Submitted electronically to: www.regulations.gov

November 27, 2023

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Medication Guides: Patient Medication Information [Docket No. FDA–2019–N–5959]

Dear Dockets Management Staff:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA on its *Medication Guides: Patient Medication Information* proposed rule, where FDA estimates dispenses will be required to provide Patient Medication Information (PMI) to patients for 4.3 billion prescription drugs.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA thanks FDA for recognizing the Citizen Petition, entitled "One Document Solution For All Pharmacy-Based Communications," submitted by Catalina Health (now part of Adheris), National Association of Chain Drug Stores, National Community Pharmacists Association, Food Marketing Institute, Healthcare Distribution Alliance, and the National Consumers League:

> 4. Citizen Petition
>
> In June 2008, we received a citizen petition (the 2008 citizen petition) from a large group of stakeholders representing pharmacy practice, medical consumers, and medical communications companies (Docket No. FDA–2008–P–0380). The 2008 citizen petition asked us to adopt an FDA-approved, concise, plain language, single-page patient information document for prescription drugs. The 2008 citizen petition requested that the one-page "single patient document" combine and simplify the many documents that patients currently receive at the pharmacy for prescription drug products (Ref. 15). In 2010, the petitioners voluntarily withdrew the 2008 citizen petition, citing FDA's significant work and strides toward

> achieving the goals of the 2008 citizen petition with the ongoing development of PMI (Ref. 16).[1]

While NCPA supports the proposed rule as an improvement to the current information available to consumers to improve patient safety, NCPA has the following concerns.

FDA does not substantiate claims of significant patient benefits. FDA expects PMI to save patients an average of 2.5 minutes each time they search for information about prescribed products. FDA estimates the proposed rule could create up to $188.0 million per year, annualized over 10 years for patients in time-savings, but does not substantiate this claim with evidence or research. FDA also believes PMI could have positive health impact on patients but does not provide evidence for this either.

FDA is unclear on precise administrative burden to pharmacies. At one point in the proposed rule, FDA estimates negligible administrative burden to dispensers:

> Estimated printing costs will be equivalent to current printing costs, because dispensers already provide written information in paper format to patients. Further, we do not expect that dispensers will incur additional costs when printing PMI, because the length of PMI will be shorter than written information currently provided to patients. Because providing prescription drug product information to patients is currently a part of authorized dispensers' business practices and we are proposing that PMI be limited to one page, we anticipate time and effort for dispensers will be reduced.[2]

However, FDA estimates that dispensers would need on average 0.5 hours (30 minutes) for dispensers to download PMI into their databases, 0.02 hours (1 minute) to provide PMI to patients, and 0.05 hours (3 minutes) for dispensers to give the medication guide to patients. FDA's full burden estimates are below:

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

21 CFR section and activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Downloading PMI into Database (§§ 208.70 and 606.123(b))	49,276	12	591,312	0.5 (30 minutes)	295,656
Providing PMI to Patients (§§ 208.70 and 606.123(b))	93,697	45,924.63	4,303,000,000	0.02 (1 minute)	86,060,000
Medication Guide from Packer/Distributor to Authorized Dispenser (§ 208.96 (previously § 208.24(c)).	191	9,000	1,719,000	1.25	2,148,750
Medication Guide from Authorized Dispenser to Patient (§ 208.96 (previously § 208.24(e)).	88,736	5,705	506,238,880	0.05 (3 minutes)	25,311,944
Total					113,816,350

[1] There are no capital or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest hundredth.

[1] FDA, *Medication Guides: Patient Medication Information,* 88 Fed. Reg., 35718, (May 31, 2023), at 35700.
[2] FDA, *Medication Guides: Patient Medication Information,* 88 Fed. Reg., 35718, (May 31, 2023), at 35718.

