DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Electronic Submission of Labeling for Certain Home-Use Medical Devices

Docket No. FDA-2016-N-2491

## Preliminary Regulatory Impact Analysis
## Initial Regulatory Flexibility Analysis
## Unfunded Mandates Reform Act Analysis

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August 2016

# I. Introduction and Summary

## A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because annualized costs to small entities are estimated to be less than 0.4 percent of firm revenue, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment

for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This rule proposes to implement provisions of the FD&C Act by requiring firms to electronically submit to FDA the device labels and package inserts, hereafter referred to as "labeling," of certain home-use medical devices. In particular, all devices regulated by the Center for Devices and Radiological Health (CDRH) as Class II and Class III devices and labeled for use in any environment outside a professional healthcare facility would be covered by this rule. FDA intends to make the labeling of these devices available to the public in a searchable FDA-managed or partner Internet website, hereafter referred to in the RIA as "labeling database." Firms would be required to submit the device labeling to FDA, initially in Portable Document Format (PDF) but later in Structured Product Labeling (SPL) format. Firms would incur three types of costs as a result of this rule: costs to read and understand the rule, costs to reformat labeling according to the rule, and costs to train personnel to comply with the rule. FDA would incur costs to establish and maintain the public, online labeling database. The public would benefit from access to information and instructions on the proper use of medical devices in home settings.

The costs and benefits of the proposed rule are summarized in the table below, entitled *Table 1. Economic Data: Costs and Benefits Statement*. This table shows the estimated average annualized costs and other quantified but not monetized effects of this rule using both seven and three percent annual discount rates over a ten-year evaluation period. We estimate that the

present value of costs over ten years would range from $48.5 to $51.7 million at a seven percent discount rate and from $52.5 to $56.5 million at a three percent discount rate. Annualizing these costs over ten years yields estimated costs ranging from $6.5 to $6.9 million at a seven percent discount rate and $6.0 to $6.4 million with a discount rate of three percent.

As Table 1 shows, the primary benefit stems from a reduced incidence of adverse events due to the increased availability of medical device labeling. We use, as a proxy for those most likely to benefit from this proposed rule, individuals who receive instruction from home health providers on the proper and safe use of their home-use devices. We estimate that the present value number of home-use device training events over ten years is 66.9 million using a seven percent discount rate or 80.1 million using a three percent discount rate. Annualized over ten years, we estimate the annual number of home-use device training events is 8.9 million with a seven percent discount rate and 9.1 million with a three percent discount rate. Under the proposed rule, we estimate that for each home-use device training event, the rule would cost between $0.73 and $0.77 using a seven percent discount rate; with a three percent discount rate, the cost per event would range from $0.66 to $0.71.

**Table 1. Economic Data: Costs and Benefits Statement**

| Economic Data: Costs and Benefits Statement | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | Units | | | |
| Category | Primary Estimate | Low Estimate | High Estimate | Year Dollars | Discount Rate | Period Covered | Notes |
| Benefits | | | | | | | |
| Annualized Monetized $millions/year | | | | | 7% | | |
| | | | | | 3% | | |
| Annualized Quantified | 8.9 million home-use device training events | | | | 7% | 10 years | Reduced incidence of adverse events due to availability of labeling. |
| | 9.1 million home-use device training events | | | | 3% | 10 years | |
| Qualitative | | | | | | | |
| Costs | | | | | | | |
| Annualized Monetized $millions/year | $6.6 million | $6.5 million | $6.9 million | 2011 | 7% | 10 years | Includes industry costs to read and understand the rule, reformat labeling, and train personnel as well as FDA costs to establish and maintain the labeling database. |
| | $6.1 million | $6.0 million | $6.4 million | 2011 | 3% | 10 years | |
| Annualized Quantified | | | | | 7% | | |
| | | | | | 3% | | |
| Qualitative | | | | | | | |
| | | | | Units | | | |
| Category | Primary Estimate | Low Estimate | High Estimate | Year Dollars | Discount Rate | Period Covered | Notes |
| Transfers | | | | | | | |
| Federal Annualized Monetized $millions/year | | | | | 7% | | None. |
| | | | | | 3% | | |
| From/To | From: | | | To: | | | |
| Other Annualized Monetized $millions/year | | | | | 7% | | |
| | | | | | 3% | | |
| From/To | From: | | | To: | | | |
| | | | | | | | |
| Effects | | | | | | | |
| State, Local, or Tribal Government | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Small Business | | | | | | | |

| | |
|---|---|
| Annual cost per affected small entity are estimated to be less than 0.4 percent of revenues. | |
| | |
| Wages: No estimated effect. | |
| | |
| | |
| Growth: No estimated effect. | |

## II. Preliminary Regulatory Impact Analysis

### A. Background and Need for Regulation

In 2011, there were over 445,000 adverse events associated with medical devices; by 2014, this number had risen to over 800,000. Medical devices used outside a professional healthcare facility (hereafter referred to as home-use devices) are particularly vulnerable to adverse events because the users of these devices may be inexperienced in the proper use and maintenance of the devices. According to FDA reviewers of medical device reports, FDA receives reports of approximately three to five of the most serious types of adverse events (deaths, fires, explosions, etc.) each week from home-use devices. Reducing the incidence of these adverse events could save lives and otherwise protect users of the devices from physical harm and property damage.

The incidence of adverse events may be mitigated by providing users of home-use devices with the labeling information covering instructions on use, cleaning, sterilizing, storage, and handling of special waste as well as trouble-shooting suggestions and contact information for the device manufacturer. Home-use devices tend to become separated from this product labeling over time, and the absence of this information may lead to adverse events.

