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]

## Final Regulatory Impact Analysis
## Final 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 final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is not a significant regulatory action under Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This final rule is not considered an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

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 costs could be as much as 0.59 percent of average annual revenue for some very small stakeholders in the pharmaceutical industry, 0.33 percent of average annual revenue for some very small stakeholders in the insurance industry, and 0.40 percent of average annual revenue for some very small stakeholders in the healthcare industry, 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 estimates of anticipated impacts, before issuing "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 $187 million, using the most current (2024) 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. Overview of Benefits, Costs, and Transfers

The final rule amends regulations governing the format of the National Drug Code (NDC) by standardizing it to 12 digits in length. Currently, the NDC assigned by

FDA (a "native" or "FDA-assigned" NDC) is 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 three segments are the labeler code, product code, and package code. Under this final rule, the standardized NDC will consist of three segments: a 6-digit labeler code, a 4-digit product code, and a 2-digit package code. When the rule becomes effective, FDA-assigned 10-digit NDCs will be converted to the uniform 12-digit format by adding leading zeros to the labeler code, product code, or package code segment of the NDC, as needed to produce the uniform 6-4-2 format.

FDA's transition to a uniform format for native NDCs is intended to facilitate the adoption of a single NDC format across the entire healthcare industry. Such an adoption will eliminate the need to convert NDCs from one of the FDA-assigned 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 the FDA-assigned NDC format to a different NDC format used by other sectors of the healthcare industry. Standardization and adoption of a single format will also eliminate the need for additional quality control and validation by certain interested parties, 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 will be to avoid any potential risks to the public health from medication errors and the risk of confusion. We do not have enough information to quantify these potential benefits, so we only qualify them in this analysis.

The costs to industry of converting current NDCs to the standardized format will include one-time costs of updating software systems, other transition costs, coordinating labeling updates, and reading and understanding the rule. Table 1 shows a summary of the quantified costs of the rule. We estimate annualized costs will be about $14.64 million ranging from $7.64 million to $22.79 million using a 7-percent discount rate over a ten-year horizon. Similarly, we estimate annualized costs will be about $14.90 million ranging from $7.79 million to $23.18 million using a 3-percent discount rate over a 10-year horizon.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule ($millions, 2024)

| Category | | Primary Estimate | Low Estimate | High Estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|---|
| | | | | | Year Dollars | Discount Rate | Period Covered | |
| Benefits | Annualized Monetized ($millions/year) | | | | | 7% | | |
| | | | | | | 3% | | |
| | Annualized Quantified | | | | | 7% | | |
| | | | | | | 3% | | |
| | Qualitative | Potential cost savings by eliminating different formats of the NDCs. Reductions in annual audits, billing issues, cost of software, and potential medication errors. | | | | | | |
| Costs | Annualized Monetized ($millions/year) | $14.64 | $7.64 | $22.79 | 2024 | 7% | 10 years | Costs to labelers increase with the quantity of NDCs they handle. |
| | | $14.90 | $7.79 | $23.18 | 2024 | 3% | 10 years | |
| | Annualized Quantified | | | | | 7% | | |
| | | | | | | 3% | | |
| | Qualitative | The net monetized costs are likely overestimated because they do not account for cost-savings. | | | | | | |
| Transfers | Federal Annualized Monetized ($millions/year) | | | | | 7% | | |
| | | | | | | 3% | | |
| | | From: | | | To: | | | |
| | Other Annualized | | | | | 7% | | |

| Category | | Primary Estimate | Low Estimate | High Estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|---|
| | | | | | Year Dollars | Discount Rate | Period Covered | |
| | Monetized ($millions/year) | | | | | 3% | | |
| | | From: | | | To: | | | |
| Effects | State, Local or Tribal Government: No estimated effect.<br>Small Business: One-time costs will be no more than 1 percent of average revenue for some very small stakeholders in the pharmaceutical, insurance, and healthcare industries. We certify that the final rule will not have a significant economic impact on a substantial number of small entities.<br>Wages: No estimated effect.<br>Growth: No estimated effect. | | | | | | | |

The total present value, in 2024 millions of dollars ranges from $53.65 million to $160.08 million with a primary estimate of $102.85 million using a 7-percent discount rate. By contrast, using a 3-percent discount rate, the total present value of estimated costs ranges from $66.42 million to $197.76 million with a primary estimate of $127.08 million. These costs are likely to be spread out over the 7-year period between publication of the rule and its effective date. Thus, we assume that one-seventh of these costs occur each year of this period and that the first year is 2026. We assume the reading and understanding costs, however, will occur the first year after the rule is published.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this rule will generate $7.90 million in annualized costs at a 7-percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Table 2. EO 14192 Summary Table of Costs and Cost Savings ($millions, 2024)

| | Primary Estimate 7% | Low Estimate 7% | High Estimate 7% |
|---|---|---|---|
| Present Value of Costs | $112.90 | $53.65 | $160.08 |
| Present Value of Cost Savings | | | |
| Present Value of Net Costs | $112.90 | $53.65 | $160.08 |
| Annualized Costs | $7.90 | $3.76 | $11.21 |
| Annualized Cost Savings | | | |
| Annualized Net Costs | $7.90 | $3.76 | $11.21 |

Note: Values discounted over an infinite time horizon and year one is assumed to be 2026.

## C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On July 25, 2022, we published the proposed rule "Revising the National Drug Code Format and Drug Label Barcode Requirements" (87 FR 44038). We received several comments on the regulatory impact analysis of the proposed rule (PRIA). We group the comments by topic and offer a brief description of each and our responses. The order of comments and responses is not a reflection of importance.

*Cost Estimates:*

(Comment) Some comments expressed that the cost estimates of transitioning 10-digit NDCs to a 12-digit format were underestimated and that they should be three to ten times the International Classification of Diseases (ICD) conversion reference cited in the PRIA.

(Response) We disagree. We clarify that the ICD-9 to ICD-10 conversion is only a reference to assess the burden of updating information systems. We agree that the NDC and the ICD conversion do not involve the same amount of effort. The mapping of ICD-9 to ICD-10 codes involved the mapping of 57 ICD-10 codes per each ICD-9 code on average (according to the RAND 2004 report we use, Ref. 1). In the PRIA, we used an effort relative to the ICD-conversion of ten percent because the mapping of NDCs is 1-to-1 instead. This was a conservative approach because estimates are likely higher than what the costs will be. However, we are updating estimates in the section of Other Transition Costs, previously named Learning and Training, in this final regulatory impact analysis (FRIA). In addition, in the sensitivity analysis in section II.I.1 of this FRIA, we included a range of 1 percent to 50 percent relative to the ICD-conversion estimates.

(Comment) We received comments expressing that the cost estimates do not represent the cost burden some large stakeholders will experience.

(Response) Feedback from industry helps us with estimates. We note that larger companies may refer to the upper bound costs rather than the average estimates for reference. This feedback, however, may only represent a few companies.

(Comment) We received comments expressing that estimating costs based on the ICD-9 to ICD-10 transition is not appropriate because ICD codes are not used by as many stakeholders as NDCs.

(Response) We disagree. We do not use the ICD estimates to calculate that the NDC transition will cost the same amount. We emphasize that the estimates that use the ICD conversion only apply to some elements in the calculation of software updates and to other transition costs. Other categories of costs, such as coordination of label updates, are estimated using other additional inputs. We also clarify that we use the ICD estimates to assess certain cost inputs rather than to claim that an entire industry group will have a fixed amount of costs; that is, we use the breakdown of cost items and not the aggregate ICD cost per stakeholder.

(Comment) Some comments expressed that the cost estimates do not account for the need to update the physical packaging in addition to the labeling.

