

# Prescription for Change

## The Impact of New Pharma Rules on Patients and Prescribers

BY VICTORIA VANCE

A trio of recent regulatory actions, ostensibly aimed at the pharmaceutical and medical device industries, are likely to recast relationships among patients, prescribers, pharmacists and industry representatives. Regulatory agencies (FDA and CMS) announced rules that when finalized and implemented will establish new standards of practice for health care providers, modernize sources of drug information for patients and prescribers, and raise public awareness of financial relationships between industry and providers.

### The Sunshine Act: Disclosures of Industry Payments to Physicians and Teaching Hospitals

Section 6002 of the Affordable Care Act (ACA) mandated a national disclosure program of the financial relationships between the drug and medical device industry and certain healthcare providers. The ACA amended the Social Security Act to require applicable manufacturers of drugs, devices, biologicals or medical supplies and applicable Group Purchasing Organizations (GPOs) to report annually certain payments or other transfers of value to physicians and teaching hospitals. The Congressional mandate implements an Institute of Medicine recommendation for such a national disclosure program in a 2009 report titled, "Conflict of Interest in Medical Research, Education and Practice." The Regulations implementing the so called "Sunshine Act" were published in February 2013 (78 Fed. Reg. 9458; codified at 42 CFR Parts 402, 403).

This mandatory reporting program, known as "Open Payments," brings transparency to the financial relationships between physicians and industry and establishes a publicly available, online repository for financial interactions to be reported and monitored. The Sunshine Act does not ban

any relationships or collaborations between industry and providers; rather, through the disclosure process, the government hopes to maintain legitimate collaborative relationships but discourage those that may cause conflicts of interest.

Under the Open Payments program, applicable manufacturers and applicable GPOs will report on the payments and other transfers of value to physicians (broadly defined to include MDs, DOs, DDSs, DPMs and DCs) and teaching hospitals. Medical residents are excluded. Manufacturers must identify the recipient, describe the form of payment (cash, in kind, ownership interest, etc.), and the reason for the payment (such as consulting fees, gifts, entertainment, food and beverage, royalty or license, honoraria and grants). Small payments — under \$10.00 — are exempt from reporting unless the annual aggregate to a recipient exceeds \$100. Physicians and teaching hospitals are not required to report, but should register in the Open Payments system to review (and challenge) the accuracy of the reported information. Drug samples intended exclusively for distribution to patients and payments for litigation services are excluded from the reporting requirements. Manufacturers risk civil monetary penalties (as much as \$1M annually) for non-compliance.

The initial posting of Sunshine Act data was made on September 30, 2014. Additional data was released in December 2014. The data includes 4.4 million payments made to 546,000 physicians and 1,360 teaching hospitals between August and December 2013 totaling \$3.5 billion. CMS will publish calendar year 2014 financial data by June 30, 2015.

The Sunshine Act program has been the subject of criticism, consternation and celebration. CMS describes the program as "a national resource" for consumers, providers and researchers to know more about the

relationships among physicians, teaching hospitals and industry. Most importantly, the system will provide consumers the opportunity to make informed decisions about their medical care. The Open Payments system is available at <http://cms.gov/openpayments/>.

### Electronic Drug Labeling

FDA wants to modernize the way drug labeling information is made available to prescribers and pharmacists. Under a proposed Rule published on December 18, 2014 (78 Fed. Reg. 75506), traditional paper "package inserts" — which provide prescribing information about a drug's indications for use, contraindications, warnings, dosing and side effects — will be replaced by real time electronic versions of the label. The proposal will require drug manufacturers to eliminate paper labeling in and on drug containers, and instead, send the labeling to FDA for posting to an electronic labeling repository. According to FDA this change will ensure that healthcare professionals have access to the most current safety and prescribing information.

FDA has found that approximately 500 safety labeling changes are made each year to drug labeling, including nearly 50 additions or changes to boxed warnings and about 60 changes to the "contraindications" section. "The serious nature of these warnings highlight the need for healthcare professionals to have access to, and utilize, the most current prescribing information from a reliable and consistent source." 78 Fed. Reg. 75512.

