- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. The proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 30, 2022.

KC Becker,

Regional Administrator, Region 8.

[FR Doc. 2022–24075 Filed 11–8–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS–0056–P]

RIN 0938–AT38

Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would adopt updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These updated versions would be modifications to the currently adopted standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. The proposed rule would also broaden the applicability of the Medicaid pharmacy subrogation transaction to all health plans. To that end, the rule would rename and revise the definition of the transaction and adopt an updated standard, which would be a modification for state Medicaid agencies and an initial standard for all other health plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, January 9, 2023.

ADDRESSES: In commenting, please refer to file code CMS–0056–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0056–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0056–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

FOR FURTHER INFORMATION CONTACT: Geanelle G. Herring, (410) 786–4466, Beth A. Karpiak, (312) 353–1351, or Christopher S. Wilson, (410) 786–3178.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. The Centers for Medicare & Medicaid Services (CMS) will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Executive Summary

A. Purpose

This rule proposes to adopt modifications to standards for electronic retail pharmacy transactions and a subrogation standard adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and to broaden the applicability of the HIPAA subrogation transaction.

a. Need for the Regulatory Action

The rule proposes to modify the currently adopted retail pharmacy standards and adopt a new standard. These proposals would provide improvements such as more robust data exchange, improved coordination of benefits, and expanded financial fields that would avoid the need to manually enter free text, split claims, or prepare and submit a paper Universal Claim Form.

But for a small modification to the requirement for the use of a particular data field, adopted in 2020, the presently adopted pharmacy standards were finalized in 2009. Since then, the National Committee on Vital and Health Statistics (NCVHS) has recommended that HHS publish a proposed rule adopting more recent standards to address evolving industry changing business needs. Consistent with NCVHS recommendations and collaborative industry and stakeholder input, we believe the updated retail pharmacy standards we propose here are sufficiently mature for adoption and that covered entities are ready to implement them.

b. Legal Authority for the Regulatory Action

Sections 1171 *et seq.* of the Social Security Act (the Act) are the legal authority for this regulatory action.

B. Summary of the Major Provisions

The provisions in this proposed ruled would adopt the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15); and NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, for non-Medicaid health plans. These updated standards would replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2); and NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0.

Industry stakeholders report that Version F6 would bring much needed upgrades over Version D.0, such as improvements to the information attached to controlled substance claims, including refinement to the quantity prescribed field. This change would enable refills to be distinguished from multiple dispensing events for a single fill, which would increase patient safety. Version F6 provides more specific fields to differentiate various types of fees, including taxes, regulatory fees, and medication administration fees. Finally, Version F6 increases the dollar amount field length and would simplify coverage under prescription benefits of new innovative drug therapies priced at, or in excess of, $1 million. The current adopted Version D.0 does not support this business need.

The current Medicaid Subrogation Implementation Guide Version 3.0 (Version 3.0) was adopted to support federal and state requirements for state Medicaid agencies to seek reimbursement from the correct responsible health plan. However, industry stakeholders reported that there is a need to expand the use of the subrogation transaction beyond Medicaid agencies, and noted that the use of a subrogation standard that would apply to other payers would be a positive step for the industry. Whereas HIPAA regulations currently require only Medicaid agencies to use Version 3.0 in conducting the Medicaid pharmacy subrogation transaction, all health plans would be required to use the Pharmacy Subrogation Implementation Guide for Batch Standard, Version 10, to transmit pharmacy subrogation transactions, which would allow better tracking of subrogation efforts and results across all health plans, and support cost containment efforts.

Should these proposals be adopted as proposed, it would require covered entities to comply 24 months after the effective date of the final rule. Small health plans would have 36 months after the effective date of the final rule to comply.

C. Summary of Costs and Benefits

We estimate that the overall cost for pharmacies, pharmacy benefit plans, and chain drug stores to move to the updated versions of the pharmacy standards and the initial adoption of the pharmacy subrogation transaction standard would be approximately $386.3 million. The cost estimate is based on the need for technical development, implementation, testing, initial training, and a 24-month compliance timeframe. We believe that HIPAA covered entities or their contracted vendors have already largely invested in the hardware, software, and connectivity necessary to conduct the transactions with the updated versions of the pharmacy standards.

II. Background

A. Legislative Authority for Administrative Simplification

This background discussion presents a history of statutory provisions and regulations that are relevant for purposes of this proposed rule.

Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in HIPAA (Pub. L. 104–191, enacted on August 21, 1996). Through subtitle F of title II of HIPAA, Congress added to title XI of the Act a new Part C, titled ''Administrative Simplification,'' which required the Secretary of the Department of Health and Human Services (the Secretary) to adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information. For purposes of this and later discussion in this proposed rule, we sometimes refer to this statute as the ''original'' HIPAA.

Section 1172(a) of the Act states that ''[a]ny standard adopted under [HIPAA] shall apply, in whole or in part, to . . . (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a [HIPAA transaction],'' which are collectively referred to as ''covered entities.'' Generally, section 1172 of the Act requires any standard adopted under HIPAA to be developed, adopted, or modified by a standard setting organization (SSO). In adopting a standard, the Secretary must rely upon recommendations of the NCVHS, in consultation with the organizations referred to in section 1172(c)(3)(B) of the Act, and appropriate federal and state agencies and private organizations.

Section 1172(b) of the Act requires that a standard adopted under HIPAA be consistent with the objective of reducing the administrative costs of providing and paying for health care. The transaction standards adopted under HIPAA enable financial and administrative electronic data interchange (EDI) using a common structure, as opposed to the many varied, often proprietary, transaction formats on which industry had previously relied and that, due to lack of uniformity, engendered administrative burden. Section 1173(g)(1) of the Act, which was added by section 1104(b) of the Patient Protection and Affordable Care Act, further addresses the goal of uniformity by requiring the Secretary to adopt a single set of operating rules for each

HIPAA transaction. These operating rules are required to be consensus-based and reflect the necessary business rules that affect health plans and health care providers and the manner in which they operate pursuant to HIPAA standards.

Section 1173(a) of the Act requires that the Secretary adopt standards for financial and administrative transactions, and data elements for those transactions, to enable health information to be exchanged electronically. The original HIPAA provisions require the Secretary to adopt standards for the following transactions: health claims or equivalent encounter information; health claims attachments; enrollment and disenrollment in a health plan; eligibility for a health plan; health care payment and remittance advice; health plan premium payments; first report of injury; health claim status; and referral certification and authorization. The Patient Protection and Affordable Care Act (Pub. L. 111–148) additionally required the Secretary to develop standards for electronic funds transfers transactions. Section 1173(a)(1)(B) of the Act requires the Secretary to adopt standards for any other financial and administrative transactions the Secretary determines appropriate. Section 1173(a)(4) of the Act requires that the standards and operating rules, to the extent feasible and appropriate: enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care; be comprehensive, requiring minimal augmentation by paper or other communications; provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process; describe all data elements in unambiguous terms, require that such data elements be required or conditioned upon set terms in other fields, and generally prohibit additional conditions; and reduce clerical burden on patients and providers.

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to them, including additions to the standards, as appropriate, but not more frequently than once every 12 months, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

Section 1175(a) of the Act prohibits health plans from refusing to conduct a transaction as a standard transaction. Section 1175(a)(3) of the Act also prohibits health plans from delaying the transaction or adversely affecting or attempting to adversely affect a person or the transaction itself on the grounds that the transaction is in standard format. Section 1175(b) of the Act provides for a compliance date not later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, which must comply not later than 36 months after such adoption. If the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than 180 days following the date of the adoption of the modification. The Secretary must consider the time needed to comply due to the nature and extent of the modification when determining compliance dates, and may extend the time for compliance for small health plans if he deems it appropriate.

Sections 1176 and 1177 of the Act establish civil money penalties (CMPs) and criminal penalties to which covered entities may be subject for violations of HIPAA Administrative Simplification rules. HHS administers the CMPs under section 1176 of the Act and the U.S. Department of Justice administers the criminal penalties under section 1177 of the Act. Section 1176(b) sets out limitations on the Secretary's authority and provides the Secretary certain discretion with respect to imposing CMPs. This section provides that no CMPs may be imposed with respect to an act if a penalty has been imposed under section 1177 with respect to such act. This section also generally precludes the Secretary from imposing a CMP for a violation corrected during the 30-day period beginning when an individual knew or, by exercising reasonable diligence, would have known that the failure to comply occurred.

