DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Revising the National Drug Code Format and Drug Label Barcode Requirements

Docket No. FDA-2021-N-1351

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

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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 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 the one-time cost could be as much as 0.56 percent of average annual revenue for some very small stakeholders in the insurance industry, 0.45 percent of average annual revenue for some very small stakeholders in the pharmaceutical industry, and 0.02 percent of average annual revenue for some very small stakeholders in the healthcare industry, we propose to certify that the proposed rule, if finalized, would 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 $165 million, using the most current (2021) 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 proposed rule, if finalized, would amend regulations governing the format of the National Drug Code (NDC) by standardizing the format of NDCs to be 12 digits in length. Currently FDA-assigned NDCs are 10-digits and can be in multiple formats. The NDC for each listed drug in the United States is a unique 3-segment number, where the 3 segments are the labeler code, product code, and package code. The proposed standardized NDC would consist of three segments: a 6-digit labeler code, a 4-digit product code, and a 2-digit package code. If the proposed rule is finalized, FDA-assigned 10-digit NDCs would need to be updated to convert to the uniform 12-digit format by adding leading zeros to the respective segments.

One expected benefit of the proposed rule, if finalized, is that the proposed standardized format would facilitate the adoption of a single NDC format by all stakeholders. Such an adoption would eliminate the need to convert NDCs from one of the FDA prescribed formats to a different standardized format used by other sectors of the healthcare industry (e.g., healthcare providers and payors). Eliminating the need to convert NDCs should reduce potential errors caused by converting from the FDA-assigned NDC format to a different format used by other sectors of the healthcare industry. Standardization and adoption of a single format would also eliminate the need for additional quality control and validation by certain stakeholders, such as payors and prescribers, to ensure a drug product and its respective NDC are accurate; this is

particularly important for insurance coverage and reimbursement claims. Another benefit of the rule would be to avoid any potential risks to the public health from potential reductions in medication errors and risk of confusion. We do not have data to quantify these potential benefits and request comments.

The costs to industry of converting current NDC codes to the proposed format would include one-time costs of updating software systems, new training for employees, coordinating labeling updates, and reading and understanding the rule. Table 1 shows a summary of the quantified costs of the proposed rule. We estimate annualized costs would be about $12.4 million ranging from $6.1 million to $19.4 million using a 7-percent discount rate over a ten-year horizon. Similarly, we estimate annualized costs would be about $10.2 million ranging from $5.1 million to $16.0 million using a 3-percent discount rate over a ten-year horizon. The present-value of the estimated costs would be $87.1 million ranging from $43.1 million to $136.3 million at both the 7- and 3-percent discount rates.

Table 1. Summary of Benefits, Costs and Distributional Effects of Proposed Rule ($millions 2020)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year				2020	7%		
					2020	3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential reductions in annual audits, billing issues, cost of software, and medication error.						
Costs	Annualized Monetized $millions/year	$12.4	$6.1	$19.4	2020	7%	10 years	
		$10.2	$5.1	$16.0	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers						7%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Federal Annualized Monetized $millions/year					3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No estimated effect. Small Business: One-time cost could be no more than 0.56 percent of annual revenue for some very small stakeholders with fewer than 5 employees in the insurance industry, 0.45 percent in the pharmaceutical industry, and 0.02 percent also for some very small stakeholders in the healthcare industry. Wages: No estimated effect. Growth: No estimated effect.							

II. Preliminary Economic Analysis of Impacts

A. Background

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires each person who registers an establishment under section 510(b), (c), (d), or (i) of the FD&C Act to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by the establishment for commercial distribution. The national drug code (NDC) is an FDA standard for uniquely identifying drug products in the United States.

Currently, NDCs assigned by the FDA contain 10 digits. NDCs consist of three segments: the labeler code, the product code, and the package code. The labeler code identifies the manufacturer, repacker, relabeler, or private label distributor of the drug. We have issued the labeler code as a unique 4-digit segment of the NDC code, and when they were exhausted, we issued 5-digit labeler codes. Similarly, when the 5-digit labeler

codes are exhausted, we will issue 6-digit labeler codes. Under existing regulations, once FDA begins assigning 6-digit labeler codes, FDA would add 2 new 11-digit NDC formats (6-3-2 and 6-4-1) to accommodate the longer labeler codes.

The second segment, the product code, is a 3- or 4-digit number that identifies a specific active ingredient, strength, and dosage form of a drug manufactured, repackaged, relabeled, or distributed by the labeler. The third segment, the package code, is a 1- or 2-digit number that identifies package sizes and types. Package codes differentiate between quantitative and qualitative attributes of the product packaging. Both the product and package codes are proposed by labelers submitting drug listings.

The NDC for a given drug is currently in one of the following configurations (with each number representing the number of digits in that segment): 4-4-2, 5-3-2, or 5-4-1. The current 5-digit labeler code format provides the FDA with 90,000 labeler codes that could be assigned to drug manufacturers and private label distributors ranging from 10000 to 99999. We anticipate running out of 5-digit labeler codes in approximately 10 to 15 years. Moving up to 6-digit labeler codes will expand NDCs to 11 digits and, per regulation, allows for two additional NDC configurations: 6-3-2 and 6-4-1, for a total of five possible NDC configurations (including the three 10-digit NDC configurations).

The Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104-191) contains provisions calling for the administrative simplification "of the national standards for electronic health care transactions and code sets, unique health identifiers, and security"[1] and specifically references the NDC. In its implementation of these rules, in August 2000, the Department of Health and Human Services (HHS) published a final

[1] See http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html (last accessed July 3, 2017).

rule on standards for electronic transactions that established NDC numbers as the standard medical data code set for reporting drugs and biologics in all standard transactions under HIPAA (65 FR 50313). In the preamble to the HIPAA regulations, HHS stated that it was adopting a uniform 11-digit format to conform with customary practice used in computer systems (65 FR 50313 at 50329). The HIPAA 11-digit NDC format is standardized such that the labeler code is always 5 digits, the product code is always 4 digits, and the package code is always 2 digits. To convert a 10-digit FDA-assigned NDC to an 11-digit HIPAA standard NDC, a leading zero has been added to the appropriate segment to create the 11-digit configuration as defined above.

