



BILLING CODE 4120-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS-0055-F]

RIN 0938-AT52

Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule adopts a modification of the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, by requiring covered entities to use the Quantity Prescribed (460-ET) field for retail pharmacy transactions for Schedule II drugs. The modification enables covered entities to distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, where the full amount prescribed is dispensed, in the HIPAA retail pharmacy transactions. This modification is important to ensure the availability of a greater quantum of data that may help prevent impermissible refills of Schedule II drugs, which will help to address the public health concerns associated with prescription drug abuse in the United States.

DATES: *Effective Date:* This final rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Incorporation by reference: The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register as of March 17, 2009.

Compliance Date: Compliance with these regulations is required by [INSERT DATE 180 DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

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SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Secretary of Health and Human Services (HHS) to adopt standards for the electronic transmission of certain health care administrative transactions conducted between health care providers, health plans, health care clearinghouses, and others. In January 2009 (74 FR 3295), the Secretary adopted the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007 (hereinafter referred to as Version D.0) for the following retail pharmacy transactions: health care claims or equivalent encounter information, referral certification and authorization, and coordination of benefits.

A. Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills

Schedule II drugs are defined, in part, by the Controlled Substances Act (CSA) as those with a high potential for abuse which may lead to severe psychological or physical dependence (21 U.S.C. 812(b)(2)). Regulators take particular interest in Schedule II drugs because of public health concerns associated with their potential for misuse. The CSA prohibits the refilling of

Schedule II drugs, but permits partial fills of Schedule II drugs in limited circumstances where a pharmacist has less than the prescribed amount of a medication in stock, the prescription is for a patient in a long-term care (LTC) facility, or a patient has a terminal illness.¹

In September 2012, the HHS Office of the Inspector General (OIG) issued a report titled “Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills” that analyzed all of the 2009 program year prescription drug event (PDE) records for refills of Schedule II drugs.² PDE records are claim summary records that contain data elements from prescription drug claims, submitted by prescription drug plan sponsors to the Centers for Medicare & Medicaid Services (CMS) for every prescription a provider fills for a Medicare Part D beneficiary. One of those data element fields is titled “Fill Number (403-D3),”³ which identifies refills. The Version D.0 implementation specifications require that a “0” be entered in the Fill Number (403-D3) field for a new prescription and that the number be sequentially increased by “1” for each refill. The OIG analyzed 20.1 million records for Schedule II drugs and, focusing on the Fill Number (403-D3) field, identified what it concluded were refills. The OIG concluded that the Medicare Part D program had inappropriately paid \$25 million for 397,203 Schedule II drug refills and that LTC facility pharmacies billed for 75 percent of such refills. The OIG stated that the Medicare Part D plan sponsors should not have paid for those drugs because Federal law prohibits Schedule II drug refills, and concluded that “[p]aying for such drugs raises public

¹The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by the Comprehensive Addiction and Recovery Act (CARA).

²Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

³National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007, defines the Fill Number Field as “403-D3.”

health concerns and may contribute to the diverting of controlled substances and their being resold on the street.”⁴

CMS took a different interpretation of the OIG’s findings. In its written response to the OIG report,⁵ CMS expressed concern that the OIG’s strict interpretation of PDE data did not support the OIG’s findings. CMS believed the OIG’s findings were based, in part, on a misinterpretation of Schedule II drug partial fills dispensed to LTC facility residents as refills. This prompted CMS to make an inquiry to an NCPDP work group, the WG9 Government Programs Medicare Part D FAQ Task Group (“Task Group”), which is designed to guide Federal pharmacy programs on NCPDP standards. CMS noted to the Task Group that, while the OIG report appeared to misinterpret partial fills as refills dispensed to patients in LTC facility pharmacies, it was not aware of any means by which a pharmacy could distinguish partial fills of a controlled substance prescription for billing purposes without using the Fill Number (403-D3) field. The Task Group replied to CMS that the Version D.0 implementation specification did not support the OIG’s findings regarding the use of the Fill Number (403-D3) field,⁶ and that the industry used the Fill Number (403-D3) field to represent the fill number—the amount actually dispensed—and not necessarily the refill number.

