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HDMA
Healthcare Distribution Management Association

Fax

Date: 5/25/12

To: FDA Desk Officier From Allison Wiley

Title: Title: Reg Affairs & HC Policy Analyst

Fax: 202-395-7285 Ext:

Phone: 703-885-0266 No. Pages (Including Cover): 10

Re: FDA Docket #: FDA-2011-N-0902;
OMB Control Number: 0910-0393

COMMENTS:

Please see the attached comments submitted on behalf of the Healthcare Distribution Management Association.

Healthcare Distribution
Management Association

May 25, 2012

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer
725 17th Street, NW
Washington, DC 20503

RE: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements [Docket No. FDA–2011–N–0902; OMB Control Number 0910–0393]

Dear FDA Desk Officer:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments to the Office of Management and Budget (OMB) on FDA's Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements, 77 FR 24961 (April 26, 2012).

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that nearly nine million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

Wholesale distributors provide substantial services, value and efficiencies to the drug distribution system. Each distribution center works with over 1,100 manufacturers to ensure needed pharmaceutical products flow quickly and smoothly through the supply chain to the provider and ultimately the patients. As part of these services, HDMA members play a key role in handling, managing and helping to ensure the distribution of certain Medication Guides by passing them from the manufacturer to the point of dispensing.

HDMA's comments will further describe and support our three main points:

1. HDMA respectfully but strongly disagrees with FDA's decision to exclude wholesale distributors from the burden hours estimate for this information collection. In particular, we believe that FDA's statement that wholesale distributors' actions to accept and transmit Medication Guides "*...is not subject to the reporting requirements of the PRA (Paperwork Reduction Act)*"[1] is factually incorrect.

2. We disagree because, under FDA regulations, wholesale distributors must accept, retrieve and either physically distribute or transmit Medication Guides – a painstaking effort comparable to the dissemination obligations that manufacturers and pharmacies undertake. Yet, the burden hours for pharmacies and manufacturers to disseminate Medication Guides are included in the final *Federal Register* notice while distributors' burden hour estimates are not.

[1] 77 Fed. Reg. 24961 (April 26, 2012).

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3. Finally, we point out that FDA's decision is contrary to the agency's prior decision to submit this information collection to OMB for review. Specifically, in the *Federal Register* notice, the agency stated: "FDA agrees with the comments and is willing to include a burden estimate..." for the wholesale distributor's requirements to provide Medication Guides.[2] These very different FDA responses to our essentially same comments that a burden estimate for wholesale distributors should be included were particularly surprising considering that there has been no change in the regulatory requirements between 2008 and now. Thus, there should be a recalculation of the burden estimate for this information collection to include an estimate for the burden on wholesale distributors.

The following discussion further explains our reasoning for the above points.

The Paperwork Reduction Act (PRA) Requirements

As FDA explained in the PRA notice for the Medication Guide rule in the December 21, 2011 *Federal Register*, an agency must estimate the "burden" upon affected parties for any "collection of information" which "includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party."[3] The PRA and implementing regulations define "burden" to mean, among other things, the "time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for ... transmitting, or otherwise disclosing the information."[4] A "collection of information" includes "any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information."[5] An agency must perform this burden estimate and it cannot sponsor or conduct a collection of information until it has conducted the specified review,[6] which includes a "specific, objectively supported estimate of burden."[7]

In the burden estimate for its Medication Guide rule, 21 C.F.R. Part 208, FDA quotes from the PRA and states:

> A "collection of information" includes an Agency request or requirement that members of the public submit reports, keep records, or provide information to third parties or the public by or for an Agency.[8]

Despite the fact that, by the plain terms of 21 C.F.R. 208.24(c), distributors must obtain Medication Guides, keep and retain them, and then provide them to third parties, FDA nevertheless concludes that these activities somehow do not require a burden estimate under the PRA. In excluding the burdens upon wholesale distributors to comply with FDA's Medication Guide rule, FDA has failed to meet its statutory obligations under the PRA.

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[2] 73 Fed. Reg. 72055, 72056 (Nov. 26, 2008).

[3] 76 Fed. Reg. 79194 (Dec. 21, 2011), citing 44 U.S.C. § 3502(3) and 5 CFR § 1320.3(c).

[4] 44 U.S.C. § 3502(2)(F); 5 C.F.R. § 1320.3(b).

[5] 5 C.F.R. § 1320.3(c).

[6] 5 C.F.R. § 1320.5.

[7] 5 C.F.R. § 1320.8 (a)(4).

[8] 77 Fed. Reg. at 24961 (emphasis supplied).