(Response) The labeling cost model that we use from RTI, Inc. accounts for the coordinated and uncoordinated relabeling costs, which include packaging updates. We opted, however, not to include the cost element of disposing old inventory or updating it with new labels over the old ones in the preliminary regulatory impact analysis of the proposed rule (PRIA) because we stated that during the three-year transition period, we

do not intend to object to products being introduced into interstate commerce with the 10-digit NDC that they were previously assigned. That is, we will generally allow old labels to be exhausted and thus minimize the need to discard old inventory.

In addition, we note that we are increasing the delay in effective date of the rule to seven years instead of five years to allow interested parties sufficient time to update their systems and make other changes necessary to ensure a safe and orderly transition to the new NDC format occurs on the effective date. This way, labelers can better assess the inventory of labels with 10-digit NDCs that will be needed. Furthermore, the three-year transition period provides time to perform updates to the affected packaging.

(Comment) We received comments expressing that the costs are underestimated as the rule will have a greater impact on products subject to the Drug Supply Chain Security Act (DSCSA) requirements. For example, under DSCSA, firms must include the NDC in transaction information.

(Response) We acknowledge that the NDC is to be included in the transaction information under the DSCSA. We do not, however, ignore this cost or other transaction costs that may arise with the new NDC format. This FRIA provides higher estimates in the category of Other Transition Costs, previously named Learning and Training, and makes it more explicit that the costs of transitioning to the uniform, 12-digit NDC format, including the transaction information required under the DSCSA, are included in this category, as well as meetings for pre-planning, execution, additional quality controls, adjustments to the reformatted NDCs, and correction of any discrepancies that arise.

(Comment) We received comments expressing that the costs are underestimated for pharmacies as there are more changes needed beyond software updates, such as updates to purchase orders and controlled substances reporting requirements.

(Response) We agree that these costs are not included in the cost category titled "Software and Updates of NDC Records" in the PRIA. We cover these potential costs, and some others, in section II.F.2 of this FRIA, titled "Other Transition Costs," previously named "Learning and Training." We update this category in this FRIA to nearly double the previous estimates to account for potential underestimates in the PRIA.

(Comment) We received comments expressing that the Regulatory Flexibility Analysis fails to recognize that many systems cannot handle two codes for the same product and there will be costs to update those systems.

(Response) We include estimated costs for such system updates, and some other costs, in a general category we call "Software and Updates of NDC Records" (see section II.F.1 of this FRIA).

(Comment) We received comments expressing that the estimated costs were based on an accurate but incomplete list of stakeholders. The commenters identified additional stakeholders that should be added, including state prescription drug monitoring programs; state Medicaid agencies; drug data vendors (compendia); drug distributors; pharmacy benefit managers; pharmacy claims processors; other payers beyond insurers, such as employers' health plans and claim sponsors; rebate processors; software vendors; auditors; intermediate and clearing houses; data aggregators; other government agencies; health information exchanges; and regulatory agencies.

(Response) We disagree with this interpretation of the PRIA. We classify stakeholders into aggregate categories. Listing all the different disaggregated stakeholders is not feasible as exemplified in the comment submitted. For example, the comment submitted expressed that the stakeholders affected "include, but are not limited to," the entities listed. By acknowledging that the stakeholders are "not limited to" the list submitted, commenters show how difficult it is to list all of them. More importantly, many stakeholders in their list can be grouped into more general and useful categories. For example, other government agencies and Medicaid agencies can be grouped together with other payers that perform that function. Pharmacy benefit managers, pharmacy claims processors, and any other intermediary in processing claims, rebates, audits, or any activity related to a drug product transaction can be grouped into the larger insurance component, as we do by referring to them as other involved intermediaries. Note that software vendors are included in the pharmaceutical industry category we use because the former will bill the latter when they perform system updates; separating these two groups and adding costs for each would double count the costs. We also acknowledge stakeholders in the analysis who process information but do not perform distribution or transactions. In sum, further dividing stakeholders into subgroups beyond what we describe in the economic analysis does not add any accuracy or completeness to the analysis.

(Comment) We received some comments with different cost estimates than what we presented in the PRIA. For example, some comments expressed an amount of $100 million per wholesale distributor due to the many databases to update and systems to

modify. Others expressed costs of $5 million for manufacturers and costs of up to $50 million for the largest generic companies.

(Response) We appreciate this type of feedback. The more information we have the better our estimates become. We have adjusted some of our estimates. However, we also note that these comments offer cost figures as an opinion and do not offer details about how these costs are estimated. We used the RAND report (Ref. 1) for these types of costs and the report dissects the different parts, which makes our estimates trackable as compared to the ones offered by the commenters. We also note that the NDC updates, unlike the ICD updates, can be programmed as the update only needs a leading digit added to the respective sequence of digits. We agree that the communication for multiple systems may add a layer of quality control. We do account for this layer, but we have updated our Other Transition Costs, previously named Learning and Training, estimates to represent a higher burden.

(Comment) We received comments expressing support for the Agency's proposal to convert 10-digit NDCs to the uniform, 12-digit format by adding a leading zero. According to the commenters, this is the most efficient solution because it minimizes mapping and programming costs, and the standardization eliminates multiple formatting options.

(Response) We agree. This comment highlights that the effort to update systems can be automated to greatly reduce the burden.

*Cost Savings in the Long Run:*

(Comment) Some comments highlighted that current processing of NDCs between providers of drug products and payors is substantial and costly due to the lack of

a standard format. These comments highlight the potential for cost savings in the long run despite some transition costs in the short run.

(Response) We agree with these comments.

(Comment) Some comments highlighted that the standardization will mitigate the potential for disruption, patient risk, and high costs by ensuring there will be a single NDC format and predetermined date for implementation. The comments also highlighted that having multiple NDC formats can lead to incorrect drug inventory and errors in sending and receiving drugs.

(Response) We agree with these comments. Although we are not able to quantify the cost savings, we agree that in the medium-to-long run, cost savings will be realized as the multiple formats for FDA-assigned NDCs are eliminated, and multiple related quality control steps become unnecessary. In the short-run, industry will experience a transition process and eliminate inefficiencies caused by multiple formats for the FDA-assigned NDC.

*Misunderstanding Incremental Cost:*

(Comment) We received comments expressing that maintaining the 10-digit NDC and adopting a limited alphanumeric labeler code for new labelers would be less costly than adopting a 12-digit NDC format. Commenters argued that fewer entities would have major conversions to perform and that any needed conversions would be less expensive than under this rule as they would be performed faster. These commenters also expressed that preserving the 10-digit NDC format and using an alphanumeric format would avoid any changes to the 11-digit NDC format used for coverage, payment, and other purposes

under the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104-191).

(Response) We disagree. The alphanumeric option may lead to some confusion for reasons discussed in the preamble to the final rule. In addition, the alphanumeric option may be costlier than commenters expect because systems that currently can process only numeric NDCs would need to be updated to handle both alphanumeric NDCs as well as the existing numeric NDCs that would be retained under the alphanumeric option. Thus, the alphanumeric option would also add to the use of multiple formats and the perpetual additional quality control costs associated with this.

As for permitting continued use of existing 10-digit NDCs after, we agree that in the short run, this part would be less costly to labelers who use them than to reformat them because it would not require them to update their drug labels to reflect a reformatted NDC. However, this option would not result in a uniform NDC format for all FDA-assigned NDCs. Even without this final rule, the 6-digit labeler code would roll out after the supply of 5-digit labeler codes is exhausted, thereby creating 11-digit native NDCs that stakeholders would have to process along with all the other different native NDC formats in perpetuity. Any quality assurance costs involved in handling multiple formats would likely negate any cost savings from grandfathering the 10-digit NDCs.

(Comment) We received several comments expressing that the rule will be overly burdensome and that it would cost billions of dollars to update IT systems across multiple stakeholders beyond labelers, such as pharmacies as well as government and private payers.