As a result, the Task Group initiated Designated Standard Maintenance Organization (DSMO) change request #1182⁷ to update the pharmacy standard to effect a clarification and avoid further misinterpretation. The Task Group advised CMS that NCPDP would recommend changes to the standard to allow Version D.0 to specify the conditional use of a field not then

⁴ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 13
<https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

⁵ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 17
<https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

⁶ https://www.ncdp.org/NCPDP/media/pdf/OESS_request_20121115.pdf.

⁷ https://www.ncdp.org/NCPDP/media/pdf/OESS_request_20121115.pdf.

used in the claim billing transaction, the Quantity Prescribed (460-ET) field, to indicate the actual quantity prescribed in the transmission of the claim, which would make data available to validate whether there are inappropriate fills in excess of the quantity prescribed. NCPDP noted this change in its November 2012 publication of Version D.0, which required the use of the Quantity Prescribed (460-ET) field when claims for Schedule II drugs are submitted to Medicare Part D. However, HHS has not adopted the November 2012 publication of Version D.0, thus HIPAA covered entities may not use it for HIPAA transactions.

B. National Committee on Vital and Health Statistics (NCVHS) Recommendation

On June 21, 2013, the NCVHS wrote to the Secretary that it agreed with NCPDP's recommendation to allow Version D.0 to specify the conditional use of the Quantity Prescribed (460-ET) field in a republished Version D.0 with an explanation in the Editorial Corrections section, and a change to the Version D.0 Editorial Document.⁸ The NCVHS indicated that, with this change, "data will be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed, a concern raised in a September 2012 report from the HHS Office of the Inspector General."

C. Congressional and Administration Actions in Response to the Opioid Crisis

During the last decade, the nation has experienced worsening issues with opioid addiction and overdose deaths, prompting various Congressional and Administration actions. For example, the Comprehensive Addiction and Recovery Act (CARA) (Pub. L. 114-198) was enacted on July 22, 2016. CARA amended the CSA to allow a pharmacist to partially fill a prescription for a Schedule II controlled substance if (1) such partial fills are not prohibited by state law; (2) a partial fill is requested by the patient or prescribing practitioner; and (3) the total

⁸To review the recommendation, see <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/130621lt1.pdf>.

quantity dispensed in a partial fill does not exceed the quantity prescribed. We believe CARA's implementation will yield an upsurge in partial fills. That view is echoed in a May 31, 2017 letter NCPDP sent to the DEA, which stated "[w]ith implementation of the CARA partial Fill Provision, the potential exists for a significant increase in the number of occurrences of a prescription for a Schedule II controlled substance being partially filled."

Pursuant to the President's direction to consider the declaration of the public health emergency, consistent with the requirements of the Public Health Service Act, the Acting Secretary declared a nationwide public health emergency to address the opioid crisis on October 26, 2017.⁹ The President also directed the heads of executive departments and agencies to use all lawful means to exercise all appropriate emergency and other relevant authorities to reduce the number of deaths and minimize the devastation the drug demand and opioid crisis inflicts upon American communities. Even prior to the President's direction, HHS had been responsive to the opioid crisis. In April 2017, the Secretary announced a 5-Point Strategy to--

- Improve access to prevention, treatment, and recovery support services;
- Target the availability and distribution of overdose-reversing drugs;
- Strengthen public health data reporting and collection;
- Support cutting-edge research on addiction and pain; and
- Advance the practice of pain management.¹⁰

The requirements finalized in this rule support one of our top opioid strategic priorities calling for better data, which may ultimately help in reducing the drug supply.

II. Provisions of the Proposed Rule and the Analysis of and Responses to Public Comments

⁹<https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf>.

¹⁰<https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

In the January 31, 2019 **Federal Register** (84 FR 633), we published the proposed rule titled "Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard" (hereafter referred to as the January 2019 proposed rule). In response to the January 2019 proposed rule, we received 15 timely pieces of correspondence from a variety of commenters, including a pharmacy standards development organization, data content committees, health plans, health care companies, professional associations, technology companies, and individuals.

