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***Via*** [**www.regulations.gov**](http://www.regulations.gov)**,**

***Docket Number*** [**FDA-2019-N-5959**](https://www.federalregister.gov/public-inspection/2023-11354/medication-guides-patient-medication-information)

Dockets Management Staff (HFA–305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852.

**Re: Comment Regarding Proposed Rule: Medication Guides: Patient Medication Information, Docket No. FDA-2019-N-5959**

**Comments from The National Consumers League**

The National Consumers League (“NCL”) thanks the Food and Drug Administration (“FDA”) for this opportunity to submit comments regarding the Proposed Rule,[[1]](#footnote-1) Medication Guides: Patient Medication Information (“Proposed Rule”). We believe that the Proposed Rule, when implemented, will greatly improve the information patients receive with their prescription medicines. The creation of the concise, one-page, FDA-approved “Patient Medication Information” (“PMI”), and its delivery to patients in a consistent and easily understandable format, will enormously aid patients in the safe and effective use of their prescription drug products.

Founded in 1899 to represent consumers in the marketplace and the workplace, NCL is the nation’s oldest nonprofit consumer advocacy organization. For over 120 years, NCL has represented the voice of consumers on matters affecting consumer protection and social justice. Today, NCL provides government, businesses, and other organizations with the consumer’s perspective on concerns including child labor, privacy, food safety, and medication information.

NCL has long been involved in protecting consumers and their health. NCL provides and participates in patient education on medication and disease awareness. the Proposed Rule. Additionally, NCL sat on the Steering Committee for the “Action Plan” for the “Provision of Useful Prescription Medicine Information.”[[2]](#footnote-2) In 2011 we launched, coordinated, and staffed, with the help of over 100 diverse organizations, “Script Your Future,” a multi-year public awareness campaign about the importance of medication adherence, to help people manage chronic health problems.

NCL was one of the original signatories, of the “One Document Solution For All Pharmacy-Based Communications”[[3]](#footnote-3) (“2008 Citizen Petition”) that was, in part, the impetus for the Proposed Rule. In the 2008 Citizen Petition, NCL, along with other consumer groups, patient groups, and industry groups, were united in the view that patients were not well-served by the state of patient-directed communications about prescription drugs. As we stated then, the current framework for providing patients with information was a “dizzying patchwork of requirements, interpretations, and government-mandated documents all collide in the pharmacy, with negative, and even comical results” for consumers. We urged the agency to adopt a new paradigm for communications with patients about prescription drugs. We recommended a single, FDA-approved document in concise, plain language, and a standard format that would consolidate the many communications patients receive about the drugs that are prescribed and dispensed to them.

We are, thus, pleased to see our “one document” vision come to fruition here in FDA’s Proposed Rule. NCL supports the Proposed Rule and believes it will provide patients with needed, and trusted, information, which will improve medication adherence and promote public health.

Below, NCL reiterates its support and provides additional recommendations.

1. **NCL Supports the PMI’s “One Document” Approach:**NCL urges the finalization and implementation of PMI as swiftly as possible. As FDA explains in the preamble to the Proposed Rule, a patient may receive numerous documents with their dispensed prescription drugs. These documents may include multiple, often repetitive pages, that may even be conflicting. Additionally, some of the information may be FDA-approved, while other documents are not. Many of these documents may also include highly technical medical and scientific content that is beyond the comprehension of many patients. Eliminating this confusion and providing patients with a document intended for them was a key principle of the 2008 Citizen Petition.

If finalized as proposed, the PMI would resolve many of the concerns the 2008 Citizen Petition sought to remedy. The PMI would be FDA-approved and provide information about the prescribed medication in a uniform, one-page presentation that is concise, useful, relevant, and, critically, intended for the patient.[[4]](#footnote-4) This single, definitive, FDA-approved, patient-friendly summary would detail the risks, benefits, and usage information a patient needs to take their prescribed medicine safely and effectively. The PMI would eliminate confusion and conflicts that arise when patients receive numerous documents, which they often never read and promptly discard. We believe the PMI would advance medication adherence and patient health.