B. Prior Rulemaking

In the August 17, 2000 **Federal Register**, we published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' (65 FR 50312) (hereinafter referred to as the Transactions and Code Sets final rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for electronic health care transactions developed by SSOs, and medical code sets to be used in those transactions. We adopted X12 Version 4010 standards for administrative transactions, and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Version 5.1 standard for retail pharmacy transactions at 45 CFR part 162, subparts K through R.

Since initially adopting the HIPAA standards in the Transactions and Code Sets final rule, we have adopted a number of modifications to them. The most extensive modifications were adopted in a final rule titled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' in the January 16, 2009 **Federal Register** (74 FR 3296) (hereinafter referred to as the 2009 Modifications final rule). Among other things, that rule adopted updated X12 and NCPDP standards, moving from X12 Version 4010 to X12 Version 5010, and NCPDP Version 5.1 and equivalent Batch Standard Implementation Guide Version 1, Release 1, to NCPDP Version D.0 and equivalent Batch Standard Implementation Guide Version 1, Release 2. In that rule, we also adopted the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0 standard for the Medicaid pharmacy subrogation transaction. Covered entities were required to comply with these standards beginning on and after January 1, 2012, with the exception of small health plans, which were required to comply on and after January 1, 2013.

In the Transactions and Code Sets final rule, we defined the terms ''modification'' and ''maintenance.'' We explained that when a change is substantial enough to justify publication of a new version of an implementation specification, such change is considered a modification and must be adopted by the Secretary through regulation (65 FR 50322). Conversely, maintenance describes the activities necessary to support the use of a standard, including technical corrections to an implementation specification. Maintenance changes are typically corrections that are obvious to readers of the implementation guides, not controversial, and essential to implementation (68 FR 8388, February 20, 2003). Maintenance changes to Version D.0 were identified by the industry, balloted and approved through the NCPDP, and are contained in the NCPDP Version D.0 Editorial. In an October 13, 2010 **Federal Register** notification titled ''Health Insurance Reform; Announcement of Maintenance Changes to Electronic Data Transaction Standards Adopted Under the Health Insurance Portability and Accountability Act of 1996'' (75 FR 62684), the Secretary announced the maintenance changes and the availability of the NCPDP Version D.0 Editorial and how it could be obtained. The NCPDP Version D.0 Editorial can

now be obtained free of charge in the HIPAA Information Section of the NCPDP website, at *https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.* This document is a consolidated reference point for questions that have been posed based on the review and implementation of the NCPDP Telecommunication Standard Implementation Guide for Version D.0.

In a final 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,'' published in the January 24, 2020 **Federal Register** (85 FR 4236) (hereafter, Modification of Version D.0 Requirements final rule), the Secretary adopted a modification of the requirements for the use of the Quantity Prescribed (460–ET) field of the August 2007 publication of Version D.0. The modification required covered entities to treat the Quantity Prescribed (460–ET) 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.

In that rulemaking, the Secretary noted that the NCPDP had issued a subsequent publication, the October 2017 Telecommunication Standard Implementation Guide, Version F2 (Version F2), that, among many other unrelated changes, revised the situational circumstances to specify an even broader use of the Quantity Prescribed (460–ET) field. The change described the field as ''required only if the claim is for a controlled substance or for other products as required by law; otherwise, not available for use.'' We explained that we chose not to adopt Version F2 at that time because, given the public health emergency caused by the opioid crisis and the urgent need to find ways to yield data and information to help combat it, we believed it was more appropriate to take a narrow, targeted approach while taking additional time to further evaluate the impact of a new version change on covered entities.

C. Standards Adoption and Modification

The law generally requires at section 1172(c) that any standard adopted under HIPAA be developed, adopted, or modified by an SSO. Section 1171 of the Act defines an SSO as an SSO accredited by the American National Standards Institute (ANSI), including the NCPDP (the SSO applicable to this proposed rule) that develops standards for information transactions, data, or any standard that is necessary to, or will facilitate the implementation of, Administrative Simplification. Information about the NCPDP's balloting process, the process by which it vets and approves the standards it develops and any changes thereto, is available on its website, *https://www.ncpdp.org.*

a. Designated Standards Maintenance Organizations (DSMO)

In the Transactions and Code Sets final rule, the Secretary adopted procedures to maintain and modify existing, and adopt new, HIPAA standards and established a new organization type called the ''Designated Standard Maintenance Organization'' (DSMO). Regulations at 45 CFR 162.910 provide that the Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the functions of maintaining the adopted standard, and receiving and processing requests for adopting a new standard or modifying an adopted standard. In an August 17, 2000 notice titled ''Health Insurance Reform: Announcement of Designated Standard Maintenance Organizations'' (65 FR 50373), the Secretary designated the following six DSMOs: X12, NCPDP, Health Level Seven, the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and the Dental Content Committee (DCC) of the American Dental Association.

b. Process for Adopting Initial Standards, Maintenance to Standards, and Modifications to Standards

In general, HIPAA requires the Secretary to adopt standards that have been developed by an SSO. The process for adopting a new standard or a modification to an existing standard is described in the Transactions and Code Sets final rule (65 FR 50344) and implemented at § 162.910. Under § 162.910, the Secretary considers recommendations for proposed modifications to existing standards or a proposed new standard if the recommendations are developed through a process that provides for: open public access; coordination with other DSMOs; an appeals process for the requestor of the proposal or the DSMO that participated in the review and analysis if either of the preceding were dissatisfied with the decision on the request; an expedited process to address HIPAA content needs identified within the industry; and submission of the recommendation to the NCVHS.

Any entity may submit change requests with a documented business case to support its recommendation to the DSMO. The DSMO receives and manages those change requests, including reviewing them and notifying the SSO of its recommendation for approval or rejection. If the changes are recommended for approval, the DSMO also notifies the NCVHS and suggests that a recommendation for adoption be made to the Secretary.

The foregoing processes were followed with respect to the modifications and new standard proposed in this rule, and stemmed from the following change requests the NCPDP submitted to the DSMO: (1) DSMO request 1201 requested replacing the adopted NCPDP Telecommunication Standard Implementation Guide, Version D.0 and the equivalent Batch Standard Implementation Guide Version 1.2 with updated versions, the NCPDP Telecommunication Standard Implementation Guide, Version F2 and the equivalent Batch Standard Implementation Guide, Version 15; (2) DSMO request 1202 requested replacing the adopted NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, for use by Medicaid agencies, with the NCPDP Batch Standard Subrogation Implementation Guide, Version 10, for use by all health plans; and (3) DSMO request 1208 updated DSMO request 1201 requested adopting an updated version of the NCPDP Telecommunication Standard Implementation Guide, Version F6 instead of Version F2.

c. NCVHS Recommendations

The NCVHS was established by statute in 1949; it serves as an advisory committee to the Secretary and is statutorily conferred a significant role in the Secretary's adoption and modification of HIPAA standards. In 2018, the NCVHS conducted two days of hearings seeking the input of health care providers, health plans, clearinghouses, vendors, and interested stakeholders regarding the NCPDP Telecommunication Standard, Version F2, as a potential replacement for NCPDP Version D.0, and the equivalent Batch Standard Implementation Guide, Version 15, as a potential replacement for Version 1.2. Testimony was also presented in support of replacing the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, with the Batch Standard Subrogation Implementation Guide, Version 10. In addition to the NCPDP, organizations submitting testimony

included the Centers for Medicare & Medicaid Services' Medicare Part D program, the National Association of Chain Drug Stores (NACDS), Ohio Medicaid, Pharmerica, CVS Health, and an independent pharmacy, Sam's Health Mart.[1]

In a letter[2] dated May 17, 2018, the NCVHS recommended that the Secretary adopt the updated versions of the standards, including the pharmacy subrogation standard. As discussed, in part, in section III.B. of this rule, we believed that proposing a modification to the retail pharmacy standard required further evaluation, including an assessment of the impact of implementing the modification, given the many significant changes a version change would require covered entities to undertake. Therefore, we did not propose to adopt Version F2 based on that NCVHS recommendation in our 2019 proposed rule entitled ''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,'' published in the January 31, 2019 **Federal Register** (84 FR 633), which led to the January 24, 2020 Modification of Version D.0 Requirements final rule.

