December 18, 2023

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via regulations.gov

Re: Regulatory Considerations for Prescription Drug Use-Related Software (FDA-2023-D-2482)

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the U.S. Food and Drug Administration (FDA) for the opportunity to provide comments in response to the draft guidance titled "Regulatory Considerations for Prescription Drug Use-Related Software" (Draft Guidance), issued on September 18, 2023.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

FDA-Required Labeling

AMCP supports FDA's intended use of its drug labelling authorities to provide oversight of prescription drug use-related software. AMCP believes that supplying health care practitioners and patients with the necessary information to make an informed decision about the benefits and risks of the prescription drug product will improve safety and effectiveness. FDA's oversight of prescription drug use-related software labeling should also be exercised to include timely incorporation of new data and information relating to software updates. AMCP's members are concerned about ensuring that prescription drug-use related software and end-user output is objective, clear, understandable, and non-promotional. AMCP's members also expressed data privacy and security concerns.

Clinical Data

AMCP believes that FDA should clarify the type of clinical data that will be required for FDA-required labeling of the end-user output. The guidance notes that the sponsor should discuss the types of data and information with the appropriate FDA review division during the development process, but AMCP believes that standardized guidance on the types of acceptable data would also be beneficial.

The guidance mentions adequate and well-controlled studies, but AMCP urges FDA to consider clarifying that alternative approaches, such as real-world evidence (RWE), may be used to demonstrate a clinical benefit, such as improved efficacy or safety. Considering a broad range of data that supports inclusion of prescription drug use-related software information in FDA-approved labeling would encourage greater innovation in digital applications.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing to work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Manager of Regulatory Affairs, Vicky Jucelin, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer