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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Device Reporting: Electronic Submission Requirements

Docket No. FDA-2008-N-0393

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

FDA has examined the impacts of the final 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 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies 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). OMB has determined that this final rule is a significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the eSubmitter program for electronic submission of reports does not impose significant costs on small entities, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most current (2012) Implicit Price

Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The principal benefit of this final rule will be the public health benefits associated with more rapid processing and analysis of the initial individual MDRs currently submitted by manufacturers and importers to FDA on a paper Form FDA 3500A (about 190,000 in 2011). In addition, requiring electronic submission of MDRs is expected to reduce FDA's annual operating costs by $1.9 million and generate annual industry savings of about $9.2 million.

The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $38.4 million to $42.8 million. Estimated annually recurring costs totaled $3.0 million and included maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some entities, the incremental cost to maintain high-speed Internet access. The total annualized cost of the rule, using a 7-percent discount rate over 10 years, would be from $8.5 million to $9.1 million; with a 3-percent discount rate, the annualized cost would be $7.5 million to $8.0 million.

II. Regulatory Impact Analysis

A. Need for Regulation

The purpose of this final rule is to require the submission of MDRs in an electronic format the Agency can process, review, and archive. It will affect all medical device manufacturers and importers.

The final rule is part of a greater Agency initiative to adopt electronic technologies to improve the quality of our operations and to use our resources more efficiently. The rule will

reduce FDA's current costs associated with processing MDRs that are currently received on the paper Form FDA 3500A. By receiving MDRs electronically, FDA should be able to access the adverse event information more quickly and at a lower cost with anticipated reduced data entry errors by eliminating the step of having manufacturers prepare and submit paper forms.

After considering various alternatives, FDA determined that user facilities may continue to submit MDRs in paper form because their reports account for only about 3 percent of reports annually. A regulation is necessary for reports from manufacturers and importers because the Agency receives around 190,000 paper reports from such entities and it would be costly for the Agency to maintain the capacity to continue to convert paper Form FDA 3500A MDRs to electronic MDR records until all manufacturers and importers voluntarily adopted the electronic submission format, possibly years in the future. Some reporters might never adopt electronic reporting of their own volition.

B. Benefits

The most important benefit of this final rule will be to the public health because the rule will enable the Agency to have quicker access to the medical device adverse event reports information and thus more quickly identify and act on any medical device problems. In 2011, FDA received approximately 201,000 initial MDRs from all sources on the paper Form FDA 3500A that needed to be processed and manually entered into the FDA database. It can take from 3 days to more than 6 months before an MDR submitted on a paper copy of the Form FDA 3500A is available for analysis in the Manufacturer and User Facility Device Experience (MAUDE) database. With a standardized electronic format, the majority of medical device reports will be available for analysis within a day or two after submission to the FDA ESG.

With a significant reduction in the time needed for MDRs to be included in the MAUDE database, analysis and action, including feedback to manufacturers and consumers, can be initiated sooner--with a corresponding benefit to public health.

The public health benefits will be supplemented with operating cost reductions within FDA. Assuming the number of MDRs remains fairly constant over time, electronic reporting will save the Agency about one-half of the cost of our data entry contract, which equals a savings of $1.9 million annually.

C. Costs

There are about 20,100 medical device manufacturers and importers identified in FDA's medical device registration database that will be covered by the rule.

The incremental cost to each affected entity will vary by the size, type, and corporate structure of the firm, as well as by its existing electronic submission capability. The total costs associated with this final rule will include one-time setup costs and annual operating costs.

1. One-Time Costs

One-time costs will be the sum of the costs of:

- Rewriting standard operating procedures (SOPs) and training the appropriate personnel,
- Installing and validating either:
    - the installation of the eSubmitter interface software or
    - the programming and configuration of a computer system to transmit reports directly to the FDA ESG using the HL7 ICSR, and
- Acquiring the electronic digital certificate required by the FDA ESG.

a. Rewriting SOPs and training personnel. All entities subject to the electronic reporting requirement will need to ensure that their SOPs include the electronic submission requirement. We estimate that it will require about 10 hours to make the modifications and train the appropriate people on the new procedures. The estimated one-time incremental cost for updating SOPs, assuming an average wage rate of $63 per hour,[1] is about $12.7 million (20,100 medical device manufacturers and importers x 10 hours x $63/hour).