FDA's Medication Guide Rule Imposes A "Collection of Information" Burden Upon Distributors; How Wholesale Distributors Receive and Pass Through Medication Guides to the Point-of-Dispensing

FDA's Medication Guide rule, 21 C.F.R. Part 208, imposes significant requirements upon distributors. The regulation states:

> *(c) Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section* ***shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser*** *to whom it ships a container of drug product.*[9]

By its plain terms, 21 C.F.R. § 208.24(c) imposes a "collection of information" burden upon distributors. To comply with 21 C.F.R. § 208.24(c), distributors must "receive" Medication Guides from manufacturers. Thus, distributors must, as contemplated in the PRA and implementing regulations, "obtain, maintain, [and] retain" information.[10] Distributors must then "provide" that information to third parties, that is authorized dispensers. We note that the term "provide" is common to both the PRA, 44 U.S.C. § 3502(2)(F), and FDA's Medication Guide rule, 21 C.F.R. § 208.24(c). Indeed, the language of the PRA and 21 C.F.R. § 208.24(c) are closely aligned.

Further, for distributors these receipt, storage and dissemination duties require a number of procedures and processes in addition to the usual effort to provide the drug product to a dispenser. Medication Guides are not always attached to the product; and even if they were, as FDA appears to have assumed, the process of obtaining, retaining and providing them is still a "burden" as defined in the PRA.

We are disappointed to see that FDA has failed in its obligations under the PRA to adequately assess the burden its own regulations impose upon our members and disagree with FDA's response about that burden. Under the plain language of the PRA, the requirement under 21 C.F.R. § 208.24(c) that distributors disseminate to third parties the Medication Guides they receive, is a collection of information for which FDA must make a burden estimate. The failure to follow the PRA would be arbitrary and capricious agency action, and action undertaken without observance of procedures required by law, in violation of the Administrative Procedure Act.[11] As a result, we strongly believe that this associated burden should not, and legally cannot, be overlooked.

It appears that FDA has, mistakenly, assumed that all Medication Guides are attached to the drug bottles distributors receive and that there is no further burden to distributors because all that is necessary is for the distributor to pass the bottle on to the dispenser. As discussed above, even if this were the sole duty of the distributor under 21 C.F.R. § 208.24(c), still this activity is a collection of information for which FDA must provide a burden estimate. Regardless, as HDMA has informed FDA in previous PRA burden estimates, the process by which manufacturers provide Medication Guides to distributors is not standardized and imposes significant additional information collection burdens.

Distributors obtain Medication Guides in multiple different formats from manufacturers. For example: 1) some manufacturers incorporate the Medication Guides into the FDA-approved package insert that is attached directly to the product or included in the product's inner packaging; 2) some manufacturers put a product's Medication Guides into pads of tear-off sheets and ship them separately from the drug product; and 3) some place the Medication Guides loosely in the bottom of the box which contains products shipped to the wholesale distributor. This is not an exhaustive example list since other manufacturers use still other methods.

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[9] 21 C.F.R. § 208.24(c) (emphasis supplied).

[10] 44 U.S.C. § 3502(2)(F); 5 C.F.R. § 1320.3(b).

[11] 5 U.S.C. § 706.

For those Medication Guides that are not attached to the product, distributors have even greater receipt, storage and dissemination burdens in order to comply with 21 C.F.R. § 208.24(c). Specifically, for these Medication Guides, distributors might have to:

- Receive shipments of Medication Guides at the warehouse receiving dock;
- Sort them and ensure all Medication Guides for a single product are grouped together;
- Find an appropriate storage location for the Medication Guides (which may mean re-arranging other product inventory depending on space availability in the warehouse);
- Collect and place the Medication Guide in storage in a manner that allows for shipping for products ordered. Depending on the format in which they arrive and other considerations, this may also include:
  - Creating an electronic product identification number so that the pharmacy can order them through the distributor's electronic ordering system;
  - Associating the Medication Guide, which may be stored separately, with the associated product and placing it in the tote during the overnight "picking, packing and shipping" process; and
  - Performing alternative steps as needed.
- Pick, pack and ship the Medication Guide per the distributor's operating procedures.

Given that a wholesale distributor may have nearly 56,000 healthcare products[12] in inventory and the average distribution center picks over 95,000 lines each day to fulfill over 2,000 customer orders, going through all of the above processes to assure compliance with 21 C.F.R. § 208.24(c) in addition to handling such high volumes of drugs products create a notable burden on our industry.