This proposed rule would standardize all FDA-assigned NDCs using a single 12-digit NDC format such that the labeler code is always 6 digits, the product code is always 4 digits, and the package code always 2 digits. This proposed format means that FDA would not issue any NDCs using an 11-digit format to mitigate risks associated with a potential overlap with FDA 10-digit NDCs that are converted to the 11-digit HIPAA standard format. In addition, we anticipate FDA's adoption of a uniform 12-digit NDC format would avoid confusion and reduce the likelihood of medication errors because it would allow stakeholders to adopt FDA's new, uniform 12-digit format. We expect this adoption should eliminate the need for stakeholders to constantly convert a drug's FDA-assigned NDC to a different standardized format. Additionally, allowing for stakeholders to adopt FDA's 12-digit format may mitigate some economic burden pertaining to maintaining multiple systems or formats.

B. Need for Federal Regulatory Action

The exhaustion of 5-digit labeler codes and the impending introduction of 6-digit labeler codes would create additional NDC formats. Without the rule, there would be 11-digit NDCs (6-3-2 and 6-4-1), and in some cases where hyphens or spaces are not used, there could be potential confusion with the HIPAA 11-digit converted NDCs. Additionally, HIPAA 11-digit NDC standard, although 11 digits in length, would be unable to handle the new FDA 11-digit NDC format because the HIPAA 11-digit NDC standard can only handle labeler codes up to 5 digits. FDA recognizes that it could facilitate standardization of all NDCs to a single format and eliminate the need for continued conversions, if we implemented a standardized format for all FDA issued NDCs prior to issuing 6-digit labeler codes and if industry adopts it. Specifically, the rule would require pharmaceutical stakeholders to use a single 12-digit format; the rest of the stakeholders in the healthcare industry that also use NDCs numbers may adopt this standard even if not required. In order to have a single standardized NDC format, rulemaking is needed because FDA has established multiple different formats for NDCs, and these formats do not allow for standardization. An additional feature of the rule-making process includes facilitating public awareness of important timelines in the process.

C. Purpose of the Proposed Rule

This proposed rule, if finalized, would standardize all FDA-assigned NDCs to a single 12-digit format. As proposed, NDCs would continue to consist of three segments: the labeler code, the product code, and the package code. FDA is proposing that the

labeler code be 6 digits, the product code be 4 digits, and the package code be 2 digits. In addition, to allow flexibility on the type of barcode used on the label of a drug product, we are proposing to revise 21 CFR 201.25(c) to allow the use of either linear barcodes, which is the standard practice and are made up of either horizontal and vertical lines; or non-linear barcodes, such as two-dimensional codes as new technologies arise, so long as the barcode meets one of the FDA prescribed standards.

We propose to delay the effective date of the final rule for a period of 5-years following the publication of the final rule. This 5-year delay is intended to allow companies to make necessary changes to accommodate the new 12-digit NDC format and plan on updating their labeling following the effective date of the final rule. On the effective date of the final rule, we would begin assigning new NDCs in the uniform 12-digit format, and all 10-digit NDCs assigned by us prior to the effective date would be required to convert to this 12-digit NDC. In addition, we propose a 3-year transition period following the effective date. During this 3-year transition period, FDA does not intend to object if drugs that were assigned a 10-digit NDC prior to the effective date continue to be labeled with the 10-digit NDC. However, we encourage firms to start labeling such drugs with the new 12-digit NDC as soon as possible during this transition period. We therefore advise that labeling updating and reprinting is planned in a way that no labeling with 10-digit NDC remains in the market after the transition period ends. We believe the best way to ensure this is the case is by transitioning early in this 3-year transition period.

The purpose of the transition period is to mitigate the potential costs associated with re-printing product labels by allowing stakeholders to use their existing stock of

labels and by allowing them time to have a coordinated labeling update. At the end of the transition period (i.e., 8 years after the publication of the final rule), all firms will be required to use a 12-digit NDC in listing files. Also, all products that include the NDC on their labeling that are introduced, or offered for introduction, into interstate commerce after the end of the transition period will be required to use the 12-digit NDC format.

D. Baseline Conditions

We will begin assigning 6-digit labeler codes once we exhaust our current inventory of 5-digit labeler codes. We anticipate running out of 5-digit labeler codes in approximately 10 to 15 years. Issuing 6-digit labeler codes would happen with or without this rule. In a baseline world without the rule, NDC formats would include the current 4-digit and 5-digit labeler code formats (4-4-2, 5-3-2, or 5-4-1), and the new 6-digit labeler code format (6-3-2 and 6-4-1). This addition of two new formats would likely result in stakeholders having to maintain or update systems that can accommodate all these formats. In addition, the HIPAA standard may also need to be updated. Further, the barcode standard may not be able to accommodate FDA-assigned 11-digit NDCs.

NDC numbers are used widely across the healthcare system; according to our registration and listing records, the count of NDC numbers affected would range from 240,000 to 250,000. We expect the proposed rule, if finalized, would affect between 2,350 and 11,000 pharmaceutical stakeholders. The lower bound count is from the Pharmaceutical and Medicine Manufacturers counts, NAICS 3254, from the 2017 economic census.[2] The upper bound is from our establishment registration and drug

[2] United States Census Bureau, U.S. Department of Commerce, Statistics of U.S. Businesses. Accessed June 2020, www.census.gov/programs-surveys/susb.html.

product listing records. Insurers would also need to update their records. According to NAICS (524114) records, there are 5,409 medical insurer establishments.

The healthcare industry would also update their NDC records. This group includes hospitals, physician offices, nursing care facilities, pharmacies, dentist offices, residential health facilities, home healthcare, outpatient care centers, medical and diagnostic offices, medical equipment retailers, and other healthcare practitioners. NAICS records indicate the total count of these establishments is about 664,046 and that 5,544 of these are general medical and surgical hospitals.

Many federal and state offices that handle NDC records would be affected including the Centers for Medicare and Medicaid Services, the National Institutes of Health, Centers for Disease Control and Prevention, Health Resources and Services Administration, and the Indian Health Service. Some dispensers would be affected including the Bureau of Prisons, Veterans Affairs, and the Department of Defense. Other potentially affected government entities include the Drug Enforcement Agency. In addition, there may be multiple third-party data vendors that do not handle drugs but record marketing information such as sales and prices by NDC.