A centralized, online resource of home-use device labeling in an electronic format could benefit both patients using the devices and their caregivers. Many manufacturers currently provide labeling on their websites, but the information can be hard to find and is often limited to currently marketed devices. A single online labeling database would be able to exploit economies of scale and would be less expensive to establish and maintain than a collection of manufacturer-specific resources.

Through this rulemaking, FDA proposes to require submission of labeling that would enable the Agency to establish a central labeling database of CDRH-regulated Class II and Class III home-use devices benefitting patients, caregivers, and the medical device industry. Despite the monetary and public health benefits of establishing a centralized labeling database, medical device firms working amongst themselves have not established one. The centralized database for device labeling would be a public good in the sense of being non-rival in consumption, although it would be potentially excludable.[1] Once established, the socially optimum price for access to the database is zero. Private firms could, in principle, establish the database and devise a pricing or fee mechanism; however, the required cost of coordination and design of an efficient fee collection mechanism among the many entities is likely too great an obstacle without some kind of public intervention. Moreover, the full benefit of the electronic availability of labeling on a centralized online database would not go to device manufacturing firms; as such, one would expect the firms to supply a suboptimal level of product information. For example, there may be no commercial value to providing labeling for older devices, but this information would be particularly valuable to device users. Even a small cost of participation in a private effort could

[1] The marginal costs of providing access to the labeling database are zero; use by one person does not reduce the amount availability to others. Excludability could be created and maintained through licensing, fees per use, and other mechanisms now in use for online sites.

induce at least some manufacturers to opt out. We therefore aim to establish a public database by requiring firms to submit electronic versions of home-use device labeling to FDA.

The proposal accomplishes the objective of increasing the availability of labeling information while minimizing costs. We have considered a universal device labeling database, but we were unsure of the benefits of including every medical device. Instead, we focus our proposal on home-use devices regulated by CDRH as Class II and Class III devices. These devices are considered moderate to high-risk devices, so we expect benefits from the labeling database are more likely for users of these devices; however, we welcome comment on the potential benefit of a universal database. We have also considered requiring labeling to be submitted using SPL, a format approved by Health Level Seven (HL7) and adopted by FDA. Concern about potential costs to smaller device firms led us to instead propose initial submission using PDF.

This proposal would also minimize costs by collecting this information as part of the device listing process. There are approximately 6,800 domestic and 5,900 foreign firms listing medical devices with FDA (REF. 1, Table 3-17). Of these, the roughly 1,700 firms with devices labeled for home use would include electronic labeling information when they list their Class II and Class III home-use devices.

We have contracted with the Eastern Research Group, Inc. (ERG) to collect data and estimate the costs of this proposed rule. The analysis in support of the effects of the proposed rule, "Cost Analysis Support for Regulations to Require Electronic Submission of Registration and Listing Information" (ERG Report) is on file with the Division of Dockets Management (REF. 1). The ERG Report was written prior to the decision to postpone the adoption of SPL, so

this analysis supplements the ERG report to account for the costs and savings from the delayed implementation of SPL.

D. Costs of the Rule

We anticipate that the rule will generate costs in the following categories: (1) costs to the medical device industry; and (2) costs to FDA of establishing and maintaining the labeling database.

1. Costs to the Medical Device Industry

Under this proposed rule, firms would incur three types of costs: costs to read and understand the rule, costs to reformat the labeling for submission to FDA according to the rule, and costs to train personnel to comply with the rule. The cost to read and understand the proposed rule would be a one-time cost that varies with the size of the firm, with larger firms facing greater costs because larger firms will have more employees reviewing the rule (REF. 1, p. 3-2). All firms that produce medical devices would incur costs to review the proposed rule; however, firms that do not produce home-use devices would incur smaller costs than those that do. The reformatting cost for each firm with home-use devices would vary with the number of devices whose labeling is to be submitted to FDA. The training cost would be the same for all firms. Firms would incur both initial and recurring reformatting and training costs; however, rather than reformatting the labeling in-house, firms may choose to outsource the reformatting if is cost-effective to do so.

To start, firms would submit device labeling to FDA as PDF files. At some point in the future, submission may be required in SPL format. In this analysis, we first estimate the cost of

submitting labeling in SPL format from the outset. Following that analysis, we estimate the cost of requiring PDF submissions initially with a transition to SPL format at some future date. For both, we calculate the total cost to the medical device industry over a ten-year horizon.

a. Cost to Read and Understand the Proposed Rule

All establishments that list medical devices would devote management time to reading and understanding the proposed rule. Establishments that do not produce home-use devices would spend less time on this task than those that do produce home-use devices. Additionally, larger establishments would spend more time reading and understanding the rule than smaller establishments and will thus incur larger costs.

Establishments without home-use devices are separated into four groups based on size (REF. 1, Table B-1). We assume that small establishments would allocate six hours of management time to reading and understanding the proposed rule, medium establishments would allocate twelve hours, large establishments would allocate eighteen hours, and very large establishments would allocate 48 hours (REF. 1, p. 3-2). The mean hourly wage for management personnel in medical device firms is $66.72 (REF. 2 2012). Multiplying this wage by two to account for benefits and capital costs yields a loaded wage for management personnel of $133.44. Multiplying the time spent reading and understanding the proposed rule by the loaded wage results in a cost to establishments without home-use devices of $6.7 million to read and understand the proposed rule.