During the March 24, 2020 NCVHS full committee meeting, there was a hearing to discuss Change Request 1208 regarding the NCPDP Telecommunication Standard, Version F6, as a potential update to the NCVHS 2018 recommendation to the Secretary to adopt Version F2. During the hearing, the NCPDP noted that several key Version F2 limitations had been resolved by Telecommunication Standard Implementation Guide, Version F6. Significantly, with respect to the number of digits in the dollar field, Version F2 would not support dollar fields of $1 million or more. To that point, since receipt of the NCVHS's May 17, 2018 recommendation, several new drugs priced at, or in excess of, $1 million have entered the market and researchers and analysts anticipate that over the next several years dozens of new drugs priced similarly or higher may enter the market, while hundreds more likely high-priced therapies, including for gene therapies that target certain cancers and rare diseases, are under development. To meet emerging business needs, the NCPDP updated the Telecommunication Standard to support dollar fields equal to, or in excess of, $1 million and made other updates, including enhancements to improve coordination of benefits processes, prescriber validation fields, plan benefit transparency, codification of clinical and patient data, harmonization with related standards, and controlled substance reporting, that necessitated the new version, F6. The transcript and testimony from the March 24, 2020 full committee meeting is available at *https://ncvhs.hhs.gov/meetings/full-committee-meeting-4/.*

In a letter dated April 22, 2020,[3] the NCVHS recommended that the Secretary adopt Version F6 to replace Version D.0. and provide a 3-year pre-implementation window following publication of the final rule. The recommendation letter stated that allowing the industry to use either Version D.0 or Version F6 would enable an effective live-testing and transition period. The NCVHS advised that the Secretary should require full compliance with Version F6 beginning May 1, 2025, and also urged that HHS act on its May 2018 recommendations to adopt the NCPDP Batch Standard Implementation Guide Version 15 and the NCPDP Batch Standard Subrogation Implementation Guide Version 10.

III. Provisions of the Proposed Rule

A. Proposed Modifications to NCPDP Telecommunication Standard Implementation Guide Version F6 (Version F6) and Equivalent Batch Standard, Version 15 (Version 15) for Retail Pharmacy Transactions

1. Overview

Should they be finalized as proposed herein, the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15) would replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2). Version F6 includes a number of changes from Version D.0 that alter the use or structure of data fields, insert new data segments, and add new functionality. Adopting Version F6 to replace Version D.0 would constitute a HIPAA modification.

We are proposing to adopt modifications to the current HIPAA retail pharmacy standards for the following transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. Covered entities conducting the following HIPAA transactions would be required to use Version F6:

- Health care claims or equivalent encounter information (§ 162.1101).
  - ++ Retail pharmacy drug claims.
  - ++ Retail pharmacy supplies and professional claims.
- Eligibility for a health plan (§ 162.1201).
  - ++ Retail pharmacy drugs.
- Referral certification and authorization (§ 162.1301).
  - ++ Retail pharmacy drugs.
- Coordination of benefits (§ 162.1801).

In its April 22, 2020 letter to the Secretary, the NCVHS considered industry testimony and recommended that HHS propose to replace Version D.0 with Version F6 as the HIPAA standard for retail pharmacy transactions. Testifiers at the March 2020 NCVHS full committee meeting advocated for HHS to adopt updated versions of the retail pharmacy standards to better accommodate business requirements that have changed significantly for covered entities since 2009 when Version D.0 was adopted, and also since Version F2 was approved. The NCVHS recommendation, and industry testimony from both the May 2018 hearing and the March 2020 full committee meeting, highlighted the benefits Version F6 would provide over Version D.0, to include benefits introduced in Version F2 that are incorporated into Version F6:

- *Accommodation of very expensive drug therapies*—Version F6 accommodates the expansion of financial fields needed for drug products priced at, or in excess of, $1 million that are now available in the market. While such products are still rare, their numbers are expected to increase, and without this functionality pharmacies must employ disparate and burdensome payor-specific methods for split claims or manual billing, which increases the risk of billing errors.
- *More robust data exchange between long-term care providers and payers*—Version F6 includes information needed for prior authorizations and enhancements to the drug utilization review (DUR) fields in the claim response transaction. This change can

[1] *https://ncvhs.hhs.gov/meetings/agenda-of-the-march-26-2018-hearing-on-ncpdp-standards-updates/.*

[2] *https://ncvhs.hhs.gov/wp-content/uploads/2018/08/Letter-to-Secretary-NCVHS-Recommendations-on-NCPDP-Pharmacy-Standards-Update.pdf.*

[3] *https://ncvhs.hhs.gov/wp-content/uploads/2020/04/Recommendation-Letter-Adoption-of-New-Pharmacy-Standard-Under-HIPAA-April-22-2020-508.pdf.*

improve communication from the payer to the pharmacy, thus enabling the pharmacy to act more quickly to the benefit of the patient.[4]

• *Coordination of benefits (COB)*—Version F6 includes new COB segment fields that would improve the identification of the previous payer and its program type, such as Medicare, Medicaid, workers compensation, or self-pay program, eliminating the need to use manual processes to identify this information. Pharmacy providers and payers that engage in COB must identify the previous payer and its program type in order to process the claim in accordance with applicable requirements, including requirements related to primary payment responsibility and payer order. For example, the new data segment fields would support compliance with the payer processing order with Medicaid as the payer of last resort, as well as prevent inappropriate access to pharmaceutical manufacturer copay coupons for drugs paid under federal programs, including Medicare Part D.

• *Prescriber Validation*—Medicare Part D program requirements to improve the validity of prescriber identifiers and improve program integrity controls have driven the need for new prescriber segment fields in Version F6 to enhance prescriber validation, such as the ability to capture a Drug Enforcement Administration (DEA) number, in addition to the National Provider Identifier (NPI), and a Prescriber Place of Service to identify telehealth. Enhancements also include new reject codes and related messaging fields to provide additional information on limitations in prescriptive authority, such as to confirm assignment as the patient's designated prescriber for opioids.

• *Controlled Substances Reporting*—Version F6 makes a number of updates to controlled substances reporting that would permit the exchange of more information for better monitoring and documentation of compliance with state and federal requirements. Changes to the Claim Billing and Response Claim segments provide additional information to enhance patient safety controls for controlled substance prescriptions. For instance, Version F6 would enable claims processors, including, for example, pharmacy benefit managers (PBMs) and health plans that process their pharmacy claims in-house, to be informed of the exact prescription quantity and fill information, improve edits from the processor, and reduce confusion that can occur today and that sometimes requires patients to obtain a new prescription. Other specific enhancements include adding a Do Not Dispense Before Date field to support providers writing multiple, 1-month prescriptions for controlled substances. This field also supports compliance with requirements certain states have on the number of days a patient has to fill a controlled substance from the date written.

• *Harmonization with Related Standards*—Version F6 accommodates business needs to comply with other industry standard requirements, such as the ability to comply with ANSI expanded field-length requirements for the Issuer Identification Number (IIN), formerly known as the Bank Identification Number. The IIN is used to identify and route the transaction to the appropriate PBM. ANSI expanded the IIN field length to accommodate more unique numbers. Version F6 also accommodates FDA-required Unique Device Identifiers (UDI) that are now up to 40 characters in length, whereas Version D.0 only allows for 11 characters.

• *Codification of Clinical and Patient Data*—Pharmacy and payer workflows are enhanced in Version F6 by replacing many clinical and non-clinical free-text fields in Pharmacy Claim and Payer Claim Response segments with discrete codified fields. The computable data in discrete fields can then be utilized to automatically trigger workflows, such as those to help combat opioid misuse or to communicate relevant information to enhance patient safety.

• *Plan Benefit Transparency*—Interoperability between the payer and pharmacy is improved in Version F6 with the ability to exchange more actionable plan-specific information. New Payer Response fields enhance the ability to target plan benefit package detail associated with the specific patient. The availability of this information may avoid prior authorization interruptions, as well as allow pharmacists to have more informative discussions with patients and provide valuable information about alternative drug or therapy solutions, which can reduce delays in therapy and improve patient adherence.

