# An Economic Assessment of the FDA Proposal Rule: "Medication Guides: Patient Medication Information"

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## I. SUMMARY

The Food and Drug Administration (FDA) is proposing to require drug manufacturers to create a new type of Medication Guides, referred to as Patient Medication Information (PMI), for prescription drug, biological, and blood transfusion products. PMI will be a one-page standardized document based on and consistent with FDA prescription information and the labeling requirements. FDA will review and upload approved PMI in its publicly available database online. Authorized dispensers, including pharmacies and transfusion service providers, will be required to download up-to-date PMI from FDA to local computers on a regular basis and must provide PMI to every patient (or the patient's agent) in each dispense. Authorized dispensers may provide PMI to the patient electronically but paper distribution must always be available.

- **FDA will require authorized dispensers to distribute over 4.3 billion PMI per year but does not quantify any significant health benefits of its proposed format versus current CMI.** FDA estimates dispensers will be required to provide PMI to patients for 4.3 billion prescription drugs and 3 million transfusions annually. Although discussing in length of the economic and health impacts of medication adherence on patients and the U.S. healthcare system, FDA does not provide evidence to support its claim that the format of PMI will have positive health impact on patients. In fact, FDA only expects PMI to save patients an average of 2.5 minutes each time they search for information about prescribed products. Using a national wage rate, FDA estimates the proposed rule will create up to $188.0 million per year for patients in time-savings.

- **FDA cost-benefit analysis does not consider the economic burden to 93,697 authorized dispensers to print PMI each time a prescription is dispensed.** The regulation would increase dispenser workloads by 71.7 million hours, the equivalent of 35,858 full-time pharmacy technicians, and $1.6 billion a year ($1.4 billion for labor and $215.2 million for supplies) to print PMI over 4.3 billion times. The average annual burden on an authorized dispenser is $17,107 for 0.4 full-time-equivalence pharmacy technician to print PMI for 45,925 prescriptions.

- **The proposal rule will create economic burdens disproportionately on authorized dispensers.** Smaller independent pharmacies, which account for 34% of total pharmacies in the United States,

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will face severe economic hardship. For a typical independent pharmacy, the printing costs alone required under the FDA rule account for 0.4% total revenue and 7.9% of owner discretionary profits.

- **FDA has not considered the negative health impacts of the PMI requirement due to the lack of Internet, power outages, and printing issues at dispensers.** Since authorized dispensers will not be allowed to dispense prescriptions without PMI, patients will suffer. The Federal Communications Commission estimates 4.4% of the U.S. population remained digitally disconnected in 2019. The U.S. Energy Information Administration reports that electricity customers, on average, experienced between seven and eight hours of electric power interruptions in 2020 and 2021 due to weather and failures of power lines and utility practices. Furthermore, authorized dispensers will be responsible for incomplete, inaccurate, and delayed information of PMI at the printing time.

In sum, FDA cost-benefit analysis shows the economic benefit of the proposed rule is immaterial and the positive health benefit is unknown. However, the unintended negative health benefit is significant. The proposed rule will create an economic hardship for smaller dispensers, heighten workload for pharmacy technicians, and add liability to authorized dispensers which in turn have negative health impact on patients, especially those live in rural areas.

## II. BACKGROUND OF THE PROPOSED RULE FOR PATIENT MEDICATION INFORMATION

In May 2023, the Food and Drug Administration (FDA) issued a proposed rule amending current prescription drug information requirements to include a new type of document: Patient Medication Information (PMI).[2] The proposed rule was developed after FDA determined that the current prescription drug information documents, including those are required and approved by FDA, do not provide patients with clear, concise, accessible, and sufficiently useful information delivered in a consistent and easily understood format to help patients use drug products safety and effectively.

Currently, patients may receive one or more of the following types of written information when they receive prescription medication in an outpatient setting: (1) Patient Package Inserts, (2) Medication Guides, (3) Consumer Medication Information, and (4) Instructions for Use documents.

Patient Package Inserts (PMI) and Medication Guides are developed by drug applicants and approved by FDA; they are required to be distributed to patients for certain types of prescriptions. Instructions for Use are developed by drug applicants and approved by FDA for medications with complicated or detailed instructions; it is not required to distribute to patients. Consumer Medication Information (CMI) is different. It is developed by organizations or companies in the private sector other than drug applicants. FDA reviews CMI and provides guidance and recommendations, but FDA does not provide approval nor requires. Pharmacies voluntarily purchase and distribute CMI to patients. (Figure 1)

[2] Federal Register. Food and Drug Administration. Medication Guides: Patient Medication Information. May 2023

Figure 1.

**Current Types of Medication Information**

| Patient Package Inserts (PPI) | Medication Guides | Consumer Medication Information (CMI) | Instructions for Use |
|---|---|---|---|
| • FDA-approved PPI is developed by drug applicants and required for oral contraceptives and estrogen-containing products.<br>• FDA-approved PPI is voluntarily for other medications but it is not required to be distributed to patients. | • FDA-approved Medical Guides are developed by drug applicants and required for certain prescription drug products.<br>• FDA determines when and what prescription drugs need Medication Guides. | • FDA-reviewed CMI is developed by an entity other than drug applicants. FDA provides guidance on CMI but does not approve the content.<br>• Pharmacies purchase and distribute CMI to patients voluntarily. | • FDA-approved Instructions for Use are developed by drug applicants for certain medications with complicated or detailed patient-use instructions.<br>• The document is generally provided when the drug is dispensed to the patient. |

The FDA proposal rule seeks to amend current prescription drug product labeling regulations for Medication Guides to improve public health. The rule would require applicants to create a new type of Medication Guides, referred to as Patient Medication Information (PMI), for prescription drug products, including biological products, used, dispensed, or administered on an outpatient basis. PMI would also be used for blood and blood components transfused in an outpatient setting. Applicants would be required to create a one-page standardized document consistent with FDA Prescribing Information (PI) and the labeling requirements, written in an easily understood language, and provided in identical electronic and paper formats. Importantly, FDA emphasizes that PMI will not have adequate directions for use and will not contain essential information for the safe and effective use of the drug. As a result, PMI will not be a substitute for Prescribing Information (PI) and counseling by healthcare providers, rather it will serve as a supplement document for outpatient patients. Detailed instructions for use will continue to be approved by FDA and provided in other labeling materials.