Establishments with home-use devices are also separated into four groups based on size (REF. 1, Table B-2). We assume that small establishments would allocate 46 hours of management time to reading and understanding the proposed rule, medium establishments would

allocate 87 hours, large establishments would allocate 152 hours, and very large establishments would allocate 306 hours (REF. 1, p. 3-3). Multiplying the time spent reading and understanding the proposed rule by the loaded management wage of $133.44 yields a cost to establishments with home-use devices of $16.6 million. Adding the costs for establishments with and without home-use devices, the total industry cost to read and understand the proposed rule is $24.6 million.

b. Costs to Reformat Home-use Device Labeling

Under the proposed rule, home-use device labeling would be submitted to FDA in a format specified by the Agency; device manufacturers would incur costs to reformat the labeling into the specified format. We calculate the cost of reformatting the labeling into SPL format; however, initially, FDA intends to allow firms to reformatlabeling into PDF with a transition to the SPL format expected in the future.

More complex labeling would require more time to be reformatted into SPL format. A basic label without a package insert would require two hours to be reformatted by IT personnel. Labeling with package inserts would require more time. A basic label with a simple package insert would require four hours, a basic label with a complex package insert would require 40 hours, and a basic label with a very complex package insert would require 80 hours to reformat (REF. 1, p. 3-3). We assume that half of all home-use devices do not have a package insert. Of those that do contain a package insert, 95 percent of the package inserts are simple, 4.5 percent are complex, and 0.5 percent are very complex (REF. 1, p. 1-2). Therefore, on average, labeling would require four hours to reformat. The reformatting of home-use device labeling would be performed by IT personnel who earn an average hourly wage of $36.30 (REF. 2 2012).

Multiplying by two to account for benefits and overhead costs yields a loaded wage for IT personnel of $72.60. Thus, the average four-hour reformat would cost the firm $290.40 per label.

Initially, all labeling of home-use devices covered by the rule would need to be reformatted. In subsequent years, establishments will need to reformat new labeling and modify existing labeling. We assume that each year, the number of devices with new labeling that needs reformatting is equal to ten percent of the number of initial devices. Reformatting new labeling in a subsequent year would take the same amount of time at the same cost as reformatting labeling initially. We also assume that each year, the number of devices with existing labeling needing modification is equal to ten percent of the number of initial devices. Modifying existing labeling would take half the time of a new reformat at half the cost (REF. 1, p. B-3). Therefore, the recurring cost in subsequent years would be 0.15 times the initial cost, or $43.56 per initial label.

c. Cost to Train IT Personnel

Establishments would need to train IT staff to perform the labeling reformats. Initially, this training would require 16 hours of IT personnel time at each establishment with home-use devices (REF. 1, p. B-2). In each subsequent year, ongoing training would require one third as much time, or 5.3 hours (REF. 1, p. B-3). At a loaded wage for IT personnel of $72.60, this implies an initial training cost of $1161.60 per establishment and an annually recurring cost of $387.20 per establishment.

d. Outsourcing

Establishments may find it advantageous to hire an outside firm to reformat labeling and train staff. An establishment would choose to outsource if the cost of outsourcing is less than the cost in-house. Establishments will assess these costs and make the decision of whether or not to outsource initially, and they may revise that decision annually when new labeling reformats and labeling modifications are necessary.

As with the cost of reformatting labeling in-house, the cost of outsourcing labeling reformatting would increase with the complexity of the labeling. Based on ERG's conversations with SPL conversion service providers, we estimate that the cost of outsourcing the reformatting of a basic label is between $200 and $330 with an average cost near $200. The cost of outsourcing the reformatting of a basic label with a simple package insert ranges from $240 to $550, averaging near $307. The cost of outsourcing the reformatting of a basic label with a complex package insert ranges from $330 to $1,300 with an average of $1,042. The cost of outsourcing the reformatting of a basic label with a very complex package insert ranges from $730 to $2,600 with an average cost of $2,083 (REF. 1, p. A-1).

We present estimates of the cost of outsourcing labeling reformatting using the lower and upper bounds as well as the average. Using the distribution of labeling complexity discussed above, the weighted average cost of outsourcing the initial labeling reformatting ranges from $223.25 to $462.00 per label. The average outsourcing costs for each level of complexity yield a weighted average cost of initial labeling reformatting of $274.48 per label. As above, the recurring cost of labeling reformatting in subsequent years will be 0.15 times the initial cost. Therefore, the weighted average recurring cost of outsourcing labeling reformatting would range from $33.49 to $69.30 per initial label. Using the average outsourcing cost estimates, we obtain

a weighted average recurring cost of outsourcing labeling reformatting of $41.17 per initial labeling.

Establishments decide whether or not to outsource labeling reformatting by comparing the costs of outsourcing to the combined cost of reformatting labeling in-house and training IT staff. For the initial labeling reformatting , establishments would face an average in-house reformatting cost of $290.40 per device plus a training cost of $1161.60 per firm. The average initial outsourcing cost would range from a low of $223.25 to a high of $462.00, with an average cost estimate of $274.48. An establishment that faces the low or average outsourcing costs would choose to outsource its initial labeling reformatting. In fact, any establishment facing an average outsourcing cost of $290.40 or less would choose to outsource its labeling reformatting. If an establishment faces the high outsourcing cost of $462.00, it would be cost effective to initially outsource its labeling reformatting only if the establishment has six or fewer devices with labeling to reformat.

