLIANCE GUIDE, 8-9 (2022).

- **Collected Data** – Educational providers and manufacturers should clearly understand the types of information collected by the social media platform. This understanding should encompass not only the types of information collected when establishing social media accounts, but also data on how account holders use the platform and specific content accessed (i.e., tracking information).

- **Reader Consent** – Education providers and manufacturers should also evaluate the consent readers provide to gather personally identifiable information. In general, any consent should be clear and understandable to the average person. It should also highlight the information collected, its retention period, and any "opt-in/opt-out" provisions. Moreover, if education providers and manufacturers want to access reader information gathered by the platform, they must ensure that the consent allows for such data-sharing.

- **Security Controls** – The loss or unauthorized access to personal digital data is an increasing problem. Therefore, education providers and manufacturers should evaluate the platform's security controls. For example, reviewing whether and what personal data is encrypted and at what encryption level.

- **Data Breaches** – It is also essential for education providers and manufacturers to review the platform's process for responding to the loss of or unauthorized access to reader's personal data.[4] If individual health information is collected, this review should encompass compliance with specific requirements concerning that information.[5]

C. Content Creation

1. Responsibility

Although not social media platform owners, manufacturers are responsible for the content of their posts and those of their agents (e.g., education providers). This responsibility extends to content that is re-shared (see Section V).

Therefore, educational content developed for and shared on social media platforms is subject to well-established requirements including:

- Product promotion (e.g., FDA regulation of advertising and promotion),

- Independence of medical education (e.g., FDA guidance and ACCME standards),

- Industry guidelines (e.g., PhRMA, AdvaMed, EFPIA, etc.), and

- Prohibitions against kickbacks, and false claims (e.g., the Anti-Kickback Statute and federal False Claims Act).

[4] *See, e.g.*, Eur. Union Gen. Data Prot. Regul, 2016/697, Arts. 33 and 34 (2016).
[5] *See, e.g.*, Health Breach Notification Rule, 74 Fed. Reg. 42961 (Aug. 25, 2009); Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42739 (Aug. 24, 2009).

In short, any social media content developed to support CE must foster true education and not be disguised promotional activities. To ensure that an engagement is proper, the Coalition recommends that education providers and manufacturers evaluate the purposed content under the "one purpose rule." In other words, if one purpose is to promote a manufacturer's specific product, then the content should be modified or avoided all together.

2. Transparency

The foundation of trust is transparency. Consequently, manufacturers should always be clear about their involvement in any communications, activities, or materials disseminated using social media. However, social media, especially in the context of platforms with space limitations, provides opportunities to be inadvertently non-transparent.

Therefore, it is incumbent upon education providers and manufacturers to ensure platform audiences know about a manufacturer's involvement and its form, including sponsorship, funding, and support. Moreover, education providers and manufacturers must avoid situations that obscure organization-related posts as individual posts.

At a minimum, this means that any disclosure of manufacturer involvement should be prominent enough to inform ordinary users of the situation at the outset.

3. Disclaimers

The use of disclaimers in educational materials is well-established. Disclaimers highlight important limitations or caveats involving the information provided to ensure that the material is not misleading. For example, it is common that materials associated with unapproved or investigational products state that.

Like disclosure of a manufacturer's involvement and support, disclaimers should be prominent enough to inform ordinary readers at the outset. As the FTC states, "[t]he ultimate test of whether a disclosure [or disclaimer] is effective is the net impression" ordinary users take from the materials.[6]

4. Use of Generative Artificial Intelligence

Some social media platforms have updated their systems to allow users to create content with generative artificial intelligence (AI) (e.g., LinkedIn). Moreover, many organizations are exploring the use of AI to streamline the content creation process.

However, the use of AI programs poses potential accuracy risks (e.g., AI hallucinations). These risks increase when AI programs (e.g., ChatGPT, Bard, etc.) harness uncontrolled data from the Internet instead of relying only on a controlled or closed data set (e.g., an organization's own internal data).

[6] *See* FTC, Health Products Compliance Guide, 8-9 (Dec. 2022). Although directed at product advertising, the general principles apply equally to educational materials; *see also* 16 C.F.R. § 255.0(f) (defining "clear and conspicuous" disclosures).

Therefore, when using AI to help generate social media content, education providers and manufacturers, at a minimum, should consider:

- **Control of the Underlying AI Program** – Education providers and manufacturers should understand who controls the underlying AI program and its algorithms. For example, is it a publicly available AI program (e.g., ChatGPT, Bard) or an AI program developed by the social media platform versus an AI program developed and controlled by the organization?

