DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be Required in Electronic Format

Docket No. FDA-2018-N-0628

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

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation and International Affairs
Office of the Commissioner

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final 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 the final rule amends the existing premarket regulations requiring multiple copies and paper submissions to instead require submissions in electronic format without imposing any new requirements, we certify that the final 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 $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule will amend device regulations describing the number of copies firms must submit with a premarket pre-submission or submission. The final rule will also amend all device regulations containing a reference to the specific form of a submission to require a submission in electronic format. The final rule will produce cost-savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency's ability to review submissions. Firms will incur minimal administrative costs to read and understand the rule. We expect the economic impact of this regulation to be a total net cost savings yielding positive net benefits.

In Table 1, we summarize the benefits, costs, and distributional effects of the final rule. We estimate that the final rule will result in annualized benefits of $1.76 million at a 3 percent discount rate and $1.76 million at a 7 percent discount rate, over 10 years. We also estimate that the final rule will result in annualized costs of $0.75 million at a 3 percent discount rate and $0.87 million at a 7 percent discount rate, over 10 years.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$1.76	$0.63	$3.73	2017	7%	10 years	All benefits are cost savings.
		$1.76	$0.63	$3.73	2017	3%	10 years	
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized ($m/year)	$0.87	$0.87	$0.87	2017	7%	10 years	
		$0.75	$0.75	$0.75	2017	3%	10 years	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)							
		From:			To:			
	Other Annualized Monetized ($m/year)							
		From:			To:			
Effects	State, Local, or Tribal Government: None Small Business: None Wages: None Growth: None							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a 7 percent discount rate, the estimated annualized net cost-savings equal $1.31 million in 2016 dollars over an infinite horizon. Based on these cost savings, this final rule is considered a deregulatory action under EO 13771.

Table 2. EO 13771 Summary Table (in $ Millions 2016 Dollars, Over an Infinite Time Horizon)

	Primary Estimate (7%)	Primary Estimate (3%)
Present Value of Costs	$6.43	$6.43
Present Value of Cost Savings	$26.45	$59.40
Present Value of Net Costs	($20.01)	($52.97)
Annualized Costs	$0.42	$0.19
Annualized Cost Savings	$1.73	$1.73
Annualized Net Costs	($1.31)	($1.54)

C. Comments on the Preliminary RIA and Our Responses

In 2018, we published the proposed rule "Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be allowed in

Electronic Format" (83 FR 46444). We prepared a comprehensive Preliminary Regulatory Impact Analysis for the 2018 proposed rule.[1] We did not receive any comments on our analysis.

D. Summary of Changes

We have updated the numbers in our preliminary impact analysis to account for more recent data on wages, prices, the number of submissions, the average length of submissions, and the number of medical device firms.

II. Final Regulatory Impact Analysis

A. Background

An eCopy is an electronic version of a device-related submission on a CD, DVD, or flash drive. Under current regulation, FDA requires the submission of one paper copy and at least one eCopy for many types of premarket pre-submissions and submissions. In some cases, such as for original Premarket Approvals (PMAs), sponsors must include multiple eCopies in addition to the paper copy. In Table 3, we describe the number of paper copies and the number of eCopies required for different types of device-related submissions under current regulation (Ref. 1).

Table 3. Current Requirements for Device-Related Submissions

Submission Type	Number of Full Paper Copies Required	Number of eCopies Required
Premarket Notifications (510(k)s)	1	1
Original Premarket Approvals (PMAs) and Humanitarian Device Exemptions (HDEs)	1	5
Panel-Track Supplements[a]	1	5
180-Day Supplements[a]	1	5
Real-Time Supplements[a]	1	2
30-Day Notices[a]	1	2
135-Day Supplements[a]	1	2
Annual Reports[a]	1	1
Post-Approval Study Reports[a]	1	1
Modular PMAs or HDEs	1	2
Average over All Types of PMAs or HDEs	1	2.78
Investigational Device Exemptions (IDEs)	1	2

[a] Indicates a supplement, report, or notice for a PMA or HDE.

