

CONFERENCE
Session Report

Moving From Worst to Best in Medical Writing for Continuing Education in the Health Professions

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Continuing education in the health professions (CEHP), including continuing medical education (CME), is a vitally important and fast-changing field in which medical writers can find challenging and rewarding work. The field draws its importance from the way all stakeholders work together to provide clinicians with the up-to-date knowledge and skills they need to improve patient health outcomes.

CEHP providers include a broad range of organizations, including health systems, medical schools, and government agencies, but freelance medical writers most often work with private medical education (med-ed) companies and medical specialty societies.

CEHP is a growing industry. According to statistics kept by the Accreditation Council for Continuing Medical Education (ACCME), the industry reported \$2.81 billion in total income in 2021. Of that amount, \$895 million came in the form of commercial support from large pharmaceutical and medical device companies, a sharp increase from \$723 million the previous year.¹

MEDICAL WRITERS HELP PRESERVE INTEGRITY

To distinguish it from advertising, CEHP instructional content must be accredited by a third party, such as the ACCME at the national level or one of its designees at the state level. Individual med-ed companies may also apply to the ACCME for the right to bestow continuing education (CE) credit upon clinicians who complete their courses.

The ACCME endorses a system for the commercial support of CEHP that aims to protect its integrity by erecting a firewall between commercial interests and the expert faculty who deliver instruction to learners. In Standard 2 of its Standards for Integrity and Independence in Accredited Continuing Education, the ACCME states, “The accred-

ited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.”² In this system, pharmaceutical companies and medical device companies are ineligible to award CE credits, but they are free to provide commercial support so long as they comply with ACCME standards.

The medical writer provides services to the med-ed company developing the accredited program. This program includes a curriculum overseen by expert faculty. The medical writer must not be influenced by any commercial supporter so that the integrity of the program remains intact at each step of the content development process, from the grant proposal to the outcome report.

Before a program can be developed, a proposal is written and submitted to obtain funding. The proposal must justify why the commercial supporter should give money to the med-ed company or specialty society. A typical proposal consists of a program agenda, an outcomes measurement plan, a budget, a delivery schedule, credit information, an audience generation plan, and a needs assessment (NA).

Med-ed companies often outsource these NAs to freelance medical writers. A strong NA is usually built around a core literature review, but it may also include several other types of evidence showing why clinicians need to learn about a particular topic. The narrative of a well-written NA will describe one or more gaps between optimal clinical practice (e.g., as laid out in practice guidelines) and actual clinical practice as observed in the field. The NA serves as the basis for developing the learning objectives for the proposed program, and these objectives in turn justify the agenda, instructional content, and faculty selection.

After a proposal is funded, medical writers typically work with expert faculty in developing content that may include test questions, case studies, monographs, and slide decks. Additionally, medical writers may draft outcome reports for supporters, text to be used with infographics, or conference posters. Well-established medical writers may

even write scripts for interactive patient case simulations or publish outcome reports in peer-reviewed journals.

WORST PRACTICES IN WRITING NAs

Though they may work from home offices spread out across the United States, freelance medical writers who develop NAs for CE grants nonetheless form a tight-knit community of practice. Members of this community often call themselves CME writers. From 2014 to 2019, several CME writers carried out an annual survey aimed at identifying best practices for writing NAs. The survey was publicized and supported by both AMWA and the Alliance for Continuing Education in the Health Professions (ACEHP or Alliance). These surveys resulted in several posters, an article jointly published in the *AMWA Journal* and the *Alliance Almanac* in 2019,³ a mini-tutorial offered to all AMWA members, a presentation at the ACEHP national conference in 2020, and a workshop at the 2022 AMWA Medical Writing & Communication Conference.

Within the 2018 survey, one question inquired about any poor practices that survey respondents might have observed in NAs written by others. Of the 104 writers responding that year, 67 reported a wide variety of poor practices. Two independent reviewers, one from AMWA and one from ACEHP, sorted these complaints into categories. The category with the greatest number of complaints was “sources and referencing,” such as outdated research, lack of proper citation, and insufficient support for gaps in education.

FOCUSING ON WRITER-RELATED SOLUTIONS

What are possible solutions to remedy these worst practices? CME writers face many challenges that may impair the quality of their work. Training programs, either employer-based or university-based, are scarce. Moreover, system-related problems, such as labor market supply and demand, industry expectations, or standard project lead times, may lie beyond the control of the individual medical writer. Rather than trying to solve these macro-level problems, it may be more beneficial to focus on micro-level problems that lie within the control of writers, such as improving their professional knowledge, skills, and attitudes as well as learning how to deliver the types of assignments that are in high demand among CEHP providers. In other words, writers can choose to focus their efforts on becoming more competent.

DEVELOPING A COMPETENCY MODEL

Although a 2-part competency model for regulatory writers has been published^{4,5} and a training outline for future

regulatory writers has been developed,⁶ there is no similar model or outline for CME writers. Yet, executives at med-ed companies have stated anecdotally that a competency model to address what they say is a lack of qualified CME writers would be beneficial. Clinicians and former clinicians who are seeking to transition into the field have also shown a strong interest in specialized training opportunities. To meet these needs, a research project using the Delphi method is currently in progress. The project has 2 primary goals:

1. Identify knowledge areas, skills, and attitudes necessary for the next generation of CME writers to excel
2. Identify deliverables that the next generation of CME writers should be able to develop

The Delphi method uses an iterative process of sending successive questionnaires to an expert panel of key stakeholders to forge consensus. In this case, the Delphi panel consists of 22 experts, balanced among writers, teachers, and company executives. Over a series of 3 rounds of questionnaires, the panelists are asked to rate a preliminary set of competencies and to suggest any additions. The competencies span the domains mentioned above: knowledge areas, skills, attitudes, and deliverables, or KSADs. Each successive round of questions contains controlled feedback in the form of ratings of the KSADs as well as rationales for these ratings. Panelists, whose identities are protected from disclosure during deliberations, are free to change their ratings between rounds if they are persuaded to do so after reading their fellow panelists’ rationales. A pre-defined group rating of 4 or higher (out of 5) indicates consensus that a given KSAD should be included in the model. Statistical analysis will be used to test for the stability of responses between rounds and to analyze for any differences between subgroups.

HELPING WRITERS MOVE FROM WORST TO BEST

The ACCME has set high ethical standards aimed at protecting the integrity of accredited instructional content for health professionals. Medical writers are involved in many stages of the content development process and are uniquely positioned to add or subtract integrity. Unfortunately, medical writers often come to this task unprepared because expectations are high yet adequate educational or training programs are limited. This situation leaves many medical writers with no choice but to muddle through and figure things out on their own. A competency model, developed by consensus among key stakeholders in CEHP, will help the next generation of writers approach this important task

more professionally and systematically. Indeed, a competency model may encourage these future writers to pursue excellence in developing high-quality, ethical, and engaging instructional content that will help clinicians, in turn, to develop the competency they need to improve patient health outcomes.

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