- **Source Data Set(s)** – It is important to understand the data set(s) that the AI program draws and "learns" from. For example, is the AI program harnessing data from the Internet, the social media platform, or a trusted third party versus data limited or controlled by the education provider or manufacturer?

- **Enhanced Review** – When reviewing AI-generated or supported content, education providers and manufacturers should enhance their typical level of review (see Section IV.C.5 below). They should require posters to disclose AI's role in generating the proposed content. For example, was AI used to create the post's wording or simply as a research tool for human creators? Regardless of the controls, source data, or use of AI, educational providers and manufacturers should exercise stricter scrutiny of the content generated or supported by AI to ensure it is accurate and not misleading.

5. Standards for Social Media Content Creation & Review

To ensure the validity and accuracy of posts, and regulatory compliance, educational providers and manufacturers should review the content prior to posting. Although the exact methods vary by organization, educational providers and manufacturers should incorporate that review into any general existing content review standards/processes (e.g., MLR, Copy Approval, etc.). However, in the case of posts by individuals, prior posting review may not be practical.

When developing social media content creation and review standards involving educational programs, education providers and manufacturers should consider the following:

- **Who Can Post** – It is important that those posting about educational programs understand that they are acting on behalf of the organization, and because of their position, their posts can be attributed to the organization. Posters should also know and have experience with the regulatory distinctions between promotional and educational programs. Thus, it may be inappropriate to allow posting by junior or non-communications staff members.

- **Content Limitations** – Consistent with the principles of independence, integrity, and transparency (see Sections III.C and IV.C.2), the standards should highlight inappropriate content types (e.g., promotional) and provide illustrative examples. The standards should also highlight the need for prior content review and any exceptions.

- **Distinguishing Between Organization-Related and Personal Posts** – The standards should also address the distinction between organization-related posts (e.g., those made

on the organization's behalf) and personal posts. While having personal social media accounts and making personal posts are not inappropriate, posters must exercise care to ensure that personal posts are not confused with or attributed as statements by the organization. Therefore, organization-related posts should only use official organization social media accounts.

Once established, organizations must train appropriate staff members to ensure they understand the requirements and their importance.

V. Directing Readers to Unaffiliated Content (Re-sharing, Links, Tags, Hashtags & Signposts)

In line with the objectives of fostering communication and interaction, social media platforms have various mechanisms to connect readers to content created by third parties that is not officially attached or connected to the originator(s) of the educational programs or materials. In addition to re-sharing posts, these mechanisms include links, tags, hashtags, and signposts.

- **Links** – A link refers to the unique address of a specific unique resource on the Internet. It also is commonly referred to as the Uniform Resource Locator or URL.

- **Tags** – Tagging refers to a poster's ability to direct readers to other unaffiliated social media accounts. Tags are used to facilitate browsing and searching.

- **Hashtags** – Hashtags are a word or key phrase preceded by a hash symbol (#). They are used to assemble a list of other potentially relevant posts on a specific topic. In other words, hashtags function within the social media platforms akin to Internet search engines (e.g., Google or Bing), but the posts must contain the same hashtag to work.

- **Signposts** – Signposts direct specific audiences to additional restricted information. However, unlike hashtags, signposts clarify the information's intended audience and require confirmation by that audience before accessing it. For example, websites that require users to identify if they are HCPs or the public before certain information is accessible.

Regardless of the mechanism, education providers and manufacturers must exercise caution when re-sharing or employing any links, tagging, hashtags, or signposts. Even if there is no express endorsement of the unaffiliated content in the original post, connecting such content makes it part of the original post. Therefore, connections can result in misleading posts or inappropriate promotion of prescription-only medicines (POMs) or devices in jurisdictions where such promotion is prohibited (e.g., the U.K. and the EU).

A. Links

When including full-length links in social media posts, education providers and manufacturers should ensure that the links are clear. For example, the link should highlight whether the reader is being directed to the manufacturer's website/material or an unaffiliated third party. Moreover, the name of the link should be appropriate. For example, a link created by a URL-shortening program that says "LEARN_ABOUT_BEST_DIABETESDRUG" is inappropriate.

Education providers and manufacturers also need to ensure that:

1. The linked material is clear about the intended audience and the role of the manufacturer in its generation.

2. Whether the linked material contains further links to other material.

3. The linked material provides information to unintended readers on where to find relevant and appropriate information for them.