In its proposed rule, FDA specifies the design and system for PMI. The agency produced four prototypes for a fictitious drug that used different labeling formats informed by FDA public workshops and consumer-focused research over the past decades. The proposed design, including specific headings, subheadings, fonts, and information for applicants. Like most other types of drug product information, PMI must be submitted to FDA for approval. PMI will be stored, managed, and maintained in an FDA database. FDA will upload PMI to its online central repository and will make it to be available to the public including dispensers, healthcare providers, and patients. Dispensers will download PMI from the FDA central repository to local computers to distribute to patients along with drug products. Dispensers will be responsible for downloading and distributing updated PMI. PMI for prescription drug products would be stored electronically in the FDA labeling repository at https:// labels.fda.gov that currently holds Prescribing Information (PI), FDA-approved patient labeling, and carton and container labeling submitted to us under current requirements, such as labeling, listing information, and annual reports. (Figure 2)

Figure 2.
**Proposed Patient Medication Information**

| Proposed Patient Medication Information (PMI) | PMI Design | PMI System |
|---|---|---|
| • FDA-approved PMI to be developed by drug applicants and required for prescription drug products dispensed and blood and blood components transfused in an outpatient setting.<br>• **PMI will not be a substitute for Prescribing Information (PI)** and counseling by healthcare providers, rather it will serve as a supplement document for outpatient patients. | • A one-page standardized electronic and paper document that meets FDA requirements.<br>• Printed in black ink on an 8.5 by 11-inch sheet of white paper.<br>• Written in easily understood language.<br>• Bold type and specific fonts for headings, subheadings, drug names and phonetic spellings, and dosage. Uppercase letters for the title and proprietary name.<br>• No use of color or page numbers. | • FDA will upload and store PMI to its online central repository and will make it to be available to the public including dispensers, healthcare providers, and patients.<br>• Dispensers will download PMI from the FDA central repository to local computers to distribute to patients along with drug products.<br>• Dispensers will be responsible for downloading and distributing updated PMI monthly. |

## III. ASSESSMENT OF THE FDA COST-BENEFIT ANALYSIS

We reviewed the FDA regulatory impact analysis and its supporting documents as well as existing research and statistics from governmental agencies and peer-reviewed journals to evaluate the assumptions and expected economic and health impacts of the FDA proposed rule. Our comments focus on the FDA benefit analysis to patients and the FDA cost analysis to authorized dispensers.

### The Objective of the FDA Proposed Rule is Unsubstantiated

FDA fails to provide evidence to support the need for a new regulation that FDA has been proposing since the 1970s in different versions.[3] The stated objective of the proposed rule is to ensure patients are provided information to use their prescription drugs safety and effectively. In its proposed rule, FDA provides a comprehensive literature review of health and economic impacts of medication adherence. Studies have shown medication adherence has a tremendous impact on quality and length of life, health outcomes, and a significant cost burden on the U.S. healthcare system. For example, a systematic review and meta-analysis found that nonadherence to chronic medication regimens is common and is a potential contributing factor to the occurrence of concomitant diseases.[4] Nonadherence can account for up to 50% of treatment failures,

[3] Federal Register. Food and Drug Administration. Medication Guides: Patient Medication Information. May 2023.
[4] Abegaz, T.M., A. Shehab, E.A. Gebreyohannes, et al., ‘‘Nonadherence to Antihypertensive Drugs: A Systematic Review and Meta-analysis,’’ *Medicine.*

around 125,000 deaths, and up to 25% of hospitalizations each year in the United States.[5] Annual costs of medication non-adherence are estimated ranging between $100 and $290 billion in the United States.[6]

However, FDA does not provide evidence to support its assertion that PMI will improve public health. In fact, the only benefit to patients demonstrated by FDA is time saved searching for drug information (2.5 minutes). The economic benefits of PMI, the new Medication Guides, are immaterial and overstated. FDA states that the primary benefit of PMI is decreased search time for patients who read prescription drug instructions. FDA estimates PMI will save patients approximately 2.5 minutes when searching for information about prescribed drug, blood, and blood component products. Then, FDA applies an average after-tax hourly wage rate to estimate PMI will save patients an average of $1.55 each time they search for drug information. Acknowledging that not all patients will read PMI, FDA calculated the present discounted value and annualized value of the search time saving over ten years to be between $180.5 million and 188.0 million a year.[7] Since the FDA cost benefit analysis monetizes the time lost to search for information, FDA overstated the economic benefits by assuming patients would forgo their working time to search for information or that they work at all. Adults at retirement age (65 or order) take more medication than those under age 65. According to a Kaiser Family Foundation, 89% of adults ages 65 and older report taking prescription medicine and 54% take four or more prescription drugs. In contrast, for adults under 65, the share with prescription drugs ranged from 38% (ages 18 to 29) to 75% (ages 50 to 64), and the share of adults taking four or more prescription drugs ranges from 7% (ages 18 to 29) to 32% (ages 50 to 64).[8]

The health benefits of PMI are not specified nor quantified by FDA. FDA fails to provide statistical evidence to demonstrate the proposed PMI format would provide an increase in cognitive accessibility of the PMI information or health benefits to patients. FDA states that the public *may* benefit from a reduction in risk associated with drug products due to the availability of PMI, *if* the new labeling helps patients make better healthcare decisions. FDA discusses these are unrelated to the health costs of patients who do not adhere to prescription drug therapy and do not use their prescribed drugs as directed by their healthcare providers.