In this section of this final rule, we present our proposals, summation of the comments received, and our responses to the comments. Some of the public comments received in response to the January 2019 proposed rule were outside of the scope of the proposed rule, and are not addressed in this final rule.

A. Modification of the Requirements for Use of the Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, NCPDP

We proposed to adopt a modification of the requirements for the use of the Quantity Prescribed (460-ET) field of the August 2007 publication of Version D.0, which is the currently adopted version. We indicated that the modification would require that covered entities treat that field as required where a transmission uses Version D.0, August 2007, for a Schedule II drug for these transactions: (1) health care claims or equivalent encounter information; (2) referral certification and authorization; and (3) coordination of benefits. HHS believes that, by modifying the requirements for the use of the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, covered entities will

be able to clearly distinguish whether a prescription is a “partial fill,” or a refill, in the HIPAA retail pharmacy transactions.

Comment: A number of commenters supported HHS’s proposal, noting that its narrow approach would not increase administrative burden and would let all covered entities accurately reflect partial fills of Schedule II drugs. A commenter stated that, while the proposal would not itself solve the opioid crisis, it would represent a step in the right direction by yielding better data to allow researchers to understand opioid prescribing trends.

Response: We thank the commenters for their support.

Comment: Some commenters did not agree with the proposal and urged HHS to adopt the November 2012 publication of Version D.0, which commenters stated was balloted and approved by the NCPDP membership and subsequently approved by the American National Standards Institute. Some of these commenters noted that NCPDP’s only modification in that November 2012 version was to alter use of the Quantity Prescribed (460-ET) field from “not used” to “situational.”

Response: We note that, regardless of whether NCPDP’s only change in its November 2012 version of D.0 was with respect to the Quantity Prescribed (460-ET) field, NCPDP had made other changes in previous D.0 releases before that time, and that all of the modifications NCPDP made to Version D.0 subsequent to the currently adopted 2007 version are included in its November 2012 publication. Thus, were we to adopt the November 2012 version here, covered entities would be required to implement a number of changes in addition to the one associated with the Quantity Prescribed (460-ET) field. Moreover, as we noted in the January 2019 proposed rule (84 FR 635), the alterations NCPDP made with respect to the Quantity Prescribed (460-ET) field in its November 2012 publication applied only to Medicare Part D

claims, which would not cover a huge swath of HIPAA covered entities. We continue to believe that the narrow, targeted approach we proposed best addresses the immediate need to yield better data and information regarding partial fills of Schedule II drugs, and is the least burdensome to the industry.

Comment: Some commenters stated that HHS's proposal to modify the requirements for the use of the Quantity Prescribed (460-ET) field in Version D.0 failed to follow the process for adopting a modification to an existing HIPAA standard as established in the Transactions and Code Sets Rule and codified at § 162.910.

Response: As we explained in the January 2019 proposed rule (84 FR 635), the proposal would not modify the currently adopted Version D.0. Rather, it would require covered entities to treat a field in Version D.0 differently than is required by the Version D.0 implementation specifications. While commenters rightly note that modifications to HIPAA standards would require HHS to use the standards modification process established through rulemaking, because we are not modifying a HIPAA standard, we are not required to follow that process.

Specifically, our regulations at § 162.923(a) require covered entities to comply with the adopted HIPAA standards, except as otherwise provided. Here, we are providing that in a narrow instance, covered entities must use the adopted HIPAA standard Version D.0 in a way other than that specified by Version D.0. This constitutes a modification to the *use* of the adopted standard, not a modification to the standard itself. The term "implementation specification" is defined broadly at 45 CFR 160.103 as "specific requirements or instructions for implementing a standard." Under the HIPAA regulations, implementation specifications are not limited to just those developed by standard setting organizations, which we adopt as HIPAA standards and incorporate by reference in the CFR. Implementation specifications are also

requirements we establish for covered entities to comply with a standard. Under §162.923(a), which specifies that we may require covered entities to comply with the adopted HIPAA standards except as otherwise provided, we are providing an exception.