E. Benefits of the Proposed Rule

We expect that FDA's adoption of a standardized NDC format would result in benefits to both industry and consumers if industry also adopts it. We do not have enough information to quantify these benefits, and we only qualify them here. We welcome comments regarding these benefits or any others we do not discuss.

1. Quality Control and Costs Savings

We expect that stakeholders currently experience some ongoing quality control efforts when they convert their 10-digit NDCs assigned by the FDA to the 11-digit HIPAA standard. Quality control efforts may include validation to ensure that any NDC conversion from 10-digit NDCs to 11-digit NDCs result in accurate transactions. For example, these efforts may include internal transactions across departments within the same entity and external transactions related to the supply chain, contracts, and any other exchange of information outside the entity that involves NDC numbers. We also expect these quality control efforts are recurring but do not know their frequency. In addition, we do not have data on how much quality control efforts cost and request input from stakeholders.

Although FDA is not responsible for establishing the HIPAA standard formats, in the baseline without the rule, we would issue 11-digit NDCs instead of 12-digit NDCs, and expect that the HIPAA standard format would have to change to a new standard to be able to accommodate an NDC with a 6-digit labeler code. In addition, if the standardization begins with FDA and HHS adopts FDA's 12-digit NDC as the new HIPAA standard format for NDCs, industry will only need to manage one NDC format.

If the rule is finalized, we expect some initial quality control from stakeholders when 10-digit NDCs assigned by FDA are updated to FDA's standardized 12-digit NDC format. We expect these quality control efforts would occur after the effective date of the rule: 5-years after the rule is finalized and during the following 3-year transition period. However, we expect that after the transition period, quality control would no longer be needed as all FDA-assigned NDCs would be 12 digits and no more conversions would be

needed if HHS adopts FDA's proposed standardized format as the new HIPAA standard format. Any potential quality control costs, their frequency and dollar amount, during the transition period are uncertain. We request comment from stakeholders on quality control costs.

2. Other Benefits

We expect that the conversion of 10-digits to 12-digits with the rule would result in quality control cost savings as compared to the recurring conversion of 10-digits to 11-digits without the rule. We expect these cost savings because without the rule there are still multiple formats handled by industry even after a conversion has been performed. By contrast, a single uniform 12-digit format would facilitate adoption by HHS and industry. Although the rule cannot mandate this adoption, if this likely adoption occurs after the rule is finalized, there would likely be only one unified format if HHS adopts FDA's proposed standardized format as the new HIPAA standard format. We do not have data on these potential quality control cost-savings and request comment from stakeholders.

Having a standardized format may also reduce potential risks to public health. For example, medication errors may occur when there is confusion between NDCs and other numbers such as batch, model, or order number, that may use an overlapping 3-segment formats with fewer than twelve digits. These errors could result in using or prescribing the wrong drug or the wrong dose.

In addition to having a six-digit labeler portion of the code, the rule would also standardize the product and package portions of the NDC code to be 4-digits and 2-digits, respectively. This is already implied when we point out that the rule would result in a unified standard. We emphasize it here, however, to highlight that without the rule, not

only will there be different NDC lengths but also different formats for each length. This provision would have the benefit of having a complete standardization across all segments of the NDC.

F. Costs of the Proposed Rule

The incremental costs of the rule would come from converting current 10-digit to a unified 12-digit NDC format. We do not have direct cost estimates from a standardization involving NDC numbers. Instead, we use estimates relating to a similar conversion as a proxy. A 2004 RAND report, *The Costs and Benefits of Moving to the ICD-10 Code Sets* (Ref. 1), explores the cost associated with the transition from International Classification of Diseases ICD-9 to the ICD-10. The ICD codes classify diseases, injuries, health encounters, and inpatient procedures. Both ICD codes and NDC codes are both used in reimbursement claims and require coordination among multiple stakeholders.

Although, the ICD transition likely required more effort than the NDC transition described in this proposed rule, the RAND report describes implementation of changes by medical and insurance groups. We assume, based on our professional judgement, that the NDC transition would fall in the lower part of the distribution of the ICD transition. Therefore, we estimate the costs of the NDC transition to be 10% of costs relative to the ICD transition. We understand that cost estimates are sensitive to this assumption and present a sensitivity analysis, in Section II.I.1, reflecting NDC transition cost estimates of 1 percent, 5 percent, 25 percent, and 50 percent relative to the ICD cost estimates.

There are many stakeholders that use NDCs. To facilitate estimation and interpretation of estimates, we focus on three major stakeholder groups:[3]

- Pharmaceutical industry: reflects manufacturers, labelers, relabelers, and wholesalers.
- Healthcare industry: reflects hospitals, physician establishments, nursing care facilities, pharmacies, dentists, residential health, home healthcare, outpatient care centers, medical and diagnostic centers, medical equipment suppliers, other health practitioners.
- Insurance industry: reflects administrators of claims for private and public sponsored insurance plans, and other involved intermediaries.

The general costs we estimate across these groups include one-time costs to implement software updates and changes to NDC records, one-time costs to learn the rule and train staff, and recurring costs during the transition period to handle validation of transactions involving NDCs. We describe costs by category and aggregate them across the three industry groups: pharmaceutical, healthcare, and insurance.

1. Software and Updates of NDC Records

We anticipate that stakeholders would update their computer systems to convert 10-digit NDCs to the standardized 12-digit format. We assume that upon updating their systems to handle 12 digits, stakeholders would not lose capabilities to handle 10-digits as they transition. However, we request comment if this is not the case. Updating records may range from a simple task of adding leading zeros to more complex tasks of tracking

[3] We acknowledge that there are other stakeholders not included in our estimates such as data providers that use NDCs as drug product identifiers in their records but do not perform drug-specific transactions.

all parts of software systems that need to be updated and synchronized. The RAND report notes that software updates may be updated by third-party vendors that manage similar systems for multiple stakeholders or by stakeholders' in-house staff.

We use the RAND report to estimate the costs of both third-party vendors and internal staff. We assume that 10 percent reflects the level of effort for NDC updates relative to ICD-code updates. We believe the description of these costs in the RAND report suits the type of costs we expect for the pharmaceutical industry and welcome comments on our estimates. We use the GDP deflator to adjust the results to 2020 dollars.