For the recurring labeling reformatting, establishments would face an average in-house reformatting cost of $43.56 per initial device labeling plus a training cost of $387.20 per establishment. The average recurring outsourcing cost would range from $33.49 to $69.30 per initial device labeling, with an average cost estimate of $41.17. As with the initial reformatting, an establishment that faces the low or average outsourcing costs would choose to outsource its recurring labeling reformatting. Further, any establishment facing a recurring outsourcing cost of $43.56 or less per initial device labeling would choose to outsource its recurring labeling reformatting. If an establishment faces the high recurring outsourcing cost of $69.30 per initial reformat, it would choose to outsource its labeling reformatting if it has fifteen or fewer initial labelings.

e. Cost to Industry Over Ten Years: SPL Labeling Database

We estimate the total cost to industry of the SPL labeling database over a ten-year time horizon. The total cost consists of three parts: the cost to read and understand the proposed rule, the initial training and labeling reformatting costs, and the recurring training and labeling reformatting costs. As described previously, the total cost to the medical device industry to read and understand the proposed rule is $24.6 million. We estimate that there are 2,280 medical device establishments with a total of 12,338 devices subject to the proposed rule with labeling to be initially reformatted (REF. 1, Tables B-3, B-4, B-5, B-6). This count of devices comes from the Registration and Listing database. To the extent that some devices covered by this rule may not be included in this database, this may underestimate the amount of labeling to be initially reformatted. On the other hand, we may be overcounting if there are devices that register and list but that are not covered by this rule (particularly Class I devices).

Our estimate of the total cost to industry of the proposed rule will vary depending on the estimate of outsourcing cost used. If we take the low estimate, all firms would outsource labeling reformatting and would not incur training costs. The initial total reformatting cost would equal the initial per-device labeling outsourcing cost ($223.25) times the number of devices (12,338), or $2.8 million. The recurring total reformatting cost would equal the recurring per-initial-device labeling outsourcing cost ($33.49) times the number of initial devices (12,338), or $0.4 million per year. Adding the reading and understanding cost, the present value of the total cost over ten years is $30.3 million using a discount rate of seven percent. Using a three percent discount rate, the present value of the total cost is $30.9 million.

With the average outsourcing cost estimate, all establishments would again outsource labeling reformatting. The initial and recurring reformatting costs are calculated as in the previous paragraph, replacing the initial and recurring per-device labeling costs with $274.48 and $41.17. This yields a present value total cost estimate of $31.6 million using a seven percent discount rate and a total cost of $32.4 million using a three percent discount rate.

If we use the high outsourcing cost estimate, all establishments with six or fewer initial devices would outsource the initial labeling reformatting. There are 2,138 of these establishments, most of which (60 percent) have only a single device labeling to reformat; combined, they would outsource a total of 4,198 initial device labeling reformats (REF. 1, Tables B-3, B-4, B-5). The initial outsourcing cost for these establishments equals the high per-device labeling outsourcing cost ($462) multiplied by the number of initial devices (4,198), or $1.9 million. The 142 establishments with more than six devices will train IT staff and reformat the initial labeling in-house. The initial training cost of these establishments equals the training cost per establishment ($1161.60) times the 142 establishments, or $0.2 million. The initial reformatting cost of these establishments equals the cost per device labeling ($290.10) times the number of initial devices with labeling (8140), or $2.4 million. Combined, these estimates provide a total initial reformatting and training cost of $4.5 million.

Continuing with the high outsourcing cost estimate to calculate the annually recurring cost, establishments with fifteen or fewer initial devices would outsource the recurring labeling reformatting each year. There are 2,176 establishments with 4,578 initial devices that would outsource the recurring labeling reformatting (REF. 1, Tables B-3, B-4, B-5). The recurring outsourcing cost of these establishments equals the high recurring cost per initial device estimate ($69.30) times the 4,578 initial devices, or $0.3 million. The remaining 104 establishments

would train staff and reformat the recurring labeling in-house. The recurring training cost equals the cost per establishment ($387.20) times the 104 establishments, or $40.3 thousand. The recurring reformatting cost equals the recurring cost per initial device ($43.56) times the 7,760 initial devices at these establishments, or $0.3 million. Combined, these estimates provide a total recurring reformatting and training cost of $0.7 million each year.

Adding the cost to read and understand, the initial training and reformatting cost, and the recurring training and reformatting cost, we estimate that the present value ten-year cost of the SPL labeling database would be $34.0 million using a seven percent discount rate. With a three percent discount rate, we estimate the total cost to be $35.0 million.

**Table 2. Cost to Industry of the SPL Labeling Database over Ten Years**

| | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate |
|---|---|---|---|
| Read and Understand | $24,635,025.60 | $24,635,025.60 | $24,635,025.60 |
| Initial Training and Reformatting | $2,754,458.50 | $3,386,503.40 | $4,468,279.20 |
| Recurring Training and Reformatting | $413,168.78 | $507,975.51 | $695,549.80 |
| **Total Present Value Cost (7% discount rate)** | $30,291,408.68 | $31,589,336.41 | $33,988,555.54 |
| **Total Present Value Cost (3% discount rate)** | $30,913,897.56 | $32,354,663.13 | $35,036,485.68 |

f. The PDF Labeling Database

The preceding analysis considers the costs to the medical device industry of SPL submission of home-use device labeling; however, FDA intends to initially allow PDF submission of home-use device labeling to reduce the immediate costs. Allowing for PDF submission of labeling initially but requiring SPL formatted labeling at some point in the future

would result in establishments conducting two sets of labeling reformats. We estimate that this approach would be less costly to the medical device industry because it postpones the more expensive SPL reformatting.