NDP Analytics issued a recent report that goes into further detail on the expected administrative burden to pharmacists.[3]

NCPA recommends that FDA allow maximum flexibility in how PMI is provided to patients by pharmacies. Downloading PMI may not be necessary, and therefore some administrative burden relieved, if the online central repository of PMI uses a permalink concept which is adopted by drug compendia in a manner such that pharmacies can provide it to patients in a manner acceptable to the patients (e.g. hyperlink in patient profile, QR code on the receipt, link delivered by SMS).

Additionally, FDA estimates that 93,697 authorized dispensers will be impacted by this rule, and concedes that the annual burden of the Proposed Rule on community pharmacies is estimated to consume approximately 86 million hours of pharmacy resources.[4]

FDA should clarify "online central repository." According to the Proposed Rule, approved PMI would be stored in an online central repository managed by FDA and be readily accessible to the public, including patients, healthcare providers and authorized dispensers.[5] However, FDA provides no information on how this repository will be created, maintained, or accessed. Elsewhere in the proposed rule, the agency alludes to a monthly update to the central repository and that it could take up to thirty (30) minutes per month to update all PMIs. We suggest FDA consider and provide detail on whether FDA provides updates via a "pull" method (i.e., pharmacies need to upload updates) or a "push" method (i.e., FDA automatically pushes out updates to pharmacies). Further, we believe the agency should explain how it would exercise enforcement discretion if an authorized dispenser provided outdated PMI to a patient due to FDA not making a timely update to its repository. As above, implementation flexibility could relieve the pharmacy of needing to pull or accept push updates.

Given the increased administrative burden, NCPA argues that FDA should:

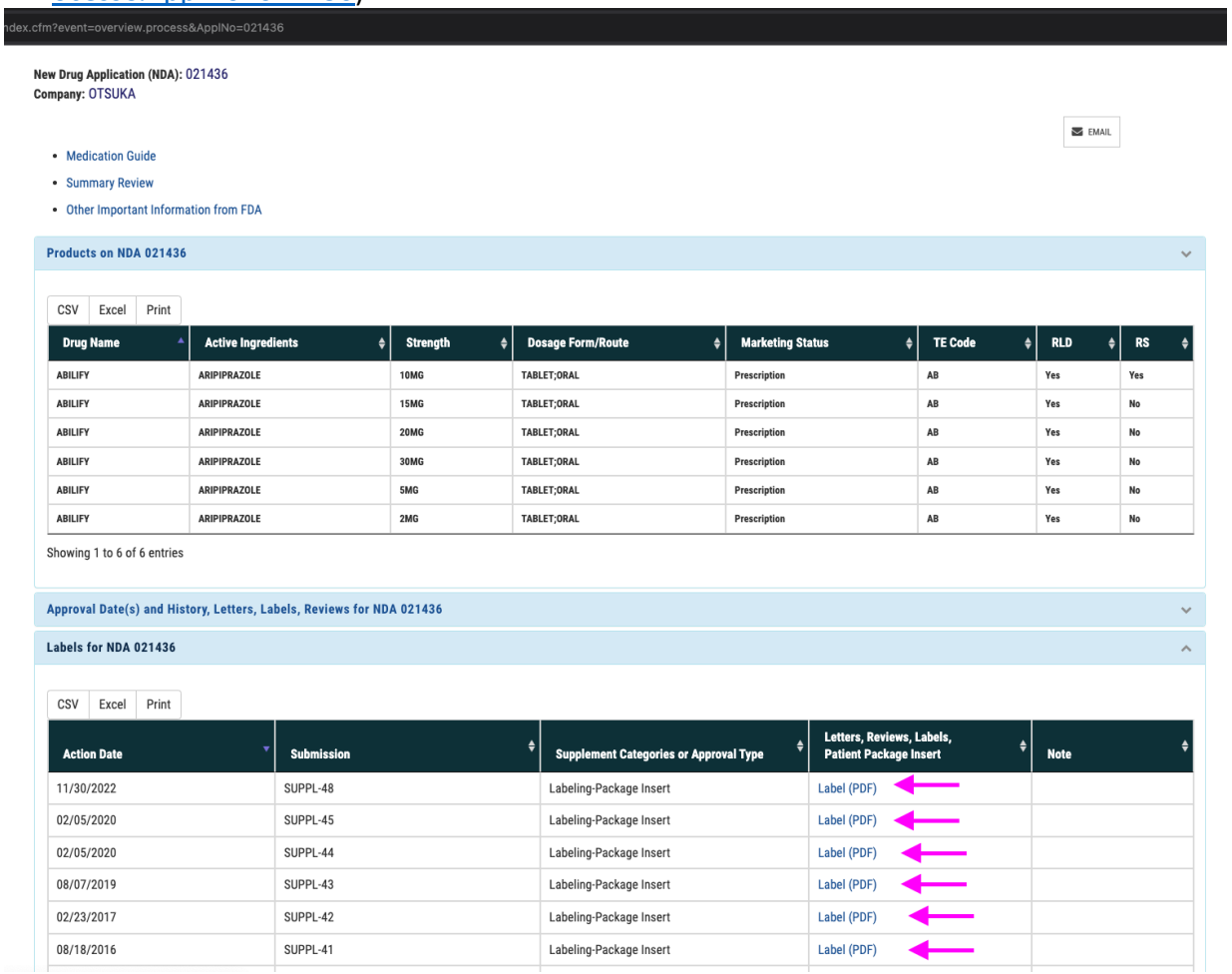
- Title the online central repository something like "Patient Medication Information Guides" and model it after existing databases;