(Response) We disagree that the rule will cost billions of dollars. We note that under current § 207.33, industry will eventually need to accommodate 11-digit NDCs, which will entail some implementation costs. The cost estimates for this final rule need only consider the incremental costs that this final rule will generate over and above the costs associated with transitioning to 11-digit NDCs. We also disagree that the cost estimates do not incorporate other stakeholders beyond labelers. The economic analysis considers the overall healthcare sector (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, etc.) and the insurance sector (administrators of claims for commercial and public sponsored insurance plans, and other involved intermediaries).

(Comment) Some commenters expressed that it would be very burdensome to convert historical medication information in patient records.

(Response) These comments are out of scope of the final rule. This final rule does not mandate that historical patient records be updated to reflect a 12-digit NDC.

(Comment) A commenter expressed that any changes to the NDC will require changing the automatic process by which GTINs are generated. The commenter believed that coordinating NDC and GTIN formatting and implementing the requisite system changes would increase costs and create opportunities for error.

(Response) We understand that a 12-digit NDC would be incompatible with the current barcode standards that utilize GS1's UPC-A and 2D data matrix barcodes because the GTIN cannot embed an NDC longer than 10 digits. We acknowledge that there are transition costs associated with reformatting 10-digit NDCs to 12-digit NDCs, and our

final economic analysis includes such costs. We note that even without the rule, under existing §207.33(b)(1), industry would incur costs to transition away from the GTIN, which cannot accommodate the 11-digit NDCs that would have been assigned absent this rule.

D. Summary of Changes

The main changes between the PRIA and the FRIA relate to the updated estimates to account for feedback we received from comments submitted. For example, we received comments expressing that large NDC holders may experience higher costs to update labels than the average estimates suggest. We update our lower, upper, and primary estimates to reflect a higher potential burden. We note, however, that the proposed five-year delay in effective date for this rule has been increased to seven years to allow interested parties sufficient time to update systems and make other necessary changes.

We also received comments expressing that the DSCSA requirements to include NDCs in transaction information will affect the NDC requirements to reformat 10-digit NDCs. We have adjusted the section titled "Other Transition Costs," previously named "Learning and Training," to reflect a higher burden. In addition, we also received comments expressing that pharmacies may experience a higher burden beyond software updates such as updates to purchase orders and controlled substances reporting requirements, and we have updated the section titled "Other Transition Costs" to reflect this possibility.

Other changes include updates to reflect inflation and present estimates in 2024 dollars instead of 2020 dollars. In addition to costs estimated over a ten-year horizon, we

include their annualized values estimated over an infinite time-horizon. Lastly, we consider that the costs of the rule will likely occur during the first seven years after publication of the rule, and we discounted the estimated costs to account for this timeframe. In these calculations, we assume that one-seventh of the costs occur each of these years, and that the first year is 2026. The reading and understanding costs, however, we assume will occur the first year after the rule is published.

In sum, our primary estimate of the present value of costs in this final analysis is $102.85 million using a 7-percent discount rate, or $127.08 million using a 3-percent discount rate, compared to the $87.1 million estimate at both discount rates in the PRIA. There are no changes to benefits, although, we clarify in Table 3 some misconceptions we noted in comments submitted regarding the incremental impact of the rule and emphasize long-run cost savings. We do not have enough information to quantify these savings but explain that they will arise from eliminating the need for multiple formats industry currently handles and would need to handle in the future.

Table 3 illustrates the incremental changes from the rule. In Table 3, a "native" NDC refers to an NDC assigned by FDA. A 10-digit native NDC will be converted to the 12-digit format by adding a leading zero to the appropriate segment of the NDC. All such converted 12-digit NDCs will start with a leading "0," and newly assigned NDCs after the transition period will begin with a leading "1." As the table illustrates, there would be some tasks to perform even without the rule. In fact, without the rule, the conversion of 10-digit FDA-assigned NDCs to HIPAA compliant 11-digit NDCs would continue along with preparation for the new FDA-assigned NDCs being introduced with 6-digit labeler codes instead of 5. Thus, without this final rule, stakeholders would need to account for

many formats in the marketplace and processing systems in perpetuity. This final rule will have perpetual cost-savings as stakeholders will not have the burden of working with multiple formats.

Table 3. Incremental Changes from the Rule

| Without this Rule | With this Rule | Incremental Cost | Incremental Savings |
|---|---|---|---|
| Systems would have to be updated to handle native 10- and 11-digit NDCs, as well as a new HIPAA NDC format. | Systems will have to be updated to handle native 10- and 12-digit NDCs, along with a new HIPAA NDC. | Handling native 12-digit NDCs simultaneously with all other NDC formats (only during transition period). | • Avoid handling multiple native NDC formats after the transition period (long-term savings in perpetuity).<br>• Additional long-term savings in perpetuity assuming HHS adopts the same 12-digit NDC format for HIPAA purposes |
| Continued quality control to ensure the accurate conversion of native NDCs to the HIPAA NDC format and vice-versa. | Native 10-digit NDCs will be converted to 12-digit NDCs. | Additional quality control to ensure the native 12-digit NDCs correspond to the respective 10-digit NDCs (only during transition period). | • Multiple native NDC formats will no longer have to be converted to 11-digit HIPAA NDCs<br>• Additional long-term savings in perpetuity assuming HHS adopts the same 12-digit NDC format for HIPAA purposes |
| Relevant drug products would be labeled with the appropriate native 10- or 11-digit NDC. | 10-digit NDC labels will need to be updated to the 12-digit format. New products will be assigned and labeled with 12-digit NDCs. | The incremental labeling cost applies only to the coordination of 10-digit NDC labels that need to be transitioned during the transition period. | N/A. |

## II. Final Economic Analysis of Impacts

### A. Background

*1. NDC Format*

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, the FDA-assigned NDC for each listed drug marketed in the United States is a unique, 10-digit number with three segments of varying lengths: the labeler code, the product code, and the package code. Currently, the labeler code is a 4- or 5-digit number that identifies the manufacturer, repacker, relabeler, or private label distributor of the drug. When the 5-digit labeler codes are exhausted, we will issue 6-digit labeler codes. The second segment, the product code, is a 3- or 4-digit number that identifies a specific active ingredient, strength, dosage form, and other distinguishing characteristics 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.

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 from the date this final rule is published. Moving to 6-digit labeler codes will expand the FDA-assigned NDC to 11 digits and, per existing regulations, would allow 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).

Under the administrative simplification provisions of HIPAA, the Department of Health and Human Services (HHS) was required to adopt "national standards for electronic health care transactions and code sets, unique health identifiers, and security."[1] In its implementation of these provisions, HHS published a final rule in August 2000, which addressed standards for electronic transactions that established NDCs as the standard medical data code set for reporting drugs and biologics in all standard transactions under HIPAA (65 FR 50312). 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 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 (i.e., 5-4-2 configuration). To convert a 10-digit FDA-assigned NDC to an 11-digit HIPAA standard NDC, a leading zero is added to the appropriate segment to create the HIPAA 11-digit configuration.

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

*2. Barcode Labeling Requirement*

FDA regulations require certain drug labels to include a barcode that contains the appropriate NDC number. The purpose of the barcode labeling requirement is to reduce medication errors; by scanning the barcode, health care professionals can verify that they are dispensing the right drug in the correct dose and route of administration. Currently, our regulations require use of a linear barcode that meets standards set by specified organizations or another standard or format approved by FDA.

## B. Need for Federal Regulatory Action

In the absence of the final rule, FDA would begin issuing 6-digit labeler codes, resulting in 11-digit NDC configurations with the same number of digits as required by the HIPAA standards, but they will not be in the same format. Specifically, an 11-digit native NDC would have an extra labeler code digit but will be short a digit in either the product code or package code. In some systems where hyphens or spaces are not used to separate the segments of the NDC, there could be potential confusion with the HIPAA 11-digit converted NDCs. Such conversions can cause medication or payment errors and require additional quality control efforts to ensure that a drug product and its respective NDC are accurate. In addition, the linear barcode commonly used for drug product labeling is not capable of encoding a 12-digit NDC.