2. Partial Fill of Controlled Substances—Quantity Prescribed (460–ET) Field

As discussed in section I. of this proposed rule, in the Modification of Version D.0 Requirements final rule (85 FR 4236), we adopted the requirements that the Quantity Prescribed (460–ET) field in Version D.0 must be treated as a required field where the transmission is for a Schedule II drug in any of the following three HIPAA transactions: (1) health care claims or equivalent encounter information; (2) referral certification and authorization; and (3) coordination of benefits. Version F6 requires the use of the 460–ET field for all controlled substances. Therefore, we would no longer need to explicitly require its situational use, and we would revise the regulation text at §§ 162.1102(d), 162.1302(d), and 162.1802(d) accordingly.

3. Batch Standard, Version 15 (Version 15) for Retail Pharmacy Transactions

Batch mode can be used for processing large volumes of transactions. For example, a retail pharmacy that has several locations can send one batch mode transaction, containing multiple claims collected over time from the various locations, to an entity with which it has contracted, or otherwise to a centralized entity, that will route each claim in the transaction to the appropriate payer. The NCPDP Batch Standard, Version 15, better supports retail pharmacy batch mode transactions than the currently adopted Version 1.2 because it was developed in coordination with F6 and includes the same benefits as Version F6, but in batch mode, including the updates that improve coordination of benefits processes, prescriber validation fields, plan benefit transparency, codification of clinical and patient data, harmonization with related standards, and controlled substance reporting.

In sum, we believe adopting Version F6 and its equivalent Batch Standard, Version 15 to replace Version D.0 and Version 1.2 would result in greater interoperability for entities exchanging prescription information, improve patient care, provide better data for drug utilization monitoring, and reduce provider burden. Because Version F6 and Version 15 would better support the business needs of the industry than Version D.0 and Version 1.2, we propose to adopt them as the standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. We would revise §§ 162.1102, 162.1202, 162.1302, and 162.1802 accordingly.

We solicit comments regarding our proposal to adopt Version F6 to replace Version D.0 and Version 15 to replace Version 1.2.

[4] *https://ncvhs.hhs.gov/wp-content/uploads/2018/05/Session-A-Schoettmer-Written-508.pdf.*

B. Proposed Modification of the Pharmacy Subrogation Transaction Standard for State Medicaid Agencies and Initial Adoption of the Pharmacy Subrogation Standard for Non-Medicaid Health Plans

In the 2009 Modifications final rule, we adopted the Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0 (Version 3.0) as the standard for the Medicaid pharmacy subrogation transaction. In that rule, we discussed that state Medicaid agencies sometimes pay claims for which a third party may be legally responsible, and where the state is required to seek recovery. This can occur when the Medicaid agency is not aware of the existence of other coverage, though there are also specific circumstances in which states are required by federal law to pay claims and then seek reimbursement afterward. For the full discussion, refer to 74 FR 3296.

1. Proposed Modification to the Definition of Medicaid Subrogation Transaction

Because we are proposing to broaden the scope of the subrogation transaction to apply to all health plans, not just state Medicaid agencies, we are proposing to revise the definition of the transaction. The Medicaid pharmacy subrogation transaction is defined at § 162.1901 as the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the state has paid on behalf of a Medicaid recipient. We are proposing to change the name of the transaction at § 162.1901 to the ''Pharmacy subrogation transaction'' and define the transaction as the transmission of a request for reimbursement of a pharmacy claim from a health plan that paid the claim, for which it did not have payment responsibility, to the health plan responsible for the claim.

There are a few notable differences between the current and proposed transaction definitions. First, the current definition defines the transaction such that it only applies to state Medicaid agencies, in their role as health plans, as the sender of the transaction. Because we are proposing to broaden the scope of the transaction to apply to all health plans, not just state Medicaid agencies, the Pharmacy subrogation transaction definition would specify that the sender of the transaction is ''a health plan that paid the claim'' instead of a ''Medicaid agency.'' In addition, the current definition identifies that the sender of the transaction is requesting ''reimbursement for a pharmacy claim the state has paid on behalf of a Medicaid recipient.'' To align this aspect of the current definition with the broadened scope that would apply to all health plans, the proposed definition identifies that the sender health plan has paid a claim ''for which it did not have payment responsibility.''

Second, the current definition identifies a pharmacy subrogation transaction as the ''transmission of a claim.'' The proposed definition would specify that a pharmacy subrogation transaction is the transmission of a ''request for reimbursement of a pharmacy claim.'' We use the term ''claim'' in a specific way with regard to the HIPAA transaction defined at 45 CFR 162.1101 to describe a provider's request to obtain payment from a health plan. We never intended that the subrogation transaction be defined as a ''claim'' in the strict sense of the word. We believe replacing ''claim'' with ''request for reimbursement'' would clarify that the purpose of a pharmacy subrogation transaction is to transmit request to be reimbursed for a claim rather than to transmit a claim.

We are proposing that the current definition of the Medicaid pharmacy subrogation transaction would remain in the regulatory text at § 162.1901(a) and the proposed definition of the Pharmacy subrogation transaction would be added at § 162.1901(b). The Medicaid pharmacy subrogation transaction would continue to apply until the compliance date of the Pharmacy subrogation transaction, in accordance with the proposed compliance dates discussed in section III.C.2. of this proposed rule. Then, beginning on the compliance date for the Pharmacy subrogation transaction, the Medicaid pharmacy subrogation transaction would no longer be in effect and all covered entities would be required to comply with the proposed standard for the Pharmacy subrogation transaction.

2. Proposed Initial Adoption of the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, for Non-Medicaid Health Plans

As discussed previously, the current HIPAA standard, Version 3.0, for the Medicaid pharmacy subrogation transaction, only applies to state Medicaid agencies seeking reimbursement from health plans responsible for paying pharmacy claims. The standard does not address business needs for other payers, such as Medicare Part D, state assistance programs, or private health plans that would seek similar reimbursement. Section 1173(a)(2) of the Act lists financial and administrative transactions for which the Secretary is required to adopt standards. The Pharmacy subrogation transaction is not a named transaction in section 1173(a)(2) of the Act, but section 1172(a)(1)(B) of the Act authorizes the Secretary to adopt standards for other financial and administrative transactions as the Secretary determines appropriate, consistent with the goals of improving the operation of the health care system and reducing administrative costs. Adopting a standard for a broader subrogation transaction that would apply to all health plans, not just Medicaid agencies, would facilitate the efficiency and effectiveness of data exchange and transaction processes for all payers involved in post-payment of pharmacy claims and would support greater payment accuracy across the industry.

At the NCVHS March 2018 hearing,[5] industry stakeholders cited in their testimony the benefits and potential burden reduction that could be achieved by adoption of the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10 (hereinafter referred to as Version 10). Testimony to the NCVHS by the NCPDP and other stakeholders explained that the health care system could benefit from greater uniformity in pharmacy subrogation transactions for both Medicaid and non-Medicaid health plans. One testifier reported that an updated pharmacy subrogation transaction would reduce administrative costs and increase interoperability by requiring a standard that could be used by Medicaid and non-Medicaid plans, which would support a uniform approach across all health plans to efficiently process post-payment subrogation claims and eliminate the need for numerous custom formats that industry currently uses. Further testimony supported that an updated standard would aid in reducing the manual processes non-Medicaid payers must perform to pay these types of claims. For example, one testifier explained that, presently, Medicare Part D commercial payer subrogation transactions are submitted for payment to responsible health plans as a spreadsheet or a paper-based universal claim form that requires manual processing by parties on both sides of the transaction. We believe our proposal

[5] *https://ncvhs.hhs.gov/meetings/agenda-of-the-march-26-2018-hearing-on-ncpdp-standards-updates/.*

would automate, and hence ease, much of that effort.