Therefore, there is no question that distributor receipt of packets, boxes, pads and stacks of Medication Guides from manufacturers and then providing that information to dispensers as required by 21 C.F.R. § 208.24(c) is a collection of information for which FDA must conduct a burden estimate under the PRA. Such dissemination is precisely contemplated in the statutory and regulatory definitions of "collection of information" and "burden."[13]

FDA's Previous Interpretation Supported A Burden Estimate for Distributors

HDMA was particularly surprised to see that FDA's response in this information collection notice differed so significantly from their response to prior our comments filed on May 19, 2008. In that response, FDA stated that:

> FDA agrees with the comments and is willing to include a burden estimate for § 208.24(c). [14]

Though the requirements have not changed, four years later, FDA now concludes, without explanation, that the same requirements now impose no burden upon distributors. HDMA believes that FDA's 2008 response, with an update to reflect the more recent burden estimates, is the appropriate action for this information collection renewal. Thus, we urge a recalculation of the burden estimate to include the burden estimate associated with the requirements under 21 C.F.R. § 208.24(c).

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[12] Source: Center for Healthcare Supply Chain Research *2011-2012 HDMA Factbook* – Table 60.

[13] *See* 44 U.S.C. § 3502(2)(F); 5 C.F.R. § 1320.3(b); 5 C.F.R. § 1320.3(c).

[14] 73 Fed. Reg. at 72056.

HDMA thanks OMB for this opportunity to comment. Should OMB wish for further clarifications, HDMA would be glad to assist. If you have any questions, please do not hesitate to contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Vice President, Regulatory Affairs

Attachment

February 8, 2012

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements

Dear FDA Desk Officer:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the Food and Drug Administration's (FDA) Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements, 76 Fed. Reg. 79194 (Dec. 21, 2011).

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that nearly nine million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

As a critical link in the drug supply chain, HDMA members play a key role in ensuring the distribution of certain Medication Guides. HDMA appreciates FDA's previous efforts to seek stakeholder input on how to improve the development, distribution, content and accessibility of Medication Guides and believes that there is continued opportunity for improvements in the program to reduce the administrative burden. Our comments on the proposed information collection will focus on the Paperwork Reduction Act (PRA) review and the estimate of the paperwork burden, including a history of HDMA's previous comments, distribution challenges of Medication Guides and the burden hour estimate for distributors.[1]

History of HDMA's Previous Comments – Include Distributor Requirements in Burden Estimate

On March 18, 2008, FDA published the previous proposed information collection notice[2] regarding the Medication Guide requirements. The 2008 proposed information collection included a list of regulations subject to the reporting requirements for Medication Guides and included the burdens hours for the associated reporting requirements. As HDMA noted in its May 19, 2008 comments, the 2008 proposed information collection list did not account for the distributor reporting requirements in 21 CFR Section 208.24(c). These requirements state that:

[1] 21 CFR Section 208.24(c).

[2] 73 FR 14471.

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> *Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product.*[3]

The amount of time required for distributors to meet these above requirements and remain compliant is extensive. In our comments, we noted that distributors and packers had a significant burden in the distribution of Medication Guides and recommended that FDA include the reporting burden associated with 21 CFR Section 208.24(c) in the final information collection.

HDMA was subsequently grateful to see that FDA agreed with HDMA's recommendation in FDA's notice of information collection submission to the Office of Budget Management (OMB).[4] The Agency stated in the notice that FDA was "*willing to include a burden estimate for Sec. 208.24(c)*" and requested comments to develop the estimate.[5] In response to FDA's notice, HDMA worked with its members and commented to FDA on December 23, 2008 with an attempt to provide an annual burden estimate for 21 CFR Section 208.24(c) as a range between 716,250 to 3,581,250 hours per year.

In FDA's December 21, 2011 notice of proposed information collection, HDMA found that FDA did not include the reporting requirements in Sec. 208.24(c) or our previous burden estimate. HDMA continues to strongly believe that Sec. 208.24(c) poses a significant burden to distributors and packers and should be included in FDA's assessment. The following comments review some of those reasons and provide an updated burden hour estimate for Sec. 208.24(c). For further information, please refer to our previous comments.

Distribution Challenges of Medication Guides

As we detailed in our previous comments, we would like to clarify some of the complexities for distributors in providing Medication Guides and why we believe it is critical to streamline the paperwork requirements. The foundation of our business model is efficiently delivering products and services to our customers at the lowest cost. Each distribution center works with over 1,100 manufacturers to ensure needed pharmaceutical products flow quickly and smoothly through the supply chain to the provider and ultimately the patient.

With Medication Guides, we have found that the varying methods for providing Medication Guides to wholesale distributors have created barriers to the effective and efficient processes and procedures within the supply chain. More specifically, the lack of standardization by manufacturers in how they provide Medication Guides to distributors and pharmacies create significant complexities in streamlining any processes or procedures for distribution of these products. The highly variable manner in which manufacturers provide Medication Guides to distributors may include:

1. Manufacturers may place loose copies of the Medication Guide in the bottom of a carton containing the first shipment to a distributor of the applicable drug. Additional copies may or may not, be included with subsequent shipments.

