

# FDA Patient Medication Information NPRM (FDA-2019-N-5959) Comment

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This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the FDA Patient Medication Information NPRM (FDA-2019-N-5959) posted in the Federal Register on May 31, 2023 and found here:

<https://www.federalregister.gov/documents/2023/05/31/2023-11354/medication-guides-patient-medication-information>

## About MHDC

Founded in 1978, MHDC, a not-for-profit corporation, convenes the Massachusetts's health information community in advancing multi-stakeholder health data collaborations. MHDC's members include payers, providers, industry associations, state and federal agencies, technology and services companies, and consumers. The Consortium is the oldest organization of its kind in the country.

MHDC provides a variety of services to its members including educational and networking opportunities, analytics services on both the administrative and clinical side (Spotlight), and data governance and standardization efforts for both clinical and administrative data (the Data Governance Collaborative/DGC and the New England Healthcare Exchange Network, respectively).

## About DGC

The DGC is a collaboration between payer and provider organizations convened to discuss, design, and implement data sharing and interoperability among payers, providers, patients/members, and other interested parties who need health data. It is a one stop interoperability resource. The DGC primarily focuses on three areas:

1. Collaboration: Development of common understanding of and specifications for data standards, exchange mechanisms, and what it means to participate in the modern health IT ecosystem
2. Education: helping members understand their regulatory obligations, the data and exchange standards they're expected to use, and modern technology and related processes
3. Innovation: Identification and development of projects and services needed to make modern health data practices and exchange a reality

## General Comments

This section comments on the general approach taken by the FDA in their posted proposal or comments on items that cross multiple sections of the proposed rule

### Electronic Patient Medication Information

As the FDA notes in its proposed rule, it is important to present standard data to patients in a clear, consistent format so they know both what it means and where to find it. However, this is not just important on paper but also in electronic medication information presented to the same patients. As more and more patients get their health information via electronic formats in patient or member portals and mobile or web apps that use APIs to pull data from various sources (payers, providers, pharmacies, etc), it becomes more and more important to make patient-facing information previously provided by paper handouts available to them electronically.

Basic patient medication information has been part of USCDI since v1 and has been expanded in later versions. CMS-mandated Patient Access APIs require that this information be made available to patients by

their payers and EHRs that have been certified by ONC have similar requirements on the provider side. Further, the CMS Patient Access APIs require that plan-specific formulary data be available to patients.

While the FDA cannot mandate that these APIs include additional information on its own, it seems important that FDA address this issue and make it possible for the same information organized in the same way be supportable by those EHRs, portals, apps, and other electronic sources of patient information so that patients can see a unified view of their medications. Having the data available this way would enable CMS and ONC to require its use at a later date and, if the FDA provided a FHIR API to access this public database it would allow developers of these electronic patient access mechanisms to get a head start on providing the data to patients should they wish to do so.

To enable this, we strongly recommend that the data for these PMI sheets be required to be entered into the FDA database as structured data elements that could then either be accessed directly via APIs or be assembled via template into printable sheets for use at pharmacies and other dispensaries.

## Legibly Printed

The proposed rule requires that the PMI be legibly printed but does not provide any specifics of what that means beyond the font and color requirements provided later in the rule (more on these later). We suggest that FDA either provide some specifics of what it means to be legibly printed, add a reference like “as defined later in this rule”, or remove the word legibly as it has no meaning on its own.

Some suggested additional format/presentation requirements not already included in the proposed rule that would help with legibility include:

- Requirements around margins, line spacing, and line breaks between content segments
- Requirement to provide a cleanly printed document each time. No photocopies allowed.
- Requirement to use a sans serif font (or requirement to use a specific common sans serif font such as Arial or Helvetica)
- Requirement to not use italics in the document

## 10pt Font Size

Using 10pt fonts as the default text size is extremely problematic. While on the very lower end of what is currently considered a normal font size for printed text (10-12 pt), this norm has been decreasing slightly over time (12-14pt was considered normal in the 80s into the 90s, for example) and 11 or 12pt fonts are much more common in everyday usage. For example, the default Microsoft Office font has been 11pt Calibri since 2007 (it was 12pt before that), AHRQ requires their proposals to use 11pt fonts, most journalistic style guides require 12pt fonts, and many academic settings require 12pt fonts as well.

