

NCPA Position Statement on FDA's Proposed Rule regarding the Electronic Distribution of Prescribing Information for Human Prescription Drugs

The Food and Drug Administration (FDA) has formally proposed to amend its 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 the product is dispensed.

In the proposed rule, published in the Federal Register on December 18, 2014, the FDA makes it clear that pharmacies will incur net costs due to initial capital costs to access the information, increased search time when accessing the information and the printing cost when a request is received for the information in printed form. The FDA estimates the annualized costs range from \$47 million to \$89 million and are a shift from manufacturers to pharmacies.

The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of nearly 23,000 independent community pharmacies. As small business owners, NCPA members are not in a position to absorb these costs. NCPA is opposed to the changes proposed in the rule until reliable systems are in place that will allow pharmacists to access electronic professional package inserts (PI) in a timely, efficient and cost neutral manner.

We would like to point to the July 2013 Government Accountability Office (GAO) report entitled *Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of its Exclusive Use* as support for our position. This report concludes that relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health by limiting the availability of drug labeling for some physicians, pharmacists, and patients by requiring them to access drug labeling through a medium with which they might be uncomfortable, that they might find inconvenient, or that might be unavailable.¹

NCPA's primary recommendation for any move to electronic labeling is that costs not be shifted to small business community pharmacies. If paper drug labeling ceases to exist, costs will undoubtedly shift to the pharmacies to obtain and/or provide this information to patients who ask for it.

The GAO report noted that if patients want to continue receiving drug labeling in paper form and pharmacies are expected to print drug labeling for distribution, it would shift the costs of printing to the pharmacies.² Please note that it is common practice in community pharmacies for pharmacists to utilize the manufacturer-provided paper insert, which patients often request.

¹United States Government Accountability Office Report to Congressional Committees; Electronic Drug Labeling No Consensus on the Advantages and Disadvantages of Its Exclusive Use; GAO-13-592; July 2013

²*Id.*

A survey of pharmacists conducted recently found that pharmacists who prefer professional prescription labeling “indicate that these inserts are fast and easy to access, are familiar and allow pharmacists to readily search for needed information. Pharmacists also state that familiarity with the professional PIs allow them [to] access information reliably, with minimal interruption to work flow, and without errors.” Moreover, 27 percent of pharmacists polled indicated “that their pharmacy either does not have Internet access or that they cannot browse the internet.”³

Small business community pharmacies are unable to bear the costs of providing this information on their own, which would include additional computer terminals, printers and other office supplies such as paper, ink and toner. The GAO report also rightly noted that disruption to pharmacy workflow that would ensue from having to access the labeling electronically reduces the time available to counsel patients and has been shown to increase the risk for errors made when dispensing a drug.⁴

For these reasons, NCPA opposes the proposed rule at this time and would ask that it be withdrawn by FDA. Alternatively, NCPA could support a dual system, whereby prescribing information is available in both electronic and paper formats. NCPA looks forward to working with the FDA to best meet their goals for healthcare providers using the most up-to-date prescribing information.

³ NERA Economic Consulting, “Pharmacy Practice: A Report on Pharmacists’ Use of Printed Package Inserts” (Jan. 2015) at 7 (hereinafter, “NERA survey”). <http://www.nera.com/publications/archive/2015/pharmacy-practice--a-report-on-pharmacists--use-of-printed-packa.html>

⁴ *Id.* at 1.