The proposed rule estimates the consumer benefit of reducing search costs. This benefit runs contrary to FDA efforts encouraging consumers to spend *more time* reviewing drug products and use information to reduce and prevent medication errors.[9] Moreover, patient information materials are not significant contributors to medication errors. In 2019, FDA received and reviewed more than 100,000 reports of suspected medication errors. The review found that prescription drug information such as PPI, Medical Guides, CMI, and Instructional Use was not among the top causes to harm consumers.[10] In an earlier study, printed reference materials contributed to less than 1% of medical errors by cause. In fact, the FDA reported that 42.5% of medication errors are caused by human factors, leading by performance deficit (13.2%) and

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[5] Kim, J., K. Combs, J. Downs, et al., ''Medication Adherence: The Elephant in the Room,'' *U.S. Pharmacist.*

[6] Cutler, R.L., F. Fernandez-Llimos, M. Frommer, et al., ''Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review,'' *BMJ.*

[7] Federal Register. Food and Drug Administration. Medication Guides: Patient Medication Information. May 2023.

[8] Kirziner, Ashle, Tricia Neuman, Juliette Cubanski, and Mollyann Brodie. 2019. "Data Note: Prescription Drugs and Older Adults." Kaiser Family Foundation.

[9] U.S. Food & Drug Administration. Working to Reduce Medication Errors. Content Current as of 8/23/2019. Web accessed on October 9, 2023.

[10] U.S. Food & Drug Administration. Working to Reduce Medication Errors. Content Current as of 8/23/2019. Web accessed on October 9, 2023.

knowledge deficit (12.3%). Therefore, the proposed regulation to require PMI for all prescription drugs would have virtually no impact on reducing medication errors. (Table 1)

Table 1.
**Medication Errors by Cause**[11]

| | % of Total |
|---|---|
| **Human Factors** | **42.5%** |
| Performance deficit | 13.2% |
| Knowledge deficit | 12.3% |
| Fatigue | 0.3% |
| Computer error | 0.3% |
| **Labeling** | **19.9%** |
| Immediate container labels of product manufacturer | 9.4% |
| Labels of dispensed product | 4.4% |
| Carton labeling of product | 4.4% |
| Printed reference materials | 0.9% |
| Electronic reference materials | 0.6% |
| Package insert | 0.3% |
| **Communications** | **18.8%** |
| **Name Confusion** | **12.9%** |
| **Packaging/Design** | **5.9%** |

## Understated Regulatory Costs to Dispensers and Transfusion Services Providers

FDA understates the regulatory and cost burdens to dispensers. The proposed regulation requires all dispensers to provide patients with a one-page Patient Medical Information (PMI) document in electronic or printed paper, paper distribution must always be available. FDA estimates 93,697 dispensers (88,736 pharmacies and 4,961 transfusion services) will be affected by the proposed rule.[12] The FDA acknowledges dispensers will have two associated costs to comply with the proposed rule: (1) to download updated PMI monthly and (2) to distribute PMI to patients. The FDA calculates a one-time cost for dispensers to set up their computer system and monthly costs to download updated PMI. However, the FDA does not estimate the regulatory burden to pharmacies and transfusion services providers to distribute PMI to patients. Under the current law, dispensers are not required to provide CMI to patients. Since the proposed rule requires dispensers to provide PMI for each prescription fill, the proposed rule has both monetary and legal implications for dispensers.

We use FDA estimates and official statistics to calculate the direct costs for dispensers and transfusion services providers to print PMI for patients to fulfil the regulatory requirement. The FDA estimates there are

[11] Thomas, Maria R., Carol Holquist, and Jerry Phillips. 2001. "Med error reports to FDA show a mixed bag." FDA Safety Page, Drug Topics.
[12] Medication Guides: Patient Medication Information.

more than 4.3 billion prescriptions and 3 million transfusions a year. The FDA also estimates it would take dispensers about one minute to provide PMI to patients. Using the FDA estimates, we calculate it would require nearly 71.8 million hours to print PMI 4.3 billion times per year for patients (4.3 billion PMI / one minute per PMI) which is the equivalent of 35,858 full-time pharmacy technicians (71.8 million hours / 2,000 working hours a year). In 2022, pharmacy technicians earned $19.35 per hour, on average, according to the Bureau of Labor Statistics (BLS). Applying the BLS figure, we calculate the annual labor costs for dispensers to print PMI for patients to be nearly $1.4 billion (71.8 million hours x $19.35 an hour). To estimate the cost of supplies, we use an average of $0.05 per page to estimate dispensers would have to pay $215.2 million for paper and black ink toners to print PMI 4.3 billion times per year. Total annual labor and supplies costs are more than $1.6 billion for dispensers to distribute PMI to patients. (Table 2)

The FDA estimates 93,697 pharmacies and transfusion service providers would be affected by the proposed rule. The most common outpatient settings are retail pharmacies and hospital ambulatory care pharmacies, where patients pick up prescriptions to take at home. Outpatient settings also include places where prescription drugs are dispensed at healthcare provider facilities, including clinics, offices, dialysis centers, and blood infusion centers. On average, each dispenser would distribute PMI 45,925 times (4.3 billion dispenses / 93,697 entities) and would require 765 hours (71.8 million hours / 93,697 entities) to print PMI, the equivalent of 0.4 of one full-time pharmacy technician. The annual costs are $17,107 per dispenser ($1.6 billion total costs / 93,697 entities) to print and to distribute PMI to patients. (Table 2)

Table 2.
**Annual Printing Costs for Pharmacies and Transfusion Services**[13]

| | Annual Cost Per Dispenser | All 93,697 Dispensers |
|---|---|---|
| Number of PMI | 45,925 | 4,303,000,000 |
| Number of required hours to print (one minute per PMI) | 765 | 71,716,667 |
| As full-time equivalent number of pharmacy technicians | 0.4 | 35,858 |
| Labor cost for printing | $14,811 | $1,387,715,500 |
| Paper and black-and-white ink | $2,296 | $215,150,000 |
| **Printing Cost** | **$17,106** | **$1,602,867,500** |

In its proposed rule, FDA states that the cost of PMI would not result in an annual expenditure of $100 million or more, the threshold for the Federal Unfunded Mandates Reform Act of 1995. However, FDA underestimates the printing costs to distribute required PMI to patients. After including the printing costs of authorized dispensers, the annual cost of the FDA proposal rule will far exceed the $100 million threshold (and $177 million threshold adjusted for inflation) of the Federal Unfunded Mandates Reform and would require FDA to prepare a written statement before proposing the rule.