10pt fonts will not just be difficult or impossible for a patient with a visual impairment, it will be difficult for many people who just have slight visual acuity loss. Many seniors, the population most likely to take a larger number of medications, will struggle with it.

We strongly feel that important documents meant to be widely readable, especially by the elderly, should use at least 12 pt fonts. 14 pt fonts would be better, but we understand the need to balance readability with conciseness (but see accessibility comment below).

## Accessibility of PMI

We applaud the goals of creating clear, concise, and consistently formatted patient information documents that fit on a single page. However, some of the decisions made to enable this decision are less than optimal from an accessibility standpoint.

As discussed in a separate comment above, 10pt font sizes will not be legible to many individuals with mild visual acuity loss, let alone individuals with an actual visual impairment. The suggestions made above under the legibility comment are essential for anyone with a visual impairment. In addition, we recommend that additional versions of the PMI be provided in:

- Large print (not limited to one page), presented in at least 18pt fonts with wider margins, more white space, and strict black/white contrast required. We note that 20 or 24 pt fonts would be better, but 18pt font is the minimum requirement for meeting large print standards and was recently adopted by the American Council of the Blind<sup>i</sup>
- Recorded audio, perhaps hosted in a library by FDA that individuals are sent a link to access via their choice of email, text, or large print.

It would be nice to have braille available, but we realize it would be difficult to manage at a practical level. Perhaps a limited number of braille versions could be created that could be checked out as needed by individuals who require it. Obviously, this is not ideal as it would involve mail delays, there may be greater demand than existing copies available, and it requires patients knowing they can make such a request so we do not feel strongly that such a program should be instituted.

Judicious use of iconography may also help visually impaired patients who have trouble reading the text. For example, use of standard caution and warning icons would be helpful in the section discussing contraindications and side effects (in both the normal and large print formats). See below for more discussions on iconography.

While included in the general legibility suggestions above that we already noted applies to this section as well, we stress the importance of using clean print outs for the large print version of any PMI as photocopies significantly degrade both the borders of letters and the contrast of the document; this is exacerbated if enlarging via photocopy.

Education around available accessible options will be a problem; in general pharmacies are not good about providing information about accessible options even to patients who complain they can't read information provided. This is a big issue for prescription labels as well.

## Languages

We understand that it is impossible to provide any information in every language that its potential users speak or read. Further, the most common language needs of the population vary greatly by location and this variation can even be town-by-town<sup>ii</sup> and not region-by-region or state-by-state.<sup>iii</sup> However, only requiring materials be provided in the primary language of a location will leave a large portion of patients unable to access the information.

According to US Census Bureau data from 2019<sup>iv</sup> 30% or more of individuals speaking the five most common foreign languages in the US have limited English proficiency; this is true for more than 50% of individuals speaking Chinese or Vietnamese.

We recommend that translation into the top 5 languages in the US plus any additional languages that are the top 3 languages in a state or in a major region (if credible data about such is available) be required. This should be tied to census data or have some other means of adjustment over time.

At the current time, based on national census and CMS state data, this would mean PMI should be available in the following languages:

- English
- Spanish
- Chinese (classification combines both Mandarin and Cantonese)
- Tagalog
- Vietnamese
- Arabic
- Korean
- Navaho

- Marshallese
- Portuguese
- Polish
- French Creole (Haitian Creole)
- Amharic
- Ilocano
- Japanese
- Serbo-Croatian
- German
- French
- Hmong
- Cushite
- Russian

If this is deemed too onerous, we strongly recommend at least requiring English and Spanish everywhere. Spanish is by far the second most common language after English, and we suspect that English is the second most common language after Spanish in locations where Spanish is more common. It is unclear how many additional people this would leave unable to access the information.

## Iconography

Members of our Data Governance Collaborative were a bit confused by the decision to forbid use of iconography and pictograms on the PMI documents. Several people noted that when they traveled to countries where they did not fluently speak the native language, they relied heavily on iconography to help them navigate the world around them successfully so this was particularly glaring given the lack of requirements to translate the documents into multiple languages.

We applaud the goal of not offending anyone and of keeping organizations from accidentally using iconography that some cultures might find offensive, but strongly feel that the benefits outweigh the potential harms of using imaging to augment text. We also gently note that it felt somewhat out of place to have the FDA comment on this aspect of iconography without addressing more pervasive inclusivity issues such as language and disability access.