B. Market Failure Requiring Federal Regulatory Action

Our current regulations have created an institutional failure by preventing industry and the Agency from adopting more efficient and less costly technologies to submit certain medical device applications. Given the ease of sharing and downloading a submission across multiple reviewers from a single eCopy, requiring multiple eCopies for each submission is unnecessary for our reviewing purposes. Additionally, our reviewers typically use electronic versions of submissions rather than paper copies. Premarket submissions are often thousands of pages long.

[1] Available at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm611569.htm.

The paper copy requirement therefore makes pre-market submissions unnecessarily costly for firms and burdensome for the Agency.

C. Purpose of the Rule

Under the final rule, we will eliminate the paper copy requirement for the types of submissions listed in Table 4. The final rule will also eliminate the paper copy requirement for related pre-submissions. Premarket pre-submissions are requests from submission sponsors for feedback from our staff on their premarket submissions. In lieu of a paper copy, firms will submit only a single copy in an electronic format. This copy may be an eCopy or an eSubmission, an electronic submission that sponsors transmit over the Internet. Therefore, the final rule will correct the institutional failure created by the unnecessary submission requirements in current regulations.

In Table 4, we summarize the new submission requirements under the final rule. The final rule will not amend regulations regarding submission types for which submissions in electronic format are voluntary, including compassionate use IDEs, Emergency Use IDEs, Emergency Use Authorizations, Device Master Files, and Requests for Information. The rule will also not change the eCopy requirements for Biologics License Applications and Investigational New Drug Applications.

Table 4. New Requirements for Device-Related Submissions

Submission Type	Number of Full Paper Copies Required	Number of Copies in Electronic Format Required
510(k)s	0	1
Original PMAs and HDEs	0	1
Panel-Track Supplements[a]	0	1
180-Day Supplements[a]	0	1
Real-Time Supplements[a]	0	1
30-Day Notices[a]	0	1
135-Day Supplements[a]	0	1
Annual Reports[a]	0	1
Post-Approval Study Reports[a]	0	1
Modular PMAs or HDEs	0	1
Average over All Types of PMAs or HDEs	0	1
IDEs	0	1

[a] Indicates a supplement, report, or notice for a PMA or HDE.

D. Baseline Conditions

In Table 5, we estimate the number of device-related submissions described in Table 3 and Table 4 using data from 2018. We estimate that FDA receives between 20,050 and 36,300 of these submissions annually.

Table 5. Number of Annual Submissions[2] by Submission Type

[2] Includes supplements, amendments, and reports.

Submission Type	Low Estimate	High Estimate
510(k)s	10,000	15,000
PMAs	5,000	6,000
HDEs	50	300
IDEs	5,000	15,000
Total	20,050	36,300

E. Benefits of the Rule

The final rule will eliminate the requirement that firms mail a full paper copy of their submission to the Agency. Submissions are, on average, hundreds of pages long, and some are much longer.[3] Such submissions are costly to print and ship. We expect that firms will instead only submit a paper copy of the submission's cover letter, an approximately 3-page document. Firms will therefore benefit from reduced printing and shipping costs.

Currently, firms must mail multiple eCopies to FDA for multiple types of medical device premarket pre-submissions and submissions. The final rule will reduce the number of electronic copies required for many submission types, eliminating the need to produce multiple eCopies. As a result, firms will benefit from reduced costs for eCopy media.

1. Assumptions

Sending a copy of a medical device premarket pre-submission or submission over the Internet is less costly than mailing an eCopy, because it does not require the purchasing of CDs, DVDs, or flash drives or paying mailing costs. However, based on the firms' low adoption of the eSubmission program for 510(k) submissions, we expect that most sponsors will submit submissions as eCopies under the final rule. For the purpose of this analysis, we conservatively assume that all firms will mail eCopies of their medical device premarket pre-submissions and submissions instead of sending eSubmissions over the Internet. To the extent that firms submit eSubmissions instead of eCopies in response to the final rule, our analysis underestimates the net benefits of the final rule.