The longer the SPL reformatting is postponed, the less costly the proposed rule would be to the industry. While we lack a precise date for the transition from PDF to SPL, we estimate it to occur in the sixth year. We also lack a reliable estimate of the cost of PDF reformatting but we know it is less costly; we assume it to be 20 percent of the cost of SPL reformatting. Therefore, we assume that initially and for the first five years, establishments would submit PDF formatted labeling at a cost equal to 20 percent of the estimated cost of training and reformatting for SPL formatted labels. In year six, we assume that the industry would incur the full initial training and reformatting costs for SPL formatted labeling. Following the sixth year, the industry would incur the full recurring training and reformatting costs for SPL formatted labeling.

g. Total Cost to Industry Over Ten Years: PDF and SPL Submission

Initially and for the first five years, the reformatting and training costs for the submission of labeling in PDF format would cost twenty percent of the costs of submitting in SPL format discussed above. Thus the initial training and reformatting cost would vary from $0.6 million with the low outsourcing cost estimate to $0.9 million with the high outsourcing cost estimate. The recurring training and reformatting cost would range from $82.6 thousand to $0.1 million per year in years one through five.

In year six, the initial labeling plus the labeling for any new devices that have been introduced in the last five years would need to be reformatted into SPL format. The cost for this

would again vary with the outsourcing cost estimate used and would range from $4.4 million to $7.4 million. After the sixth year, the recurring cost of reformatting the labeling to SPL format would be the same as for the solely SPL submission, ranging from $0.4 million to $0.7 million per year. Summing these costs along with the $24.6 million cost to read and understand the proposed rule and discounting at a rate of seven percent, we obtain a ten-year present value cost of the proposed rule ranging from $29.4 million to $32.6 million. Using a discount rate of three percent yields a ten-year cost ranging from $30.5 million to $34.5 million.

**Table 3. Cost to Industry of the PDF and SPL Labeling Database over Ten Years**

| | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate |
|---|---|---|---|
| Read and Understand | $24,635,025.60 | $24,635,025.60 | $24,635,025.60 |
| Initial PDF Training and Reformatting | $550,891.70 | $677,300.68 | $893,655.84 |
| Recurring PDF Training and Reformatting | $82,633.76 | $101,595.10 | $139,109.96 |
| Initial SPL Training and Reformatting | $4,407,133.60 | $5,418,405.43 | $7,383,894.14 |
| Recurring SPL Training and Reformatting | $413,168.78 | $507,975.51 | $695,549.80 |
| **Total Present Value Cost (7% discount rate)** | $29,393,930.44 | $30,485,920.58 | $32,589,145.21 |
| **Total Present Value Cost (3% discount rate)** | $30,541,459.81 | $31,896,764.89 | $34,514,913.87 |

2. Costs to FDA

The costs to FDA to establish and maintain the labeling database would likely be similar to the costs for other FDA databases. We use the cost estimates of the Global Unique Device Identification Database as proxies for the costs to establish and maintain the home-use device labeling database (REF. 3). The one-time cost to develop and launch the online labeling

database would be approximately $5.8 million. Once launched, we estimate that the annual costs to operate and maintain the labeling database would be $1.9 million. Over ten years, the cost to FDA to establish and maintain the labeling database would be approximately $19.1 million using a seven percent discount rate; discounting at three percent, the cost to FDA over ten years would be $22.0 million. These cost estimates are presented in Table 4.

**Table 4. Cost to FDA of the Labeling Database over Ten Years**

| | |
|---|---|
| Initial Cost | $5,800,000 |
| Annual Recurring Cost | $1,900,000 |
| **Total Present Value Cost (7% discount rate)** | $19,144,805 |
| **Total Present Value Cost (3% discount rate)** | $22,007,385 |

3. Summary of Total Costs of the Rule

Table 5a presents the present value total cost of rule, assuming that the labeling database begins in PDF and switches to SPL format in the sixth year. Using a seven percent discount rate, the present value total cost is expected to fall between $48.5 and $51.7 million; with a three percent rate of discount, the present value total cost is expected to range from $52.5 to $56.5 million.

**Table 5a. Total Present Value Cost of the PDF and SPL Labeling Database over Ten Years**

| | 7% Discount Rate | | | 3% Discount Rate | | |
|---|---|---|---|---|---|---|
| | Low | Average | High | Low | Average | High |
| Cost to Industry | $29,393,930 | $30,485,921 | $32,589,145 | $30,541,460 | $31,896,765 | $34,514,914 |
| Cost to FDA | $19,144,805 | $19,144,805 | $19,144,805 | $22,007,385 | $22,007,385 | $22,007,385 |
| **Total Present Value Cost** | $48,538,735 | $49,630,726 | $51,733,950 | $52,548,845 | $53,904,150 | $56,522,299 |

Table 5b presents the annualized total cost of the rule. With a seven percent discount rate, we expect the annualized cost to range from $6.5 to $6.8 million; using a three percent discount rate, the annualized cost will range between $6.0 and $6.4 million.

**Table 5b. Total Annualized Cost of the PDF and SPL Labeling Database over Ten Years**

| | 7% Discount Rate | | | 3% Discount Rate | | |
|---|---|---|---|---|---|---|
| | Low | Average | High | Low | Average | High |
| Cost to Industry | $3,911,247 | $4,056,551 | $4,336,412 | $3,476,108 | $3,630,363 | $3,928,350 |
| Cost to FDA | $2,547,467 | $2,547,467 | $2,547,467 | $2,504,793 | $2,504,793 | $2,504,793 |
| **Total Annualized Cost** | $6,458,714 | $6,604,018 | $6,883,879 | $5,980,901 | $6,135,156 | $6,433,143 |

C. Benefits

When individuals lack immediate access to information and instructions on the proper use of their home-use devices, it can result in the misuse of devices (particularly in emergency situations), improper disposal of hazardous waste, and improper hygienic maintenance. In 2011, FDA received reports of 445,219 adverse events associated with all medical devices (those used in both clinical and non-clinical settings); by 2014, this number had increased to over 800,000. While we cannot quantify how many of these adverse events were associated with a lack of information and instructions, user errors are the cause of many adverse events; and this proposed rule, if finalized, seeks to reduce their incidence.