b. Setting up systems for submission. MDRs will be submitted through the FDA ESG using one of two methods: The eSubmitter software or the HL7 ICSR. Because most entities are small and submit few if any MDRs annually, we assume they will use the eSubmitter software, which allows for the submission of one MDR at a time. To comply using this submission method, manufacturers and importers will need high-speed Internet connections[2] and will have to download and install up to three free software programs, validate the installation, and train the appropriate personnel on the new procedures. Entities that have dedicated information technology staff will be able to install and validate the installation themselves. Smaller manufacturers and importers will probably choose to hire an outside contractor for the installation and the validation of the installation.

FDA does not have data on the amount of time required to install and validate the installation of the software or the percentage of entities that might need to contract out the installation. For this analysis, FDA assumes that it will take 8 to 16 hours to install and validate the installation of the eSubmitter software (and to install, if necessary, Java Runtime Edition

[1] $63 per hour wage is based on U.S. Bureau of Labor Statistics (BLS) Occupational Employment and Wages, May 2010, for Medical and Health Service Managers, Standard Occupational Classification 11-9111. Forty percent was added to the mean hourly wage of $45.03 to account for benefits and the total was rounded to $63.

[2] While it is possible to submit reports with a slower, dial-up, connection, we believe most manufacturers and importers that do not have high-speed connections already would upgrade their Internet access because it is more efficient. The efficiencies of high speed Internet access could also benefit other parts of firms' business systems.

software and Java security policy files for their Internet browser) for manufacturers and importers who maintain paper records. FDA assumes it could take about 40 hours for manufacturers and importers who maintain electronic records (and thus need extra time to ensure that their systems can communicate with FDA ESG). These time totals also include the time required to notify FDA, run a test submission through the FDA ESG, and to train the appropriate staff to use the new program. FDA also assumes that almost all medical device manufacturers and importers will use this method to submit MDRs. Using an average wage of $52 for computer and mathematical occupations,[3] we estimate the cost to install and use the software to be between $25.2 million and $29.4 million [((8 hours x $52 wage x 10,050 manufacturers and importers) + (40 hours x $52 wage x 10,050 manufacturers and importers)) to ((16 hours x $52 wage x 10,050 manufacturers and importers) + (40 hours x $52 wage x 10,050 manufacturers and importers))].

Entities that submit a large number of MDRs each year may choose to use the HL7 ICSR method to submit the reports. This method allows for the batch submission of multiple MDRs at faster transmission rates. The Agency does not know the threshold at which it becomes cost effective for an entity to submit medical device reports using this method. An analysis of FDA submission data for a 6-year period indicated that about 20 medical device manufacturers submit 500 or more MDRs each year and about 85 submit close to 100 medical device reports per year. We assume that the actual number of entities that would begin using the HL7 ICSR as a result of this rule would fall somewhere within this range (20 to 105). We also assume that only entities

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[3] BLS Occupational Employment and Wages, May 2010 by occupation, for all industries (http://www.bls.gov). Wage ($52) includes mean hourly wage of $37.13 for Standard Occupational Classification 15-0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits and rounded to $52 for ease of calculations. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

that have existing infrastructure to support HL7 ICSR transmissions would choose this method to submit MDRs. We estimate that it will take about 50 hours to set up their gateway to be compatible with the Agency's system. Using the wage $52, the one-time cost for establishing HL7 ICSR submission capabilities will range between $52 thousand and $273 thousand [($52 x 50 hours) x 20 entities) and ($52 x 50 hours) x 105 entities)].

c. Electronic certificates. All entities will need an electronic certificate to submit any electronic regulatory document to the FDA ESG. The electronic certificate identifies the sender and serves as an electronic signature. Entities that have not submitted any electronic documents to the Agency will incur a one-time cost to acquire the certificate and recurring costs to keep the certificate active as a result of this final rule. The certificates cost about $20 and are valid for one year. We assume that the search and transactions costs involved in the initial acquisition of the certificate doubles the cost of the certificate to a total cost of $40 for the first year, half of which would be setup costs. If all entities needed to acquire electronic certificates, the one-time initial costs of the certificates would be $402,000 ($20 initial acquisition cost x 20,100 entities).

d. Summary of one-time costs. In addition to the costs we have estimated, manufacturers and importers affected by this final rule may have to hire outside experts to install and validate the software installation to comply with these requirements.