We estimate the lower bounds for the pharmaceutical industry and the healthcare industry are $4.5 million, each. This estimate is the average of $50 million from internal staff and $16.7 million from third-party contractors from the 2004 RAND report. We then scale the average to ten percent to reflect the lower level of effort assumed for NDC conversion and update to 2020 dollars. We estimate the lower bound for the insurance industry is $9.5 million. This estimate reflects 10 percent of the average of $125 million from internal staff and $16.7 million from third-party contractors, updated to 2020 dollars. We estimate the combined lower bound estimate is $18.4 million (= $4.5 million for the pharmaceutical industry + $4.5 million for the healthcare industry + $9.5 million for the insurance industry).

We estimate the upper bounds for the pharmaceutical industry and the healthcare industry are $16.2 million, each. This estimate is the average of $200 million from internal staff and $41.7 million from third-party contractors from the 2004 RAND report. We then scale the average to ten percent to reflect the lower level of effort assumed for NDC conversion and update to 2020 dollars. We estimate the upper bound for the

insurance industry is $27.9 million. This estimate reflects 10-percent of the average of $375 million from internal staff and $41.7 million from third-party contractors, updated to 2020 dollars. We estimate the combined upper bound estimate is $60.3 million (= $16.2 million for the pharmaceutical industry + $16.2 million for the healthcare industry + $27.9 million for the insurance industry).

The primary estimate of expected costs from software and updates of NDC records is the average of the lower and upper bound estimates, or $39.4 million (= ($18.4 million + $60.3 upper bound) / 2). Table 2 shows these estimates in row 3.

We emphasize that these cost estimates represent the incremental cost if the rule is finalized compared to the baseline scenario without the rule. For example, without the rule, stakeholders would not need to convert their FDA-assigned 10-digit NDCs to an FDA-assigned 11-digit NDC, but it is possible that there could be some software costs to allow systems to handle the additional digit. Thus, the incremental cost from the proposed rule, if finalized, as compared to a baseline scenario without the rule, is the conversion of 10-digit NDCs to 12-digits.

2. Learning and Training Costs

Pharmaceutical, healthcare, and insurance staff would spend resources to learn to use the updated software and updates to NDC records. This cost would reflect time for meetings and trainings. The RAND report estimates this cost based on forty labor hours for the ICD conversion for about fifty thousand full-time coders employed in the hospital industry, which equates to between $100 million and $150 million in 2004 dollars. We expect that the NDC updates would take approximately five percent of the time, or two hours per coder, and adjust RAND estimates to reflect this assumption. We then use the

GDP deflator to adjust the results to 2020 dollars. We welcome comments on these estimates.

We estimate the lower bound for the pharmaceutical industry is $6.7 million (5 percent of $100 million from the RAND report, updated to 2020 dollars).[4] We estimate the lower bound costs for hospitals separate from the rest of healthcare industry. For hospitals, we assume the same estimate of $6.7 million calculated the same way as the pharmaceutical industry. For the rest of the healthcare industry, we use the RAND report estimates for part-time coders as we expect less effort to handle the conversion. The report estimates costs based on 200,000 part-time coders resulting in an estimate of $50 million. We assume the resulting learning and training cost estimates for the remainder of the healthcare industry would be $3.4 million (5 percent of $50 million adjusted to 2020 dollars). We estimate the learning and training costs to the insurance industry using the RAND report estimates of $25 million for one hundred and fifty thousand employees for the ICD conversion. Assuming that the NDC update is five percent of those estimated in the RAND report, we estimate that the lower bound for the insurance industry would be $1.7 million after adjusting to 2020 dollars. We estimate the combined lower bound estimate for all three industries would be $18.4 million (= $6.7 million for the pharmaceutical industry + $6.7 million for hospitals + $3.4 million for the rest of the healthcare industry + $1.7 million for the insurance industry).

We estimate the upper bound for the pharmaceutical industry is $10.1 million (5 percent of $150 million from the RAND report updated to 2020 dollars). We estimate the

[4] We do not have data on the number of coders employed in the pharmaceutical industry, and we assume the same number as in the hospital industry. This assumption likely overestimates the costs for the pharmaceutical industry.

upper bound costs for hospitals separate from the rest of healthcare industry. For hospitals, we assume the same estimate of $10.1 million calculated the same way as the pharmaceutical industry. For the rest of the healthcare industry, we use the RAND report estimates for part-time coders as we expect less effort to handle the conversion. The report estimates this cost to be $150 million. We assume the resulting learning and training cost estimates for the remainder of the healthcare industry would be $10.1 million (5 percent of $150 million, adjusted to 2020 dollars). We estimate the learning and training costs to the insurance industry using the RAND report estimates $50 million for 250,000 employees for the ICD conversion. Assuming that the NDC update is 5 percent of those estimate in the RAND report, we estimate the upper bound for the insurance industry to be $3.4 million after adjusting to 2020 dollars. We estimate the combined upper bound estimate is $33.5 million (= $10.1 million for the pharmaceutical industry + $10.1 million for hospitals + $10.1 million for the rest of the healthcare industry + $3.4 million for the insurance industry).

The primary estimate of expected costs to industry from learning and training is the average of the lower and upper bound estimates, or $26 million (= ($18.4 million + $33.5 million) / 2). Table 2 shows these estimates in row 4.

3. Reading and Understanding Costs

Pharmaceutical, healthcare, and insurance staff would incur one-time costs to read and understand the rule. We use 3 hours to read and understand the rule per stakeholder.

Following HHS guidance, this range is based on reading speed of 200 to 250 words per minute, which reflects low and high complexity.[5]

We estimate the lower bound by valuing the reader's time using the mean wage for an operation manager from the 2020 Bureau of Labor Statistics-Occupational Employment Statistics for Pharmaceutical and Medicine Manufacturing[6] and multiplying by two to reflect overhead and benefits. Using our count of 2,350 pharmaceutical stakeholders from the 2017 economic census of Pharmaceutical and Medicine Manufacturers, we estimate the lower bound cost of reading and understanding the rule, rounded to the nearest decimal, would be $1.1 million (= 3 hours to read the rule x $158.8 mean fully loaded wage x 2,350 labelers).

Although the rule would not require the healthcare and insurance industries to implement changes directly, the healthcare industry would likely read the rule to understand how changes to the pharmaceutical industry would impact them; however, the number of entities affected and the extent of effort to read and understand the rule are uncertain. Thus, we use the same estimate for reading and understanding costs of $1.1 million from the pharmaceutical industry as the reading and understanding costs to the healthcare and insurance industries. We estimate the combined lower bound estimate is $3.36 million (= $1.1 million for the pharmaceutical industry + $1.1 million for the healthcare industry + $1.1 million for the insurance industry).