[13] Authors estimate.

## IV. ASSESSMENTS OF UNINTENDED CONSEQUENCES OF THE PROPOSED RULE

The FDA cost benefit analysis left out the crucial health effects (both positive and negative) and other unintended negative effects to Americans across the country. None of these areas has received adequate consideration in the FDA analysis of the regulatory impacts of the proposed rule. FDA overlooks the unintended economic hardship to small businesses, which will spillover to patients, especially in the rural communities where pharmacists are already overworked to provide their multiple services. The proposed rule will have legal implications for all dispensers in the event of printing malfunctions, power failure, Internet disruptions, and not-up-to-date PMI information. All of the economic hardship to dispensers and unforeseen disruptions will negatively impact patient health.

### Economic Hardship for Smaller Authorized Dispensers

The negative economic impacts of the proposed regulation affect dispensers disproportionally. The regulatory costs have negative impacts on the smaller independent pharmacies and the industry workforce. The PMI printing costs to be complied with the proposed regulation will create a significant economic hardship for smaller independent pharmacies who already have a thin operating margin. In 2021, 42% of pharmacies and drug stores were small businesses with less than 9 employees.[14] (Appendix A.1. for state data)

In 2021, a typical independent pharmacy generated $4.0 million in revenue. With 76.7% of cost of goods sold, gross profit of an independent pharmacy was $939,223 (23.3% of revenues). Operating expenses of independent pharmacies accounted for nearly 18% of revenues and $721,549.[15] Owner discretionary profit, which includes owner's compensation, was $217,674 in 2021. In Table 2 above, we estimate the regulatory cost burden to be $17,110, the equivalent of 0.4% of revenues ($17,110 / $4.0 million) and 7.9% of owner discretionary profit ($17,111 / $217,674) in 2021. (Table 3)

Table 3.
**Income Statement of a Typical Independent Pharmacy[16]**

| | 2021 | As % of Revenue |
|---|---|---|
| Annual revenues | $4,031,000 | 100.0% |
| Cost of goods sold | $3,091,777 | 76.7% |
| Gross profit | $939,223 | 23.3% |
| Operating expenses | $721,549 | 17.9% |
| Owner discretionary profit | $217,674 | 4.1% |

Data has shown that the financial performance of independent pharmacies has been declining over the years and has affected rural communities negatively. In 2022, independent and individually owned pharmacies in

[14] U.S. Census Bureau, County Business Patterns. 2021.
[15] Operating expenses ratio in 2021 is not available. We use operating expense ratio in 2019. 2020 NCPA Digest, National Community Pharmacists Association; Elements, PBAHealth.
[16] 2022 NCPA Digest, National Community Pharmacists Association.

the United States accounted for 18,752 of 55,921 total pharmacies (33.5%). The role of independent pharmacies is highly essential in states and rural areas where independent pharmacies account for a large share of total pharmacies. For example, independent pharmacies account for 73% of total pharmacies in North Dakota, 50% in New York, and 53% in Arkansas.[17] With additional financial burdens and restrictive regulations, independent pharmacies will face more difficulties to survive. The negative economic impacts of the proposed regulation on rural independent pharmacies would spillover to patients in those communities.

## Shortage of Pharmacy Technicians

The proposed rule will add workload to the pharmacy staff who has already overloaded since the COVID-19 outbreak. According to the BLS, there were 453,630 pharmacy technicians employed during May 2022. The proposed rule requires 35,883 full-time equivalent pharmacy technicians to print PMI for patients. This is equivalent to 7.9% of the employed pharmacy technicians across the country. The BLS projects that pharmacy technicians will increase by 6%, faster than average, adding 25,900 jobs during 2022-32. Since the BLS employment projections are less than the required pharmacy technicians to print PMI, the proposed rule will certainly create the shortage as well as stress for pharmacy technicians which, in turn, will reduce the quality of service for patients as a whole.[18]

While overall there is a high rate of accuracy in medication dispensing (97.3%)[19], mistakes made by pharmacists are contributing factors to medication errors and are found in different forms. FDA's own research found that the top cause of medication errors were human factors. (Table 1) Research findings over the past several decades consistently showed that the leading cause of medication errors made by pharmacists is their workload. For example, the Massachusetts Board of Registration in Pharmacy conducted a study to determine the impact of various factors on the incidence of medication errors made by practicing pharmacists in the 1990s. The study found that three leading causes to medication errors were too many telephone calls (62%), overload/unusual busy day (59%), and too many customers (53%).[20] Similarly, a study that combined survey data from community pharmacies in 18 metropolitans in the mid-2000s also found a strong positive relationship between the risk of dispensing and pharmacy workload.[21] Another national observational study of prescription dispensing accuracy and safety in 50 pharmacies across the U.S. found that errors in *the computer order entry process* used to create the label occur most frequently.[22]

As shown above, the proposed rule would not reduce medication errors. On the contrary, it requires dispensers to distribute PMI to patients which heightens pharmacy workloads. Many independent pharmacies in rural communities have only one pharmacist who performs multiple tasks with long hours throughout the year.[23] As a result, the proposed system will unintentionally create more medication errors which in turn will have negative health impact on patients.