## C. Purpose of the Rule

This rule standardizes all FDA-assigned NDCs to a single 12-digit format consisting of three segments: the labeler code with 6 digits, the product code with 4 digits, and the package code with 2 digits. In addition, to allow flexibility on the type of barcode used on the label of a drug product, the rule revises 21 CFR 201.25(c) to allow

the use of either linear or nonlinear barcodes, so long as the barcode format conforms to the standards developed by a widely recognized international standards development organization and the barcode format and standard is recognized by FDA.

By standardizing a uniform NDC format, this rule will eliminate the use of multiple formats for FDA-assigned NDCs and the potential for medication errors that would exist if FDA began to assign 11-digit NDCs that are indistinguishable from the HIPAA standard 11-digit NDC. In addition, we anticipate FDA's transition to a uniform 12-digit NDC format may facilitate the adoption of a single NDC format across the entire healthcare industry, eliminating the need to convert NDCs from one of FDA's 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 would reduce potential data and medication errors. Standardization and adoption of a single NDC format would also reduce burden by eliminating the need for additional quality control and validation by certain parties, such as payors and prescribers, to ensure a drug product and its respective NDC are accurate.

The effective date of the final rule is seven years following its publication. This delay is intended to allow companies to make necessary changes to accommodate the new 12-digit NDC format as of the effective date and prepare for updating product labeling following the effective date. On the effective date of the final rule, we will convert all existing 10-digit NDCs in all drug listing files to the 12-digit format, and we will convert all existing labeler codes to 6 digits in labeler code request files. In addition, we will begin assigning new NDCs in the uniform 12-digit format and will respond to NDC labeler code requests by assigning 6-digit labeler codes. All drug listing files

submitted to FDA after the effective date must identify the NDC using the 12-digit NDC format.

In addition, the rule has a three-year transition period following the effective date. During this three-year transition period, we do not intend to object to continued use of 10-digit NDCs on the labeling of unexpired products remaining in interstate commerce after the effective date. The final rule also clarifies that products introduced into interstate commerce or delivered for introduction into interstate commerce before the effective date can remain on the market and accessible to patients after the 3-year transition period, as long as they have not expired. However, any products that are introduced into interstate commerce with a 10-digit NDC after the effective date and before the end of the transition period are subject to enforcement action if they remain in interstate commerce after the end of the transition period. Accordingly, firms should start labeling drugs with the 12-digit NDC format as soon as possible after the effective date.

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.

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 will 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 formats (6-3-2 and 6-4-1). This addition of two new formats would likely result in

stakeholders having to maintain or update systems such that they can accommodate all these formats. In addition, the HIPAA standard would need to be updated because it currently uses an 11-digit configuration that cannot accommodate a 6-digit labeler code.

NDC numbers are used widely across the healthcare system; according to our registration and listing records, the count of NDC numbers affected range from 240,000 to 250,000. We expect the rule will affect between 2,350 and 11,000 pharmaceutical stakeholders. The lower bound is from the Pharmaceutical and Medicine Manufacturers counts, North American Industry Classification System (NAICS).[2] The upper bound is from our establishment registration and drug product listing records. Insurers will also need to update their records. According to NAICS (524114) records, there are 5,409 medical insurer establishments.

The healthcare industry will also need to update systems to accommodate a new NDC format, whether the format is the new FDA-assigned 12-digit format or another NDC format adopted by industry that can accommodate the FDA 12-digit NDC format. Such systems updates are necessary to enable the purchase and billing of drugs by health care providers, including hospitals, physician offices, nursing care facilities, pharmacies, dentist offices, residential health facilities, home healthcare, outpatient care centers, medical and diagnostic offices, and medical equipment retailers. 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 will be affected including the Centers for Medicare and Medicaid Services, the National Institutes of Health,

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

Centers for Disease Control and Prevention, Health Resources and Services Administration, and the Indian Health Service. Some dispensers will 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 Rule

We expect that FDA's adoption of a standardized NDC format will result in benefits to both industry and consumers. We do not have enough information to quantify these benefits, and we only qualify them here. We received comments supporting these benefits.

### *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 results 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.

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

accommodate an NDC with a 6-digit labeler code. By contrast, with standardization to FDA's 12-digit NDC as the new HIPAA standard, industry will only need to manage one NDC format.

After the rule is in effect, we expect stakeholders to conduct some initial quality control when 10-digit NDCs assigned by FDA are updated to FDA's standardized 12-digit NDC format. We expect these additional quality control efforts will occur after the effective date of the rule through the end of the three-year transition period. We expect, however, that after the transition period, additional quality control will no longer be needed as all FDA-assigned NDCs will be 12 digits and no more conversions will be needed if HHS adopts FDA's standardized 12-digit format as the new HIPAA standard format. Thus, a single format will result in cost-savings in perpetuity, and some commenters expressed support and agreement with these expected cost-savings.

*2. Other Public Health Benefits*

Having a standardized format may also reduce potential risks to public health. Without this final rule, the native NDC would be either 10 or 11 digits in length with three segments of varying lengths, resulting in five different formats. In addition, the HIPAA 11-digit NDC standard would need to be revised to accommodate 6-digit labeler codes, resulting in yet another variation of the NDC code used in industry. Medication errors may occur when there is confusion between native NDCs, the HIPAA NDC standard, or other numbers, such as batch, model, or order numbers that may use overlapping three-segment formats with fewer than twelve digits. These errors could result in using or prescribing the wrong drug or the wrong dose.

In a retrospective analysis of the prior barcode requirements, updated by this final rule, FDA researchers noted that "bar codes would be part of a system where healthcare professionals would use bar code scanning equipment and software to electronically verify against a patient's medication regimen that the correct medication is being given to the patient before it is administered, which could ultimately reduce medication errors."[3] Updating the barcode requirements to accommodate a 12-digit NDC will allow for these sources of benefits to continue.

F. Costs of the Rule

The incremental costs of the rule will come from converting current 10-digit NDCs to a standardized 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 NDCs are used in reimbursement claims and require coordination among multiple stakeholders.

The ICD transition involved mapping of each ICD-9 code to multiple ICD-10 codes, thus involving more effort than the NDC transition described in this rule. The 2004 RAND report describes implementation of changes by medical and insurance

[3] Kearsley, Aaron, Nellie Lew, and Clark Nardinelli. "A Retrospective and Commentary on FDA's Bar Code Rule." Journal of Benefit-Cost Analysis 9, no. 3 (2018): 496-518. https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/abs/retrospective-and-commentary-on-fdas-bar-code-rule/840DD92ECEB358B0ECDB08D459C92053

groups. This is helpful to estimate a range of costs involved in the NDC transition as they are also processed by these stakeholders. We assume that the NDC transition will fall in the lower part of the distribution of the ICD transition. We believe this assumption is valid as the ICD transition involved a mapping of about 57 ICD-10 codes per each ICD-9 on average, whereas the NDC mapping is a one-to-one mapping. Therefore, we estimate the costs of software updates and other transition costs items for the NDC transition to be 10 percent of costs relative to the ICD transition. We understand that cost estimates are sensitive to this assumption and present a sensitivity analysis reflecting NDC transition cost estimates of 1 percent, 5 percent, 25 percent, and 50 percent relative to the ICD cost estimates. We emphasize that the estimates that use the ICD conversion only apply to software updates and to other transition costs. Other categories of costs such as coordination of label updates are estimated using other additional inputs. We also clarify that we use the ICD estimates to assess certain cost inputs rather than to claim that an entire industry group will have a fixed amount; that is, we use the breakdown of cost items and not the aggregate ICD cost per stakeholder. We understand that there are some users that may be the same and yet others that may be completely different in using ICD or NDCs.

As there are many stakeholders that use NDCs, to facilitate estimation and interpretation of estimates, we refer to three major stakeholder groups:

- 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 list of stakeholder groups is not exhaustive as we understand there are other stakeholders not mentioned such as data providers that use NDCs as drug product identifiers in their records but do not perform drug-specific transactions.