Table 1 of this document summarizes the estimated one-time costs for this rule. The estimate of the total one-time costs for all affected entities ranges from $38.4 million to $42.8 million. Much of the cost involves acquiring the electronic certificate to submit any regulatory document to the FDA, including installation and validation of the eSubmitter software or establishment of HL7 ICSR capabilities. For this analysis we assume all manufacturers and

importers will incur these costs when in fact some already have electronic certificates and voluntarily submit MDRs electronically.

Table 1.--Summary of One-Time Costs ($ million)

Industry	Modifying SOPs	Install and Validate eSubmitter Software		Establish HL7 ICSR capability		Acquiring e-Certificate[1]	Total	
		Low	High	Low	High		Low	High
One-time costs	12.7	25.2	29.4	0.05	0.3	0.4	38.4	42.8
Annualized at 3-percent over 10 years							4.5	5.0
Annualized at 7-percent over 10 years							5.5	6.1

[1]This refers to the $20 initial cost to acquire the e-certificate; the rest of the cost of the certificate is captured in the calculation of annual costs.

2. Annual Costs

The annual costs of this final rule will include the costs of:

• Maintaining certificates and

• High-speed Internet access.

a. Maintaining electronic certificates. Manufacturers and importers will bear the cost of maintaining the electronic certificate that identifies the sender. In addition to having to renew the certificate on a regular basis, those entities who have not submitted MDRs will also have to ensure that they are capable of transmitting electronic MDRs to FDA should such a report submission be necessary. To add these costs to the cost of the certificate itself, we assume that entities will incur an additional annually recurring cost equal to one-half the price of the certificate ($10), for a total annually recurring cost of $30. If all manufacturers and importers need to acquire electronic certificates, the annual cost would be $0.6 million ($30 acquisition certificate renewal and acquisition cost x 20,100 entities).

b. High-speed Internet access. We have assumed that entities will also use high-speed Internet access to use either of the submission methods. A 2010 study of small businesses

sponsored by the Small Business Administration (SBA) found that essentially all small firms had Internet access and about 80 percent had high-speed Internet access (Columbia Telecommunications Corp., 2010). The average cost of high speed access was about $40 per month more than dial-up access. Because the average medical device manufacturer is very small and very small firms had somewhat lower access than the average, we estimate that by the time this final rule is in effect, about 75 percent of manufacturers and importers will have high speed access. The average annual recurring increase in cost for high speed Internet access for the remaining 25 percent of the entities would be approximately $2.4 million (($40 x 12 months) x 0.25 x 20,100 manufacturers and importers).

c. Summary of annual costs. The annual costs of the rule are $3 million ($0.6 million for electronic certificates + $2.4 million for internet access). As with the one-time costs, only entities not already making electronic regulatory document submissions of any kind to the Agency when this rule is published will incur these costs. There will be no change in the actual time required to research and prepare the MDRs, nor will there be any additional reporting requirements as a result of this final rule. Manufacturers and importers that maintain Form FDA 3500A records in paper format for their internal MDR files can still do so under this final rule.

d. Cost savings. FDA estimates an industry savings of about $9.2 million annually because electronic submission should reduce the time it takes to submit documents and reduce postage expenditures. The time savings estimate was derived using the estimated savings (i.e., from reduced burdens) reported in section VII of this document. Device manufacturers and importers are expected to save a weighted average of 0.89 hours per submission. Savings from reduced postage costs will be around $0.4 million. FDA assumed that without this rule the

Agency would continue to receive about 190,000 submissions in paper format.[4] FDA calculated the total savings as 190,000 submissions x 0.89 hour savings x $52 wage cost per hour + .8 x [(1,630 firms x 12 months x ($5 flat rate priority mail + $20 flat rate express mail))].[5]