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[17] 2022 NCPA Digest, National Community Pharmacists Association.
[18] Occupational Outlook Handbook, Bureau of Labor Statistics.
[19] Flynn Elizabeth Ann, Kenneth N. Barker, and Brian J. Carnahan. 2003. "National Observational Study of Prescription Dispensing Accuracy and Safety in 50 Pharmacies." Journal of the American Pharmaceutical Association.
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[23] Stratton, Timothy P. 2001. "The Economic Realities of Rural Pharmacy Practice." The Journal of Rural Health.

## Increased Liabilities for Dispensers

The proposed rule *requires* dispensers to provide PMI to patients each time a prescription drugs is dispensed for patients. Unlike CMI which is distributed on a voluntarily basis, pharmacies and transfusion service providers cannot dispense prescription drugs without PMI. In the event of power failure, Internet disruptions, and printing errors, dispensers are liable for incomplete, inaccurate, and not up-to-date information.

The FDA proposed rule implicitly assumes that all dispensers, including independent pharmacies, have reliable Internet access to download PMI from the FDA database on a regular basis. Although the share of Americans without internet access has declined significantly over the past decade, the FCC estimates that 14.5 million people—4.4% of the U.S. population—remained digitally disconnected in 2019. The vast majority of those people resided in rural areas, where more than 11.2 million people, or 17% of the rural population, lacked internet access. (Table A.3 in the Appendix provides population without Internet access in all areas and rural areas by state).[24] Furthermore, IT disruptions at the FDA as well as third-party Internet service providers have not been considered. According to two surveys in June 2014 conducted by Symantec, 70% of government agencies experienced downtime of 30 minutes or more in a month. The surveys found that network or server outage and Internet connectivity loss are the top two causes of downtime, 42% and 29%, respectively. Nine out of ten government field workers, who participated in the surveys, said their agency's most recent downtime affected their ability to do their job.[25]

Dispensers might not have power to access to FDA database to download up-to-date PMI or to print or email PMI to patients when prescription drugs are dispensed. On average, U.S. electricity customers experienced between seven and eight hours of electric power interruptions in 2020 and 2021 due to weather and failures of power lines and utility practices. When major natural disasters such as snowstorms, hurricanes, and wildfires are excluded, the average duration of interruptions annually remained consistently at around two hours per year.[26] The annual number of weather-related power outages in the U.S. continues rising. During 2000-21, there were 1,542 major outages related to severe weather conditions. Texas, Michigan, California, North Carolina, and Pennsylvania experienced the greatest number of weather-related outages.[27]

In the emergency cases that cause limited access to electricity, Internet connectivity problems, and printing disruption at an authorized dispenser, the proposed rule will cause harm to patients. Since PMI is required for each prescription fill, pharmacies will not be allowed to provide prescriptions if they cannot print PMI for patients. Pharmacies would have to refer patients to another pharmacy to fill the prescription. In addition to the inconvenience, it is sometimes implausible for patients in rural communities to go to another pharmacy, especially in states such as Maine and Vermont where more than 60% of the population live in rural areas. Data shows residents in certain rural communities had to travel an average 20 miles and up to 81 miles (27 minutes and 88 minutes) to find another pharmacy.[28]

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[24] FCC. 2021. "Fourteenth Broadband Deployment Report." Before the Federal Communications Commission.
[25] Hunter, Lindsey. 2014. "The Drive to Thrive: Ensuring the Agile Data Center." Meritalk, Underwritten by Symantec.
[26] U.S. Energy Information Administration. Today in Energy, November 14, 2022.
[27] Climate Central. Surging Weather-Related Power Outages. September 14, 2022.
[28] Todd, Kelli, Fred Ulrich, and Keith Mueller. 2013. "Rural Pharmacy Closures: Implications for Rural Communities." Rural Policy Brief, RUPRI Center for Rural Health Policy Analysis.

## V. CONCLUSION

The FDA's proposed regulation requiring pharmacies and transfusion service providers to print Patient Medical Information (PMI) for patients with prescriptions will create significant financial burdens for dispensers while patient benefits are minimal. The FDA has not provided adequate evidence to support its assertion that the regulation would improve patient health. While the health benefits are unknown, the FDA cost benefit analysis shows minimal monetary benefits. FDA estimates the rule is to save patients 2.5 minutes if and when patients search for drug information. Importantly, FDA has not considered the unintended consequences of the proposed rule on dispensers. First, the proposed rule will impose significant labor and material costs for authorized dispensers, these costs were not estimated by FDA. Our calculations show annual labor and materials costs will be over $1.6 billion for authorized dispensers to print PMI for patients. Second, the proposed regulation will increase the workload for all pharmacists and pharmacy technicians. Using FDA printing time estimates, we estimate 35,883 more pharmacy technicians are needed to print PMI over 4.3 billion times per year for patients, equivalent to 7.9% of total pharmacy technicians employed in 2022. Thirdly, the proposed rule will have unintended consequences. It will create economic hardship for small pharmacies that will have negative health impacts on patients across the country. Lastly, since PMI will be required for each prescription, authorized dispensers will be accountable for distributing the information to patients. In the event of technical disruptions such as Internet disconnections, lost power, and printing failures, authorized dispensers will not be allowed to provide prescription drugs to patients because they are not able to print PMI. Consequently, patients will suffer and have negative health consequences. Our analysis suggests the FDA should reconsider its position on PMI and adopt a PMI format that is proven by cognitive science to improve the knowledge and comprehension of patients and a distribution methodology that reduces the burden on dispensers.

