APhA
American Pharmacists Association

November 27, 2023

Dockets Management Staff
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-N-5959: Medication Guides: Patient Medication Information

Submitted electronically via www.regulations.gov to Docket No. FDA-2019-N-5959

Dear FDA Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) proposed rule "Medication Guides: Patient Medication Information." APhA supports the FDA's intention to provide patients with prescription drug product information delivered in a standardized and easily accessible format to help patients use their prescription drug products safely and effectively.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

For decades, pharmacists have been providing patients with various forms of medication information, such as consumer medication information, patient package inserts, or Medication Guides. Consequently, APhA agrees that an informed and educated patient is more likely to be compliant and adherent in taking their medications correctly. Pharmacists often use this information as a reference tool when educating and counseling patients about their medications. APhA appreciates FDA recognizes the value of the pharmacist in providing patient medication information (PMI) and the historical role dispensers have played. However, APhA has several comments and questions about the proposed rule, which are outlined below.

A. Subpart A -- General Provisions for Patient Medication Information (88 FR 35721)

1. §208. 20 Definitions (and corresponding Definitions in Subparts C and D §208.92) – The definition of "Dispensed."

The proposed definition of "dispensed" in §208.20 (and correspondingly in proposed §208.92) "means the act of providing a prescription drug product to a patient (or the patient's agent) in either of the following ways: (1) By a licensed healthcare provider (or a licensed healthcare provider's agent) either directly or indirectly, for administration by the patient (or the patient's agent) under or outside of the licensed healthcare provider's direct supervision. (2) By an authorized dispenser (or an authorized dispenser's agent) under a lawful prescription of a licensed healthcare provider."

Further, the proposed definition of "licensed healthcare provider "means an individual who is licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice."

Under current §208.3(b) in the existing Medication Guide provisions, "Dispense to patients "means the act of delivering a prescription drug product to a patient or an agent of the patient either: (1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or (2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner."

Further, the current definition of "licensed practitioner "means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice."

FDA notes in the preamble on page 35704 that these definitions would be revised for clarity and consistency, but the substantive meaning remains the same. APhA appreciates FDA recognized the need to revise the current definition of licensed practitioner in Part 208. Pharmacists are licensed practitioners and licensed health care providers. They provide care to patients and are widely recognized and respected across professions as healthcare practitioners and providers. In many states, pharmacists are permitted under their scope of practice to prescribe drug products, independently or under a state protocol, state order, or collaborative practice agreement. Furthermore, in all states, pharmacists are permitted under their scope of practice to administer drug products. Defining a healthcare practitioner or healthcare provider specifically as one who prescribes in the course of practice creates confusion by being too narrow and too broad at the same time. More accurately, APhA proposes FDA use the term "licensed prescriber" instead of "licensed healthcare provider."

Accordingly, APhA proposes FDA revise § 208.20 and § 208.92 to:

> *"**Dispensed** means the act of providing a prescription drug product to a patient (or the patient's agent) in either of the following ways: (1) By a licensed prescriber (or a licensed prescriber's agent) either directly or indirectly, for administration by the patient (or the patient's agent); or (2) By an authorized dispenser (or an authorized dispenser's agent) under a lawful prescription of a licensed prescriber."*
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> *"**Licensed prescriber** means an individual who is licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice."*

2. §208.30: Format of Patient Medication Information

    a. Proposed §208.30(a)(1) – PMI language

Proposed §208.30(a)(1) would require PMI in English, except in Puerto Rico or in a Territory where the predominant language is not English, the prominent language could be used. According to the preamble on page 35705, FDA recognizes that flexibility is needed to provide access to PMI for individuals with limited English proficiency. APhA recommends FDA require manufacturers to provide PMI in commonly used languages other than English.

    b. Proposed §208.30(a)(2) – One-page limit

APhA strongly supports the proposed requirement that the PMI be provided as a single page in length, on one side of the page. However, there may be situations where a patient has compromised vision and finds it difficult to read a 10-point font. In these cases, a pharmacy may print the PMI in a larger font size, however, the information may be longer than one page. It is more important for PMI to be readable for the patient. Accordingly, APhA recommends the final rule provide exceptions when the PMI can exceed the one-page limit if the patient requests a larger font size.

    c. Proposed §208.30(a)(3) – Electronic format

APhA also strongly supports FDA's proposal to allow authorized dispensers to distribute a one-page standardized PMI guide to patients electronically, while also maintaining the option for patients to receive this information in paper form by request. This new one-page PMI would help reduce the number of documents a patient receives with their prescription medications and many patients would prefer to have their prescription drug information sent to them by text or email.