B. Tags & Hashtags

1. Using Tags

When tagging other unaffiliated social media accounts, education providers and manufacturers should consider (1) the content of specific posts **and** (2) the wider context of the social media accounts where the posts are located. For example, the U.K.'s PCMPA suggests that tagging a social media account of an HCP who is an educational program speaker but which contains promotional content about a POM might constitute an APBI Code of Practice violation.[7]

Thus, education providers and manufacturers must determine that the tags do not direct readers to inappropriate material. For example, it may be inappropriate for educational providers to tag a manufacturer's social media account. However, it may be appropriate for an educational provider to tag a manufacturer's general corporate social media account that does not contain product-specific (i.e., promotional) information for the purposes of disclosing sponsorship transparency. These determinations should be made on a case-by-case basis.

2. Using Hashtags

When using hashtags, education providers and manufacturers need to ensure that the hashtags are relevant and appropriate. For example, disease state or symptom hashtags may be inappropriate in cases where only a single product is available to treat the disease state or symptom. Moreover, it is inappropriate to use hashtags to circumvent regulatory restrictions (e.g., using a hashtag that directs the reader to a company's logo where inclusion of the logo is not permitted).

Moreover, education providers and manufacturers should use hashtags cautiously because in many instances, they do not own or control the hashtag. Therefore, specific hashtags can often be used for multiple different purposes simultaneously. For example, simply including #compliance in a post can direct users to posts about healthcare compliance, financial services compliance, compliance policies, and compliance training.

C. Signposts

Signposts are an appropriate mechanism for situations where education providers and manufacturers need to limit information access to specific stakeholder groups (e.g., HCPs or U.S.

[7] *See* U.K. Prescription Med. Code of Prac. Auth., *PMCPA Social Media Guidance 2023,* 10 (2023).

HCPs). When employing signposts, education providers and manufacturers need to ensure the following:

- **Clarity** – Although the original post is likely appropriate for the public, any signposting must clearly identify the intended target audience.

- **Appropriate Access to Linked Material** – The linked material must be housed in a separate section labeled for the intended target audience.

- **Appropriate Intended Target Audience** – Access to any signposted materials requires some form of self-validation or acknowledgment that a reader is a member of the intended target audience.

VI. Addressing Social Media Misinformation

Science and the scientific method are fundamental to developing new, innovative, and effective drugs, devices, biologicals, and medical supplies. Moreover, scientific conclusions are not static or fixed but evolve based on new high-quality data and evidence (collectively "information") developed through robust review and discussion.

With the advent of the Internet and social media, audiences are exposed to an unprecedented amount of healthcare information of varying quality. At the low end of the spectrum is healthcare misinformation.

A. Defining Misinformation

Although "misinformation" has no universal definition, the U.S. Surgeon General has defined it as "information that is false, inaccurate, or misleading ***according to the best available evidence at the time***."[8] Thus, the definition aligns with the well-established FDA concepts of "false or misleading."

Moreover, misinformation can take many forms. Some examples of misinformation include AI hallucinations (see Section IV.C.4) and the now-discredited study identifying the measles, mumps, and rubella (MMR) vaccine as a cause of autism.

B. Responsibility to Address

Manufacturers and their agents (e.g., education providers) are responsible for correcting inaccurate information in their posts, because they exert influence or control over them (see Section IV.C.1).

[8] *See* U.S. Surgeon Gen., *Confronting Health Misinformation: The U.S. Surgeon General's Advisory on Building a Healthy Information Environment*, 4 (2021) (emphasis added). Misinformation is distinguished from "disinformation," although the terms are often used together. Disinformation is the intentional spreading of misinformation for malicious or nefarious purposes. *Id.* The discussion in this Compliance Guide is confined only to misinformation.

However, it is unclear what responsibilities manufacturers have when it involves content created by unaffiliated third parties (i.e., in the absence of influence or control). For example, the FDA in a 2014 draft industry guidance stated:

> Firms are not generally responsible for third-party UGC [User-Generated Content] about their products when the UGC is truly independent of the firm (e.g., is not produced by, or on behalf of, or prompted by the firm in any particular) regardless of whether the firm owns or operates the platform on which the communication appears.[9]

A joint statement by the IFPMA and EFPIA mirrors the FDA's position but is somewhat narrower, noting, "Member companies are not generally expected to monitor or police independent third-party activity ***on non-company*** social media or digital channels."[10] Finally, the PMCPA simply states that:

> Responding to misinformation … published on social media is a difficult area and is a question of policy for a company.[11]

Taken together, the regulatory guidance suggests that manufacturers and their agents are not required to correct misinformation in unaffiliated content but can choose to do so.