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## APPENDIX

### Table A.1: Pharmacies and Drug Stores by Employment Size and by State, 2021[29]

| | Establishments with 1-9 employees | Establishments with 10-19 employees | Establishments with >20 employees |
|---|---|---|---|
| **United States** | **42%** | **19%** | **39%** |
| Alabama | 39% | 30% | 31% |
| Alaska | 44% | 26% | 31% |
| Arizona | 21% | 13% | 67% |
| Arkansas | 52% | 27% | 21% |
| California | 44% | 20% | 36% |
| Colorado | 29% | 28% | 44% |
| Connecticut | 26% | 17% | 57% |
| Delaware | 39% | 19% | 42% |
| District of Columbia | 34% | 11% | 55% |
| Florida | 37% | 13% | 50% |
| Georgia | 46% | 18% | 36% |
| Hawaii | 36% | 9% | 55% |
| Idaho | 45% | 34% | 20% |
| Illinois | 26% | 16% | 58% |
| Indiana | 17% | 16% | 67% |
| Iowa | 42% | 22% | 36% |
| Kansas | 42% | 22% | 36% |
| Kentucky | 47% | 27% | 26% |
| Louisiana | 43% | 20% | 37% |
| Maine | 57% | 19% | 24% |
| Maryland | 47% | 17% | 36% |
| Massachusetts | 24% | 13% | 62% |
| Michigan | 58% | 13% | 29% |
| Minnesota | 32% | 22% | 46% |
| Mississippi | 47% | 24% | 29% |
| Missouri | 36% | 22% | 42% |
| Montana | 47% | 27% | 26% |
| Nebraska | 42% | 21% | 37% |
| Nevada | 30% | 10% | 61% |
| New Hampshire | 41% | 19% | 39% |
| New Jersey | 51% | 16% | 33% |
| New Mexico | 35% | 13% | 52% |
| New York | 55% | 20% | 24% |
| North Carolina | 41% | 20% | 39% |
| North Dakota | 63% | 30% | 7% |
| Ohio | 35% | 18% | 47% |

[29] U.S. Census Bureau, County Business Patterns. 2021.

| *Table A.1. Continued* | Establishments with 1-9 employees | Establishments with 10-19 employees | Establishments with >20 employees |
|---|---|---|---|
| Oklahoma | 47% | 24% | 28% |
| Oregon | 43% | 31% | 26% |
| Pennsylvania | 50% | 20% | 30% |
| Rhode Island | 26% | 18% | 56% |
| South Carolina | 41% | 19% | 40% |
| South Dakota | 43% | 32% | 25% |
| Tennessee | 36% | 24% | 40% |
| Texas | 42% | 12% | 46% |
| Utah | 34% | 30% | 36% |
| Vermont | 51% | 24% | 26% |
| Virginia | 29% | 20% | 52% |
| Washington | 40% | 32% | 28% |
| West Virginia | 56% | 22% | 22% |
| Wisconsin | 30% | 16% | 54% |
| Wyoming | 59% | 28% | 13% |

## Table A.2: Pharmacy by Type and by State, 2022[30]

### Panel A. Number of Pharmacies

| | Chain | Supermarket | Mass Merchant | Independent | Total |
|---|---|---|---|---|---|
| **United States** | **20,533** | **9,406** | **7,230** | **18,752** | **55,921** |
| Alabama | 366 | 160 | 140 | 504 | 1,170 |
| Alaska | 11 | 25 | 27 | 19 | 82 |
| Arizona | 390 | 298 | 176 | 100 | 964 |
| Arkansas | 115 | 106 | 100 | 358 | 679 |
| California | 2,020 | 653 | 641 | 1837 | 5,151 |
| Colorado | 188 | 263 | 146 | 123 | 720 |
| Connecticut | 309 | 108 | 62 | 123 | 602 |
| Delaware | 118 | 18 | 15 | 34 | 185 |
| District of Columbia | 66 | 19 | 8 | 41 | 134 |
| Florida | 1,596 | 1,011 | 439 | 1175 | 4,221 |
| Georgia | 602 | 438 | 234 | 647 | 1,921 |
| Hawaii | 78 | 37 | 27 | 44 | 186 |
| Idaho | 55 | 72 | 46 | 97 | 270 |
| Illinois | 877 | 301 | 317 | 428 | 1,923 |
| Indiana | 496 | 151 | 193 | 128 | 968 |
| Iowa | 175 | 126 | 87 | 194 | 582 |
| Kansas | 123 | 104 | 88 | 200 | 515 |
| Kentucky | 275 | 116 | 116 | 483 | 990 |
| Louisiana | 305 | 123 | 121 | 453 | 1,002 |
| Maine | 107 | 72 | 29 | 49 | 257 |
| Maryland | 387 | 222 | 109 | 332 | 1,050 |
| Massachusetts | 622 | 124 | 99 | 141 | 986 |
| Michigan | 807 | 182 | 298 | 801 | 2,088 |
| Minnesota | 297 | 159 | 165 | 157 | 778 |
| Mississippi | 156 | 45 | 83 | 309 | 593 |
| Missouri | 341 | 184 | 180 | 327 | 1,032 |
| Montana | 27 | 45 | 23 | 93 | 188 |
| Nebraska | 89 | 63 | 54 | 147 | 353 |
| Nevada | 163 | 117 | 61 | 78 | 419 |
| New Hampshire | 131 | 42 | 38 | 20 | 231 |
| New Jersey | 708 | 202 | 135 | 835 | 1,880 |
| New Mexico | 94 | 62 | 53 | 59 | 268 |
| New York | 1,401 | 274 | 212 | 2579 | 4,466 |
| North Carolina | 694 | 272 | 233 | 598 | 1,797 |
| North Dakota | 37 | 2 | 0 | 106 | 145 |

[30] 2022 NCPA Digest, National Community Pharmacists Association.