We estimate the upper bound as follows. We use the mean wages for operation managers from the 2020 Bureau of Labor Statistics-Occupational Employment Statistics

[5] For further details, see "Guidelines for Regulatory Impact Analysis. US Department of Health and Human Services – May 2015 update."
[6] https://www.bls.gov/oes/current/naics4_325400.htm#11-0000

for Pharmaceutical and Medicine Manufacturing[7] and multiply by two to reflect overhead and benefits. We use a count of 11,000 pharmaceutical stakeholders from our listing and registration records. For the pharmaceutical industry, the resulting upper bound is $5.24 million (= 3 hours to read the rule x $158.8 mean wages x 11,000 labelers). As a conservative approach, we use the same estimates for reading and understanding costs from the pharmaceutical industry to reflect healthcare and insurance reading costs. Adding all estimates for the three industry groups the combined upper bound estimate is $15.7 million (= $5.24 million pharma + $5.24 million healthcare + $5.24 million insurance).

The primary estimate of expected costs to reading and understanding the rule is the average of the lower and upper bound estimates, or $9.5 million (= $3.4 million + $15.7 million) / 2). Table 2 shows these estimates in row 5.

4. Coordination of Label Updates

FDA is proposing to delay the effective date of the final rule for a period of 5-years following the publication of the final rule. On the effective date of the final rule, we would begin assigning new NDCs in the uniform 12-digit format, and all 10-digit NDCs assigned by us prior to the effective date would be required to convert to this 12-digit NDC. In addition, FDA is proposing a 3-year transition period following the effective date. During this 3-year transition period, FDA does not intend to object if drugs that were assigned a 10-digit NDC prior to the effective date continue to be labeled with the 10-digit NDC. However, we encourage firms to start labeling such drugs with the new 12-digit NDC as soon as possible during this transition period. We therefore advise that

[7] https://www.bls.gov/oes/current/naics4_325400.htm#11-0000

labeling updating and reprinting planned in a way that no labeling with a 10-digit NDC remains in the market after the transition period ends. We believe the best way to ensure this is the case is by transitioning early in this 3-year transition period. While relabeling costs can be avoided, we account for the time and effort that it would take pharmaceutical stakeholders to carry out this internal coordination of label updates. We use the 2014 Labeling Cost Model (LCM) Report from RTI, Inc. (the RTI Report) (Ref. 2) to estimate this one-time cost. The report describes these costs in terms of hours from general management and recordkeeping staff. The healthcare and insurance industries would not incur these costs.

For the lower bound, we estimate $1,219 dollars per stakeholder. This includes 6 hours from general and operation management multiplied by a fully-loaded hourly wage of $158.8, plus 6 hours from production occupations multiplied by a fully-loaded wage of $44.32. The hourly wages are from the 2020 BLS for Pharmaceutical and Medicine Manufacturers, NAICS 325400. Then, we multiply by 2,350 pharmaceutical stakeholders from the Pharmaceutical and Medicine Manufacturers counts, NAICS 3254, from the 2017 economic census.[8] The resulting lower-bound of coordination costs for the pharmaceutical industry is $2.9 million (= ($158.8 x 6 + $44.32 x 6) x 2,350) stakeholders.

For the upper bound, we estimate $2,437 dollars per stakeholder, estimated as 12 hours from general and operation management multiplied by a fully-loaded hourly wage of $158.8 plus 12 hours from production occupations multiplied by a fully-loaded wage of $44.32. Then, we multiply by 11,000 stakeholders from our registration and listing

[8] United States Census Bureau, U.S. Department of Commerce, Statistics of U.S. Businesses. Accessed June 2020, www.census.gov/programs-surveys/susb.html.

records. The resulting upper-bound of coordination costs for the pharmaceutical industry is $26.8 million (= ($158.8 x 12 + $44.32 x 12) x 11,000) stakeholders.

The primary estimate is $1,828 dollars per stakeholder. We estimate it as the weighted average of the low and upper bound estimates per stakeholder. Then, we multiply by the average count of stakeholders, 6,675. The resulting primary estimate of coordination costs for the pharmaceutical industry is $12.2 million. Table 2 shows these estimates.

5. Summary of Industry Costs

Table 2 summarizes all estimated costs by cost item. Each cost category includes the sum across all three industries – pharmaceuticals, healthcare, and insurance – except for the coordination of label updates, which are specific to labelers in the pharmaceutical industry. The total present value, in 2020 millions of dollars, across all three industries would range from $43.1 million to $136.3 million with a primary estimate of $87.1 million.

Table 2. Summary of Industry Estimated Costs ($2020 millions)

Cost Items	Primary Estimates	Lower Bound Estimates	Upper Bound Estimates
One-Time Costs			
Software and Updates of NDC Records	39.4	18.4	60.3
Learning and Training	26.0	18.4	33.5
Coordination of label updates	12.2	2.9	26.8
Reading and Understanding	9.5	3.4	15.7
Present Value of Total Industry Costs	87.1	43.1	136.3

Note: Costs estimates are in present values of $millions 2020.

G. Distributional Effects

We do not anticipate any significant distributional effects as a result of this proposed rule, if finalized. The estimated costs would arise from updating 10-digit NDC formats to a standard 12-digit format. In some cases, stakeholders may contract out software updates to third-party contractors. However, in other cases, contractors may perform NDC format updates as part of a routine service they provide to their customers (see RAND report).

H. International Effects

We do not expect any significant effects on international trade because this proposed rule, if finalized, would not require the performance of any additional tasks from foreign stakeholders than it would require from domestic ones. Therefore, this proposed rule, if finalized, would not impose any additional burden on foreign entities.

I. Uncertainty and Sensitivity Analysis

1. Sensitivity Analysis

We made several conservative assumptions to estimate the costs of the proposed rule, if finalized. For example, we assumed that the one-time costs of software updates could be about 10 percent relative to the ICD conversion in the RAND 2004 report. A second assumption was that the learning and training costs would be about 5 percent relative to the ICD conversion in the RAND 2004 report to reflect about two hours per trainee. In this sensitivity analysis, we present a wider range of costs estimates using 1 percent, 5 percent, 20 percent, and 50 percent across these three cost items. The estimated

costs for reading and understanding the proposed rule and the coordination of label updates are not affected by these assumptions.

