American Academy of PAs

September 5, 2023

Amy Chi
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Rm. 3128
Silver Spring, MD 20993-0002

Re: FDA-2023-D-1955. E6(R3) Guideline for Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry; Availability

Dear Ms. Chi,

The American Academy of PAs (AAPA), on behalf of the more than 168,300 PAs (physician assistants/associates) throughout the United States, appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft Good Clinical Practice (GCP) Guideline. AAPA appreciates the use of inclusive language within the draft guideline to potentially include PAs. However, AAPA believes the language should be improved for clarity.

Variations of the language in question are found in two places. First in 1.5 (lines 99-105)[1], which reads (emphasis added):

> 1.5 A qualified physician or, when appropriate, a qualified dentist **(or other qualified healthcare professionals in accordance with local regulatory requirements)** should have the overall responsibility for the trial-related medical care given to, and medical decisions made on behalf of, participants; however, the practical interactions and the delivery of medical care and decisions can be carried out by appropriately **qualified healthcare professionals** in accordance with applicable regulatory requirements.

Second in 2.7.1 *Medical Care of Trial Participants* (lines 547-554), which reads (emphasis added):

> (a) A qualified physician or, where appropriate, a qualified dentist **(or other qualified healthcare professionals in accordance with local regulatory requirements)** who is an investigator or a sub-investigator for the trial should have the overall responsibility for trial-related medical care and decisions.
> (b) Other appropriately **qualified healthcare professionals** may be involved in the medical care of trial participants, in line with their normal activities and in accordance with local regulatory requirements.

[1] Found under **1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure that rights, safety and well-being of participants.**

While the language appears to be inclusive of PAs within the term "qualified healthcare professionals," there is no additional context or definition of the term anywhere within the draft guidance, and the placement of the parenthetical that includes the term is potentially confusing to the reader.

AAPA recommends moving the parenthetical to immediately follow "physician" and providing a non-exhaustive list of examples of providers that are qualified healthcare professionals. If amended as such, the language in both 1.5 and 2.7.1 would read:

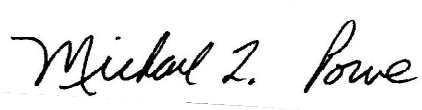
1.5 A qualified physician (or other qualified healthcare professionals, e.g. physician assistants and nurse practitioners, in accordance with local regulatory requirements) or, when appropriate, a qualified dentist ~~(or other qualified healthcare professionals in accordance with local regulatory requirements)~~ should have the overall responsibility for the trial-related medical care given to, and medical decisions made on behalf of, participants; however, the practical interactions and the delivery of medical care and decisions can be carried out by appropriately **qualified healthcare professionals** in accordance with applicable regulatory requirements.

Second in 2.7.1 *Medical Care of Trial Participants* (lines 547-554), would read (emphasis added):

(c) A qualified physician (or other qualified healthcare professionals, e.g. physician assistants and nurse practitioners, in accordance with local regulatory requirements) or, when appropriate, a qualified dentist ~~(or other qualified healthcare professionals in accordance with local regulatory requirements)~~ who is an investigator or a sub-investigator for the trial should have the overall responsibility for trial-related medical care and decisions.

AAPA urges the FDA to consider the above amendments to the draft guidance to provide clarity and inclusion of appropriately qualified healthcare providers such as PAs and nurse practitioners, among others. Thank you for the opportunity to provide feedback on FDA-2023-D-1955. E6(R3), GCP Guideline. For any questions you may have please do not hesitate to contact me at michael@aapa.org.

Sincerely,



Michael L. Powe, Vice President
Reimbursement & Professional Advocacy