Comment: Some commenters, recognizing that NCPDP's November 2012 Version of D.0 was limited to just Medicare Part D, recommended, as a work-around, that HHS adopt the November 2012 publication of Version D.0 and include language in the final rule stating that "covered entities must designate the situational field, Quantity Prescribed (460-ET) field as required for Schedule II Drugs, within applicable trading partner materials." To that end, the commenters suggested that NCPDP payer sheets, which are used to define required field submission, could be used as part of trading partner materials where payers could require the submission of the Quantity Prescribed (460-ET) field for all claims or equivalent encounter information, prior authorization, and coordination of benefits transactions where the drug dispensed is a Schedule II drug.

Response: We considered the commenters' suggestion, but continue to believe that our proposal to modify the requirements for the use of Version D.0 is the least burdensome approach for covered entities. As noted earlier in this final rule, that November 2012 publication includes modifications NCPDP made subsequent to the version we adopted as the HIPAA standard; if we were to adopt the November 2012 publication, covered entities would be required to implement a number of changes in addition to the one associated with the Quantity Prescribed (460-ET) field.

Comment: A commenter noted that the proposed change would make apparent the discrepancies between the prescribed and dispensed quantities, but would not help explain the discrepancies. The commenter illustrated this point with the following example. "[I]f the physician wrote the prescription for #60 and the pharmacy only dispenses #30, this does not

mean it is a ‘partial fill,’ the discrepancy could instead be due to insurance restricting the drug supply, or other insurance requirements. The Quantity Prescribed (460-ET) field does not specifically indicate if a partial fill happens. This could lead to erroneous conclusions about the fill event in certain instances, such as when the insurance plan may have limited how much was allowed for coverage, or if there was not enough quantity in stock, which would not provide the intended data surrounding actual partial fills.” The commenter recommended that HHS instead utilize the following combination of fields, which the commenter asserted would clarify a discrepancy between prescribed and dispensed quantities—Dispensing Status (343-HD) field; Quantity Intended To Be Dispensed (344-HF) field; and Day Supply Intended To Be Dispensed (345-HG) field. The commenter noted that these fields are not required, but are available and supported by Version D.0.

Response: The fields to which the commenter refers are presently and purposefully only intended for use in the case of a pharmacy inventory shortage. We believe the approach we proposed, and adopt here, is superior to the commenter’s recommended approach, which would be significantly more burdensome to covered entities by requiring them to comply with different requirements for each type of partial fill and to implement more software systems updates.

Comment: A commenter suggested that it would be easier for many pharmacies to implement systems changes to effectuate HHS’s proposal so that the modification to the requirements for the use of the Quantity Prescribed (460-ET) field could cover more than just Schedule II drugs. Therefore, the commenter suggested that HHS expand this proposal to include Schedule III through V drugs as well. Conversely, several commenters supported HHS’s proposed approach, which limits the modification to just Schedule II drugs.

Response: As discussed earlier in this final rule, the need for regulatory action to modify the requirements for the use of the August 2007 version of the NCPDP D.0 standard and the concerns motivating our proposed modification stem partly from CARA's change to the partial fill requirements for Schedule II drugs. We believe that requiring the Quantity Prescribed (460-ET) field to apply to all drugs, not just Schedule II drugs, would increase the burden on pharmacies, nor would it further the goals discussed herein. Therefore, we are finalizing our proposal without modification, but appreciate the commenters' varied perspectives, and may in the future consider expanding this requirement to include prescribed drugs in Schedules III through V.

Comment: A commenter encouraged the Secretary to expedite a proposed rule seeking the adoption of the NCPDP Telecommunication Standard Implementation Guide Version F2, which the commenter asserts provides enhanced transparency and improves patient safety measures for all controlled substances. By contrast, another commenter was pleased that we did not propose to adopt Version F2 because the commenter believes the language of the relevant field to be "chilling" as it suggests penalties may apply when the field is misused.