| *Table A.2. Panel A Continued* | Chain | Supermarket | Mass Merchant | Independent | Total |
|---|---|---|---|---|---|
| Ohio | 872 | 333 | 325 | 398 | 1,928 |
| Oklahoma | 183 | 88 | 120 | 342 | 733 |
| Oregon | 167 | 116 | 126 | 90 | 499 |
| Pennsylvania | 1043 | 397 | 235 | 829 | 2,504 |
| Rhode Island | 105 | 16 | 13 | 16 | 150 |
| South Carolina | 363 | 154 | 121 | 287 | 925 |
| South Dakota | 48 | 19 | 21 | 70 | 158 |
| Tennessee | 414 | 273 | 164 | 475 | 1,326 |
| Texas | 1,515 | 935 | 662 | 1487 | 4,599 |
| Utah | 69 | 149 | 76 | 140 | 434 |
| Vermont | 73 | 23 | 7 | 18 | 121 |
| Virginia | 559 | 295 | 206 | 282 | 1,342 |
| Washington | 355 | 252 | 183 | 205 | 995 |
| West Virginia | 163 | 45 | 49 | 193 | 450 |
| Wisconsin | 368 | 85 | 150 | 255 | 858 |
| Wyoming | 10 | 30 | 17 | 46 | 103 |

## Panel B. As % of Total Pharmacies

| | Chain | Supermarket | Mass Merchant | Independent | Total |
|---|---|---|---|---|---|
| **United States** | **36.7%** | **16.8%** | **12.9%** | **33.5%** | **100.0%** |
| Alabama | 31.3% | 13.7% | 12.0% | 43.1% | 100.0% |
| Alaska | 13.4% | 30.5% | 32.9% | 23.2% | 100.0% |
| Arizona | 40.5% | 30.9% | 18.3% | 10.4% | 100.0% |
| Arkansas | 16.9% | 15.6% | 14.7% | 52.7% | 100.0% |
| California | 39.2% | 12.7% | 12.4% | 35.7% | 100.0% |
| Colorado | 26.1% | 36.5% | 20.3% | 17.1% | 100.0% |
| Connecticut | 51.3% | 17.9% | 10.3% | 20.4% | 100.0% |
| Delaware | 63.8% | 9.7% | 8.1% | 18.4% | 100.0% |
| District of Columbia | 49.3% | 14.2% | 6.0% | 30.6% | 100.0% |
| Florida | 37.8% | 24.0% | 10.4% | 27.8% | 100.0% |
| Georgia | 31.3% | 22.8% | 12.2% | 33.7% | 100.0% |
| Hawaii | 41.9% | 19.9% | 14.5% | 23.7% | 100.0% |
| Idaho | 20.4% | 26.7% | 17.0% | 35.9% | 100.0% |
| Illinois | 45.6% | 15.7% | 16.5% | 22.3% | 100.0% |
| Indiana | 51.2% | 15.6% | 19.9% | 13.2% | 100.0% |
| Iowa | 30.1% | 21.6% | 14.9% | 33.3% | 100.0% |
| Kansas | 23.9% | 20.2% | 17.1% | 38.8% | 100.0% |
| Kentucky | 27.8% | 11.7% | 11.7% | 48.8% | 100.0% |
| Louisiana | 30.4% | 12.3% | 12.1% | 45.2% | 100.0% |
| Maine | 41.6% | 28.0% | 11.3% | 19.1% | 100.0% |
| Maryland | 36.9% | 21.1% | 10.4% | 31.6% | 100.0% |
| Massachusetts | 63.1% | 12.6% | 10.0% | 14.3% | 100.0% |
| Michigan | 38.6% | 8.7% | 14.3% | 38.4% | 100.0% |
| Minnesota | 38.2% | 20.4% | 21.2% | 20.2% | 100.0% |
| Mississippi | 26.3% | 7.6% | 14.0% | 52.1% | 100.0% |
| Missouri | 33.0% | 17.8% | 17.4% | 31.7% | 100.0% |
| Montana | 14.4% | 23.9% | 12.2% | 49.5% | 100.0% |
| Nebraska | 25.2% | 17.8% | 15.3% | 41.6% | 100.0% |
| Nevada | 38.9% | 27.9% | 14.6% | 18.6% | 100.0% |
| New Hampshire | 56.7% | 18.2% | 16.5% | 8.7% | 100.0% |
| New Jersey | 37.7% | 10.7% | 7.2% | 44.4% | 100.0% |
| New Mexico | 35.1% | 23.1% | 19.8% | 22.0% | 100.0% |
| New York | 31.4% | 6.1% | 4.7% | 57.7% | 100.0% |
| North Carolina | 38.6% | 15.1% | 13.0% | 33.3% | 100.0% |
| North Dakota | 25.5% | 1.4% | 0.0% | 73.1% | 100.0% |
| Ohio | 45.2% | 17.3% | 16.9% | 20.6% | 100.0% |
| Oklahoma | 25.0% | 12.0% | 16.4% | 46.7% | 100.0% |
| Oregon | 33.5% | 23.2% | 25.3% | 18.0% | 100.0% |

| *Table A.2. Panel B Continued* | Chain | Supermarket | Mass Merchant | Independent | Total |
|---|---|---|---|---|---|
| Pennsylvania | 41.7% | 15.9% | 9.4% | 33.1% | 100.0% |
| Rhode Island | 70.0% | 10.7% | 8.7% | 10.7% | 100.0% |
| South Carolina | 39.2% | 16.6% | 13.1% | 31.0% | 100.0% |
| South Dakota | 30.4% | 12.0% | 13.3% | 44.3% | 100.0% |
| Tennessee | 31.2% | 20.6% | 12.4% | 35.8% | 100.0% |
| Texas | 32.9% | 20.3% | 14.4% | 32.3% | 100.0% |
| Utah | 15.9% | 34.3% | 17.5% | 32.3% | 100.0% |
| Vermont | 60.3% | 19.0% | 5.8% | 14.9% | 100.0% |
| Virginia | 41.7% | 22.0% | 15.4% | 21.0% | 100.0% |
| Washington | 35.7% | 25.3% | 18.4% | 20.6% | 100.0% |
| West Virginia | 36.2% | 10.0% | 10.9% | 42.9% | 100.0% |
| Wisconsin | 42.9% | 9.9% | 17.5% | 29.7% | 100.0% |
| Wyoming | 9.7% | 29.1% | 16.5% | 44.7% | 100.0% |