We noted in the accessibility comment above that there are standard accepted icons for things like cautions and warnings that would greatly enhance the contraindications/side effects section of the PMI. We strongly recommend not outlawing but requiring the use of these and other standard icons as applicable. If nothing else, use of these icons in a reasonable size next to essential content would likely prompt someone who cannot read the nearby text (because of disability, inability to read the language, or some other reason) to ask someone about it.

We also note that when CVS redesigned its prescription labels a few years ago to try to make them easier to understand they added a variety of graphical elements to augment text including pictures of the sun in various stages of rising/setting to indicate when patients should take doses.

## Allergies and Intolerances

The PMI requires inclusion of a statement not to take the medication if you are allergic to it or any of its ingredients but no ingredients are provided. Without providing this, how is a patient supposed to judge if they are allergic to an ingredient in the medication or not?

We also suggest that any alternate names for the same drug be included as part of the allergy discussion (as opposed to at the top identifying the dispensed drug) as patients may be aware of an allergy to one form of the

drug but not know all of its possible names. For example, they may know they're allergic to Flexeril but not to Amrix or Cyclobenzaprene. If they are dispensed the generic or the alternate brand name, they may not be aware that they are, in fact, being given the forbidden drug.

## Contraindications

It seems almost misleading to include a contraindications section of the PMI that does not have to include all contraindications. We realize this may affect the length of the document, but our Data Governance Collaborative felt strongly that if a contraindications section is supplied it needs to be complete. In addition to patient safety worries, our participants noted liability concerns around not providing all of the relevant information to a patient who then goes on to have an adverse reaction.

One option to maintain the single page format might be to provide a supplemental sheet with secondary/less commonly encountered/less consequential contraindications. That is, the most commonly encountered contraindications and those that, even if uncommon, have the most severe potential consequences should be on the main PMI sheet but that sheet should reference supplemental information provided on a second page.

## Side Effects and Potential Risks

We also feel like it's important to discuss the prevalence and risks of side effects including both symptoms and potential development of new medical conditions. One issue with pharmaceutical advertisements is the lack of perspective around potential side effects. There's no discussion of how likely a particular side effect is and this can make it difficult to do any sort of real risk/benefit analysis. It can also serve to scare a patient away from medications that may be helpful to them if a particular side effect they find problematic is mentioned without any context to judge its likelihood.

We do not want to see the same issues with PMI documents. In these times of short encounters, providers do not necessarily go through any of this information with patients unless they ask (and even that may be greatly abbreviated). Seeing an unexpected side effect on the PMI document may be sufficient to make a patient not take a medication that they should be taking for some urgent need unless they see it occurs in less than 0.01% of patients or similar. Other patients with certain medical histories may be particularly sensitive to side effects in certain areas. For example, someone who is legally blind and trying to preserve as much of their existing vision as possible may be more sensitive than other patients to medications that can lead to decreased visual acuity and may choose not to take drugs that can cause visual loss even if vision loss is not a particularly common side effect.

## Look at Medication Prescription, Dispensing, and Consumption Holistically

Participants in our Data Governance Collaborative felt strongly that a more holistic view of the prescription medication landscape is needed to properly determine what should and should not be considered essential information on a PMI. Common scenarios that were raised and discussed include:

- The use of algorithms that tell a provider to prescribe a medication to a patient
- The inundation of patients with drug advertising
- The likelihood of missing data and short appointment times making a fulsome discussion of new medications, the potential risk/reward balance, side effects, and even sometimes contraindications difficult if not impossible

All of these and more can make it difficult to know if a particular medication is right for a particular patient at a particular time, and more problematic, whether it is potentially detrimental or even dangerous. Providers may not know why a particular medication is being recommended for the patient and may not have time to try to dig into the rationale at the end of a short visit. Patients may be scared to take a certain recommended medication because of the scary warnings in advertisements provided without any context or try to demand their providers give them medications that do not suit their situation because they saw them on television or on their mobile device. Providers may not have long-term diagnoses handled by other providers or know everything that might make a certain drug the wrong choice and, again, not have time to dig deeply into it if no warning pops up in their normal workflows.

## Scientific Accuracy/Lack of Misinformation

Participants in our Data Governance Collaborative agree with the comment that information must be scientifically accurate and not be false or misleading in any way. However, in present times, we feel that some additional discussion of how this will be determined and policed is likely warranted given the unfortunate prevalence of false or misleading medical information at this time.