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 general groups: pharmaceutical, healthcare, and insurance.

*1. Software and Updates of NDC Records*

We anticipate that stakeholders will update their computer systems to convert 10-digit NDCs to the standardized 12-digit format. We assume that upon these updates, stakeholders will not lose capabilities to handle 10-digits as they transition. Updating records may range from a simple task of adding leading zeros to more complex tasks of tracking 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 a factor of ten 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. We use the GDP deflator to adjust the results to 2024 dollars.

We estimate the lower bounds for the pharmaceutical industry and the healthcare industry are $5.28 million, each. This estimate is derived from 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 2024 dollars. We estimate the lower bound for the insurance industry is $11.21 million. This estimate reflects ten percent of the average of $125 million from internal staff and $16.7 million from third-party contractors, updated to 2024 dollars. We estimate the combined lower bound estimate is $21.76 million (= $5.28 million for the pharmaceutical industry + $5.28 million for the healthcare industry + $11.21 million for the insurance industry). These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period, and that the first year is 2026, the resulting present value is $14.63 million in 2024 using a 7-percent discount rate or $18.26 using a 3-percent discount rate.

We estimate the upper bounds for the pharmaceutical industry and the healthcare industry are $19.12 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 2024 dollars. We estimate the upper bound for the insurance industry is $32.97 million. This estimate reflects ten percent of the average of $375 million from internal staff and $41.7 million from third-party contractors, updated

to 2024 dollars. We estimate the combined upper bound estimate is $71.21 million, rounded to the nearest decimal (= $19.12 million for the pharmaceutical industry + $19.12 million for the healthcare industry + $32.97 million for the insurance industry).

These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period and that the first year is 2026, the resulting present value is $47.89 million in 2024 using a 7-percent discount rate or $59.74 using a 3-percent discount rate.

The primary estimate of expected costs from software and updates of NDC records is the average of the lower and upper bound estimates, or $46.49 million (= ($21.76 million + $71.21 million) / 2). These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period and that the first year is 2026, the resulting present value is $31.26 million in 2024 using a 7-percent discount rate or $39 million using a 3-percent discount rate. Table 4 shows these estimates in row 3.

We emphasize that these cost estimates represent the incremental cost 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 a reformatted 12-digit NDC, but there would be some software costs to allow systems to handle the additional labeler code digit in an 11-digit native NDC.

*2. Other Transition Costs*

Pharmaceutical, healthcare, and insurance staff will spend resources to learn to use the updated software and make updates to NDC records. This cost category was

previously named Learning and Training Costs in the proposed analysis. After feedback on the proposed rule, we are expanding this category to more general costs that reflect other potential transition costs. This cost category may also include meetings for pre-planning, execution, additional quality controls, adjustments to the reformatted NDCs, and correction of any discrepancies that may arise, etc. Other comments we received expressed that the DSCSA requirements to include NDCs in transaction information will affect the NDC requirements to reformat 10-digit NDCs. In addition, we also received comments expressing that pharmacies may experience a higher burden beyond software updates such as updates to purchase orders and controlled substances reporting requirements.

We use the RAND report cited in the PRIA and describe costs in terms of how the report presented these estimates in terms of coders rather than a breakdown of all potential costs mentioned in the previous paragraph. We note, however, that the estimates provided may overestimate the cost of the rule because they are based on the ICD transition that required more training than potentially the NDC transition will. For example, the RAND report estimates this cost based on 40 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. In the PRIA, we estimated this cost item to be five-percent relative to the ICD conversion. In this analysis, we update these costs using a factor of ten-percent instead.

We estimate the lower bound for the pharmaceutical industry is $15.83 million (ten percent of $100 million from the RAND report, updated to 2024 dollars).[4] For

[4] We do not have data on the number of coders employed in the pharmaceutical industry, and we assume

hospitals, we assume the same estimate of $15.83 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 other transition cost estimates for the remainder of the healthcare industry will be $7.91 million (ten percent of $50 million adjusted to 2024 dollars). We estimate the other transition costs to the insurance industry using the RAND report estimates of $25 million for 150,000 employees for the ICD conversion. Assuming that the NDC update is ten percent of those estimated in the RAND report, we estimate that the lower bound for the insurance industry will be $3.96 million after adjusting to 2024 dollars.

We estimate the combined lower bound estimate of other transition costs for all three industries will be $43.52 million (= $15.83 million for the pharmaceutical industry + $15.83 million for hospitals + $7.91 million for the rest of the healthcare industry + $3.96 million for the insurance industry). These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period and that the first year is 2026, the resulting present value is $29.26 million in 2024 using a 7-percent discount rate or $36.51 using a 3-percent discount rate.

We estimate the upper bound for the pharmaceutical industry is $23.74 million (ten percent of $150 million from the RAND report updated to 2024 dollars). We estimate the upper bound costs for hospitals separate from the rest of healthcare industry.

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the same number as in the hospital industry. This assumption likely overestimates the costs for the pharmaceutical industry.

For hospitals, we assume the same estimate of $23.74 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 other transition costs estimates for the remainder of the healthcare industry will be $23.74 million (ten percent of $150 million, adjusted to 2024 dollars). We estimate the other transition 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 ten percent of those estimate in the RAND report, we estimate the upper bound for the insurance industry to be $7.91 million after adjusting to 2024 dollars. We estimate the combined upper bound estimate is $79.13 million (= $23.74 million for the pharmaceutical industry + $23.74 million for hospitals + $23.74 million for the rest of the healthcare industry + $7.91 million for the insurance industry). These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period and that the first year is 2026, the resulting present value is $53.21 million in 2024 using a 7-percent discount rate or $66.38 using a 3-percent discount rate.

The primary estimate of expected costs to industry from other transition costs is the average of the lower and upper bound estimates, or $61.32 million (= ($43.52 million + $79.13 million) / 2). Thus, assuming that one-seventh of these costs occur each year of the first seven years after publication of the rule and that the first year is 2026, the resulting present value is $41.24 million in 2024 using a 7-percent discount rate or $51.45 using a 3-percent discount rate. Table 4 shows these estimates in row 4.

*3. Reading and Understanding Costs*

Pharmaceutical, healthcare, and insurance staff will incur one-time costs to read and understand the rule. We use three 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 2024 Bureau of Labor Statistics (BLS)-Occupational Employment Statistics for Pharmaceutical and Medicine Manufacturing and multiplying by two to reflect overhead and benefits.[6] Using our count of 2,882 pharmaceutical stakeholders from the 2022 economic census of Pharmaceutical and Medicine Manufacturers, we estimate the lower bound cost of reading and understanding the rule, rounded to the nearest decimal, will be $1.65 million (= 3 hours to read the rule x $190.96 mean fully loaded wage x 2,882 labelers).

Although the rule does not impose requirements directly on the healthcare and insurance industries, the healthcare industry will likely read the rule to understand how changes to the pharmaceutical industry will impact them; the number of entities affected, however, and the effort to read and understand the rule are uncertain. Thus, we use the same estimate for reading and understanding costs of $1.65 million from the pharmaceutical industry. We estimate the combined lower bound estimate is $4.95 million (= $1.65 million for the pharmaceutical industry + $1.65 million for the

[5] For further details, see U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Guidelines for Regulatory Impact Analysis. https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.
[6] https://www.bls.gov/oes/current/naics4_325400.htm#11-0000.

healthcare industry + $1.65 million for the insurance industry). These costs are likely to occur during the first year after the rule is published. Assuming the first year after the rule is published is 2026, the resulting present value is $4.04 million in 2024 using a 7-percent discount rate or $4.53 using a 3-percent discount rate.

