



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

March 18, 2015

Leslie Kux
Associate Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Electronic Distribution of Prescribing Information

Dear Ms. Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, I write in response to the [proposed rule](#) titled, "Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products" as published in the December 18, 2014 *Federal Register*.

The FDA proposes to amend prescription drug and biological product labeling regulations to require electronic distribution of the prescribing information intended for health care professionals, which is currently distributed in paper form on or within the package from which a prescription drug or biological product is dispensed. The FDA is also proposing that prescribing information intended for health care professionals will no longer be permitted to be distributed in paper form with the package from which a prescription drug or biological product is dispensed, with an exceptions process noted in the proposed rule.

The AAFP shares the FDA's goal of pursuing policies that help ensure that the most current prescribing information is publicly accessible for the safe and effective use of human prescription drugs. We support the concept that health care professionals receive information electronically. However we urge FDA to continue to mandate that printed prescribing information be included on or within drug packaging, even if FDA also makes the information available electronically. This would allow health care professionals the option to access prescribing information according to their individual preferences and needs. There are still medical practices that, through no fault of their own, do not yet have access to the Internet. These physician practices without access at all, often in rural, frontier, or mountainous areas are out of range of cell phones and reliable Internet. These practices, largely because of their location and the surrounding terrain and remoteness, still need access to printed pharmaceutical materials that accompany a prescription.

The FDA attempts to address concerns that certain health care providers may not have ready access to electronic prescribing information because of a lack of Internet access by proposing that these providers could call a toll-free number to access current prescribing information through mail, fax, or email. We believe this backup plan to be insufficient. To the extent there are internet outages, there may also be

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Ms. Kux
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phone outages. Also mail, fax, or email takes time that disrupts the prescriber's workflow. We therefore urge the FDA to maintain that printed prescribing information be included on or within drug packaging, even if FDA also makes the information available electronically.

We appreciate the opportunity to comment on this proposed rule. For any questions you might have please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Reid B. Blackwelder MD". The signature is written in a cursive style with a large, stylized initial "R" and a distinct "D" at the end.

Reid B. Blackwelder, MD, FFAFP
Board Chair