3. Proposed Modification of the Pharmacy Subrogation Transaction Standard for State Medicaid Agencies

We are proposing to replace the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0, with the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10 as the standard for Pharmacy subrogation transactions at § 162.1902(b). For state Medicaid agencies, this proposal would be a modification from Version 3.0. While Version 10 is called the ''Pharmacy Subrogation Implementation Guide'' rather than the ''Medicaid Subrogation Implementation Guide,'' Version 10 still applies to subrogation transactions originating from Medicaid agencies and preserves the data elements in Version 3.0 except in the following instances, the purpose of which is to accommodate non-Medicaid plans' use of the modified standard:

- The Medicaid Agency Number definition is changed to accommodate use of the field by Medicaid and non-Medicaid health plans.
- The Medicaid Subrogation Internal Control Number/Transaction Control Number field, which is designated as ''not used'' in Version 3.0. is replaced with the required use of the Reconciliation ID field.
- The Medicaid Paid Amount field, which is designated as ''not used'' in Version 3.0, is replaced with the required use of the Subrogation Amount Requested field.
- The Medicaid ID Number field, which is a required field in Version 3.0, is changed to a situational field that is only required when one of the health plans involved in the transaction is a Medicaid agency.

While state Medicaid agencies would be required to implement these changes in order to comply with Version 10, the changes would be de minimis and state Medicaid agencies' use of the modified standard would essentially be the same as their use of the current standard.

We solicit comments on our proposal related to the adoption of Version 10.

C. Proposed Compliance and Effective Dates

1. Proposed Compliance Date for Version F6 and Version 15

Section 1175(b)(2) of the Act addresses the timeframe for compliance with modified standards. The section provides that the Secretary must set the compliance date for a modification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. However, the compliance date may not be sooner than 180 days after the effective date of the final rule. In the discussion later in this rule, we explain why we are proposing that all covered entities would need to be in compliance with Version F6 and its equivalent Batch Standard Version 15 for retail pharmacy transactions 24 months after the effective date of the final rule, which we would reflect in §§ 162.1102, 162.1202, 162.1302, and 162.1802.

In its April 22, 2020 recommendation letter to the Secretary, discussed in section I.C.3. of this proposed rule, the NCVHS, upon consideration of industry feedback, recommended the following implementation timelines and dates for Version F6 and Version 15: [6]

- Provide a 3-year pre-implementation window following publication of the final rule, allowing (but not requiring) industry use beginning at the end of the three years.
- Allow both Versions D.0 and F6 to be used for an 8-month period after the 3-year pre-implementation window, which the NCVHS suggested would enable an effective live-testing and transition period.
- Require full compliance by the end of the third year, that is, exclusive use of Version F6, after the 8-month period.

After carefully considering the NCVHS's recommended implementation timelines and dates, for the following reasons we are not proposing a 3-year pre-implementation compliance window or an 8-month transition period. While industry feedback on which the NCVHS relied to make its recommendations did include some discussion on specific changes necessary to implement Version F6 (for example, the expansion of the financial fields), the majority of feedback was not specific to Version F6, but, rather, concerned general challenges that would be associated with implementing any standard modification. For example, feedback related to concerns about general budget constraints, as well as compliance dates that conflict with other pharmacy industry priorities such as the immunization season or times of year where prescription benefits plans typically experience heavy new member enrollment. In addition, several industry stakeholders, including the NCPDP, stated that they were not aware of any significant implementation barriers specific to Version F6. In its May 17, 2018 letter industry testimony asserted, and the NCVHS agreed, that the process to implement Version F6 would be similar to the process necessary to implement Version F2.[7] Therefore, we are proposing a 24-month compliance timeframe that aligns with the recommendation that the NCVHS made in its May 17, 2018 letter to implement Version F2.[8]

Additionally, the proposed modification, to move from Version D.0 to Version F6, pertains only to retail pharmacy transactions. That is different in scope, for example, from the modifications finalized in the 2009 Modifications final rule (74 FR 3296), which affected all of the then-current HIPAA transactions. There, we implemented an extended compliance date for the modified standards in response to the numerous comments advocating for it given the extensive changes in Versions 5010 and D.0 from Versions 4010 and 5.1, which commenters asserted necessitated a coordinated implementation and testing schedule. Given that the scope of the modification in this proposed rule is limited to just retail pharmacy transactions, we believe the industry has the capability of implementing the modification within a 24-month period after the effective date of the final rule.

Further, we believe the benefits that would be derived from implementing Version F6 and Version 15 (discussed in section III.A.1. of this proposed rule) as soon as possible are significant. Those benefits include mitigating existing inefficient work-arounds, allowing for more robust data exchanges between long-term care providers and payers, improving coordination of benefits information, improving controlled substances reporting, codifying clinical and patient data, harmonizing with related standards, and improving plan benefit transparency. We solicit industry comment on the proposed 24-month compliance date for F6 and Version 15, including any barriers specific to compliance with Version F6 and Version 15 that would require additional time for compliance.

[6] *https://ncvhs.hhs.gov/wp-content/uploads/20s20/04/Recommendation-Letter-Adoption-of-New-Pharmacy-Standard-Under-HIPAA-April-22-2020-508.pdf.* NCVHS April 22, 2020 Recommendation letter.

[7] *https://ncvhs.hhs.gov/wp-content/uploads/2020/03/Public-Comments-NCPDP-Change-Request-March-2020.pdf.*

[8] *https://ncvhs.hhs.gov/wp-content/uploads/2018/08/Letter-to-Secretary-NCVHS-Recommendations-on-NCPDP-Pharmacy-Standards-Update.pdf.*

2. Proposed Compliance Dates for the Batch Standard Subrogation Implementation Guide, Version 10 (Version 10), September 2019, National Council for Prescription Drug Programs

As discussed previously, we are proposing to adopt a Pharmacy subrogation transaction standard that would apply to all health plans, not just state Medicaid agencies. As we discuss in section III.B. of this proposed rule, Version 10 would be a modification for state Medicaid agencies, which would be moving to Version 10 from Version 3.0. For all other health plans, Version 10 would be an initial standard. As previously noted, section 1175(b)(2) of the Act addresses the timeframe for compliance with modified standards. That section requires the Secretary to set the compliance date for a modification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification, but no sooner than 180 days after the effective date of the final rule in which we adopt that modification. Section 1175(b)(1) of the Act requires that the compliance date for initial standards—which Version 10 would be for covered entities that are not state Medicaid agencies—is no later than 24 months after the date of adoption for all covered entities, except small health plans, which must comply no later than 36 months after adoption.

We are proposing to align the compliance dates for state Medicaid agencies and all other health plans (except small health plans) to comply with Version 10. Should we not to do this, some health plans would need to use Version 10 at the same time as state Medicaid agencies in order to conduct Pharmacy subrogation transactions with those state Medicaid agencies, while other health plans could use different standards. Aligning the compliance timeframes would reduce confusion and administrative burden that would arise were there concurrent standards in effect. Thus, we propose to require all health plans (except small health plans) to comply at the same time. The alignment of compliance dates also makes it more feasible for state Medicaid agencies and non-Medicaid health plans to invest in system upgrades to accommodate one specific standard rather than divide resources to maintain two concurrent transaction standards. Therefore, we propose to revise § 162.1902(b) to reflect that all health plans, except small health plans, would be required to comply with Version 10 for Pharmacy subrogation transactions 24 months after the effective date of the final rule. We would also revise § 162.1902(a) to reflect that state Medicaid agencies would be required to comply with the current standard, Version 3.0, until the compliance date of Version 10.

Small health plans, as defined in 45 CFR 160.103, are those health plans with annual receipts of $5 million or less. In accordance with section 1175(b)(1) of the Act, we are proposing that small health plans, other than small health plans that are state Medicaid agencies, would be required to comply with the new standard 36 months after the effective date of the final rule.

We solicit industry and other stakeholder comments on our proposed compliance dates.

D. Proposed Incorporation by Reference

This proposed rule proposes to incorporate by reference: (1) the Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020; (2) equivalent Batch Standard Implementation Guide, Version 15 (Version 15) October 2017; and (3) the Batch Standard Subrogation Implementation Guide, Version 10 (Version 10), September 2019 National Council for Prescription Drug Programs.

The Telecommunication Standard Implementation Guide, Version 6 contains the formats, billing units, and operating rules used for real-time pharmacy claims submission. The equivalent Batch Standard Implementation Guide, Version 15, provides instructions on the batch file submission standard that is to be used between pharmacies and processors or among pharmacies and processors. Both implementation guides contain the data dictionary, which provides a full reference to fields and values used in telecommunication and its equivalent batch standard.