Table 3 compares all the sensitivity scenarios relative to the main estimates showing only primary estimates ranging from $30.8 million to $478.2 million. We think that our main estimates are conservative and that the estimates in the columns 1-percent and 5-percent may reflect the potential incremental costs. We request comments on these comparisons.

Table 3. Sensitivity Comparison of Estimated Costs ($millions, 2020)

Cost Items	Primary Estimates (Main)	Primary Estimates (1%)	Primary Estimates (5%)	Primary Estimates (20%)	Primary Estimates (50%)
One-Time Costs					
Software and Updates	39.4	3.9	19.7	78.7	196.8
Learning and Training	26.0	5.2	26.0	103.9	259.7
Coordination of label updates	12.2	12.2	12.2	12.2	12.2
Reading and Understanding	9.5	9.5	9.5	9.5	9.5
Total Industry Costs	87.1	30.8	67.4	204.3	478.2

Note: Costs estimates are in present values of $millions, 2020.

2. Uncertainty Analysis

i. Coordination of Label Updates

This proposed rule, if finalized, would allow flexibility for pharmaceutical stakeholders to update their labels to reflect the new 12-digit NDC format. In addition, during the 3-year transition period, FDA does not intend to object to products being introduced into interstate commerce continuing to be labeled with the 10-digit NDC that they were previously assigned. However, we encourage firms to start labeling such drugs with the new 12-digit NDC as soon as possible during this transition period. We therefore advise that labeling updating and reprinting is planned in a way that no labeling with 10-

digit NDC remains in the market after the transition period ends. We believe the best way to ensure this is the case is by transitioning early in this 3-year transition period. Thus, we encourage stakeholders to plan accordingly and update their labels during this period to avoid any relabeling costs from the rule that arise after the last day of the transition period. Pharmaceutical stakeholders, however, that do not update their labels before the end of the transition period, may face compatibility challenges in their transactions with respect to any drugs remaining in the market that are labeled with a 10-digit NDC. This may result in the respective stakeholders choosing to remove these products from the market and potentially relabeling them before reintroducing them. However, these potential costs are unlikely and uncertain because we do not know the number of stakeholders and the number of units they would relabel. Cost estimates in this analysis include coordination of label updates but do not include relabeling costs. To offer some idea about these avoidable costs, relabeling costs may include two potential scenarios: disposing of outdated labels and containers or replacing labels. The average of the sticker-cost per label would be about $0.49 and the cost to disposing of the outdated containers would be about $0.20. These estimates are from the RTI 2014 Report (table 4-11) (Ref. 2).

ii. Uncertain Additional Stakeholders

In the costs section, we estimate potential costs to the pharmaceutical, healthcare, and insurance industries. We acknowledge that there may be additional stakeholders that use NDCs for recordkeeping. Additional stakeholders may include, among others, data vendors, government units, and researchers. Government units that need to process reimbursements or contract out these tasks are by in large reflected in the insurance group

estimates. We do not know what costs, if any, additional stakeholders that handle records but do not perform transactions with NDC records would experience. We request comment on the likelihood of these additional stakeholders experiencing any costs resulting from finalization of the proposed rule and estimates of these costs.

J. Analysis of Regulatory Alternatives

We held a public meeting[9] on November 5, 2018 where we outlined several options that we could adopt upon issuing 6-digit labeler codes. We also requested comments from stakeholders on the impact of the transition to 6-digit labeler codes and the various options discussed during the public meeting. We discuss each of the options presented at the public meeting and some of the comments we received below.

1. Option A: No Changes to the Regulations

The first option would consist in not revising the regulations and continue with the status quo. Specifically, FDA would continue assigning the remainder of the 5-digit labeler codes, and whenever the agency runs out, start issuing 6-digit labeler codes. This would expand our NDC inventory to 10 and 11 digits, resulting in five different configurations. This option would result in HIPAA standards having to be updated to accommodate the additional digit in the labeler portion of the NDC. In addition, under this option, potential benefits of unifying the NDC standard would not be realized. In the benefits section we discuss potential cost-savings if the 12-digit NDC standard is adopted as stakeholders would not have to manage multiple formats and perform constant

[9] November 2018 public hearing, 83 FR 38666.

conversions and the resulting quality control. We also discuss potential benefits to public health by having a single unified format that could eliminate risks to public health.

2. Option B: Issue 6-digit Labeler Codes

The second option would be like Option A except that we would stop issuing 5-digit labeler codes and start issuing 6-digit labeler codes on a specified date in the future, before we anticipate running out of 5-digit labeler codes. This option is intended to provide more certainty to stakeholders by establishing a designated future date on which they would need to have systems in place to handle 11-digit NDCs in either 6-4-1 or 6-3-2 format. This option would also result in HIPAA standards having to be updated to accommodate the additional digit in the labeler portion of the NDC but sooner than under option A. In addition, just like Option A, the potential benefits and cost-savings would not be realized.

3. Option C: Adopt a Hyphenated 11-digit NDC in the 5-4-2 Format

The third option would be to adopt the hyphenated 11-digit NDC format (5-4-2 format), commonly used by the payer industry and in expenditures reimbursed by government and convert all current 10-digit NDCs to the hyphenated 11-digit format by adding a leading zero to the short segment of the NDC. Under this option, when the supply of 5-digit labeler codes is exhausted, we would begin assigning 6-digit labeler codes for use in 6-3-2 and 6-4-1 formats. Although this would establish a uniform length for all NDC codes, there would still be multiple formats. Additionally, there is the potential for an 11-digit format with a 6-digit labeler code and an 11-digit with a 5-digit labeler code to be identical when the hyphens separating the various segments are

removed. The potential benefits of the proposed rule would not be accomplished under this option, and it would also introduce a complexity to navigate converted 11-digit NDCs and new 11-digit NDCs.

