

Congress of the United States
House of Representatives
Washington, DC 20515

April 29, 2021

The Honorable Rosa DeLauro
Chairwoman
Committee on Appropriations
H-307 The Capitol
Washington, D.C. 20515

The Honorable Kay Granger
Ranking Member
House Committee on Appropriations
1036 Longworth House Office Building
Washington, D.C. 2051

The Honorable Sanford Bishop Jr.
Chairman
House Appropriations Subcommittee on
Agriculture, Rural Development,
Food and Drug Administration and Related
Agencies
2362-A Rayburn House Office Building
Washington, D.C. 20515

The Honorable Jeff Fortenberry
Ranking Member
House Appropriations Subcommittee on
Agriculture, Rural Development,
Food and Drug Administration and Related
Agencies
1036 Longworth House Office Building
Washington, D.C. 20515

Dear Chairwoman DeLauro, Chairman Bishop, Ranking Member Granger and Ranking Member Fortenberry:

We write to urge you to not include language in the FY 2022 appropriations bill that would prohibit the U.S. Food and Drug Administration (FDA) from requiring pharmaceutical prescribing information (PI) be delivered primarily by digital form instead of paper.

As you are aware, a 2014 regulation proposed by the FDA would have updated current practice by removing the requirement that PI be delivered primarily by paper, a commonsense modernization that would improve the speed of labeling updates, and thus the speed of patient care delivery. Electronic information is currently provided to FDA and will continue to be available publicly and free of charge. Unfortunately, FDA has been blocked from finalizing this rule by annual appropriations language that prohibits the expenditure of funds for any such action. This language was again included in the fiscal year 2021 Agriculture, Rural Development, Food and Drug Administration (FDA) and Related Agencies Appropriations bill.

Today, the interaction between healthcare providers, pharmacists, and patients has benefitted from modernization and the transition to a digital interface. This includes the widespread adoption of electronic health records and the utilization of electronic prescribing. Providers are already very familiar with electronic labeling information. Since 2005, FDA has required submission and posting of the electronic version of the FDA-approved PI on the NIH DailyMed Website in structured product label (SPL) format, making the paper version obsolete. Prescribers can also request additional copies of the PI to be provided at no charge.

Electronic PI allows prescribers easy access to the most up-to-date product information available through a digital platform. Product information is frequently updated, requiring numerous label changes for crucial dosing information, particularly with new therapies to reflect emerging medical and safety information, which can take 8-12 months for these changes to be reflected in paper-based information.

Prescribers are already comfortable with receiving information via digital means. Today, a majority of prescriptions are sent and filled electronically. In 2019, 98.7% of prescriptions were sent to the pharmacy electronically. 79% of prescribers used electronic prescribing in 2019, up from 73% in 2018.¹ The vast majority of pharmacists and health care practitioners are Medicare providers, and Medicare requires providers to bill electronically.² 79 billion e-prescriptions were filled in 2019.³

To be clear, PI is the paper included in the bulk shipment boxes of pharmaceutical products that pharmacists or prescribers receive directly from a distributor. It is important to recognize that PI modernization will not impact the information patients receive with their prescriptions, as PI is intended to be used by medical professionals and is rarely, if ever, provided to a patient. When delivered in paper form, PI is often discarded as unnecessary. Nothing in the FDA proposed rule would alter the material that a patient receives with a prescription.

FDA estimates as many as three billion Prescription Inserts are produced annually, ranging from a few pages to as many as 45 pages.⁴ If the average length of an Insert is 30 pages, that would mean 90 billion pieces of paper. Eliminating much of the paper can lead to smaller shipping packages, minimizing greenhouse gas emissions, reducing waste, and have a beneficial environmental impact – saving approximately 4.8 million trees annually.⁵

Common sense modernization of the PI requirements will not only avoid a negative impact to patients but may actually improve patient care by allowing labeling updates to be shared more readily than updates made in paper form would permit. FDA's PI modernization proposal was prudent in 2014 and should be self-evident in 2021. We urge you to not include this language in the FY 2022 appropriations bill and permit FDA to finalize its rule and bring PI into the digital standard we have come to expect for 21st century information exchange.

Sincerely,



MIKIE SHERRILL
Member of Congress



ADAM KINZINGER
Member of Congress

¹ Surescripts 2019 National Progress Report. <https://surescripts.com/news-center/national-progress-report-2019/>.

Also brings operational efficiency in the distribution process and reduces maintenance costs

² CMS Website, <https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans>

³ Surescripts 2019 National Progress Report. <https://surescripts.com/news-center/national-progress-report-2019/>.

Also brings operational efficiency in the distribution process and reduces maintenance costs

⁴ GAO, p.15

⁵ Sierra Club Website. [How Much Paper Does One Tree Produce?](#)

_____/s/_____
David B. McKinley P.E.
Member of Congress

_____/s/_____
Lisa Blunt Rochester
Member of Congress

_____/s/_____
Billy Long
Member of Congress

_____/s/_____
Paul Tonko
Member of Congress

_____/s/_____
Nanette Diaz Barragán
Member of Congress

_____/s/_____
Adrian Smith
Member of Congress

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Gregorio Kilili Camacho Sablan
Member of Congress

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Josh Gottheimer
Member of Congress

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Bill Pascrell, Jr.
Member of Congress

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Deborah Ross
Member of Congress

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Tom O'Halleran
Member of Congress

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Bill Johnson
Member of Congress

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Donald M. Payne, Jr.
Member of Congress

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John Curtis
Member of Congress

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Richard Hudson
Member of Congress

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Fred Upton
Member of Congress

_____/s/_____
Bobby L. Rush
Member of Congress

_____/s/_____
Robin L. Kelly.
Member of Congress