



**Testimony by  
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**Use of Medication Guides to Distribute  
Drug Risk Information to Patients  
Docket No. 2007N-0121 (72 Fed. Reg. 17559; April 9, 2007)**

**June 12 & 13, 2007**

Good afternoon, I am Anita Ducca, the Senior Director for Regulatory Affairs and Healthcare Policy for the Healthcare Distribution Management Association (HDMA). On behalf of HDMA, I commend the FDA for holding this important public meeting, and I thank you for the opportunity to comment on behalf of HDMA and our members.

HDMA is here today to represent approximately 40 primary, full-service healthcare distributors, including national, regional and small, family-owned businesses that comprise our membership. Each day, HDMA member companies deliver nine million prescription medicines and healthcare products to more than 144,000 pharmacies, hospitals, nursing homes and clinics across the United States.

HDMA thanks the FDA for seeking comment on ways to improve communications to patients who receive Medication Guides. Today, HDMA will discuss the following:

- How distributors use Medication Guides,

- How distributors are informed that a Medication Guide is required for a specific medication,
- How distributors receive Medication Guides,
- Additional operational considerations, and
- HDMA recommendations for the Medication Guide program.

## **HOW DISTRIBUTORS USE MEDICATION GUIDES**

Although we are aware of the specifications under 21 CFR 208.24 for providing Medication Guides or the means to produce them to the authorized dispenser,<sup>1</sup> distributors do not use Medication Guides in any way. Medication Guides contain patient information, and HDMA's distributor members do not interact with patients. Our connection with pharmacies and other dispensers is through a business relationship; we provide a product to them at their request. Developing or interpreting medical or risk information contained in the Medication Guide is the sole purview of the product manufacturer, not the distributor. Similarly, patient information is needed by the prescriber, pharmacist or similar healthcare practitioner, not the distributor.

## **HOW DISTRIBUTORS ARE INFORMED THAT A MEDICATION GUIDE IS REQUIRED FOR A SPECIFIC MEDICATION**

There is no standard or formal method for informing the distributor that a Medication Guide must be provided with the drug. Typically, distributors are first informed that a drug has a Medication Guide because a shipment of them arrives at their distribution centers

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<sup>1</sup> Quoting regulation: 21 C.F.R. § 208.24(c).

(which are essentially very large warehouses). In most cases, the shipment of Medication Guides is the only alert that the distributor receives and there are usually no accompanying instructions or other information about providing Medication Guides to customers.

## **HOW DISTRIBUTORS RECEIVE MEDICATION GUIDES**

Similarly, there is no standard way that a drug with a Medication Guide arrives at a distribution center. Some manufacturers attach the Guides to their products in the same way they attach a Package Insert (to each individual package, container or bottle). Medication Guides also may be appended to, and included in, the drug's Package Insert, or glued to the drug's package or container. Other manufacturers put a few loose copies of the Medication Guides in the cases holding the product, or send distributors Medication Guides in a tear-off pad form. Occasionally, these tear-off pads are included in the shipping case, but usually, manufacturers ship entire cases of tear-off pads separately from the drug. Typically, Medication Guide tear-off pad shipments do not include instructions for connecting the Medication Guides with the appropriate drug products and customers.

For HDMA members, Medication Guides that are already attached to the packages and/or Package Inserts are the easiest to manage. When they are attached, they are automatically included with the product when ordered by a dispenser. However, under these conditions, the Medication Guides are also the least likely to be evident when they are added to the bottom of the Package Insert, since distributors currently have no specific notice of the Medication Guides' presence. Distributors do not open a product package or unfurl the product's Package Insert to determine if a Medication Guide is included, as distributors do not

want to risk compromising the integrity of the product or the Package Insert. It's especially confusing when Medication Guides arrive separately from the product itself.

None of these methods are very efficient. Providing Medication Guides to distributors in varying ways creates substantial operational difficulties at the distribution center, undercuts attempts to streamline or standardize procedures for receiving and distributing Medication Guides to our customers, and results in additional staff time and costs to handle them.