We estimate the upper bound as follows. We use the mean wages for operation managers from the 2024 BLS-Occupational Employment Statistics for Pharmaceutical and Medicine Manufacturing and multiply by two to reflect overhead and benefits.[7] We use a count of 11,000 pharmaceutical stakeholders from our listing and registration records. For the pharmaceutical industry, the resulting upper bound is $6.30 million (= 3 hours to read the rule x $190.96 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 $18.91 million (= $6.30 million pharma + $6.30 million healthcare + $6.30 million insurance), rounded to the nearest decimal. These costs are likely to occur during the first year after the rule is published. Assuming the first year after the rule is published is 2026, the resulting present value is $15.43 million in 2024 using a 7-percent discount rate or $17.30 using a 3-percent discount rate.

The primary estimate of expected costs to reading and understanding the rule is the average of the lower and upper bound estimates, or $11.93 million (= $4.95 million + $18.91 million) / 2). These costs are likely to occur during the first year after the rule is published. Assuming the first year after the rule is published is 2026, the resulting present

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

value is $9.74 million in 2024 using a 7-percent discount rate or $10.92 using a 3-percent discount rate. Table 4 shows these reading and understanding estimates in row 5.

*4. Coordination of Label Updates*

The final rule is effective seven years after its publication. On the effective date of the final rule, we will begin assigning new NDCs in the uniform 12-digit format, and FDA will convert all existing 10-digit NDCs in drug listing files to the 12-digit NDC format by adding a leading zero to the appropriate segment(s) of the NDC. All drug listing files submitted to FDA after the effective date must identify the NDC using the 12-digit NDC format. In addition, there will be a three-year transition period following the effective date. We encourage firms to start labeling such drugs with the new 12-digit NDC format as soon as possible during this transition period. While relabeling costs can be largely avoided by coordinating NDC labeling updates with other planned labeling changes, we account for the time and effort that it might take labelers to carry out this internal coordination, which should be started well before the effective date of the rule. We use the 2014 Labeling Cost Model (LCM) Report from RTI, Inc. (the RTI Report) (Ref. 2) to estimate these one-time costs. The report describes these costs in terms of hours from general management and recordkeeping staff. We received comments that these costs were underestimated, and we are updating the labor hours to perform the coordination of these label update efforts to just over double what we estimated in the PRIA.

For the lower bound, we estimate $2,944 dollars per stakeholder. This includes 10 hours from general and operation management multiplied by a fully-loaded hourly wage of $190.96, plus 20 hours from production occupations multiplied by a fully-loaded wage

of $51.72. The hourly wages are from the 2024 BLS for Pharmaceutical and Medicine Manufacturers, NAICS 325400. Then, we multiply by 2,882 pharmaceutical stakeholders from the Pharmaceutical and Medicine Manufacturers counts, NAICS 3254, from the 2022 economic census.[8] The resulting lower-bound of coordination costs for the pharmaceutical industry is $8.48 million (= ($190.96 x 10 + $51.72 x 20) x 2,882) stakeholders. These costs are likely to take place during the seven-year period between publication of the rule and its effective date. Thus, assuming that one-seventh of these costs occur each year of this period and that the first year is 2026, the resulting present value is $5.71 million in 2024 using a 7-percent discount rate or $7.12 using a 3-percent discount rate.

For the upper bound, we estimate $5,888 dollars per stakeholder, estimated as 20 hours from general and operation management multiplied by a fully-loaded hourly wage of $190.96 plus 40 hours from production occupations multiplied by a fully-loaded wage of $51.72. Then, we multiply by 11,000 stakeholders from our registration and listing records. The resulting upper-bound of label coordination costs for the pharmaceutical industry is $64.77 million (= ($190.96 x 20 + $51.72 x 40) x 11,000) stakeholders. Thus, assuming that one-seventh of these costs occur each of the first seven years after publication of the rule and that the first year is 2026, the resulting present value is $43.55 million in 2024 using a 7-percent discount rate or $54.34 using a 3-percent discount rate.

The primary estimate is $4,416 dollars per stakeholder. We estimate it as the average of the low and upper bound estimates per stakeholder. Then, we multiply by the average count of stakeholders, 6,941. The resulting primary estimate of coordination

[8] United States Census Bureau, U.S. Department of Commerce, Statistics of U.S. Businesses. Accessed Spring 2024, www.census.gov/programs-surveys/susb.html.

costs for the pharmaceutical industry is $30.65 million. Thus, assuming that one-seventh of these costs occur each of the first seven years after publication of the rule and that the first year is 2026, the resulting present value is $20.61 million in 2024 using a 7-percent discount rate or $25.71 using a 3-percent discount rate. Table 4 shows these estimates in row 6 rounded to the nearest decimal.

We received some comments noting that we did not include the cost of discarding inventory of the old labels. We do not include this cost element in the analysis because we stated that during the three-year transition period, we do not intend to object to products being introduced into interstate commerce with the 10-digit NDC that they were previously assigned. In addition, the final rule clarifies that products introduced into interstate commerce or delivered for introduction into interstate commerce before the effective date can remain on the market and accessible to patients after the 3-year transition period if they have not expired. In addition, we note that we have extended the effective date from the proposed five years after publication to seven years, which allows for inventory planning and more precise timing of labeling changes. By delaying the effective date and clarifying our enforcement policy for products labeled with a 10-digit NDC introduced or delivered for introduction into interstate commerce before the effective date, we allow labels bearing a 10-digit NDC to be exhausted and eliminate the need to discard inventory of labels with the 10-digit NDC.

*5. Summary of Industry Costs*

Table 4 summarizes all estimated costs. 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 2024 millions of dollars, across all three industries ranges from $53.65 million to $160.08 million with a primary estimate of $102.85 million using a 7-percent discount rate. By contrast, using a 3-percent discount rate, the total present value of estimated costs ranges from $66.42 million to $197.76 million with a primary estimate of $127.08 million.

Table 4. Summary of Industry Estimated Costs ($millions, 2024)

| Cost Items | Primary 7% | Lower 7% | Upper 7% | Primary 3% | Lower 3% | Upper 3% |
|---|---|---|---|---|---|---|
| One-Time Costs | | | | | | |
| Software and Updates of NDC Records | $31.26 | $14.63 | $47.89 | $39.00 | $18.26 | $59.74 |
| Other Transition Costs | $41.24 | $29.26 | $53.21 | $51.45 | $36.51 | $66.38 |
| Reading and Understanding | $9.74 | $4.04 | $15.43 | $10.92 | $4.53 | $17.30 |
| Coordination of Label Updates | $20.61 | $5.71 | $43.55 | $25.71 | $7.12 | $54.34 |
| Present Value of Total Industry Costs | $102.85 | $53.65 | $160.08 | $127.08 | $66.42 | $197.76 |
| Annualized Values | $14.64 | $7.64 | $22.79 | $14.90 | $7.79 | $23.18 |

Note: Costs estimates are in present values of $millions 2024 considering that the first year of the rule will be 2026. Annualized values are calculated over a ten-year horizon.

We assume these costs are likely to be spread out over the seven-year period after publication of the rule. Thus, we estimate that one-seventh of these costs occur each year of this period and use 2026 as the first year of the rule. The reading and understanding costs, however, we assume will occur only during the first year after the rule is published.

The annualized values over a ten-year horizon range from $7.64 million to $22.79 million with a primary estimate of $14.64 million using a 7-percent discount rate. By contrast, using a 3-percent discount rate, the annualized values of estimated costs range from $7.79 million to $23.18 million with a primary estimate of $14.90 million.

These estimates are conservative and likely overestimate the cost of the rule. In addition, the rule does not require healthcare and insurance groups to use the single format 12-digit NDCs, and thus, although we include them in the analysis, they are second order effects.

## G. Distributional Effects

We do not anticipate any significant distributional effects as a result of this rule. The estimated costs will 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 2004 report, Ref. 1).