The Batch Subrogation Implementation Guide, Version 10, is intended to meet business needs when a health plan has paid a claim that is subsequently determined to be the responsibility of another health plan within the pharmacy services sector. This guide provides practical guidelines for software developers throughout the industry as they begin to implement the subrogation transaction, and to ensure a consistent implementation throughout the pharmacy industry.

The materials we propose to incorporate by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850. Copies may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the internet at *https://www.ncpdp.org.* A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. If we wish to adopt any changes in this edition of the Code, we would submit the revised document to notice and comment rulemaking.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. Submission of Paperwork Reduction Act (PRA)-Related Comments

In this proposed rule we are soliciting public comment on each of these issues for the following sections of the rule that contain proposed ''collection of information'' requirements as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations. If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. We estimate there are currently 104 affected entities (which also includes PBMs and vendors), (416 reviewers total). We assume each entity will have four designated staff members who will review the entire proposed rule. The particular staff members involved in this review will vary from entity to entity, but will generally consist of lawyers responsible for compliance activities and individuals familiar with the NCPDP standards at the level of a

computer and information systems manager.

In this proposed rule we are soliciting public comment on each of these issues for the following sections of the rule that contain proposed ''collection of information'' requirements as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations. If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed, then we should estimate the cost associated with regulatory review. We estimate there are 104 affected entities (which also includes PBMs and vendors). We assume each entity will have four designated staff member who would review the entire rule, for a total of 416 reviewers. The particular staff involved in this review will vary from entity to entity, but will generally consist individuals familiar with the NCPDP standards at the level of a computer and information systems manager and lawyers responsible for compliance activities.

Using the wage information from the Bureau of Labor Statistics (BLS) for computer and information systems managers (code 11–3021), we estimate that the labor cost of having two computer and information systems managers reviewing this proposed rule is $95.56 per hour, including fringe benefits and overhead costs (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 4 hours for the two computer and information systems managers to review this proposed rule. For each entity that has two computer and information systems managers reviewing this proposed rule, the estimated cost is, therefore, $764.48 (4 hours × $95.56 × 2 staff). Therefore, we estimate that the total cost of when two computer and information systems manager review this proposed rule is $78,742 ($764.48 × 104 entities).

We are also assuming that an entity would have two lawyers reviewing this proposed rule. Using the wage information from the BLS for lawyers (code 23–1011), we estimate that their cost of reviewing this proposed rule is $113.12 per hour per lawyer, including fringe benefits and overhead costs (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 4 hours for two lawyers to review this proposed rule. For each entity that has two lawyers reviewing this proposed rule, the estimated cost is, therefore, $904.96 (4 hours × $113.12 × 2 staff). Therefore, we estimate that the total cost of when two lawyers reviews this proposed rule is $93,211 ($904.96 × 104 entities).

We solicit comments on our assumptions and calculations.

B. Modification to Retail Pharmacy Standards (Information Collection Requirement (ICR))

The following requirements and burden associated with the information collection requirements contained in §§ 162.1102, 162.1202, 162.1302, 162.1802, and 162.1902 of this document are subject to the PRA; however, this one-time burden was previously approved and accounted for in the information collection request previously approved under OMB control number 0938–0866 and titled ''CMS–R–218: HIPAA Standards for Coding Electronic Transactions.''

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 that would substantially reduce administrative costs. (See 65 FR 50350 (August 17, 2000)) This document, which proposes to update adopted electronic transaction standards that are being used, would usually constitute an information collection requirement because it would require third-party disclosures. However, because of OMB's determination, as previously noted, 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).

Should our assumptions be incorrect, this information collection request will be revised and reinstated to incorporate any proposed additional transaction standards and proposed modifications to transaction standards that were previously covered in the PRA package associated with OMB approval number 0938–0866.

V. Regulatory Impact Analysis

A. Statement of Need

This rule proposes modifications and an initial adoption to standards for electronic retail pharmacy transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under HIPAA, the National Committee on Vital and Health Statistics (NCVHS) recommends standards and operating rules to the Secretary of the Department of Health and Human Services (HHS) following review and approval of standards or updates to standards from the applicable SSO—in this case, the National Council for Prescription Drug Programs (NCPDP). The HHS Secretary must generally promulgate notice and comment rulemaking to adopt new or updated standards before they can be utilized to improve industry processes.

On May 17, 2018, the NCVHS recommended that the Secretary adopt the NCPDP Telecommunications Implementation Guide Version F2 (Version F2) and two related batch standards: Batch Standard Implementation Guide, Version 15, and the Batch Standard Subrogation Implementation Guide, Version 10 (Version 10). On April 22, 2020, the NCVHS recommended that the Secretary adopt NCPDP Telecommunications Implementation Guide Version F6 (Version F6) in lieu of Version F2, as well as the two batch standard recommendations set forth in the May 2018 letter. (For purposes of this analysis, Version F6 and its equivalent Batch Standard Version 15 are collectively referred to as Version F6.) These standards have been developed through consensus-based processes and subjected to public comment which indicated, without opposition, that the updates are required for current and future business processes. Based on informal communication with industry, should the updates to the standards not be adopted, industry will need to continue using NCPDP Version D.0 and the associated work arounds, including manual claims processing and claims splitting for drugs priced at or in excess of $1 million.

B. Overall Impact

We have examined the proposed 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 (September

19, 1980; Pub. L. 96–35496354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the 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), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is anticipated to have an annual effect on the economy in costs, benefits, or transfers of $100 million or more. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

We have prepared an RIA that, to the best of our ability, presents the costs and benefits of this proposed rulemaking. We anticipate that the adoption of these new versions of the retail pharmacy standard would result in costs that would be outweighed by the benefits.

C. Limitations of the Analysis

1. Data Sources

This portion of the analysis is based in part on industry research conducted in 2019 and 2020 by the CMS Alliance to Modernize Healthcare (CAMH), a Federally Funded Research and Development Center, to assess the costs and benefits associated with the potential adoption of Versions F2 and F6. As part of this effort, CAMH did the following: identified the relevant stakeholders that would be affected by the adoption of a new HIPAA standard for retail pharmacy drug transactions; obtained expert opinion, expressed qualitatively and quantitatively, on impacts on affected stakeholders of moving from the current version to the updated standards; and developed a high-level aggregate estimate of stakeholder impacts, based on available information from public sources and interviews. References to conversations with industry stakeholders in this section of the proposed rule are based on the interviews conducted by CAMH unless otherwise noted.

In conversations with industry stakeholders, we have been informed that entity-specific financial impact analyses of modifications to HIPAA transaction standards are not initiated until formal HHS rulemaking has been initiated, since proposed timing is a critical variable in cost development. For instance, in public comments submitted to the NCVHS,[9] the NCPDP urged that a timeline be communicated as soon as possible to allow stakeholders to begin budgeting, planning, development work, and coordinating the necessary trading partner agreements. Another commenter noted that corporate information technology (IT) budgets and timelines are dependent on the rulemaking process. We further understand that stakeholders likely would choose to implement only components of standards relevant to their business use cases, such that irrelevant components (and any additional expense they might require) may simply be disregarded.

In lieu of financial cost estimates, industry stakeholders have provided preliminary assessments that the conversion to Version F6 would entail between two to four times the level of effort as the previous HIPAA pharmacy standard conversion from Version 5.1 to Version D.0. But, we do not have reliable baseline data on the actual costs of that previous conversion to which to apply the multipliers because we: (1) are not aware of any available information on the final costs of the conversion to Version D.0; (2) have been told that stakeholders do not track expenditures in this way; and (3) our previous regulatory estimates combined the Version D.0 implementation with the concurrent X12 Version 5010 conversion, and so would be ambiguous at best. Moreover, as discussed in connection with comments received on the 2009 Modifications proposed rule generally, many commenters mentioned underestimated costs or overestimated benefits of transitioning to the new versions, but few provided substantive data to improve the regulatory estimates.[10] Therefore, we use certain estimates provided in public comments reported in the 2009 Modifications final rule as the starting point for our cost estimates. Our general approach is to develop estimates of the true baseline D.0 conversion costs and then apply a Version F6 multiplier.

With respect to benefits, we are not aware of any available information or testimony specifically quantifying cost savings or other benefits, although there is ample testimony supporting the business need and benefits of the proposed changes.