Response: We appreciate that there are arguments for and against expedited rulemaking for the adoption of NCPDP Telecommunication Standard Implementation Guide Version F2. Were we to adopt Version F2, covered entities would need to make significant changes. While we continue to carefully evaluate the NCVHS's May 17, 2018 recommendation encouraging HHS to adopt the updated NCPDP pharmacy standards, we believe the public health emergency caused by the opioid crisis, and the urgent need for better data and information to help combat it, dictate that we now take this narrow, targeted approach as proposed.

Comment: A number of commenters supported HHS’s proposal that the term “Schedule II drugs,” be included in the modifications to §§ 162.1102, 162.1302, and 162.1802, to mirror the Drug Enforcement Administration's definition of the term at 21 CFR 1308.12. Some of these commenters agreed with HHS that Schedule III through V drugs should not be included in this rule.

Response: We thank the commenters for their support. We note that in this final rule, we are making a technical change to the regulation text to remove the phrase “as updated” from each of the three provisions that define Schedule II drugs, that is, §§ 162.1102(d)(1), 162.1302(d)(1), and 162.1802(d)(1), because the phrase is superfluous.

After reviewing the public comments received, we are finalizing the modification of the requirements for the use of the Quantity Prescribed (460-ET) field for retail pharmacy transactions, which will be reflected in the regulations at §§ 162.1102, 162.1302, and 162.1802.

B. Effective and Compliance Dates

We proposed that the final rule would be effective 60 days after publication in the **Federal Register** and that the compliance date would be 180 days after the effective date, in accordance with section 1175(b)(2) of the Social Security Act.

Comment: A number of commenters supported HHS’s proposed effective and compliance dates for the modification.

Response: We thank the commenters for their support.

Comment: Some commenters urged HHS to revise the implementation timeline of the proposed modification. These commenters suggested that HHS should not adopt a compliance date that would interfere with end-of-year industry processing requirements. Commenters explained that they estimated the compliance date for this final rule would be January 2020,

which coincides with the 2020 Medicare Part D rule's implementation timeframe for the NCPDP SCRIPT Standard Version 2017071 as well as the normal annual benefit plan changes. Another commenter stated that a short compliance timeframe would cause beneficiaries to be unable to access their medications because payers would not have sufficient time to make the necessary systems changes. A commenter recommended that HHS implement a transitional period for this modification whereby payers may begin using the Quantity Prescribed (460-ET) field on the effective date of the final rule, but mandatory use of the field for all entities be no earlier than June 2020. Finally, some commenters stated their belief that the compliance date and effective date are the same, which they believed would result in a hard cut-over that could engender risks in patient access to care as well as burdensome administrative and operational challenges.

Response: In considering these comments, we recognize commenters' confusion with respect to the distinct concepts of compliance and effective dates, and we have clarified the regulation text in this final rule to be clear that the compliance date is 180 days after the effective date of the rule. As we noted previously in this document, this final rule will be effective 60 days after publication in the **Federal Register**. The compliance date, or the date on which covered entities must comply with the modification, follows that by 180 days. In the spring 2019 Unified Regulatory Agenda, we noted that, this final rule would be published in December 2019. Based on that, we anticipate that the effective date of this rule will be in February 2020 and the compliance date will be in August 2020. We believe this explanation ameliorates commenters' concerns. After consideration of the public comments received and the clarification offered here, we are finalizing the effective and compliance dates of this final rule without modification.

III. Incorporation by Reference

The incorporation by reference of the standards referenced in this rule (Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs) was previously approved for the amended sections. We are making no changes to the incorporation.

