# Patient Medication Information: A 2023 Proposed Rule to Help Patients Understand Their Prescription Medication Information

Patients often receive several types of informational documents with their prescription medication. These documents are intended to help patients take their drugs safely and effectively, help reduce preventable adverse drug reactions, and improve health outcomes. After years of research, FDA determined that existing documents (Consumer Medication Information) do not consistently provide patients with clear, easily understood information about their prescription medications.

To address this issue, FDA proposed in May 2023 (/news-events/press-announcements/fda-proposes-new-easy-read-medication-guide-patients-patient-medication-information) to amend its human prescription drug product labeling regulations for Medication Guides that, if finalized, will require a new type of information known as Patient Medication Information (/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information-pmi) (PMI). PMI is a new type of Medication Guide proposed by FDA, designed to provide concise, easy-to-understand information about a prescription medicine for patients.

*In this CDER Conversation, Christopher Diamant, J.D., regulatory counsel in CDER's Office of Medical Policy, discusses how the proposed rule regarding PMI could help provide patients with clear instructions, ultimately helping them take their prescription medications as intended.*

**Why did FDA propose PMI for prescription medications?**

There are currently several (/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources) types of information a patient may receive when their prescription is filled. These include Patient Package Inserts (PPI), Medication Guides (MG), and Consumer Medication Information (CMI). The information in these documents can be difficult to understand, repetitive, incomplete, or conflicting, which may cause some patients to take their prescription medication incorrectly. Although studies have found several reasons some patients don't take their prescription medications as directed, a patient's knowledge about a prescription medication plays a key role in their ability to use the drug as intended. Communications that do not provide clarity regarding prescription medications may lead to patient nonadherence, which may, in turn, be responsible for increased hospitalizations, treatment failures, and even increased death rates in the United States each year.



*Christopher Diamant, J.D.*

In an effort to improve clarity for patients, FDA issued a proposed rule regarding PMI. The

purpose of PMI would be to provide the information patients need about the drug in a format that is concise and easy-to-read.

**How did CDER develop the PMI format?**

CDER conducted extensive research and obtained input from interested parties including consumers and consumer groups; industry; health care professional groups; physicians; pharmacists; and pharmacy organizations. From there, we developed several prototypes for PMI that would deliver prescription medication information in a clear, easy-to-read document. For example, research suggests patients prefer a simple, one-page document because they have difficulty understanding and are overwhelmed by lengthy information materials. We took this insight, along with other factors, into consideration when creating the PMI prototypes.

Once CDER developed several prototypes, we conducted studies on the PMI prototypes, held public workshops and obtained input on what specific information patients need to use their prescription drugs safely and effectively. We focused on the key elements that a patient would find relevant and useful.

CDER ultimately decided the PMI format would be a one-page document, highlighting the most important information for patients. PMI would be organized by the following sections:

- Drug Name
- Important Safety Information
- Common Side Effects
- Directions for Use

**How would patients receive PMI?**

PMI would be distributed to patients who receive prescription drugs in an outpatient setting, such as retail pharmacies and hospital outpatient care pharmacies. Authorized dispensers, such as pharmacists, would provide the FDA-approved PMI to patients with their prescription drugs. Transfusion services would also be required to provide PMI to each patient who receives blood or blood components on an outpatient basis.

Patients will have a choice to receive PMI in either paper or electronic format, to ensure that relevant information is communicated in whatever form the patient deems most useful. Paper format will be the default method of distribution and must always be provided unless a patient specifically requests electronic delivery.

PMI will eventually replace current Medication Guides and Patient Package Inserts. PMI is not intended to replace Prescribing Information, Instructions for Use, or patient counseling.

PMI will be stored in an online central repository managed by CDER and will be freely accessible to the public, including patients, health care professionals, and authorized dispensers. FDA will also provide a batch download option, which is an easy way to download many PMI sheets at one time.

### Who can patients reach out to with comments or questions?

While the comment period has ended on the proposed rule, we are able to answer questions. We can be contacted at (855) 543-3784 or by email at druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov), or CDEROMP@fda.hhs.gov (mailto:CDEROMP@fda.hhs.gov).

Was this helpful? Yes No