FDA is aware that the paper labeling is often printed months, if not years, in advance, and may be outdated by the time the drug is prescribed and purchased. Such delays can compromise patient safety. By contrast, e-labeling will give providers timely access to current information about the safe and effective use of the drug. *Id.* 75511. The proposed Rule would require manufacturers

to submit prescribing information to FDA's publicly available website (<http://labels.fda.gov/>) every time there is a change in the labeling. Manufacturers must also review the website to verify that the correct version of the labeling appears.

The proposed Rule directs that the product's immediate container label and outside package include a statement directing healthcare professionals to FDA's labeling repository to obtain prescribing information, and provides a toll-free telephone number, staffed by the manufacturer 24/7, to receive requests for paper copies of the prescribing information.

Material intended to reach the patient, such as patient package inserts and Medication Guides will still be printed. FDA may also grant an exemption from the electronic labeling requirements when compliance could adversely affect the safety or effectiveness of the drug, is not technologically feasible, or is otherwise inappropriate (for example, products intended for use in an emergency room or stockpiled for an emergency).

The website will link prescribing information to product-specific National Drug Code (NDC) numbers, and will be searchable by, among other things, active ingredient and proprietary name to provide the public and prescribers with a complete source of the most current prescribing information available for a range of pharmaceutical products.

FDA acknowledges that although electronic labeling will save money for the pharmaceutical industry, it will increase costs and disrupt workflows for pharmacies (for example, increased search time when accessing information, and printing costs when a request is received for prescribing information in printed form). FDA estimates there will be no cost increases to most healthcare professionals under this new approach, perhaps due to the common perception that healthcare professionals are used to consulting electronic databases and on-line sources for summary drug information.

This proposed Rule is open for public comment until March 18, 2015.

### **Coming Soon: Controversial Changes to Generic Drug Labeling**

The generic drug industry is premised on notions of sameness: providing a low-cost alternative to brand name drugs using equivalent drug formulations and labeling. The industry is bracing for fundamental changes when the FDA finalizes a generic drug labeling rule to require generic drug manufacturers to revise their labeling to reflect newly acquired safety information. Instead of simply duplicating the brand name drug's labeling changes, the new rule imposes a duty on generic drug manufacturers to act independently and on their own initiative to change their product labeling. While FDA touts this as providing a public health benefit — after all, generics comprise 80% of the prescription drug market — others fear this mandate will lead to inconsistent labeling, confusing the standard of care for prescribers, and increasing liability for generic drug manufacturers.

FDA issued the proposed generic drug labeling rule in November 2013 in response to Supreme Court decisions that held that state law failure to warn suits against generic manufacturers were preempted by the federal drug labeling requirements. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). In those decisions the Court recognized that under existing federal law generic manufacturers are limited in changing a drug's label, whereas brand name manufacturers have the ability to unilaterally revise the labeling of their drugs to incorporate new safety information. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). FDA claims that the proposed rule will “create parity” between the brands and generics with respect to safety-related labeling submissions.

Not surprisingly, the labeling rule has been met with a chorus of opposing views. Many fear a multiplicity of potentially inconsistent drug labels for the same drug formulation engendering confusion among patients and prescribers and exposing the generic

manufacturers to failure to warn suits. There is a concern that generic manufacturers will practice “defensive labeling” including information about remote risks, thus diluting the overall effectiveness of the warning.

There are often multiple manufacturers of the same generic drug product, and if each feels obligated to write and update its own label on its own terms and timetable, the confusion and burden on prescribers to first recognize, and then weigh different manufacturer's labeling for the same drug product will create a new standard of care for prescribers. FDA officials dismiss these concerns and defend the proposed rule, stating it will “[m]ake sure that generic drug companies actively participate with the FDA to ensure that product safety information is accurate and up to date.”

This vociferous debate is far from over and may have prompted the FDA to delay finalizing the new rule. Instead of taking effect in December 2014 as expected, the final generic drug labeling law will not be published until Fall 2015.

### **Conclusion**

As these Rules show, regulation of the pharmaceutical industry does not occur in isolation, but inevitably benefits (or burdens) providers and patients, sometimes in unintended ways.



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