D. Regulatory Alternatives to the Final Rule

The Agency identified and assessed two additional regulatory alternatives to this final rule. The first of these alternatives would allow manufacturers and importers to voluntarily submit MDRs electronically. This regulatory alternative would allow firms to choose paper or electronic submissions, but would require any electronic submissions to use either the eSubmitter or the HL7 ICSR. This alternative would reduce the one-time set costs (see Table 1 of this document) for firms choosing not to make electronic submissions; those firms would also fail to realize corresponding savings. For many firms, the expected private costs of adopting electronic submissions will exceed expected private benefits due to having higher discount rates, higher costs than the averages presented here, or shorter planning horizons than the 10 years used in this analysis; FDA therefore expects that under this alternative a number of medical device firms would resist changing their procedures for a long period of time, perhaps indefinitely. If a substantial number failed to voluntarily adopt electronic submission of MDRs, FDA would not obtain the benefits of standardized formats and quicker access to medical device adverse event data. The Agency would also have to maintain significant capacity for accepting and processing written MDRs. A voluntary system, therefore, would fail to achieve the public health benefits and efficiency goals of the final rule.

[4] The estimated 190,000 submissions from 1,630 firms are based on the number of submissions for 2011.
[5] This estimate differs from the paperwork estimates in section VII of this document because it measures the incremental change from current practice rather than the time to comply with specific requirements. Postage was calculated using flat rate charges by the United States Postal Service and assuming that 80 percent of the firms submitting paper MDRs in a given year would submit one express package and one priority mail package per month.

The second regulatory alternative would allow small entities more time to comply with the electronic submission requirements. This alternative would allow small entities to delay compliance. Under this alternative, FDA would not achieve meaningful data entry savings from requiring electronic submissions or all the benefits of quicker access to these reports until the small entity compliance date. Because so many device companies are small entities, and in many cases their private costs will exceed their private benefits, small entities would likely postpone compliance, which would significantly postpone the benefits the rule is intended to confer. As shown in the following section, the estimated incremental costs per small entity from the final rule are small, so the cost reduction per small entity from delayed compliance would also be small. Moreover, postponing compliance would not reduce the future setup costs once the later compliance date is reached. In other words, postponing compliance would simply postpone the costs and benefits with no change in their amounts.

III. Regulatory Flexibility Analysis

SBA defines a small medical device manufacturer as having fewer than 500 employees (NAICS 325413, 334510, 334517, 339112, 339113, 339114, and 339115). Over 90 percent of registered device firms affected by this final rule are considered small entities under this definition. While this final rule will now require many MDR reports submitted to the Agency to be in electronic format, the content of a report is not being changed from that already addressed on the paper Form FDA 3500A. The average costs for these manufacturers and importers are listed in Table 2 of this document. The average total annualized cost per small entity, assuming

a 7-percent discount rate over 10 years, would range from $590 to $720 ($575 to $680 at a 3-percent discount rate).

Because the costs per affected entity are low compared to revenues, FDA finds that although this final rule will affect a substantial number of small entities, it will not have a significant economic impact on those entities. For example, for a facility in NAICS 339114, dental equipment and supplies, which have the lowest value of shipments of all affected industries, $4.4 million, $721 in annualized costs represents about 0.02 percent of revenues. We therefore certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Table 2.--Incremental Compliance Costs per Small Entity

	One-Time Costs		Annually Recurring	Total Annualized	
	Low	High		Low	High
Rewriting SOPs	123	613			
Software Installation and Validation Of Installation	411	822			
Acquiring Electronic Certificate	40				
Maintaining Submission Capabilities			30		
Upgrade Internet Access			480		
7-Percent Discount Rate				590	720
3-Percent Discount Rate				575	680

IV. References

1. U.S. Census Bureau, 2007 Economic Census Industry Series: NAICS Code 62, Health Care and Social Assistance, (http://www.census.gov), April 1, 2011.

2. BLS Occupational Employment and Wages, May 2009 for Medical and Health Service Managers, Standard Occupational Classification, 11-19111, (http://www.bls.gov), April 1, 2011.

3. Columbia Telecommunications Corp., The Impact of Broadband Speed and Price on Small Business, SBA Office of Advocacy Contract Number SBAHQ-09-C-0050, (http://archive.sba.gov/advo/research/rs373tot.pdf), November, 2010.