- Host a PDF for every single current and future PMI, as they currently do for every product label (example: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf)

    - FDA currently keeps a running list of every version and a link to each product label. Here is an example product page showing how the Drugs@FDA database keeps product label version history and link to PDF for each:

[3] *An Economic Assessment of the FDA Proposal Rule: "Medication Guides: Patient Medication Information.* Nov. 2, 2023." Available at: FDA-Comments-November-2-2023.pdf (ndpanalytics.com)
[4] FDA, *Medication Guides: Patient Medication Information,* 88 Fed. Reg., 35718, (May 31, 2023), at 35718.
[5] 88 Fed. Reg. at 35712.

(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021436)



- FDA should make the online central repository database queriable on openFDA API (https://open.fda.gov/apis/drug/), just like how the Drugs@FDA and NDC directory are currently. The API should be able to return the link to where the latest PDF version is hosted (e.g., a link like this to PMI PDFs): https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf)

- The pharmacy information system should incorporate patient preference for a printout, printed link (e.g., QR code on purchase receipt) or electronic delivery (SMS, portal). It could provide a hyperlink or generate a QR code if a permalink is incorporated in the drug compendia files to the latest PDF from the API. API could also have XML or JSON of the PMI content to be injected into PMS or other product if desired.

- A QR code fundamentally would resolve to a link (e.g., https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf).

FDA should allow for maximum implementation flexibility. Therefore, **NCPA recommends that FDA says that QR codes, SMS, and portal access are an acceptable means to present patients with PMI, and that FDA allow the details to be worked out by the pharmacy and its technology vendor.**

FDA API should also provide a permanent link for each product in the PMI database which is set in their server to automatically redirect to the latest PMI PDF label. This would enable pharmacists to be able to print a QR code that resolves to the current version of a PMI PDF.

Pharmacies can then distribute the PMI either as a one-page insert (upon request of the patient, or as preferred by the pharmacy) or in an electronic manner acceptable to the patient. Pharmacies should not bear any financial costs associated with accessing PMI in the online central repository. The decrease in paper would save pharmacies additional burden folding inserts, and reduce risk of HIPAA breaches.

The proposed rule states that manufacturers would be required to provide the PMI either in sufficient numbers to pharmacies or provide them with the means to distribute them. **While NCPA supports this proposed rule, it believes that the final rule should require PMI that: 1) has demonstrated optimum understanding for patients; 2) is provided electronically at no additional cost to pharmacies; and 3) minimizes the administrative burden to community pharmacies.**

NCPA appreciates the opportunity to share with FDA our comments and suggestions on the *Medication Guides: Patient Medication Information* proposed rule. Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
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National Community Pharmacists Association