IV. Collection of Information Requirements

The Office of Management and Budget (OMB) has determined that the establishment of standards for electronic transactions under HIPAA (which mandate that the private sector disclose information and do so in a particular format) constitutes an agency-sponsored third-party disclosure as defined under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). (See 65 FR 50350 (August 17, 2000).) With respect to the scope of its review under the PRA, however, OMB has concluded that its review would be limited to the review and approval of initial standards, and to changes in industry standards which would substantially reduce administrative costs. (See 65 FR 50350 (August 17, 2000).) This document, which requires the use of a data element that was not previously used and the disclosure of additional information in a particular location in the transaction, would usually constitute an information collection requirement because it requires third-party disclosures. However, because of OMB's determination, noted above, there is no need for OMB review under the PRA. But see 5 CFR 1320.3(b)(2) (time, effort, and financial resources necessary to comply with an information collection that would otherwise be incurred in the normal course of business can be excluded from PRA "burden" if the agency demonstrates that such activities needed to comply with the information collection are usual and customary).

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. We did not receive any comments on the regulatory impact statement from the January 2019 proposed rule. Therefore, we are finalizing it in this rule with no modifications.

Covered entities inconsistently reflect partial fills and fill numbers for Schedule II drugs in retail pharmacy transactions that utilize Version D.0 because Version D.0 does not permit covered entities to use the Quantity Prescribed (460-ET) field. As a result, stakeholders cannot reliably discern from transactions data when a Schedule II drug has been partially filled or refilled. To help understand the economic burden of this issue, in the January 2019 proposed rule, HHS referred back to the previously mentioned 2012 OIG report, which estimated that

pharmacies inaccurately billed \$25 million worth of partial fills as refills in 2009 paid by the Medicare Part D program. The OIG also expressed concerns about the possibility of these inappropriately dispensed Schedule II drugs being resold on the street.¹¹ As previously stated, and discussed in the January 2019 proposed rule, CMS noted its concern that the OIG's strict interpretation of PDE data did not support the OIG's findings, instead believing that the OIG's findings were based in part on a misinterpretation that Schedule II drug partial fills dispensed to LTC facility residents were refills. However, these findings represent a helpful starting point for this estimate. The White House Council of Economic Advisers estimates that opioid abuse exacted a cost of \$504 billion in 2015 and contributed to a significant number of prescription and illicit drug overdose deaths.¹² Furthermore, in the January 2019 proposed rule and in this final rule, HHS discussed that the Secretary declared a public health emergency to combat the opioid crisis.

For this analysis, HHS continues to leverage the historical cost and benefit data from the study conducted to support the Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards August 2008 proposed rule and the January 2009 final rule (73 FR 49742 and 74 FR 3295 and 3296, respectively) (hereinafter referenced as the study). The impact analysis for this final rule utilizes the historical cost estimates derived from the study across covered entities. The final estimate provided an overall cost of \$38 million to fully implement the then-new requirements of the 2007 Version D.0 for chain pharmacies (73 FR 49772). Since this is a very narrow, targeted modification that is limited to requiring covered entities to use the Quantity Prescribed (460-ET) field of the

¹¹ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

¹² <https://www.whitehouse.gov/opioids/>

currently adopted Version D.0 in certain specified situations, we anticipate the aggregate costs will be minimal. HHS expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. We continue to believe the investments to adopt this modification and update existing systems have the same cost variables as the adoption of the current Version D.0. As discussed in the January 2019 proposed rule (84 FR 636), we used these same considerations from the January 16, 2009 final rule (74 FR 3296) to formulate our assumptions on implementing system upgrades, and staff training costs. While it is difficult to determine aggregate costs across the industry, we believe system costs for this modification to the requirements for use of Version D.0 to be limited IT resources, training, and business processes, and that this modification would cost between 1 to 5 percent of the original estimated cost, or between \$380,000 and \$1,900,000. The study also estimated a maximum upgrade fee cost of \$1.08 million per year for independent pharmacies (73 FR 49772). This results in an estimated cost for this modification of \$10,800 to \$54,000 per year in service fees across all independent pharmacies.

Pharmacies will benefit from using the Quantity Prescribed (460-ET) field because it will facilitate better monitoring of Schedule II drugs for over- or inappropriate prescribing. By virtue of the more robust data that we believe can be used to help avoid audits and incorrect payments, HHS believes that large pharmacy chains can save up to \$500,000 per year, while smaller chains can save approximately \$100,000 per chain. Therefore, this can yield a total 10-year benefit of up to \$10 million, and that does not account for the value of the time pharmacists and pharmacy technician staff who process these claims can save.

