November 27, 2023

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

Submitted electronically via regulations.gov

Re: Medication Guides: Patient Medication Information (Docket No. FDA-2019-N-5959)

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the "Medication Guides: Patient Medication Information" (Proposed Rule) published in the Federal Register on May 30, 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.

AMCP's core focus includes value, access, affordability, technologies, and quality. AMCP commends FDA for its continued efforts to ensure that patients have clear and concise knowledge of the prescription drugs and blood or blood components that they will be administered to improve the health outcomes of patients.

Patient Medication Information

AMCP and its members commend the FDA for ensuring that patients have clear, concise, accessible, and useful written prescription drug product information, provided in a consistent and easily understood format in the Patient Medication Information (PMI). This will help patients use their prescription drug products safely and effectively. Our members remain concerned about whether this rule does enough to reduce overall confusion for patients given the potential volume of documents provided to patients with each prescription, such as medication guides, consumer medication information, and Instructions for Use. For patients with low health literacy, having multiple documents for each prescription could cause frustration and confusion, especially if the documents are conflicting or difficult to understand. AMCP recommends that FDA consider the universe of labeling information that patients receive as part of a comprehensive strategy to streamline the information provided to patients.

Printing, Distribution, and Storage of PMIs

AMCP and its members support the FDA's suggestion that authorized dispensers and transfusion services be capable of providing PMI at patients' request in electronic format, identical to the paper version. However, rather than requiring dispensers to manually check the FDA labeling repository for updates each month, AMCP urges FDA to consider an automated system that would notify dispensers of newly FDA-approved PMI or revised PMI. Additionally, the FDA repository should be developed in a way that allows dispensers to leverage technology and automated processes to identify and pull all FDA-required patient information, including medication guides, PMIs, and PPIs during transition. AMCP also suggests providing guidance on whether dispensers should retain the patient's request for the electronic format of PMI. This could allow the patient to make a one-time request for the electronic format of PMI for future prescriptions, eliminating the need for repetitive requests.

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 mailto:vjucelin@amcp.org or (571) 858-5320.

Sincerely,

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