## H. International Effects

We do not expect any significant effects on international trade because this rule does not impose any additional requirements on foreign stakeholders compared to domestic ones. Therefore, this rule will 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 rule. For example, we assumed that the one-time costs of software updates can be about 10 percent relative to the ICD conversion (see RAND 2004 report, Ref. 1). We also assume that the other transition costs will be about ten percent relative to the ICD conversion. In this sensitivity analysis, we present a wider range of costs estimates using 1 percent, 5

percent, 25 percent, and 50 percent across these three cost items. The estimated costs for reading and understanding the rule and the coordination of label updates are not affected by these assumptions. Table 5 compares all the sensitivity scenarios relative to the main estimates showing only primary estimates ranging from $37.60 million to $392.83 million. These costs are likely to be spread out over the seven-year period between publication of the rule and its effective date. Thus, we assume that one-seventh of these costs occur each year of this period and that the first year is 2026. The reading and understanding costs, however, we assume will occur the only during first year after the rule is published. We only present values using a 7-percent discount rate in this table.

Table 5. Sensitivity Comparison of Estimated Costs ($millions, 2024)

| Cost Items | Primary Estimates (Main 10%) | Primary Estimates (1%) | Primary Estimates (5%) | Primary Estimates (25%) | Primary Estimates (50%) |
|---|---|---|---|---|---|
| One-Time Costs | | | | | |
| Software and Updates | $31.26 | $3.13 | $15.63 | $78.15 | $156.30 |
| Other Transition Costs | $41.24 | $4.12 | $20.62 | $103.09 | $206.18 |
| Coordination of Label Updates | $20.61 | $20.61 | $20.61 | $20.61 | $20.61 |
| Reading and Understanding | $9.74 | $9.74 | $9.74 | $9.74 | $9.74 |
| Total Industry Costs Present Value | $102.85 | $37.60 | $66.60 | $211.59 | $392.83 |

Note: Costs estimates are in present values of $millions, 2024 considering that the first year of the rule will be 2026. Estimates are present values discounted at 7-percent.

*2. Uncertainty Analysis*

*i. Coordination of Label Updates*

This rule allows flexibility to update drug product labels to reflect the new 12-digit NDC format. During the three-year transition period, no enforcement action will be taken with respect to products that are labeled with the 10-digit NDC and are introduced into interstate commerce before the effective date. However, products that are labeled

with the 10-digit NDC and are introduced into interstate commerce after the effective date would be subject to enforcement action if they remain in interstate commerce after the end of the transition period. For this reason, we encourage firms to start labeling such drugs with the new 12-digit NDC format as soon as possible during this transition period. We, therefore, advise that label updating and reprinting be planned in a way that no such products remain in the market after the transition period ends. 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 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 (disposing of old inventory of packages or new labels on top of old ones). 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 will be about $0.58 and the cost to disposing of outdated containers is about $0.27. These estimates are from the RTI 2014 Report, updated to 2024 dollars (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 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 will experience.

The rule will likely result in some cost-savings from not having to process multiple formats of the 10-digt NDCs or having to convert them into or from an 11-digit HIPAA mandated format. These cost-savings will accrue over the long-run in perpetuity. Uncertainty about the level of effort saved from use of a single format prevents us from estimating such cost savings. We note that if HHS adopts the same 12-digit NDC format for HIPAA purposes, all costs associated with converting an FDA-assigned NDC to a different HIPAA NDC format will be eliminated.

*iii. Uncertain Allocation of Resources for Preparation of Transition*

In the cost section we assumed that some costs such as software updates, other transition costs, and coordination of label updates are likely to be spread over the seven-year period between publication of the rule and its effective date. Thus, we assume that one-seventh of these costs occur each year of this period and that the first year is 2026. This scenario may be uncertain if stakeholders allocate their efforts in preparation for the NDC transition in a different way focusing more on some years than others.

## J. Analysis of Regulatory Alternatives

We held a public meeting on November 5, 2018, where we outlined several options that we could adopt upon issuing 6-digit labeler codes, including the option to adopt a uniform 12-digit NDC format.[9] 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. In this section, we discuss each of the alternative options presented at the public meeting (i.e., those that did not involve promulgating a uniform, 12-digit NDC format), as well as some of the comments from the public meeting and comments we received on the proposed rule.

### *1. Option A: No Changes to the Regulations*

One option would be not to revise the regulations and continue with the status quo. Specifically, we would continue assigning the remainder of the 5-digit labeler codes, and whenever we run 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 conversions and the resulting additional quality control. We also discuss potential benefits to public health by having a single unified format that could eliminate risks to public health.

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

*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 would 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 FDA-assigned 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 code segment of the NDC, but this update would need to be implemented 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 NDCs, 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 rule would not be accomplished under this option, and it could result in medication errors.

*4. Public Comments*

We received oral comments during the public meeting 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 ten-year delay. The rule has a delayed effective date of seven years following its publication and provides for an additional three-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 will need to be able to handle the standardized 12-digit NDC format. A longer transition period would result in having multiple formats for a longer period and delay the benefits of the standardized NDC format.

The public meeting comments and a comment on the proposed rule 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. Switching responsibility of assigning NDCs to a third party has the potential to cause significant disruption in how NDCs are assigned and used in the supply chain and reimbursement practices. In addition, delegating this responsibility would also require rulemaking. As a result, we expect that industry would face larger coordination costs under this scenario.

At the public meeting and in response to the proposed rule, we received comments advocating that we retain the 10-digit NDC format after we exhaust the supply

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 with systems used for certain minimally manipulated human cells, tissue, and cellular and tissue-based products (HCT/P), it would likely not relieve many stakeholders of the requirement to update their systems to be capable of handling the new NDC format. We are also concerned that the introduction of alphabetic characters into the labeler code could increase the risk of medication errors because a letter can be confused for a different letter or for a numeral (e.g., an "F" could be misread as an "R" or as the numeral "7"), and a numeral can be misread as a letter (e.g., the numeral "6" may be confused for the letter "G").

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

We have examined the economic implications of the final rule as required by the Regulatory Flexibility Act. Because the one-time cost is unlikely to exceed 0.59 percent of average annual revenue for some very small stakeholders in the pharmaceutical industry, 0.33 percent of average annual revenue for some very small stakeholders in the insurance industry, and 0.40 percent of average annual revenue for some very small stakeholders in the healthcare industry, we certify that the final rule will 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 will be about 0.04 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 and the Preamble of the final rule, serves as the Final 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 6 displays the SBA 2022 size standards for the industries affected by the rule by NAICS code.[11] SBA size thresholds are provided by employment size or by annual revenues.

Table 6. Small Business Administration Size Standards for Industries Potentially Affected by the Rule (Revenue in $millions, 2024)

| 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 | | $47.0 |
| 524114 | Direct Health and Medical Insurance Carriers | | $47.0 |

[10] The SBA cutoffs are provided for the four subclassifications of NAICS code 3254, but not for the category as a whole.
[11] The SBA size standards are from 2022 and effective since March 2023 onward: https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

We use data from the 2022 Statistics of U.S. Businesses (SUSB) from the U.S. Census to identify the number of firms and their size by employment and by annual revenues.[12] These data show that the total count of Pharmaceutical and Medicine Manufacturing, NAICS code 3254, is 2,882 establishments; the total count of General Medical and Surgical Hospitals, NAICS code 622110, is 6,048 establishments; and the total count of Direct Health and Medical Insurance Carriers, NAICS code 524114, is 6,220 establishments.

The SUSB data show employment records in several brackets according to the number of employees which may not match exactly the SBA size standards of 1,250 employees to be considered a small company. Using the closest cutoff of 1,000 employees, the SUSB records show 2,332 small entities for the pharmaceutical industry. For the healthcare industry, the threshold to be considered a small entity is $47.0 million, and the closest corresponding threshold from the SUSB records is under 1,000-employees, which altogether have an average annual revenue of $42 million per establishment, in 2024 dollars. Thus, there are 1,778 small entities in the healthcare industry following these criteria. For the health insurance industry, the threshold to be considered a small entity is also $47.0 million, and the closest corresponding threshold from the SUSB records is under 400-employees, which altogether have an average annual revenue of $41.9 million per establishment. The resulting count is 947 small entities for the health insurance industry.