We believe health plans and their associated pharmacy benefit managers (PBMs) will also incur minimal cost since most have existing hardware and software platforms capable of

using this field with their current technology and networks. Thus, we expect this change will have a similarly minimal cost impact of between 1 and 5 percent of the original implementation costs. The study originally estimated the total cost to implement the 2007 Version D.0 for plans and PBMs to be a maximum of \$10.6 million for the industry (73 FR 49773). Thus, we continue to believe that the total cost for this change for health plans and PBMs to be between \$106,000 and \$530,000.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. We anticipate that the modification to the requirements for the use of the Quantity Prescribed (460-ET) field will yield more data and information with respect to the dispensing, facilitate better monitoring of Schedule II drugs, and reinforce the Administration's commitment to lowering overall health care costs by reducing administrative burden and improving the quality of health care.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate the great majority of independent retail pharmacies are small businesses as defined by the Small Business Administration's (SBA) definition of having revenues of less than \$7.5 million up to \$38.5 million in any 1 year. The SBA defines a size threshold in terms of annual revenues for pharmacies as \$27.5 million. Our proposed estimate stated that 95 percent of independent retail pharmacies have revenues below \$27.5 million or are nonprofit organizations

and are considered small entities. Individuals and states are not included in the definition of a small entity. As stated earlier, for this analysis HHS used the same considerations from the January 16, 2009 final rule to formulate our assumptions for this RFA, we the reader to refer to that analysis for additional information. We continue to believe that the modification to the requirements for the use of the Quantity Prescribed (460-ET) field will have a de minimis effect on that analysis; therefore, the Secretary has determined that this final rule will not have a significant economic impact on independent retail pharmacies and is not preparing an analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we continue to define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. This final rule will affect the operations of a substantial number of small rural hospitals because they are covered entities under HIPAA and must comply with the regulations; however, we do not believe the rule will have a significant impact on those entities, for the reasons stated above in reference to small businesses. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals and is not preparing an analysis under section 1102(b) of the Act.

Based on the information contained herein, including the 2009 analysis referenced above, the Secretary has determined and certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, HHS is not required to, and does not, prepare a regulatory impact analysis under the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. We believe that this final rule will have no consequential effect on state, local, or tribal governments or on the private sector in excess of that threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. We believe that since this final rule does not impose substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” OMB’s interim guidance, issued on April 5, 2017, <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>, explains that the requirements (as previously discussed) only apply to each new “significant regulatory action that imposes costs.” We have determined that this final rule is not a “significant regulatory action” and thus does not trigger the previously discussed requirements of Executive Order 13771.

We have assessed the anticipated costs and benefits of this final rule and continue to believe that it will yield more data and information with respect to the dispensing of Schedule II drugs.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

List of Subjects in 45 CFR Part 162

Administrative practice and procedures, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 162 as set forth below:

PART 162 – ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: 42 U.S.C. 1320d-1320d-9 and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

2. Section 162.1102 is amended by adding paragraph (d) to read as follows:

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

* * * * *

(d) For the period on and after [INSERT DATE 180 DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the Quantity Prescribed (460-ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

- (1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
 - (2) Uses the standard identified in paragraph (b)(2)(i) of this section.
3. Section 162.1302 is amended by adding paragraph (d) to read as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(d) For the period on and after [INSERT DATE 180 DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the Quantity Prescribed (460-ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

- (1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
- (2) Uses the standard identified in paragraph (b)(2)(i) of this section.

4. Section 162.1802 is amended by adding paragraph (d) to read as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(d) For the period on and after [INSERT DATE 180 DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the Quantity Prescribed (460-ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

- (1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
- (2) Uses the standard identified in paragraph (b)(2)(i) of this section.

CMS-0055-F

Dated: December 19, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2020-00551 Filed: 1/23/2020 8:45 am; Publication Date: 1/24/2020]