4. Public Meeting Comments

FDA received oral comments during the hearing. Written comments were submitted to FDA after the meeting. Most of the comments were in favor of FDA's adoption of a single, standardized format that could be used by all stakeholders. Most of the commenters were also in favor of us establishing a date when stakeholders would be required to handle the new format, with many advocating for a 10-year delay. The rule proposes to delay the effective date for 5 years following the publication of the final rule and provides for an additional 3-year transition period. We believe this time frame balances out the certainty of issuing 6-digit labeler codes before running out of 5-digit codes and the time stakeholders would need to be able to handle the proposed 12-digit NDC format. A longer transition period would result in having multiple formats for a longer period and delay the benefits of the proposed standardized NDC format.

Those comments also suggested that we no longer be responsible for assigning NDCs and instead delegate assignment of NDCs to third parties, similar to unique device identifiers. However, we chose not to adopt this alternative because, unlike the implementation of the unique device identifier requirements, we are already deeply involved in the assignment of NDCs and changing this has the potential to cause significant disruption particularly with the handling of a transition from FDA-assigned NDCs to a new, third-party assigned NDC. In addition, delegating this responsibility

would also require rulemaking. We also expect that industry would face a larger coordination costs under this scenario.

One commenter suggested that we could retain the 10-digit NDC format after we ran out of the current lot of 5-digit labeler codes by starting to issue 5-digit, alpha-numeric labeler codes. Although this would allow firms to continue using their existing 10-digit NDCs, it would not accomplish the goal of uniformity advocated by many commenters. Additionally, except systems used for certain minimally manipulated human cells, tissue, and cellular and tissue-based products (HCT/P), it would not likely relieve many stakeholders of the requirement to update their systems to be capable of handling the new NDC format. Finally, we are concerned that the introduction of alphabetic characters into the labeler code could increase the risk of medication errors because some may misread a letter as a number (e.g., letter I as number one and letter O as number zero).

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to prepare an initial regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. If a rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities.

To assess the proposed rule's economic impact on small entities, we divide the estimated one-time costs per establishment by its annual revenues. Analyzing the effects of the proposed rule on small businesses requires revenue and cost data, and a measure to

assess whether the establishment is "small". We explain the data we use and our conclusion in this section.

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. Because the one-time cost could be as much as 0.56 percent of annual revenue for some very small stakeholders, with fewer than 5 employees, in the insurance industry; 0.45 percent in the pharmaceutical industry; and 0.02 percent for some very small stakeholders in the healthcare industry, we propose to certify that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. More generally, across all small stakeholders the average costs to annual revenues would be 0.03 percent for pharmaceutical stakeholders, 0.01 percent for healthcare stakeholders, and 0.01 percent for insurance stakeholders. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We use the North American Industry Classification System (NAICS) to identify industry groups potentially affected by the rule. We also use the NAICS codes to identify the Small Business Administration's (SBA) thresholds for small firms.[10] Table 4 displays the SBA 2019 size standards for the industries affected by the proposed rule by NAICS code.[11] SBA size thresholds are provided by employment size or by annual revenues.

[10] The SBA cutoffs are provided for the four subclassifications of NAICS code 3254, but not for the category as a whole.
[11] SBA 2019 size standards: https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.

Table 4. Small Business Administration Size Standards for Industries Potentially Affected by the Proposed Rule (Revenue in $ Millions, 2020)

NAICS Code	Industry Description	Employee SBA Threshold	Annual Revenue SBA Threshold
3254	Pharmaceutical and Medicine Manufacturing		
325411	Medicinal and Botanical Manufacturing	1,000	
325412	Pharmaceutical Preparation Manufacturing	1,250	
325414	Biological Product (except Diagnostic) Manufacturing	1,250	
622110	General Medical and Surgical Hospitals		$41.5
524114	Direct Health and Medical Insurance Carriers		$41.5

We use data from the 2017 Statistics of U.S. Businesses (SUSB) from the U.S. Census[12] to identify the number of firms and their size by employment and by annual revenues. These data show that the total count of Pharmaceutical and Medicine Manufacturing, NAICS code 3254, is 2,350 establishments; the total count of General Medical and Surgical Hospitals, NAICS code 622110, is 5,544 establishments; and the total count of Direct Health and Medical Insurance Carriers, NAICS code 524114, is 5,409 establishments.

The SUSB data also reports employment records in several categories, and the closest to the SBA size standards tables is 1,000 employees. In this analysis, we assume that pharmaceutical establishments with fewer than 1,000 employees are small entities. Following this assumption, the SUSB records show 1,839 small entities for the pharmaceutical industry. For the healthcare industry, the threshold to be considered a small entity is $41.5 million, and the closest corresponding threshold from the SUSB records is under 1,000-employees, which altogether have an average annual revenue of $40 million per establishment. Thus, there are 1,697 small entities in the healthcare industry following these criteria. For the health insurance industry, the threshold to be

[12] SUSB link: https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html

considered a small entity is also $41.5 million, and the closest corresponding threshold from the SUSB records is under 300-employees, which altogether have an average annual revenue of $43.9 million per establishment. The resulting count is 586 small entities for the health insurance industry.

B. Description of the Potential Impacts of the Rule on Small Entities

To estimate the proposed rule's potential impact on small entities, we compare the one-time costs per small entity to the average annual revenue of small entities within each industry group from the SUSB 2017 data updated to 2020 using the GDP deflator. The one-time costs represent the highest, single year costs an entity may face. We use the primary cost estimates as a conservative approach, as we believe many small entities may experience lower costs. Table 5 shows the primary estimates of one-time costs per small entity. The total costs rounded to the nearest dollar are $5,107 per pharmaceutical stakeholder, $3,279 per healthcare stakeholder, and $4,400 per insurance stakeholder.

Table 5. Costs Per Entity by Type ($Dollars, 2020)

Cost Item	Pharmaceutical Industry	Healthcare Industry	Insurance Industry
Software	$1,548	$1,548	$3,459
Learning and Training	$1,255	$1,255	$465
Reading and Understanding	$476	$476	$476
Coordination of Labeling Updates	$1,828	$0	$0
Total Cost	$5,107	$3,279	$4,400

Note: These costs reflect medium-to-small stakeholders only

Table 6 shows the cost-to-revenue percentages for small pharmaceutical stakeholders calculated as cost per stakeholder divided by average revenue. For example, for the smallest stakeholders with fewer than 5 employees, the cost-to-revenue percentage

is 0.45 percent (= $5,107 dollars in one-time costs / $1.1 million in average annual revenues). Considering all small pharmaceutical stakeholders with fewer than 1,000 employees, the one-time costs represent no more than 0.03 percent of annual revenues on average (= $5,107 dollars in one-time costs / $18.6 million in average annual revenues).