2. Interpreting Cost

Standard economics recognizes cost in several different ways. Marginal cost describes the resources needed to produce one additional unit of a good. Rule-induced costs may include new inputs of labor, materials, capital, etc.; but exclude sunk costs (already invested). The recommended methodology for a RIA considers government intervention to impose costs.[11] It assumes that stakeholders must make new expenditures to change their business systems. Under this interpretation, pharmacies and vendors would hire coders and other software development and testing specialists or consultants to modify their production code to accommodate Version F6. This one-time, out-of-pocket expenditure would constitute a cost attributable to the proposed rule. Costs to transmit transactions using the F6 standard after business systems have been modified to implement the proposed standard, as

[9] NCVHS Subcommittee on Standards Comments Received in Response to Request for Comment **Federal Register** Notice 85 FR 11375. *https://ncvhs.hhs.gov/wp-content/uploads/2020/03/Public-Comments-NCPDP-Change-Request-March-2020.pdf.*

[10] 74 FR 3314 (January 16, 2009); see also ''Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' proposed rule (73 FR 49796 (August 22, 2008)) (hereinafter referred to as the 2009 Modifications proposed rule).

[11] *aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.*

well as costs to maintain those systems for compliance with the standard, were not factored into this RIA. These ongoing costs are currently incurred by affected entities that are required to use the current standard and are attributable to conducting electronic transactions in general. Therefore, in this RIA, we do not anticipate any costs attributable to the proposed rule after completion of the proposed 2-year compliance timeframe. We solicit comment, including industry comment, on our cost interpretations.

Opportunity cost refers to the benefits forgone by choosing one course of action instead of an alternative. A business that invests in venture X loses the opportunity to use those same funds for venture Y. Based on oral and written NCVHS testimony by the retail pharmacy industry and pharmacy management system vendors, it was suggested that their software development process for a HIPAA standard conversion would represent an opportunity cost. For instance, some large pharmacy chains maintain permanent technical staff to make day-to-day changes in their pharmacy management systems and management adjusts staff assignments according to the organization's needs. HIPAA standard transaction version changes like the proposed Version F6 implementation, would, we believe, shift priorities for these staff, potentially delaying other improvements or projects. In this scenario, the opportunity cost consists of the time-value of delayed projects. Other pharmacy firms have an ongoing relationship with their pharmacy management software vendors. The purchaser generally obtains a hardware and software package with an ongoing agreement that includes periodic payments for maintenance, updates, upgrades, training, installation, financing, etc. Thus, the software is expected to evolve, rather than being just a one-time installation. The balance between upfront charges and monthly maintenance fees more closely resembles a multiyear lease than the one-time sale of an off-the-shelf application to a consumer. Thus, the parties often contemplate an ongoing supplier relationship in which maintenance and upgrades represent an opportunity cost.

Average cost equals total cost divided by the total units of production. Average costs for goods and labor come from industry surveys and public reports. Researchers can determine average cost relatively easily, whereas marginal cost would require complex analyses of a particular industry, firm, or production volume. This RIA uses average costs because of their availability and verifiability.

However, the proposed changes to adopt Version F6 and Version 10 generally do not require new out-of-pocket expenditures, so average cost may not describe the realities of actual budget impacts to firms. We seek comment on these assumptions.

D. Anticipated Effects

The objective of this RIA is to summarize the costs and benefits of the following proposals:

- Adopting modified real time and batch standards for retail pharmacy transactions for health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits, transitioning from Telecommunications Standard Version D.0 to Version F6.
- Adopting a new pharmacy subrogation transaction standard, replacing the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, with the Batch Standard Subrogation Implementation Guide, Version 10, applicable to all prescription drug payers.

Consistent with statutory and regulatory requirements, the NCVHS recommends HIPAA standards, which are developed by Standard Setting Organizations (SSOs), in this case the NCPDP, through an extensive consensus-driven process that is open to all interested stakeholders. The standards development process involves direct participatory input from representatives of the industry stakeholders required to utilize the transactions, including pharmacies (chain and independent), health plans and other payers, PBMs, and other vendors that support related services. We are not aware of any opposition to moving forward with these updates.

We are proposing a 2-year compliance date following the effective date of the final rule. For purposes of this analysis, we assume a 2-year implementation period. The remainder of this section provides details supporting the cost-benefit analysis for each of the proposals referenced previously.

Table 1 is the compilation of the estimated costs for all of the standards being proposed in this rule. To allocate costs over the proposed 2-year implementation period, we assumed a 50–50 percent allocation of IT expenses across the 2-year implementation period and all training expenses in the second year. However, this is just an informed guess, as we did not locate any source information on this assumption. We note again that we are not aware of any data or testimony describing quantifiable benefits or cost savings attributable to these proposals, and have solicited comments on whether there are significant quantifiable benefits or cost savings that should be included in our analysis.

TABLE 1. ESTIMATED COSTS ($ MILLIONS) FOR YEARS 2023 THROUGH 2032 FOR IMPLEMENTATION OF VERSIONS F6 AND VERSION 10 (S10)

Cost Type	Industry	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total
F6	Chain Pharmacy	43.5	52.1	---	---	---	---	---	---	---	---	95.6
	Independent Pharmacy	---	61.0	---	---	---	---	---	---	---	---	61.0
	Health Plan	---	---	---	---	---	---	---	---	---	---	---
	PBM	64	64	---	---	---	---	---	---	---	---	128.0
	Vendors*	47.2	52.5	---	---	---	---	---	---	---	---	99.7
S10	Health Plan	---	---	---	---	---	---	---	---	---	---	
	Medicaid Agency	---	---	---	---	---	---	---	---	---	---	
	PBM	---	---	---	---	---	---	---	---	---	---	
	Vendors	1.0	1.0	---								2.0
	Annual Total	**155.7**	**230.6**	---								**386.3**
											Total	**386.3**

*Vendors" as used in Table 1 refers to pharmacy management system and telecommunication system vendors.

1. Adoption of Version F6 (Including Equivalent Batch Standard Version 15)

The objective of this portion of the RIA is to summarize the costs and benefits of implementing Version F6. We invite the industry or other interested entities or individuals to comment on all of our assumptions and projected cost estimates, and to provide current data to support alternative theories or viewpoints throughout.

a. Affected Entities

Almost all pharmacies and all intermediaries that transfer and process pharmacy claim-related information already use Version D.0 for eligibility verification, claim and service billing, prior authorization, predetermination of benefits, and information reporting transaction exchanges (the latter two categories are not HIPAA-adopted pharmacy standards). Pharmacies utilize technology referred to as pharmacy management systems that encode Version D.0 to submit these transactions for reimbursement on behalf of patients who have prescription drug benefits through health and/or drug plan insurance coverage (health plans). These submissions are generally routed through two intermediaries: a telecommunication switching vendor (switch) and a specialized third-party administrator for the health plan, generally a PBM. Billing transactions may occur in one of two modes: real time or batch. Pharmacy claims are generally transacted in real time as a prerequisite to dispensing prescription medications. For instance, Medicare Part D rules generally require each claim to be submitted online in real time to permit accumulator balances to be updated after every claim so cost sharing on each subsequent claim will accurately reflect changes in benefit phases. The equivalent batch standard enables transmission of non-real-time transactions. For instance, a batch submission could be sent following a period when real-time response systems were unavailable or following a retrospective change in coverage. Technically, the batch standard uses the same syntax, formatting, data set, and rules as the telecommunications standard, ''wraps'' the telecommunication standard around a detail record, and then adds a batch header and trailer to form a batch file. The claims processor may then process the batch file either within a real-time system or in a batch-scheduling environment.

Based on the 2017 Census business data, pharmacies have a bimodal size distribution. About 99 percent of firms have a single location, predominantly the traditional independent, owner-operated storefront and the remainder of fewer than 200 large firms operate an average of approximately 150 establishments (locations) each. According to other industry data, the largest five chain pharmacy firms represent over 28,000 locations, and the two largest chains each exceed 9,000 locations.[12] However, the Census business data's Pharmacy and Drug Store segment (North American Industry Classification System (NAICS) code 446110) does not capture all pharmacy firms affected by this proposed rule. While we believe this source is enough to capture most small pharmacies, we need another data source to capture the additional larger firms.