2. Manufacturers may ship a set of tear-off pads containing the Medication Guides separately from the drug product.

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[3] 21 CFR Section 208.24(c).

[4] 73 FR 72055.

[5] 73 FR 72056. Column 3.

3. Manufacturers may provide pharmacies with their own means of obtaining Medication Guides directly, such as via a toll-free number or electronically. If so, the distributor will know nothing of the Medication Guide's dissemination.

4. Medication Guides may be incorporated internally within the product packaging and/or package insert.

All of these processes require different procedures to manage and distribute and because they are not provided in a consistent format, it is virtually impossible to simplify and standardize their receipt and handling within the typical distributor's warehouse, further exacerbating the paperwork burden. Absent any standardization in manufacturers' Medication Guide dissemination practices, distributors must track, sort and otherwise process incoming Medication Guides separately in order to provide them to dispensers. For these reasons, HDMA continues to urge FDA to simplify and streamline the Medication Guide requirements, for distributors as well as pharmacies.

Burden Hour Estimate for Distributors

Similar to our previous comments, HDMA has attempted below to develop an updated estimate of the burden hours associated with 21 CFR Section 208.24(c). As noted in our previous comments, due to several factors, we emphasize that the numbers below are only estimates. We also note that in developing our estimate we do not have the means of counting non-HDMA distributors who may receive Medication Guides and have a responsibility to provide them to their dispensing customers. Additionally, our estimate does not account for certain extenuating circumstances such as, for instance, cases where a Medication Guide is required for a drug, but is not being provided, at all.

Under our scenarios, the burden estimates for distributors will range from none if a Medication Guide is transmitted directly from the manufacturer to the dispenser or included in the product packaging or labeling, to untold hours for those products with a paper Medication Guide that is not incorporated into the drug package and is shipped in bulk separately from the drug.

However, to respond to the request, HDMA asked its members to estimate the time it takes to receive, process, store and transmit a copy of a paper Medication Guide to each dispenser/customer required to receive one when the distributor receives the Medication Guide, on paper, separate from the drug product it is supposed to accompany. The responses ranged from 60 to 90 minutes per Medication Guide, so we used a mid-point of 75 minutes (1.25 hours) per Medication Guide. Below we explain the assumptions used to provide the estimate in a "range."

- Assume approximately 30 new, or revised, Medication Guides are created per year;[6]
- Approximately 1.25 burden hours are required per paper Medication Guide to receive, process, copy, store, select and ship the Medication Guide to a customer upon first order of the product after a Medication Guide is received by the distributor;
- Assume that approximately 10 - 50 percent of Medication Guides are provided to distributors in a paper format that is physically separate from the drug product and must be handled and processed separately;[7]

[6] The number 30 was reached by adding the number of respondents under § 21 CFR 208.20 = 25 to the number of respondents under §314.70(b)(3)(ii) and §601.12(f) = 5, as shown on Table 1, 76 FR 79195.

[7] HDMA reemphasizes that we do not know the exact number or percentage of Medication Guides that are provided to distributors, thus we chose to present the estimate in a range for illustrative purposes.

- 158 HDMA-member distribution centers receive copies of Medication Guides along with shipments of the drug and are responsible for providing them to their customers;[8] and
- Each distribution center has 1,200 customers who must receive at least one copy of the Medication Guide.[9]

The approximate annual paperwork burden would range from 711,000 hours to 3,555,000 hours per year, calculated as follows:

- 30 Medication Guides X 1.25 burden hours X 10 percent X 158 distribution centers X 1,200 customers = 711,000 hours
- 30 Medication Guides X 1.25 burden hours X 50 percent X 158 distribution centers X 1,200 customers = 3,555,000 hours

As can be seen from these numbers, the amount of time required for distributors to remain in compliance is significant and should be included in the information collection notice. Especially with FDA's efforts to standardize Risk Evaluation and Mitigation Strategies (REMS), the need to simplify and standardize the Medication Guide requirements has never been greater and is critical for reducing the administrative burden associated with Medication Guides. HDMA continues to welcome any opportunity to work with the Agency to improve and standardize the distribution process for Medication Guides to help ease the existing paperwork burden.

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Conclusion

We thank FDA, again, for this opportunity to comment. If you have any questions, please do not hesitate to contact me at 703-885-0240 or aducca@hdmanet.org.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Vice President, Regulatory Affairs

[8] Source: Center for Healthcare Supply Chain Research *2011-2012 HDMA Factbook* – Table 7.

[9] Source: Center for Healthcare Supply Chain Research *211-2012 HDMA Factbook* – Table 69. We have estimated approximately 1,200 for each distribution center.