Given this assumption, and the information in Table 3 and Table 4, Table 6 shows our assumptions about the reduction in the number of full paper copies and eCopies submitted for each submission type under the final rule.

Table 6. Change in Submission Requirements for Device-Related Submissions

Submission Type	Reduction in Number of Full Paper Copies Required	Reduction in Number of eCopies Required
510(k)s	1	0
Original PMAs and HDEs	1	4
Panel-Track Supplements[a]	1	4
180-Day Supplements[a]	1	4
Real-Time Supplements[a]	1	1
30-Day Notices[a]	1	1

[3] The average original PMA submitted in 2018 was over 25,000 pages long.

135-Day Supplements[a]	1	1
Annual Reports[a]	1	0
Post-Approval Study Reports[a]	1	0
Modular PMAs or HDEs	1	1
Average over All Types of PMAs or HDEs	1	1.78
IDEs	1	1

[a] Indicates a supplement, report, or notice for a PMA or HDE.

Based on current data from device-related submissions, we assume that each submission is, on average, 700 pages long, with a low estimate of 400 pages and a high estimate of 1,000 pages. We also assume that, under the final rule, firms will submit a 3-page paper copy of each submission's cover letter with the eCopy by priority mail using the United States Postal Service or FedEx.

2. Printing Cost Savings

In 2017 dollars, a piece of paper costs between $0.01 and $0.02 per page (Ref. 2). The cost of printing black-and-white ink ranges from $0.04 to $0.06 per page (Ref. 3). Therefore, the total cost of printing per pages ranges from $0.05 to $0.08 per page.

Table 7 shows our estimates of the printing cost savings from the final rule. The final rule will benefit firms by avoiding the cost to print a paper copy of each submission. On average, the Agency receives 26,175 submissions annually each 700 pages long. We assume that under the final rule firms will instead submit only a single eCopy and a 3-page copy of the cover letter. The average annual reduction in the number of pages printed for submission to FDA will equal around 18.24 million pages.

The total annual cost savings from printing fewer pages equals the cost to print a page times the reduction in the number of printed pages with the final rule. We estimate that the cost savings from printing fewer pages will range from $0.38 million to $2.64 million annually, with a primary estimate of $1.18 million.

Table 7. Estimated Annual Printing Cost Savings[a]

Row Number	Value	Low Estimate	Primary Estimate	High Estimate	Source
(1)	Total Annual Submissions	20,050	26,175	32,300	Table 5
(2)	Baseline Pages per Submission	400	700	1,000	CDRH
(3)	Final Rule Pages per Submission	3	3	3	Final Rule
(4)	Reduction in Pages per Submission	397	697	997	Row 2 - Row 3
(5)	Total Annual Reduction in Pages Submitted	7,959,850	18,243,975	32,203,100	Row 1 * Row 4
(6)	Cost of Paper per Page	$0.01	$0.01	$0.02	Ref (2)
(7)	Cost of Ink per Page	$0.04	$0.05	$0.06	Ref (3)
(8)	Total Cost of Printing per Page	$0.05	$0.06	$0.08	Row 6 + Row 7

(9)	**Annual Printing Cost Savings**	**$380,275**	**$1,184,577**	**$2,643,403**	**Row 5 * Row 8**

[a] Values presented in this table are rounded.

3. eCopy Media Cost Savings

In Table 8 and Table 9, we show our estimate of the annual cost savings from fewer eCopy Media for PMAs, HDEs, and IDEs. By reducing the number of eCopies needed for some types of submissions, the final rule will produce additional cost savings for fewer eCopy media. In 2017 dollars, the least expensive type of eCopy media is a CD which costs on average $0.20 per unit.[4] DVDs cost $0.29 per unit on average, and flash drives cost $2.40 per unit on average. If we assume that firms submit one-third of eCopies as CDs, one-third of eCopies as DVDs, and one-third of eCopies as flash drives, then the average cost per eCopy is $0.95.