The primary benefit of this proposed rule would be a reduction in adverse events that occur due to incomplete information. Because we are unable to estimate the number of adverse events that would be reduced due to this proposed rule, we use the following framework to devise a proxy. First, we assume that the adverse events that occur due to incomplete information are largely associated with devices that are inherently difficult or risky to operate;

devices that are easy or safe to operate would be unlikely to yield adverse events caused by incomplete information on proper usage. Second, we assume that users of these difficult or risky home-use devices receive instruction from home health care providers on the proper and safe use of the devices and that the incomplete information stems from imperfect recall of the instruction received. We then conclude that the population most at risk of experiencing adverse events associated with home-use devices consists of those individuals who receive instruction from home health care providers on the proper and safe use of their home-use devices but who experience difficulties recalling and following such instruction.

We use this population as a proxy for those most likely to benefit from the proposed rule for two reasons. First, we envision the labeling database as a tool to be used in the instruction provided by home health providers much like the physical labeling; thus, individuals receiving this instruction may be more likely to refer back to the labeling database in the future when they face imperfect recall of the instruction received. Second, while not everyone in this population would suffer an adverse event in the absence of the labeling database, this is balanced by the fact that others who do not receive home health instruction would also benefit from the labeling database.

Using data from the Medical Expenditure Panel Survey (MEPS), we estimate the number of events where people receive home-use device training from home health care providers on an annual basis (REF. 4). MEPS is a nationally representative source of data on the use of health care in the United States. As Table 6 shows, between 1996 and 2011, the annual number of home-use device training events ranged from a low of 5.2 million in 2001 to a high of 8.2 million in 2008. These numbers represent those who stand to benefit most from the proposed rule. We cannot predict how many would in fact use the labeling database; however, the number of people

experiencing serious adverse events associated with home-use devices indicates the potential demand for the information made available by the labeling database.

**Table 6. Annual Number of Home-Use Device Training Events**

| Year | Number of People |
|---|---|
| 1996 | 7,024,653 |
| 1997 | 6,406,931 |
| 1998 | 6,683,608 |
| 1999 | 6,271,873 |
| 2000 | 5,589,289 |
| 2001 | 5,295,434 |
| 2002 | 6,719,393 |
| 2003 | 5,422,181 |
| 2004 | 6,079,421 |
| 2005 | 7,061,943 |
| 2006 | 6,271,725 |
| 2007 | 6,359,116 |
| 2008 | 8,179,558 |
| 2009 | 7,643,786 |
| 2010 | 7,188,062 |
| 2011 | 7,917,054 |

To estimate the number of home-use device training events in the future, we fit an econometric model to the past MEPS data and use that model to forecast the annual number of people receiving device instruction from home health providers from 2015 through 2025.[2] The results are presented in Table 7. Over this eleven-year period, we expect 93.0 million events of home health instruction in the use of a medical device. This translates to a present value total of approximate 67 million using a discount rate of seven percent; with a three percent discount rate,

[2] The forecast model is a second-order autoregressive (AR(2)) model with a first-order difference. The first-order difference is required to achieve stationarity. We conducted a Dickey-Fuller test and rejected the null hypothesis of a unit root with the first-order difference at a significance level of one percent.

that number is 80 million. The annualized number is approximately 9 million. We use this number as our proxy for benefit because it represents the population most at risk for adverse events associated with imperfect information and the population most likely to make use of the labeling database.

**Table 7. Forecasted Number of Home-Use Device Training Events, 2015-2025**

| Year | Forecast |
|---|---|
| 2015 | 7,740,120 |
| 2016 | 7,646,587 |
| 2017 | 8,075,597 |
| 2018 | 8,057,695 |
| 2019 | 8,085,983 |
| 2020 | 8,464,282 |
| 2021 | 8,553,316 |
| 2022 | 8,681,526 |
| 2023 | 9,046,392 |
| 2024 | 9,226,379 |
| 2025 | 9,440,226 |
| **Present Value Total (7% discount rate)** | 66,909,563 |
| **Present Value Total (3% discount rate)** | 80,094,717 |
| **Annualized Total (7% discount rate)** | 8,903,193 |
| **Annualized Total (3% discount rate)** | 9,116,062 |

D. Cost Effectiveness of the Rule

We measure the effectiveness of the proposed rule as the number of people who stand to benefit the most from it: those who use medical devices that require instruction from home health providers. We compared the present value of costs (shown in Table 5a) to the present value of home-use device training events (shown in Table 7) using discount rates of both seven and three percent. The cost effectiveness measures are presented in Table 8. We estimate that for each home-use device training event, the labeling database would cost between $0.73 and

$0.77 at a seven percent discount rate and between $0.66 and $0.71 using a three percent discount rate.