C. Choosing to Correct Misinformation

If manufacturers chose to correct social media misinformation, the PMCPA cautions that the "[c]orrection of misinformation might lead to more challenges as it would be beholden on the pharmaceutical company to ensure that everything was correct."[12]

However, in situations where education providers and manufacturers are determined to correct the misinformation, there are two potential approaches. First, they can work with the unaffiliated poster or the platform's owner to remove the misinformation (best solution) or, if the poster or platform cannot or is unwilling to remove the misinformation, request a correction be issued by the poster or the platform's owner.

Alternatively, the education provider or manufacturer can provide a direct response to the misinformation. When responding to misinformation either directly or indirectly (i.e., through the original poster or platform), education providers and manufacturers should consider the following:

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[9] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY INTERNET/SOCIAL MEDIA PLATFORMS: CORRECTING INDEPENDENT THIRD-PARTY MISINFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES, DRAFT GUIDANCE, 4 (June 2014); *see also* 47 U.S.C. § 230(c)(1). The Communications Decency Act provides that "[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider."

[10] *See* IFPMA and EFPIA, Joint Note for Guidance on social media and digital channels, 4 (Sept. 3, 2022) (emphasis added).

[11] *See* U.K. Prescription Med. Code of Prac. Auth., *PMCPA Social Media Guidance 2023,* 11(2023).

[12] *Id.*

- **Tailoring the Response** – Any response should be relevant and responsive to the misinformation. This approach includes making a limited and tailored response that is accurate, balanced, and non-promotional.

- **Including Supporting Evidence** – Whenever possible the response should include or link to sufficient evidence to refute the misinformation. Supporting evidence can include information from a wide variety of sources such as package inserts or directions for use, regulatory documents in the public domain (e.g., Summaries of Product Characteristics, ClinicalTrials.gov postings), or other internal company reference information that is not promotional in tone or content.

- **Connecting the Response & Misinformation** – When responding directly to misinformation, education providers and manufacturers should evaluate how best to connect the response with the misinformation it is addressing.

  One option is to post the response in the same area where the misinformation is located or as a comment to the original post (best solution). Alternatively, if it is not possible to provide the correction in the same area as the misinformation or as a comment to the original post, the response can be made in another location provided it clearly references the misinformation targeted for correction.

  However, regardless of the option employed, the connection between the misinformation and the response should be clearly discernable to the reader.

- **Providing Disclosure** – Like content creation (see Section IV.C.2), any response should clearly indicate the manufacturer's connection to the corrected information.

VII. Working with Unaffiliated Posters

It is common for education providers and manufacturers to work with unaffiliated third parties when developing and delivering CE (e.g., HCPs serving as content advisors, faculty, and speakers). Typically, HCPs involved with continuing education are so-called Key Opinion Leaders (KOLs). However, with the expansive use of social media as a communication channel, two new terms have emerged – social media influencer and digital opinion leader ("DOL"). Throughout this section, "influencer" refers to both DOLs and social media influencers unless otherwise specified.

A. Definitions

1. Key Opinion Leader (KOL)

The term "KOL" has no formal accepted definition. However, for healthcare CE purposes, traditionally, it refers to HCPs who are experts in their respective fields of study and whom others engage (formally or informally) for their insights and advice. Thus, achieving that moniker involves more than just being a high prescriber or an important customer.

2. Social Media Influencer

The PMCPA defines a social media influencer as "a person or brand with a notable following in a particular area and the power to affect views/decisions of their audience."[13] More specifically, influencers tend to embody the following:

- **Strong Social Media Presence** – Beyond frequently posting content on social media, influencers are "followed" by a large audience that can number in the tens of thousands or more. These followers actively access, and frequently comment, on content posted by the influencer. Therefore, determining whether someone is an influencer combines reach (i.e., number of followers) and impact (i.e., the ability to affect views and decisions).

- **Monetizing Their Influence** – Many (but not all) influencers capitalize on their social media following by highlighting products and services. Their compensation can be based on a pay-per-post basis or commissions for sales tracked via unique discount codes.