Firms must currently submit more than one eCopy for some types of PMAs and HDEs, including original PMAs and HDEs and supplements to PMAs and HDEs. As shown in Table 6, the final rule will decrease the average number of eCopies required per PMA or HDE submission by between 0 and 4 eCopies, with a primary estimate of 1.78 eCopies.[5] The total annual reduction in the number of eCopies submitted for PMAs or HDEs will range from 0 to 25,200 eCopies, with a primary estimate of 10,089 eCopies.

Table 8. Annual eCopy Media Cost Savings from PMAs and HDEs[a]

Row Number	Value	Low Estimate	Primary Estimate	High Estimate	Source
(1)	Cost of eCopy Media	$0.20	$0.95	$2.40	Amazon
(2)	Annual PMAs Submitted	5,000	5,500	6,000	Table 5
(3)	Annual HDEs Submitted	50	175	300	Table 5
(4)	Annual PMAs and HDEs Submitted	5,050	5,675	6,300	Row 2 + Row 3
(5)	Baseline eCopies per Submission	1	2.78	5	eCopy Guidance
(6)	Final Rule eCopies per Submission	1	1	1	Final Rule
(7)	Reduction in eCopies per Submission	0	1.78	4	Row 5 - Row 6
(8)	Total Annual Reduction in eCopies Submitted	0	10,089	25,200	Row 4 * Row 7

[4] All eCopy media unit cost estimates derived from an Amazon search.

[5] Annual Reports and Post-Approval Study Reports for PMAs and HDEs currently require only a single eCopy, and the final rule will not change their submission requirements. Other submissions, like Original PMAs or HDEs, Panel-Track Supplements, and 180-Day Supplements, require 5 eCopies. If we receive only Annual Reports and Post-Approval Study Reports each year, then the average reduction in the number of eCopies per PMA or HDE submission will be 0 eCopies. If we receive only Original PMAs, Panel-Track Supplements, or 180-Day Supplements in a year, then the average reduction in the number of eCopies per PMA or HDE submission will be 4 eCopies. If we receive an equal number of all types of PMAs and HDEs in a year, then the average reduction in the number of eCopies required per PMA or HDE submission will be 1.78 eCopies.

(9)	**Annual eCopy Media Cost Savings for PMAs and HDEs**	**$0**	**$9,630**	**$60,456**	**Row 1 * Row 8**

[a] Values presented in this table are rounded.

Firms must also submit more than one eCopy for eligible IDEs. As shown in Table 6, the final rule will reduce the number of eCopies required for each IDE by 1 eCopy per submission. The total annual reduction in the number of eCopies submitted for IDEs will range from 5,000 to 15,000 eCopies, with a primary estimate of 10,000 eCopies. Using our estimated cost of eCopy media, the annual cost savings from fewer eCopy media will range from $0.00 million to $0.10 million, with a primary estimate of $0.02 million.

Table 9. Annual eCopy Media Cost Savings from IDEs[a]

Row Number	Value	Low Estimate	Primary Estimate	High Estimate	Source
(1)	Cost of eCopy Media	$0.20	$0.95	$2.40	Amazon
(2)	Annual IDEs Submitted	5,000	10,000	15,000	Table 5
(3)	Baseline eCopies per Submission	2	2	2	eCopy Guidance
(4)	Final Rule eCopies per Submission	1	1	1	Final Rule
(5)	Reduction in eCopies per Submission	1	1	1	Row 4 - Row 3
(6)	Total Annual Reduction in eCopies Submitted	5,000	10,000	15,000	Row 2 * Row 5
(7)	**Annual eCopy Media Cost Savings for IDEs**	$978	$9,545	$35,986	**Row 1 * Row 6**

[a] Values presented in this table are rounded.

4. Shipping Cost Savings

The final rule will reduce the size and weight of submissions shipped to FDA. Based on baseline practices by industry and the recommendations of the eCopy guidance (Ref. 1). we assume that firms ship all submissions using 2-day priority, flat-rate mail. We obtain data on shipping costs using information from FedEx and the USPS websites. Based on information from CDRH, most firms use FedEx. We assume that baseline submissions fit in a large box. Given this assumption, the baseline shipping cost per submission in 2017 dollars ranges from $19.56, using the flat-rate USPS shipping cost, to $54.43, using the national, flat-rate FedEx shipping cost. The average cost of shipping a baseline submission equals $36.99.