## **ADDITIONAL OPERATIONAL CONSIDERATIONS**

Before I turn to specific recommendations, I would like to make an observation about the Medication Guide program from the distributors' perspective. Pharmaceutical distributors' expertise, as well as our operations, distribution center layout, equipment, computer systems and staffing are all designed to move millions of drug and healthcare products, per day, through distribution centers to dispensers.

The Medication Guide program has superimposed an information transmission requirement onto this product distribution system. These are two very different types of businesses, and require very different sets of internal operations, staff training, storage provisions, retrieval mechanisms, as well as packing and shipping processes. This information transmission requirement adds operational costs and requires manual effort, which can lead to a significant increase in the worker headcount in order to perform the process. Not only are additional staff and shipping processes needed, these operational problems are mounting concurrently with the increasing number and length of the Medication

Guides. Inventory space is also becoming an issue for distributors. More Medication Guides take up more inventory space, turning revenue-producing space into non-revenue producing space, which becomes a hidden, but significant, cost increase.

We share the concerns others have expressed about the growth in the number and length of these documents, as the cumulative impact of these factors escalates the difficulty of providing them.

To put it simply, distributors have had to revise the picking, packing and shipping systems to transmit a form of information they do not need or use, sent in a variety of ways (if at all) and without advance notification. Further, distributors have been expected to do this while experiencing an exponential growth in the number of Medication Guides coming through the distribution centers.

We urge FDA and other stakeholders to consider proposals for simplifying the Medication Guide system, in light of the operational impact on distributors that do not typically provide this service.

## **HDMA RECOMMENDATIONS FOR THE MEDICATION GUIDE PROGRAM**

HDMA is familiar with the recommendations offered by pharmacy trade associations representing our customers who receive Medication Guides. We believe many of their recommendations merit full consideration, especially those designed to streamline the entire program.

We particularly want to emphasize the need for an electronic Medication Guide system that is easy to use at the dispensing site. We recommend that FDA require electronic versions of this information and eliminate the paper approach entirely. We believe this is the most efficient method for ensuring that this information reaches patients.

It is our strong belief that if a paper system continues in the interim, FDA, and affected stakeholders, should move very quickly to simplify the paper system:

1. First, we recommend having physicians and other providers give the Medication Guides directly to the patient at the time the prescription is being written. The physician is in a position to discuss not only the possible risks associated with the medication, but to also discuss alternative therapies if necessary. All this could take place before the prescription is even given to a patient, much less filled. This has been suggested in previous communications to FDA. We understand FDA may have some reluctance to use this approach since their regulatory authority is over the product and manufacturing processes,

not over physicians and patients. However, given the many difficulties with getting Medication Guides into the hands of the patients, and the questions raised about their value to the patients they're intended for, we suggest that it may be time to revisit this approach.

2. We urge the agency to consider limiting the information contained on a Medication Guide by setting a page length maximum, or other information limitation. A page limit could be coupled with an 800 number on the label or on the Medication Guide itself, where patients or pharmacists obtain further information if they so desire.
3. We also recommend considering the use of an 800 number, Web site, or fax-on-demand approach for pharmacists to order Medication Guides directly from the manufacturers. Such an approach would meet the requirements of 21 CFR 208.24(b)(2) as it would provide the means for authorized dispensers to make a Medication Guide available to each patient receiving a prescription for the drug product.
4. Finally, we agree with recommendations we have heard for grouping Medication Guides into a "class" when the risks are the same among similarly-acting drugs. This will limit the number of different pieces of paper that must be tracked by all parties involved, from the manufacturer through to the patient.

## **FINAL COMMENTS AND CONCLUSION**

I would like to make one final comment regarding repackaging operations, as this has not been an FDA focus with Medication Guides so far. Many retail pharmaceutical and other healthcare entities rely upon repackaged products, which can encompass many different forms. Should FDA dispense with paper Medication Guides and permit their distribution electronically, we ask that the agency clarify responsibilities for preparing and transmitting electronic Medication Guides for repackaged products.

Thank you for including pharmaceutical product distributors in this discussion today. I'll be happy to answer any questions you may have.