Further, a discussion of how to address newly discovered information that supersedes previously accepted information is likely necessary, including an explanation of why changing something does not mean either the new or previous version was misinformation even if they disagree with each other. This discussion should give some type of required timeframe for rolling out updates and perhaps some type of requirement of notification of existing users who are not likely to read their PMI information sheets every month. Perhaps a NEW INFO label should be required in the header and the subheading of any affected content and, perhaps as supplemental information, some way to get a delta between the old and new version of the form. We realize that a version date is required at the bottom of the document, but this is likely to be overlooked by most patients, and those who realize something is new may have difficulty figure out exactly what changed.

In addition, perhaps a prompt for the pharmacist to mention that the drug information has changed with an option to review it with the patient should be required.

## Order of Required Important Safety Information Subsections

Participants in our Data Governance Collaborative thought that the order of the four required subsections of the Important Safety Information section should be rearranged in order of importance/likelihood that it leads to a contraindication. We propose the following order:

- Warnings
- Do not take
- Tell your healthcare provider before taking
- Serious side effects

This also has the benefit of putting the serious and common side effects next to each other, meaning patients can get all side effect information by looking at a single contiguous section of the document.

## Response to Specific Questions

This section will list specific questions asked in the proposal and our responses to them.

### **FDA seeks comment on whether the proposed format and content requirements support the accessibility of patient medication information for all intended users, including patients with low health literacy.**

We addressed accessibility for low vision patients and availability of multiple languages above as the discussion around this question seemed very focused on health literacy and literacy in general.

We agree that the bulk of the information should be written for patients who read at a 6<sup>th</sup>-8<sup>th</sup> grade level. However, in certain sections it may not be possible to concisely discuss the relevant information at that level and we worry that requiring everything in the document be at that reading level might disadvantage those patients who are capable of reading and absorbing more complex language and would benefit from more complex discussions of particular side effects or contraindications to make informed risk/benefit analyses for themselves.

We are not certain of the best solution here, but think this may be an area where having user testing across patients with a wide variety of backgrounds, educations, and experience with the medical system would be beneficial (see next comment). We also think supplemental information could augment the sheet for some users, but worry that having a single page PMI with three pages of supplemental information defeats the



purpose and thus would seek to limit what needs to be cordoned off from the main document while still ensuring all of the pertinent information is provided in ways that patients can absorb it.

## **FDA carefully considered the question of whether consumer testing of PMI would be an appropriate requirement for this regulation...we invite comment on this**

We believe consumer testing with a variety of potential patients of various backgrounds would be appropriate. Efforts should be made to mirror the demographics of the cohort likely to take the medication as much as possible and should include some percentage of visually impaired individuals and individuals with other disabilities that might have difficulty reading or understanding a PMI document.

Further, we believe there are some areas of the PMI proposal that would benefit from some consumer testing prior to finalization of the rule. Finding the proper balance between conciseness and providing necessary information, determining the right level of language, and the order/readability of content all might benefit from such testing.

## **FDA is seeking comment on possible PMI requirements for which waivers could be requested and the criteria that FDA might consider when evaluating such requests.**

We understand that FDA does not wish to grant many (if any) waivers to the one page requirement, but participants in our Data Governance Collaborative believe that the following circumstances could warrant waivers:

- Listing all do not take criteria
- Listing all Call your doctor criteria
- Large print versions of the PMI
- Alternate language versions where the language takes up more space than English does or accurate conversion requires longer phrasing

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<sup>i</sup> <https://www.acb.org/large-print-guidelines>

<sup>ii</sup> MHDC did an informal study of five contiguous near north/northeast suburbs of Boston based on library circulation of foreign language materials for an AHRQ grant proposal and found that, while there was some overlap on the edges, even towns directly adjacent to each other had very different primary language needs on whole

<sup>iii</sup> CMS data on top 15 languages by state: <https://www.cms.gov/ccio/resources/regulations-and-guidance/downloads/appendix-a-top-15.pdf>

<sup>iv</sup> See heading "English Proficiency by Language" here: <https://www.census.gov/library/stories/2022/12/languages-we-speak-in-united-states.html>; the full report is available here: <https://www.census.gov/content/dam/Census/library/publications/2022/acs/acs-50.pdf>