[12] 2022 is the most recent economic census available. The economic census is performed in years ending in 2 and 7. The next economic census will be performed in 2027 and available two years later. SUSB link: https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html.

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

To estimate the 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 2022 data updated to 2024 dollars 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 7 shows the primary estimates of one-time costs per small entity. The total costs rounded to the nearest dollar are $9,596 per pharmaceutical stakeholder, $5,180 per healthcare stakeholder, and $5,078 per insurance stakeholder.

Table 7. Costs Per Entity by Type ($dollars, 2024)

| Cost Item | Pharmaceutical Industry | Healthcare Industry | Insurance Industry |
|---|---|---|---|
| Software | $1,757 | $1,757 | $3,551 |
| Other Transition Costs | $2,850 | $2,850 | $954 |
| Reading and Understanding | $573 | $573 | $573 |
| Coordination of Labeling Updates | $4,416 | $0 | $0 |
| Total Cost | $9,596 | $5,180 | $5,078 |

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

Table 8 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 five employees, the cost-to-revenue percentage is 0.59 percent (= $9,596 dollars in average one-time costs per entity / $1.6 million in average annual revenues). Considering all small pharmaceutical stakeholders with fewer than 1,000 employees, the one-time costs represent no more than 0.04 percent of annual revenues on average (= $9,596 dollars in one-time costs / $24.3 million in average annual revenues).

Table 8. Costs Relative to Annual Receipts for the Pharmaceutical Industry by Entity Size (Revenue in $millions, 2024)

| Employment Size | Number of Establishments | Total Revenue | Average Revenue Per Establishment | Cost to Revenue Percent |
|---|---|---|---|---|
| <5 employees | 782 | $1,264.8 | $1.6 | 0.59% |
| 5-9 employees | 318 | $888.2 | $2.8 | 0.34% |
| 10-14 employees | 182 | $1,056.2 | $5.8 | 0.17% |
| 15-19 employees | 91 | $688.2 | $7.6 | 0.13% |
| <20 employees | 1,373 | $3,897.5 | $2.8 | 0.34% |
| 20-24 employees | 67 | $478.1 | $7.1 | 0.13% |
| 25-29 employees | 73 | $714.3 | $9.8 | 0.10% |
| 30-34 employees | 52 | $511.9 | $9.8 | 0.10% |
| 35-39 employees | 44 | $473.0 | $10.8 | 0.09% |
| 40-49 employees | 69 | $1,018.0 | $14.8 | 0.07% |
| 50-74 employees | 90 | $2,707.1 | $30.1 | 0.03% |
| 75-99 employees | 66 | $1,847.9 | $28.0 | 0.03% |
| 100-149 employees | 89 | $3,705.7 | $41.6 | 0.02% |
| 150-199 employees | 87 | $5,029.6 | $57.8 | 0.02% |
| 200-299 employees | 93 | $6,906.8 | $74.3 | 0.01% |
| 300-399 employees | 58 | $6,084.9 | $104.9 | 0.01% |
| 400-499 employees | 40 | $4,445.2 | $111.1 | 0.01% |
| <500 employees | 2,201 | $37,820.2 | $17.2 | 0.06% |
| 500-749 employees | 79 | $10,607.2 | $134.3 | 0.01% |
| 750-999 employees | 52 | $8,243.8 | $158.5 | 0.01% |
| <1000 employees | 2,332 | $56,671 | $24.3 | 0.04% |

Table 9 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 five employees, the cost-to-revenue percentage is 0.40 percent (= $5,180 dollars in one-time costs / $1.3 million in average annual revenues). Considering all small healthcare stakeholders with fewer than 1,000 employees, the one-time costs represent no more than 0.01 percent of annual revenues on average (= $5,180 dollars in one-time costs / $42 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.

Table 9. Costs Relative to Annual Receipts for the Healthcare Industry by Entity Size (Revenue in $millions, 2024)

| Employment Size | Number of Establishments | Total Revenue | Average Revenue Per Establishment | Cost to Revenue Percent |
|---|---|---|---|---|
| <5 employees | 273 | $350 | $1.3 | 0.40% |
| 5-9 employees | 23 | $125 | $5.4 | 0.10% |
| <20 employees | 303 | $490 | $1.6 | 0.32% |
| 20-24 employees | 9 | $18 | $2.0 | 0.26% |
| 25-29 employees | 9 | $13 | $1.4 | 0.36% |
| 30-34 employees | 4 | $565 | $141.3 | 0.00% |
| 40-49 employees | 16 | $118 | $7.4 | 0.07% |
| 50-74 employees | 62 | $528 | $8.5 | 0.06% |
| 75-99 employees | 92 | $1,142 | $12.4 | 0.04% |
| 100-149 employees | 212 | $3,998 | $18.9 | 0.03% |
| 150-199 employees | 187 | $5,093 | $27.2 | 0.02% |
| 200-299 employees | 288 | $10,788 | $37.5 | 0.01% |
| 300-399 employees | 163 | $8,813 | $54.1 | 0.01% |
| 400-499 employees | 136 | $9,984 | $73.4 | 0.01% |
| <500 employees | 1,483 | $41,561 | $28.0 | 0.02% |
| 500-749 employees | 171 | $17,090 | $99.9 | 0.01% |
| 750-999 employees | 124 | $16,074 | $129.6 | 0.00% |
| <1000 employees | 1,778 | $74,725 | $42.0 | 0.01% |

Table 10 shows the cost-to-revenue percentages for small direct health insurance stakeholders calculated as cost per stakeholder divided by average revenue. For the smallest stakeholders with fewer than five employees, the cost-to-revenue percentage is 0.33 percent (= $5,078 dollars in one-time costs / $1.5 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 400 employees with average revenues of $41.9 million is the closest to the SBA cut-off of $47.0 million for small entities.

Table 10. Costs Relative to Annual Receipts for the Insurance Industry by Entity Size (Revenue in $millions, 2024)

| Employment Size | Number of Establishments | Total Revenue | Average Revenue Per Establishment | Cost to Revenue Percent |
|---|---|---|---|---|
| <5 employees | 644 | $977 | $1.5 | 0.33% |
| 5-9 employees | 66 | $247 | $3.7 | 0.14% |
| 10-14 employees | 25 | $372 | $14.9 | 0.03% |
| 15-19 employees | 16 | $155 | $9.7 | 0.05% |
| <20 employees | 751 | $1,750 | $2.3 | 0.22% |
| 20-24 employees | 7 | $194 | $27.8 | 0.02% |
| 25-29 employees | 9 | $895 | $99.4 | 0.01% |
| 30-34 employees | 5 | $183 | $36.7 | 0.01% |
| 35-39 employees | 13 | $542 | $41.7 | 0.01% |
| 40-49 employees | 15 | $458 | $30.5 | 0.02% |
| 50-74 employees | 27 | $1,698 | $62.9 | 0.01% |
| 75-99 employees | 15 | $1,738 | $115.9 | 0.00% |
| 100-149 employees | 31 | $3,191 | $102.9 | 0.00% |
| 150-199 employees | 24 | $16,411 | $683.8 | 0.00% |
| 200-299 employees | 38 | $10,090 | $265.5 | 0.00% |
| <400 | 947 | $39,686 | $41.9 | 0.01% |

To summarize, the highest cost-to-revenue estimates across the three industry groups are 0.59 percent of average annual revenue for some very small stakeholders in the pharmaceutical industry, 0.33 percent of average annual revenue for some very small stakeholders in the insurance industry, and 0.40 percent of average annual revenue for some very small stakeholders in the healthcare industry, we certify that the final rule will 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.