Table 6. Costs Relative to Annual Receipts for the Pharmaceutical Industry by Entity Size (Revenue in $ Millions, 2020)

Employment Size	Number of Establishments	Total Revenue	Average Revenue Per Establishment	Cost to Revenue Percent
<5 employees	598	$672	$1.1	0.45%
5-9 employees	262	$803	$3.1	0.17%
10-14 employees	151	$909	$6.0	0.08%
15-19 employees	73	$661	$9.1	0.06%
<20 employees	1,084	$3,044	$2.8	0.18%
20-24 employees	64	$593	$9.3	0.06%
25-29 employees	55	$448	$8.2	0.06%
30-34 employees	36	$424	$11.8	0.04%
35-39 employees	37	$370	$10.0	0.05%
40-49 employees	60	$1,035	$17.2	0.03%
50-74 employees	88	$1,620	$18.4	0.03%
75-99 employees	58	$1,838	$31.7	0.02%
100-149 employees	81	$3,083	$38.1	0.01%
150-199 employees	64	$2,662	$41.6	0.01%
200-299 employees	69	$3,529	$51.1	0.01%
300-399 employees	38	$3,997	$105.2	0.00%
400-499 employees	27	$2,733	$101.2	0.01%
<500 employees	1,761	$25,376	$14.4	0.04%
500-749 employees	46	$4,141	$90.0	0.01%
750-999 employees	32	$4,741	$148.2	0.00%
<1000 employees	1,839	$34,258	$18.6	0.03%

Table 7 shows the cost-to-revenue percentages for small healthcare stakeholders calculated as cost per stakeholder divided by their average revenue. For the smallest stakeholders with fewer than 5 employees, the cost-to-revenue percentage is 0.02 percent (= $3,279 dollars in one-time costs / $16.4 million in average annual revenues). The

highest cost-to-revenue percent, however, is not for the smallest stakeholders, but for the 30-to-34 employee group with an estimate of 0.19 percent of revenue (= $3,279 dollars in one-time costs / $1.8 million in average annual revenues). Considering all small healthcare stakeholders with less than $41.5 million in average annual revenue (fewer than 1,000 employees), the one-time costs represent no more than 0.01 percent of annual revenues on average (= $3,279 dollars in one-time costs / $40.3 million in average annual revenues). We use SUSB records on hospitals for these calculations; however, there may be many other healthcare stakeholders that may also handle NDCs. We request comment and data from any other healthcare stakeholder on whether they expect any costs.

Table 7. Costs Relative to Annual Receipts for the Healthcare Industry by Entity Size (Revenue in $ Millions, 2020)

Employment Size	Number of Establishments	Total Revenue	Average Revenue Per Establishment	Cost to Revenue Percent
<5 employees	60	$985	$16.4	0.02%
5-9 employees	19	$157	$8.3	0.04%
10-14 employees	82	$1,147	$14.0	0.02%
15-19 employees	5	$32	$6.5	0.05%
<20 employees	4	$16	$4.0	0.08%
20-24 employees	7	$12	$1.8	0.19%
25-29 employees	5	$19	$3.8	0.09%
30-34 employees	15	$80	$5.3	0.06%
35-39 employees	72	$526	$7.3	0.04%
40-49 employees	106	$1,094	$10.3	0.03%
50-74 employees	217	$3,239	$14.9	0.02%
75-99 employees	202	$4,206	$20.8	0.02%
100-149 employees	315	$9,230	$29.3	0.01%
150-199 employees	164	$7,001	$42.7	0.01%
200-299 employees	145	$9,660	$66.6	0.00%
300-399 employees	1,339	$36,262	$27.1	0.01%
400-499 employees	199	$15,769	$79.2	0.00%
<500 employees	159	$16,429	$103.3	0.00%
500-749 employees	1,697	$68,461	$40.3	0.01%
750-999 employees	60	$985	$16.4	0.02%
<1000 employees	19	$157	$8.3	0.04%

Table 8 shows the cost-to-revenue percentages for small direct health and medical insurance stakeholders calculated as cost per stakeholder divided by average revenue. For the smallest stakeholders with fewer than 5 employees, the cost-to-revenue percentage is 0.56 percent (= $4,400 dollars in one-time costs / $0.8 million in average annual revenues). Considering all small insurance stakeholders, the one-time costs represent no more than 0.01 percent of annual revenues on average. The cut-off of 300 employees and $43.9 million is the closest to the SBA cut-off of $41.5 million for small entities.

Table 8. Costs Relative to Annual Receipts for the Insurance Industry by Entity Size (Revenue in $ Millions, 2020)

Employment Size	Number of Establishments	Total Revenue	Average Revenue Per Establishment	Cost to Revenue Percent
<5 employees	303	$237	$0.8	0.56%
5-9 employees	54	$296	$5.5	0.08%
10-14 employees	21	$186	$8.9	0.05%
15-19 employees	24	$265	$11.0	0.04%
<20 employees	402	$983	$2.4	0.18%
20-24 employees	12	$237	$19.8	0.02%
25-29 employees	9	$282	$31.3	0.01%
30-34 employees	7	$282	$40.3	0.01%
35-39 employees	6	$132	$22.0	0.02%
40-49 employees	12	$383	$31.9	0.01%
50-74 employees	20	$2,972	$148.6	0.00%
75-99 employees	37	$2,829	$76.5	0.01%
100-149 employees	28	$5,569	$198.9	0.00%
150-199 employees	14	$1,997	$142.6	0.00%
200-299 employees	39	$10,067	$258.1	0.00%
<300	586	25,733	$43.9	0.01%

Note: The cut-off of 300 employees and $43.9 million is the closest to the SBA cut-off of $41.5 million.

The highest cost-to-revenue estimates across the 3 industry groups are 0.56 percent for the insurance industry, 0.45 percent for the pharmaceutical industry, and 0.19

percent for the healthcare industry. Therefore, we propose to certify that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities.

IV. References

1. RAND Corporation "The Costs and Benefits of Moving to the ICD-10 Code Sets" prepared by Martin Libcki, and Irene Brahmakulam, Contract No. ENG-9812731, March 2004.

2. RTI International. "2014 FDA Labeling Cost Model." Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.