- **Expertise** – While obviously helpful, especially in the healthcare context, expertise in a particular field of study is not required to be deemed an influencer. Moreover, influencers can self-identify as an "expert." For example, a person with a wide following who frequents restaurants and posts about their experiences can deem themselves a "food critic" in the formal journalistic sense of that term. Likewise, a diabetic patient with a wide social media following who regularly posts about their condition and treatments, could be considered a diabetes influencer.

Thus, under the PMCPA's rubric, HCPs, patients, patient advocates, and celebrities can all be social media influencers if they have a notable social media following.

3. Digital Opinion Leader (DOL)

The terms "social media influencer" and "Digital Opinion Leader" are commonly used together. However, in the context of continuing education, the Coalition believes a Digital Opinion Leader is someone who combines the attributes of expertise with a strong notable social media following (social media influencer).[14]

B. <u>Engagement Considerations</u>

Engaging with a DOL or social media influencer can benefit education providers and manufacturers. However, it also presents risks. Therefore, as an initial consideration, the Coalition recommends that, in most medical education situations, engagement be limited to DOLs as defined above (see Section VII.A.3).

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[13] *See* U.K. Prescription Med. Code of Prac. Auth., *PMCPA Social Media Guidance 2023*, 18 (2023).

[14] *See, e.g.*, WITHIN3, NEW 2024 GUIDE TO DIGITAL OPINION LEADERS: HOW TO WORK WITH THEM TO GET BETTER INSIGHTS (June 3, 2023), https://within3.com/blog/who-are-digital-opinion-leaders-dols; Marcus Bergler, *Understanding the Key Opinion Leader Universe in a Digital World – from KOLs to DOLs and MOLs*, LinkedIn (Oct. 20, 2020), https://www.linkedin.com/pulse/understanding-key-opinion-leader-universe-digital-world-bergler/.

1. Qualifications & Background

Depending on the expected role of the influencer, education providers and manufacturers should evaluate an influencer's qualifications (i.e., vet them) to ensure they are "fit for purpose." For example, do they have the requisite expertise in their field of study to speak knowledgeably on or about the CE's topic? Also, do they have a verifiable target audience following?

In addition, education providers and manufacturers should examine previous social media activity of the influencer to determine that there are no "red flags." For example, does the influencer's previous posts reveal a tendency to engage in misinformation or do their statements consistently reflect the best available evidence at the time (see Section VI.A)?

2. Degree of Control

Because influencers are unaffiliated third parties, education providers and manufacturers generally have limited control over their social media activities (as distinguished from employees). Relationships with influencers can take two forms: formal or informal.

3. Endorsements & Testimonials

Since 1975, the FTC has provided guidance on using endorsements and testimonials, which was updated in July 2023.[15] In the guidance, the FTC treats endorsements and testimonials (collectively "endorsements") synonymously to mean messages "that consumers are likely to believe reflect the opinions, beliefs, findings or experiences other than" the sponsor.[16]

While the guidance specifically applies to advertising, many of the principles and examples provided by the FTC are relevant to social media and the rise of influencers. Therefore, education providers and manufacturers should consider the following when using influencers for endorsements:

- **Honesty** – Like the FDA's principles of truthful and not misleading, endorsements should reflect the honest opinions, findings, and beliefs of the endorser. Therefore, education providers and manufacturers need to be careful that the information is not presented out-of-context or in a manner that distorts the endorser's views, including any changes in the endorser's views.

- **Transparency** – Connections between the endorser and the education provider or manufacturer should be disclosed when the connection is not reasonably obvious, or nondisclosure may affect the endorsement's credibility (i.e., is material).

- **Type of Endorser** – Education providers and manufacturers need to consider who is making the endorsement. For example, whether the endorser is a consumer (i.e., a patient) or an expert (i.e., a healthcare professional or healthcare organization). Where

[15] *See* Guides Concerning the Use of Endorsements and Testimonials in Advertising 88 Fed. Reg. 48092 (July 26, 2023) (codified at 16 C.F.R. pt. 255).
[16] *See* 16 C.F.R. §§ 255.0(b-c).

healthcare organizations are endorsers, their endorsements should represent the group and be free of individual variations.

- **Responsibility** – Education providers and manufacturers are responsible for ensuring that statements by endorsers are not misleading, have adequate substantiation, and disclose materials connections between them and the endorsers. For healthcare products or therapies, adequate substantiation means having "appropriate, competent, and reliable scientific evidence to support express or implied claims" made by the endorser.[17]

VIII. Special Situations Involving Patients and the Public

In addition to the general guidance on using social media, at least three situations involving patients and the public warrant special attention.