**Table A.3: Internet Access in Urban and Rural Areas by State, 2019**[31]

| | Total | | Urban | | Rural | |
|---|---|---|---|---|---|---|
| | Population Without Access (1,000s) | Percentage of Population (%) | Population Without Access (1,000s) | Percentage of Population (%) | Population Without Access (1,000s) | Percentage of Population (%) |
| **United States** | **14,520** | **4.4%** | **3,260** | **1.2%** | **11,261** | **17.2%** |
| Alabama | 608 | 12.4% | 62 | 2.2% | 546 | 27.0% |
| Alaska | 108 | 14.8% | 13 | 2.8% | 95 | 36.3% |
| Arizona | 377 | 5.2% | 68 | 1.1% | 309 | 33.5% |
| Arkansas | 574 | 19.0% | 80 | 4.8% | 493 | 36.7% |
| California | 594 | 1.5% | 214 | 0.6% | 381 | 15.8% |
| Colorado | 161 | 2.8% | 36 | 0.7% | 126 | 13.6% |
| Connecticut | 27 | 0.8% | 24 | 0.8% | 3 | 0.7% |
| Delaware | 22 | 2.2% | 14 | 1.8% | 7 | 4.0% |
| District of Columbia | 15 | 2.0% | 15 | 2.0% | --. | -- |
| Florida | 804 | 3.7% | 340 | 1.8% | 464 | 21.4% |
| Georgia | 654 | 6.2% | 156 | 1.9% | 499 | 19.0% |
| Guam | 55 | 33.0% | 48 | 30.6% | 7 | 65.8% |
| Hawaii | 30 | 2.1% | 9 | 0.7% | 21 | 15.3% |
| Idaho | 83 | 4.7% | 7 | 0.6% | 77 | 13.5% |
| Illinois | 259 | 2.0% | 84 | 0.7% | 175 | 12.0% |
| Indiana | 261 | 3.9% | 28 | 0.6% | 234 | 12.6% |
| Iowa | 127 | 4.0% | 26 | 1.3% | 102 | 8.8% |
| Kansas | 125 | 4.3% | 29 | 1.3% | 96 | 12.7% |
| Kentucky | 257 | 5.7% | 11 | 0.4% | 244 | 13.3% |
| Louisiana | 538 | 11.6% | 99 | 2.9% | 438 | 35.0% |
| Maine | 46 | 3.5% | 2 | 0.4% | 44 | 5.3% |
| Maryland | 152 | 2.5% | 102 | 1.9% | 51 | 6.2% |
| Massachusetts | 140 | 2.0% | 103 | 1.6% | 37 | 6.7% |
| Michigan | 421 | 4.2% | 69 | 0.9% | 351 | 13.7% |
| Minnesota | 139 | 2.5% | 10 | 0.2% | 130 | 8.6% |
| Mississippi | 587 | 19.7% | 33 | 2.2% | 555 | 36.6% |
| Missouri | 422 | 6.9% | 34 | 0.8% | 388 | 21.0% |
| Montana | 142 | 13.3% | 11 | 2.0% | 131 | 26.4% |
| Nebraska | 71 | 3.7% | 3 | 0.2% | 68 | 13.0% |
| Nevada | 88 | 2.9% | 12 | 0.4% | 76 | 33.9% |
| New Hampshire | 44 | 3.2% | 11 | 1.4% | 33 | 6.0% |
| New Jersey | 129 | 1.5% | 119 | 1.4% | 10 | 2.2% |
| New Mexico | 270 | 12.9% | 56 | 3.5% | 214 | 42.0% |
| New York | 250 | 1.3% | 116 | 0.7% | 133 | 5.7% |

[31] FCC. 2021. "Fourteenth Broadband Deployment Report." Before the Federal Communications Commission.

| *Table A.3. Continued* | Total | | Urban | | Rural | |
|---|---|---|---|---|---|---|
| | Population Without Access (1,000s) | Percentage of Population (%) | Population Without Access (1,000s) | Percentage of Population (%) | Population Without Access (1,000s) | Percentage of Population (%) |
| North Carolina | 472 | 4.5% | 18 | 0.3% | 453 | 13.0% |
| North Dakota | 24 | 3.2% | 4 | 1.0% | 20 | 5.8% |
| Ohio | 328 | 2.8% | 29 | 0.3% | 299 | 11.6% |
| Oklahoma | 481 | 12.2% | 97 | 3.7% | 384 | 28.2% |
| Oregon | 216 | 5.1% | 37 | 1.1% | 179 | 20.5% |
| Pennsylvania | 525 | 4.1% | 161 | 1.6% | 364 | 13.3% |
| Rhode Island | 15 | 1.4% | 13 | 1.3% | 2 | 2.4% |
| South Carolina | 451 | 8.7% | 76 | 2.3% | 374 | 21.3% |
| South Dakota | 45 | 5.0% | 1 | 0.3% | 43 | 10.7% |
| Tennessee | 433 | 6.3% | 62 | 1.4% | 371 | 16.0% |
| Texas | 1,230 | 4.2% | 439 | 1.8% | 791 | 16.1% |
| Utah | 138 | 4.3% | 20 | 0.7% | 119 | 27.7% |
| Vermont | 43 | 6.9% | 3 | 1.2% | 40 | 10.4% |
| Virginia | 498 | 5.8% | 122 | 1.9% | 376 | 17.8% |
| Washington | 283 | 3.7% | 64 | 1.0% | 219 | 16.4% |
| West Virginia | 319 | 17.8% | 57 | 6.5% | 263 | 28.7% |
| Wisconsin | 394 | 6.8% | 10 | 0.2% | 385 | 21.8% |
| Wyoming | 42 | 7.3% | -- | -- | 42 | 19.0% |

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## ABOUT US

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