**Table 8. Summary of Cost Effectiveness of the Proposed Rule, 2015-2025**

| | 7% Discount Rate | | | 3% Discount Rate | | |
|---|---|---|---|---|---|---|
| | Low | Average | High | Low | Average | High |
| Total Cost | $48,538,735 | $49,630,726 | $51,733,950 | $52,548,845 | $53,904,150 | $56,522,299 |
| Number of Home-Use Device Training Events | 66,909,563 | 66,909,563 | 66,909,563 | 80,094,717 | 80,094,717 | 80,094,717 |
| **Cost per Home-Use Device Training Event** | $0.73 | $0.74 | $0.77 | $0.66 | $0.67 | $0.71 |

E. Regulatory Alternatives

The principal regulatory alternatives considered were as follows: (1) Require submission of labeling for all devices, not just Class II and III home-use devices; and (2) Allow PDF submission of home-use device labeling indefinitely instead of switching to SPL format in year six. The following two sections discuss the costs and benefits associated with these alternatives.

1. Database for All Device Labeling

This alternative would require that firms submit the labeling for all devices, not just home-use devices, increasing the number of domestic firms affected by the rule from roughly 1,700 (those with home-use devices) to almost 6,800 (all medical device firms) (REF. 1, p. 2-21). We calculate the present value total cost of the rule requiring submission of home-use device labeling over ten years and using a seven percent discount rate to range between $28.6 and $30.4 thousand per firm; using a three percent discount rate, the total present value cost per firm ranges between $30.9 and $33.2 thousand. Multiplying these estimates of total present

value cost per firm by the total number of domestic firms in the industry, this alternative carries a total present value cost ranging between $194.2 and $206.9 million with a seven percent discount rate and between $210.2 and $226.1 million with a three percent discount rate.

While the costs would be significantly higher under this alternative, the benefits would likely be larger as well, although we cannot quantify the increase. Benefits would accrue to users of medical devices labeled for use in both clinical and non-clinical settings, increasing the number of people who would benefit from the rule.

2. PDF Format Only

Under this alternative, FDA would allow home-use device firms to continue to submit labeling to FDA in PDF format indefinitely rather than switching to SPL format in the sixth year. This would reduce costs in two ways. First, PDF labeling is less costly to produce than SPL labeling; so allowing PDF submission will cost less than requiring SPL submission from the sixth year on. Second, allowing submissions to continue in PDF will eliminate the need for firms to produce two sets of labeling: PDF labeling initially and SPL formatted labeling in year 6. We estimate that the total present value cost of this alternative over ten years would range from $44.9 to $45.7 million using a seven percent discount rate; using a three percent discount rate, the present value cost of this alternative over ten years would range between $47.9 and $48.7 million.

This alternative may convey slightly fewer benefits than the proposed rule, although we cannot quantify the difference. While PDF is common and familiar to most people, the SPL format is much better suited for a searchable database of labeling information. Thus, requiring

submission in PDF format rather than switching to SPL format may make searching the database more difficult and reduce the benefit that home-use device users can gain from the database.

## III. Initial Regulatory Flexibility Analysis

If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires FDA to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities. This analysis serves as the preliminary regulatory flexibility analysis as required under the Regulatory Flexibility Act.

### A. Description of Affected Small Entities

The affected entities can be divided into four types of firms: manufacturers, reprocessors, specification developers, and repackagers/relabelers (REF. 1,). The Small Business Administration (SBA) determines the size standards of small businesses matched to the industries described in the North American Industry Classification System (NAICS). Manufacturing firms (NAICS codes 325413, 334510, 334517, 339112, 339113, 339114, and 339115) are considered small if they employ fewer than 500 workers, reprocessors of medical devices (NAICS code 811219) are considered small if their average annual receipts are less than $19 million, and repackagers/relabelers (NAICS codes 42345 and 42346) are considered small if they employ fewer than 100 workers (REF. 5). Specification developers are included under Engineering Services in NAICS (REF. 1, p.2-9). According to the SBA, Engineering Services firms are small if their average annual receipts are less than $14 million (REF. 5).

We assume that small firms are composed of one establishment each. Given this assumption, over 98 percent of all affected firms are considered small by the SBA's standards.

Therefore, we further disaggregate the affected firms into three categories based on the number of employees to ascertain the impact of this proposed rule on very small firms as well as larger small firms. We also consider the impact of the proposed rule assuming that each firm is composed of three equal-sized, similar, establishments, although we believe that most small businesses are not this large and that these estimates should be taken as upper bounds.

B. Economic Impact on Small Entities

To determine the impact of the proposed rule on small entities, we compare the estimated cost of the rule to the average revenues of the small entities. Just as before, small entities would incur three types of costs under the proposed rule: costs to read and understand the rule; costs to reformat labeling according to the rule; and costs to train personnel to comply with the rule. These costs are computed as described previously; however, here the cost is calculated for a representative firm rather than for the industry as a whole. For each type and size of firm, we calculate the cost estimates of a representative firm, assuming that each small firm consists of only one establishment. As described previously, we calculate three cost estimates using the low, average, and high estimates of the outsourcing cost; the annualized cost is calculated using both a seven percent and a three percent discount rate.

The estimates are presented in Tables 9 and 10. Assuming that each small firm is composed of a single establishment, the annualized cost to small entities of the proposed rule is not expected to exceed 0.22 percent of firm revenue. The largest impact will be felt by firms with fewer than 100 employees. If instead we assume that each small firm is composed of three establishments, the annualized cost to small entities of the proposed rule is not expected to exceed 0.38 percent of firm revenue. Given that we estimate the cost of the proposed rule to be a

very small percentage of firm revenue, the agency concludes that this rule will not have a significant adverse impact on small entities. We invite comment on this conclusion.