We assume that firms will switch to a padded envelope under the final rule. Given this assumption, the shipping cost per submission ranges from $7.40, using the flat-rate USPS shipping cost, to $23.83, using the national, flat-rate FedEx shipping cost. The average cost of shipping a submission equals $15.62. Therefore, the final rule will reduce the shipping cost per submission by between $12.16 and $30.60, with a primary estimate of $21.38.

In Table 10, we show our estimate of the total annual cost savings from reduced shipping costs. The shipping cost savings range from $0.24 million to $0.99 million, with a primary estimate of $0.56 million.

Table 10. Annual Shipping Cost Savings of the Final Rule[a]

Row Number	Value	Low Estimate	Primary Estimate	High Estimate	Source
(1)	Total Annual Submissions	20,050	26,175	32,300	Table 5
(2)	Baseline Shipping Cost per Submission	$19.56	$36.99	$54.43	USPS & Fedex
(3)	Final Rule Shipping Cost per Submission	$7.40	$15.62	$23.83	USPS & Fedex
(4)	Reduction in Shipping Cost per Submission	$12.16	$21.38	$30.60	Row 2 - Row 3
(5)	**Annual Shipping Cost Savings**	**$243,806**	**$559,567**	**$988,248**	**Row 1 * Row 4**

[a] Values presented in this table are rounded.

5. Total Benefits of the Final Rule

In total, the final rule will save firms between $0.63 million and $3.73 million in avoided shipping, printing, and eCopy media costs annually (Table 11). Over 10 years, the present value of the total benefits of the final rule at a 3 percent discount rate will range from $5.49 million to $32.76 million, with a primary estimate of $15.49 million. Over 10 years, the present value of the total benefits of the final rule at a 7 percent will range from $4.70 million to $28.02 million, with a primary estimate of $13.25 million.

Table 11. Total Benefits of the Final Rule ($ millions)

Value	Low Estimate	Primary Estimate	High Estimate
Total Annual Benefits	$0.63	$1.76	$3.73
Present Value of Benefits over 10 years (3%)	$5.49	$15.49	$32.76
Present Value of Benefits over 10 years (7%)	$4.70	$13.25	$28.02

F. Costs of the Rule

Firms that plan to submit any of the affected submission types shown in Table 6 will incur one-time costs to read and understand the final rule and the one-time costs to change their SOPs. Assuming an average reading speed of 200 words per minute, we estimate that general management at existing firms will require approximately 0.5 hours to read and understand the rule and 1.5 hours to change their SOPs. An update of the eCopy guidance published with this final rule helps keep the time needed to understand the rule to a minimum. Because we already require at least one eCopy for the submission types affected by this rule, there are no incremental training costs to produce eCopies.

The mean hourly wage rate for a manager in the medical equipment and supplies manufacturing industry in 2017 is $68.96. Assuming benefits equal 100 percent of hourly

wages, the mean cost of an hour of labor is $137.92. The one-time incremental administrative cost per firm will be $275.84 (2 hours × $137.92).

According to our registration data, 23,764 firms registered as medical device establishment owner-operators in 2018. We assume that all medical device firms will immediately change their standards of practice to reflect the new submission requirements. Given this assumption, the total one-time administrative cost of the rule will be $6.56 million. The annualized cost over 10 years equals $0.75 million at a 3 percent discount rate and $0.87 million at a 7 percent discount rate.

This value likely overstates the cost of the rule. Firms may not read the rule and change their standards of practice until they prepare a new submission. Not all firms prepare a new submission each year. In this case, fewer firms will incur the one-time administrative cost, and those firms that will change their standards of practice may stagger their response to the final rule.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the total, one-time costs of the final rule will only include small administrative costs to read and understand the rule (approximately $276 per firm), we certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

1. **U.S. Food and Drug Administration**, eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff. 2015. Available from: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf.
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