1. **NCL Supports Electronic Distribution Options:** We are pleased that under the PMI Proposed Rule, electronic distribution is permitted upon a patient’s request. In our view, this flexibility will empower consumers by meeting them “where they are.” Many consumers prefer to have information delivered to them via their smartphone, text, and/or email because it is readily available and easier to reference on an as-needed basis. Additionally, electronically delivered PMI information is more likely to be current and can be formatted by the patient to be as useful and accessible as possible. For example, an electronic format would allow patients to enlarge the format and/or the text, as needed. Further, embedded hyperlinks in mobile or web applications allow patients to navigate within the document and can easily direct the patient to more information, such as definitions of unfamiliar terms and adverse event reporting.
2. **NCL Recommends The PMI Be The Default Document For All Patient-Directed Communication About A Prescription Drug:** In the PMI Proposed Rule, FDA states that “this [P]roposed [R]ule is not intended to address the use of other avenues, outside of PMI, to communicate to patients, including to provide promotional messaging.”[[5]](#footnote-5) We urge FDA to reconsider this approach and clarify that the PMI should become ***the*** document for all risk communication to patients, regardless of whether it accompanies a pharmacy-dispensed prescription drug or a manufactured-sponsored promotion. In the 2008 Citizen Petition, we proposed the “one-page solution” for ***all*** consumer and patient-directed communications about prescription drugs. The reasons for that position remain as important today. Consumers are not well-served by multiple documents with similar, but not identical, content and format, where some are FDA-approved, and others are not.

We urge FDA to clarify that the PMI could also replace the consumer brief summary. We see no reason to continue the patchwork of prescription drug information patients receive. Consumers should receive one, FDA-approved document about a dispensed or promoted prescription drug, available in a variety of formats, with clear directions to where they can go for more information.

1. **NCL Recommends FDA Provide Further Detail On The Central Repository:**Under the Proposed Rule, approved PMI would be stored in a “central repository.” FDA would manage this database and it would be readily accessible to the public, including patients, healthcare providers, and authorized dispensers.[[6]](#footnote-6) NCL supports this proposal. However, in the PMI Proposed Rule, FDA provides little information on how this repository will be created, maintained, or accessed. The agency alludes to a monthly update to the central repository and estimates it could take up to thirty-minutes per month to update all PMIs.[[7]](#footnote-7)

We ask that FDA provide further details on the central repository and, especially, how it will be maintained and kept current. We suggest the agency also consider adding functionality so that consumers can opt to receive a notification if PMI is updated.

1. **NCL Recommends The Final Rule Provide Additional Language Duality Requirements:** Under the Proposed Rule, FDA acknowledges the benefits of making PMI accessible to persons with limited English proficiency.[[8]](#footnote-8) We appreciate the agency’s flexibility and encouragement but ask for additional clarification. When considering those with “limited English proficiency,” the final rule should additionally account for those who speak language(s) other than English and thus, align the final rule with dual language requirements already set in various states.

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**Conclusion**

Improving the quality of the information patients receive about prescription drugs has been a goal we have long sought. In the 2008 Citizen Petition, and in our advocacy that preceded it, and since, we have urged providing patients with an FDA-approved, uniform document with the flexibility to deliver it electronically or in print.

NCL commends FDA for initiating this rulemaking. We greatly appreciate the work the agency has done to develop the PMI Proposed Rule. This rule, when finalized, will ensure there is an FDA-approved, concise, plain-language document to assist patients in using their prescription drug products safely and effectively.

Thank you for your consideration and please contact me at 202-835-3323 if you would like to discuss NCL’s position further.

Sincerely,



Sally Greenberg

Chief Executive Officer

National Consumers League

1. 88 Fed. Reg. 35,694 (May 31, 2023). [↑](#footnote-ref-1)
2. See, e.g., Guidance, [Useful Written Consumer Medication Information](https://www.fda.gov/media/72574/download) (CMI) (2006). [↑](#footnote-ref-2)
3. Docket (FDA-1019-N-5959), Reference 15 – National Association of Chain Drug Stores – Citizen Petition requesting FDA Action on a “One Document Solution” for All Pharmacy-Based Communications – 2008 – Docket FDA-2008-P-0380 RE Medication Guides: Patient Medication Information. (<https://www.regulations.gov/document/FDA-2019-N-5959-0018>). [↑](#footnote-ref-3)
4. 88 Fed. Reg. at 35,698. [↑](#footnote-ref-4)
5. 88 Fed. Reg. at 35,707. [↑](#footnote-ref-5)
6. 88 Fed. Reg. at 35,712. [↑](#footnote-ref-6)
7. 88 Fed. Reg. at 35,718. [↑](#footnote-ref-7)
8. 88 Fed. Reg. at 35,705. [↑](#footnote-ref-8)