Table 9. Annualized Cost per Small Firm as a Percent of Revenue, One Establishment per Firm

| | | | Annualized Cost as a Percent of Revenue | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 7% Discount Rate | | | 3 % Discount Rate | | |
| Firm Type | Number of Employees | Average Revenue per Firm[1] | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate |
| Manufacturer | 0-19 | $606,330 | 0.14% | 0.15% | 0.16% | 0.12% | 0.13% | 0.13% |
| Manufacturer | 20-99 | $1,769,111 | 0.10% | 0.10% | 0.12% | 0.09% | 0.09% | 0.10% |
| Manufacturer | 100-499 | $16,799,277 | 0.04% | 0.04% | 0.05% | 0.03% | 0.04% | 0.04% |
| Reprocessor | 0-19 | $472,803 | 0.19% | 0.19% | 0.20% | 0.16% | 0.16% | 0.17% |
| Reprocessor | 20-99 | $1,842,061 | 0.09% | 0.09% | 0.09% | 0.07% | 0.08% | 0.08% |
| Reprocessor | 100-499 | $16,969,485 | 0.02% | 0.02% | 0.02% | 0.01% | 0.01% | 0.01% |
| Specification Developer | 0-19 | $606,330 | 0.17% | 0.18% | 0.22% | 0.15% | 0.16% | 0.19% |
| Specification Developer | 20-99 | $1,769,111 | 0.12% | 0.13% | 0.16% | 0.11% | 0.11% | 0.15% |
| Specification Developer | 100-499 | $16,799,277 | 0.03% | 0.04% | 0.04% | 0.03% | 0.03% | 0.04% |
| Repackager/Relabeler | 0-9 | $861,679 | 0.11% | 0.11% | 0.12% | 0.09% | 0.10% | 0.11% |
| Repackager/Relabeler | 10-49 | $2,992,473 | 0.07% | 0.08% | 0.10% | 0.06% | 0.07% | 0.09% |
| Repackager/Relabeler | 50-99 | $8,977,419 | 0.06% | 0.07% | 0.08% | 0.06% | 0.07% | 0.07% |

[1] Source: Eastern Research Group (ERG). (2013). *Cost Analysis Support for Regulations to Require Electronic Submission of Registration and Listing Information* . Lexington, MA: Eastern Research Group.

Table 20. Annualized Cost per Small Firm as a Percent of Revenue, Three Establishments per Firm

| Firm Type | Number of Employees | Average Revenue per Firm[1] | Annualized Cost as a Percent of Revenue | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 7% Discount Rate | | | 3 % Discount Rate | | |
| | | | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate | Low Outsourcing Cost Estimate | Average Outsourcing Cost Estimate | High Outsourcing Cost Estimate |
| Manufacturer | 0-19 | $606,330 | 0.16% | 0.17% | 0.20% | 0.14% | 0.15% | 0.17% |
| Manufacturer | 20-99 | $1,769,111 | 0.13% | 0.14% | 0.17% | 0.11% | 0.12% | 0.15% |
| Manufacturer | 100-499 | $16,799,277 | 0.08% | 0.10% | 0.10% | 0.08% | 0.09% | 0.10% |
| Reprocessor | 0-19 | $472,803 | 0.21% | 0.22% | 0.25% | 0.18% | 0.19% | 0.22% |
| Reprocessor | 20-99 | $1,842,061 | 0.09% | 0.10% | 0.10% | 0.08% | 0.08% | 0.09% |
| Reprocessor | 100-499 | $16,969,485 | 0.02% | 0.02% | 0.02% | 0.01% | 0.01% | 0.02% |
| Specification Developer | 0-19 | $606,330 | 0.26% | 0.28% | 0.38% | 0.23% | 0.26% | 0.35% |
| Specification Developer | 20-99 | $1,769,111 | 0.19% | 0.21% | 0.25% | 0.17% | 0.20% | 0.23% |
| Specification Developer | 100-499 | $16,799,277 | 0.07% | 0.08% | 0.09% | 0.07% | 0.08% | 0.08% |
| Repackager/Relabeler | 0-9 | $861,679 | 0.14% | 0.15% | 0.18% | 0.12% | 0.13% | 0.16% |
| Repackager/Relabeler | 10-49 | $2,992,473 | 0.11% | 0.13% | 0.15% | 0.10% | 0.12% | 0.14% |
| Repackager/Relabeler | 50-99 | $8,977,419 | 0.13% | 0.16% | 0.17% | 0.12% | 0.14% | 0.16% |

[1] Source: Eastern Research Group (ERG). (2013). *Cost Analysis Support for Regulations to Require Electronic Submission of Registration and Listing Information* . Lexington, MA: Eastern Research Group.

## IV. References


1. Eastern Research Group (ERG). (2013). *Cost Analysis Support for Regulations to Require Electronic Submission of Registration and Listing Information.* Lexington, MA: Eastern Research Group.

2. U.S. Bureau of Labor Statistics. (2012, March 27). *May 2011 National Industry-Specific Occupational Employment and Wage Estimates. NAICS 339100 - Medical Equipment and Supplies Manufacturing*. Retrieved September 09, 2013, http://www.bls.gov/oes/2011/may/naics4_339100.htm

3. U.S. Food and Drug Administration. (2013). *Unique Device Identification System; Final Rule. Final Regulatory Impact Analysis. Final Regulatory Flexibility Analysis. Unfunded Mandates Reform Act Analysis.* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM368961.pdf

4. Agency for Healthcare Research and Quality. (2013). Home Health data files, 1996 – 2011. Retrieved November 13, 2013 from http://meps.ahrq.gov.

5. U.S. Small Business Administration (SBA). (2013). *Table of Small Business Size Standard Matched to North American Industry Classification System Codes.* Retrieved October 21, 2013, from http://www.sba.gov/sites/default/files/files/size_table_07222013.pdf