

Alliance to Modernize Prescribing Information

The undersigned organizations represent a broad cross-section of health care stakeholders who support efforts to modernize access to prescribing information through digital platforms (electronic labeling) to improve patient safety and reduce waste. Electronic labeling of prescribing information will help ensure that providers have access to the most up-to-date information available almost instantaneously, instead of the average 8-12 months that it often takes to develop, print, and deliver a paper label for prescribers. However, this will only be possible if the Food and Drug Administration (FDA) can advance its proposed rule for electronic labeling of prescribing information.

Recognizing the need to keep pace with the information needs of modern health care providers and consumers, FDA published a proposed rule in 2014 ([79 Fed. Reg. 75506](#)) that would provide for electronic distribution of prescribing information for human prescription drugs and biological products. As FDA explained, “these actions...help ensure that the most current prescribing information is publicly accessible for the safe and effective use of human prescription drugs.”¹ Unfortunately, Congress has used the appropriations process to block FDA from implementing its proposed rule.

Electronic labeling advances a vision for FDA labeling that supports patient safety, facilitates informed physician and patient decision making, adds digital convenience, addresses health literacy, and reduces unnecessary waste from paper-based information for pharmaceuticals.

The undersigned organizations support efforts to advance regulatory or legislative reforms to facilitate the dissemination of FDA-approved pharmaceutical labeling information via modern digital platforms. Additional benefits include:

- Avoiding provider confusion that can result from outdated labels in the marketplace, thereby reducing risk to patient safety by ensuring providers have the most up-to-date information.
 - In 2018, 85% of prescriptions were sent electronically, up from 73% in 2016. Most pharmacists and health care practitioners are Medicare providers, and Medicare requires providers to bill electronically.²
- E-labeling can provide an authoritative source of FDA-approved information in a format that is searchable, linkable, customizable, and accessible using modern digital tools and devices such as Electronic Health Records systems, smartphones, and tablets.
- A decreased environmental impact by eliminating paper and other packaging materials consumed and helping with long-term targets to reduce carbon emissions, water, and waste. FDA estimates as many as 3 billion Prescription Inserts are produced annually, ranging from a few pages to as many as 45 pages.³

We urge Congress to remove all language from the FY2021 appropriations bill that would prevent the use of electronic labeling.

AbbVie
Allergy & Asthma Network
AmerisourceBergen
Association for Accessible Medicines (AAM)
Asthma and Allergy Foundation of America
Beyond Type 1
Boomer Esiason Foundation
Eli Lilly and Company
Healthcare Distribution Alliance

Johnson and Johnson
LUNgevity Foundation
Lupin
Merck
Mylan
Pfizer
Teva
Zero Cancer

¹ FDA Website, <https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/electronic-distribution-prescribing-information-human-prescriptions-drugs-including-biological>

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

³ GAO, p.15