A. Safety Reporting

All pharmaceutical and medical device manufacturers are subject to safety reporting (i.e., adverse events) requirements and guidance. Therefore, it is the responsibility of education providers and manufacturers to ensure that those requirements and guidance are clearly communicated and documented. Moreover, contractual education agreements must incorporate any safety reporting expectations before the development of any grant-funded education.

B. Public Disease Awareness Information

As a communication channel, education providers and manufacturers can use social media to convey important disease awareness information to the public. However, doing so requires education providers and manufacturers to consider:

- **Accessibility**[18] – Education providers and manufacturers should use language, design, and formatting at level it can be readily understood by the public. Thus, the Coalition suggests applying similar standards to those used to develop meaningful informed consent.

- **Avoiding Misperceptions** – In addition to the considerations for developing social media content (see Section IV), education providers and manufacturers should scrutinize public disease awareness information for possible misperceptions or unintended messages. For example, providing disease awareness information that is treatable only by a single product could be misconstrued as disguised product promotion.

- **Balance** – Although the concept of "fair balance" is well-enshrined in the context of labeling and advertising, education providers and manufacturers need to take additional care when providing public disease awareness information. For example, as outlined by the Medicines & Healthcare Regulatory Agency ("MHRA"), the information should be

[17] *Id.* at § 255.2(a).
[18] Accessibility, as outlined in the Americans with Disabilities Act ("ADA"), is not within the purview of this Compliance Guide.

"realistically conveyed without being alarmist" or unduly emphasize "particular options or the need to seek treatment."[19]

C. Patient Support Information

Although education providers do not discuss patient assistance programs addressing medication affordability for specific patient populations, manufacturers can use social media to highlight their patient support efforts. Where they do so, manufacturers need to craft content that is accessible to patients (see Section VIII.A) and address limitations posed by social media (e.g., character limits – see Section IV.B.2).

Thus, patient support information should include the following as appropriate:

- **Program Limitations** - While not an exhaustive list, patient support program limitations can include the following:
    - **Insurance** – Are federal healthcare beneficiaries or those with private health insurance eligible for patient support?
    - **Income** – Moreover, if support is conditioned on income level, the information should state those restrictions in a comprehensible manner. Thus, it may not be appropriate to state only patients at a percentage of the federal poverty level are eligible rather than listing a precise dollar amount.
    - **Scope** – Does the program provide unlimited support or are there limitations to the scope (e.g., amounts or duration)?
- **Access** – How can patients access the support? This information should disclose any relationships with the education providers or manufacturers. For example, is the support underwritten by a manufacturer but administered through an independent charitable organization?

[19] *See* MED. AND HEALTHCARE PRODUCTS REGUL. AGENCY, BLUE GUIDE: ADVERT. & PROMOTING MEDS., 104 (updated Dec. 31, 2020) (Appendix 7).

IX. References

For those wanting further information, the table below list the various source guidance documents used to develop this Compliance Guide. However, users are cautioned that additional guidance on using social media may exist that are not listed here.

SOURCE ORGANIZATION(S)	SPECIFIC REFERENCE
Accreditation Council for Continuing Medical Education (ACCME)	Standards for Integrity and Independence in Accredited Continuing Education (2020).
CME Coalition	Independent Medical Education Compliance Guide (2022)
International Federation of Pharmaceutical Manufacturers and Associations & European Federation of Pharmaceutical Industries and Associations	Joint Note for Guidance on social media and digital channels (Sept. 3, 2022).
Medicines & Healthcare Products Regulatory Agency	Blue Guide: Advertising & Promoting Medicines, Appendix 7 (updated Dec. 31, 2020).
U.K. Prescription Medicines Code of Practice Authority	PMCPA Social Media Guidance (2023).
U.S. Food & Drug Administration	Guidance for Industry Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs & Medical Devices: Draft Guidance (June 2014).
U.S. Food & Drug Administration	Guidance for Industry Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, Draft Guidance (June 2014).
U.S Federal Trade Commission	Health Products Compliance Guide (Dec. 2022)
U.S Federal Trade Commission	Guides Concerning the Use of Endorsements and Testimonials in Advertising, 88 Fed. Reg.48092 (July 26, 2023) (codified at 16 C.F.R. pt. 255).
U.S. Surgeon General	Confronting Health Misinformation: The U.S. Surgeon General's Advisory on Building a Healthy Information Environment (2021).