To further inform APhA's comments on this proposed rule, APhA conducted a pulse survey ("APhA Pulse Survey") of our members. Of the 223 responses, thirty-five percent are currently providing a way for their patients to receive PMI electronically, mostly via text, email, a QR code on the receipt, through a patient portal, or other electronic means. Eighty-eight percent of APhA Pulse Survey respondents said they would offer patients a way to receive medication electronically in lieu of paper if permitted by FDA.

Allowing pharmacies to provide this PMI electronically would ease burdens on pharmacies by reducing the time and expense associated with printing paper that patients may not read. However, there could likely be an increase in subscription costs to pharmacies for upgrades to their medication information system, particularly as new PMI is approved in the coming years.

Patients would also benefit from a clear and concise electronic PMI. Although APhA recognizes PMI is approved labeling, APhA requests FDA provide additional guidance on whether embedded hyperlinks in mobile or web applications that allow a patient to navigate within the PMI document would be permitted, or links that direct the patient to more information, such as definitions of unfamiliar terms and adverse event reporting if needed.

3. §208.40– Content of Patient Medication Information

Proposed §208.40(7) would allow the name and business of the authorized dispenser to be included in the PMI. APhA requests this provision also specifically state that the phone number, contact email address, and website also be included in the PMI. A patient will likely read this information at home and if they have questions, having the information on how to contact their pharmacist would enable them to follow up their reading more quickly and conveniently on the PMI. APhA also requests FDA provide guidance on whether a pharmacy logo can appear next to the dispensing pharmacy information on PMI.

4. §208.70 – Providing Patient Medication Information to patients

Proposed §208.70(a) would require PMI to be provided, electronically or on paper when a product is used, dispensed, or administered to a patient or patient's agent, with paper always available. Pharmacies maintain patient profiles on all patients, which includes medication, personal and health information, patient preferences, and other interactions and interventions, among other things. If a patient prefers non-childproof caps on bottles, this information is included. It is likely that as a best practice, patient preference for paper or electronic PMI will be included in their patient profile.

5. §208.80 – Schedule for implementing the general requirements for Patient Medication Information

Proposed §208.80(c) would require authorized dispensers to provide FDA-approved PMI to patients once it becomes available starting two years after the effective date of the final rule. According to the proposed rule, once a product with an FDA-approved Medication Guide has FDA-approved PMI, a Medication Guide would no longer be dispensed. APhA anticipates the during the roll out and conversion from Medication Guides to PMIs, it may not be obvious when FDA-approved PMI is newly available for all other products. Accordingly, APhA urges FDA maintain a "grace period" or implement a longer effective date that allows FDA-approved Medication Guides to be dispensed even if FDA-approved PMI is available in the event that software systems have not caught up with the changeover to PMI for a drug product that previously required a Medication Guide.

Online Central Repository (FR 35712)

According to the proposed rule, FDA plans to create and manage an online central repository for all approved PMI to be stored and freely accessible to patients, healthcare providers, and authorized dispensers (e.g., pharmacies). FDA also states they expect dispensers to check this repository every month for new or revised FDA-approved PMI and update their systems. APhA notes, however, that FDA incorrectly assumes that pharmacies will be checking the repository and downloading new and updated PMI. According to our members, pharmacists will likely rely on their software vendors to integrate this new PMI into their systems. According to the APhA Pulse Survey, 95% of respondents stated FDA should ensure PMI can be easily integrated into the existing distribution capabilities. Therefore, APhA urges FDA to become familiar with the various vendors and capabilities of their software to ensure efficient and effective integration into systems used by pharmacies across the country. APhA also recommends the Paperwork Reduction Act analysis be revised to reflect the correct anticipated burdens, both economic and reporting, related to obtaining and maintaining updated PMI.

Conclusion

APhA appreciates the opportunity to provide feedback on FDA's proposed rule, "Medication Guides: Patient Medication Information." APhA supports FDA's proposal to provide patients with easily accessible prescription drug product information in a consistent one-page format, including electronically, to help patients safely and effectively use their prescription drug products. APhA urges FDA to closely consider the implementation timeline for dispensers to provide a long runway of enforcement discretion during a phase-in period after the effective date when mixed formats and types of patient information will still be in the marketplace. If

American Pharmacists Association

you have any questions or require any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

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