Pharmacies are typically classified by ownership as either chain or independents. Health data analytics company IQVIA estimated[13] in 2019 that there were 88,181 pharmacies, of which 55 percent (48,196) were part of chains and 45 percent (39,985) were independents. Open-door retail pharmacies, which provide access to the general public, comprised the clear majority of pharmacy facility types at 91 percent (80,057). The five largest pharmacy chains owned about 35 percent (close to 28,000) of retail locations. The remaining 8 percent of facility types included closed-door pharmacies, which provide pharmaceutical care to a defined or exclusive group of patients because they are treated or have an affiliation with a special entity such as a long-term-care facility, as well as central fill, compounding, internet, mail service, and hospital-based nuclear and outpatient pharmacies. Most of these pharmacy types may be included in Medicare Part D sponsor networks. We are aware that the largest pharmacy chains are increasingly likely to operate multiple pharmacy business segments (channels), such as retail, mail, specialty, and long-term care. However, we are not aware of information that would allow us to treat these non-open-door retail pharmacy firm types any more granularly than our usual chain and independent categories. We welcome comments on whether there are meaningful distinctions in cost structures that should be considered, as well as on any publicly available data sources to assist in quantifying entities in these segments and any potential differential impacts.

As noted, pharmacies utilize pharmacy management systems to encode Version D.0 for claim-related data exchanges via telecommunication switches. Pharmacies that do not internally develop and maintain their pharmacy management systems will contract with technology vendors for these services. Based in part on communications with industry representatives, such as the American Society for Automation in Pharmacy, we believe there are approximately 30 technology firms providing computer system design, hosting, and maintenance services in this market. Based on testimony provided to the NCVHS, in 2018 this market represented approximately 180 different software products.[14] Some pharmacies may also utilize other vendors, generally clearinghouses, for mapping Version D.0 claims to the X12 837 claim format (for instance, to bill certain Medicare Part B claims). However, since mapping between the X12 and NCPDP standards is not an element of Version F6, we do not consider this practice in scope for this proposed rule and do not account for it in this RIA.

Pharmacies also contract with telecommunication switches for transaction routing. In addition to routing, switches validate the format of pharmacy transactions prior to transmission to the payer and then check the payer response to make sure it is formatted correctly for the pharmacy to interpret. Based on conversations with industry representatives, we believe there are three telecommunication switches in this segment of the market.

Some healthcare providers that dispense medications directly to their patients, known as dispensing physicians, may use Version D.0 to submit these outpatient prescription drug claims on behalf of their patients to health plans via health plans' PBMs. However, we do not believe this practice to be widespread and therefore do not account for it in this RIA.

Health plans generally provide some coverage for outpatient prescription drugs, but do not generally contract and transact with pharmacies directly. Instead, health plans typically contract with PBM firms to receive and process pharmacy claim transactions for their enrollees. We assume even the relatively

[12] 2019 ''U.S. National Pharmacy Market Summary.'' IQVIA. *https://www.onekeydata.com/downloads/reports/IQVIA_Report_US_Pharmacy_Market_Report_2019.pdf.*

[13] 2019 ''U.S. National Pharmacy Market Summary.'' IQVIA. *https://www.onekeydata.com/downloads/reports/IQVIA_Report_US_Pharmacy_Market_Report_2019.pdf.*

[14] NCVHS Hearing on NCPDP Standards and Updates—March 26, 2018 Virtual Meeting. *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-march-26-2018-hearing-on-ncpdp-standards-and-updates/.*

few health plans that directly purchase prescription drugs for their own pharmacies utilize PBMs, either owned or contracted, to manage billing for drugs and pharmacy supplies. Likewise, the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services (VA PBM) runs its own PBM unit for VA prescription drug operations.

As previously noted, in 2017 there were 745 Direct Health and Medical Insurance Carriers and 27 Health Maintenance Organization (HMO) Medical Centers—a total of 772 health plan firms. Comparable data limited specifically to PBMs is not available, but based on Part D experience, we estimate that approximately 40 firms conduct some PBM functions involved with processing some pharmacy claim transactions. Based on testimony provided to the NCVHS, in 2018 these 40 firms represented approximately 700 different payer sheets,[15] or payer-specific endpoints and requirements for submitting pharmacy claims. Industry analysis by Drug Channels Institute's website based on 2018 data [16] indicated that the top six PBMs controlled approximately 95 percent of total U.S. equivalent prescription claims, and the top three PBMs controlled 75 percent. We assume that the VA PBM is in addition to these numbers, but that Medicaid claim processing PBMs are included in the 40 firms. Industry trends include significant consolidation of firms in these sectors and vertical integration among health plans, PBMs, and pharmacies.

b. Costs

(1) Chain Pharmacies

Pharmacies either internally develop or externally purchase pharmacy management information systems to bill and communicate with PBMs. Based on public comments related to Version F6 submitted to the NCHVS, available at *https://ncvhs.hhs.gov/wp-content/uploads/2020/03/Public-Comments-NCPDP-Change-Request-March-2020.pdf,* we are aware that some chain pharmacy firms (with as many as 1,800 pharmacies) utilize systems managed by third-party technology vendors. For purposes of this RIA, we assume that, generally, the largest chain pharmacy firms internally develop and manage their own pharmacy management system upgrades and transaction standard conversion development, implementation, testing, and training. We further assume that these costs are generally incurred at the firm level. Based on the 2019 IQVIA data, the top 25 pharmacy firms accounted for 38,464 stores. If these top 25 firms represented chain-owned entities, they represented almost 80 percent (38,464/48,196) of total chain pharmacy stores in 2019. We assume these 25 firms, as well as the VA and the Indian Health Service (IHS), would finance and manage their pharmacy system conversion requirements internally, and the remainder of chain pharmacy firms would rely on their technology vendor for technical development, implementation, testing, and initial training.

To determine whether our assumptions were reasonable, we met with representatives from IHS. Based on those conversations, we understand that IHS, tribal, and urban (I/T/U) facilities with pharmacies would have multiple Version F6 implementation scenarios. Although these facilities are not legally chain pharmacies, we believe their implementation costs may be roughly similar and, thus, we treat I/T/U facilities with pharmacies under this category for this analysis. IHS manages a significant federal health information technology (HIT) system with a suite of modules, including pharmacy dispensing and billing, that supports IHS pharmacies, as well at least 16 urban entities and 114 tribal entities; however not all of these entities include pharmacies. In contrast to other pharmacy entities treated as chain pharmacies, we understand that additional budget funding may be required for IHS to implement Version F6 within the proposed implementation timeframe. We estimate that IHS would incur implementation costs at a level roughly equivalent to the VA system, and that this expense would be a marginal cost for the IHS. We also understand that approximately another 60 tribal entities and another 25 urban entities do not utilize the federal system, but, rather, contract with commercial vendors for HIT; although again, not all of these entities operate their own pharmacies. As a result, we estimate that about 60 percent of these smaller I/T/U entities (51) would rely on existing maintenance agreements with commercial vendors for implementation and, like smaller chain pharmacies, would incur direct implementation costs to support user training costs. We solicit comments on our assumptions.

In the 2017 Census business data there were 190 firms classified as Pharmacies and Drug Stores with more than 500 employees, representing 27,123 establishments. This classification does not include grocery store pharmacies, which were elsewhere reported to number 9,026 in 2017, and to be decreasingly offered by smaller grocery chains in 2020.[17] The 2017 Census business data includes 72 firms classified as Supermarkets and Other Grocery (except Convenience) Stores with more than 5,000 employees, which we assume is a proxy for the number of such firms still offering grocery store pharmacies in 2020. (The Census Bureau and Bureau of Labor Statistics [BLS] include ''big box'' department stores in this category.) Thus, we assume a total of 262 (190+72) chain pharmacy firms based on this data. Since we assume 25 firms would manage their Version F6 conversion costs internally, we estimate the remainder of 237 (262 − 25) would rely upon their technology vendor. As an alternative data point, Drug Channels Institute estimated that the top 15 pharmacy organizations in 2019 represented over 76 percent market share in revenues.[18] Although there is not complete consistency between the top organizations listed in the two analyses, both tend to support a view of the set of market participants as heavily skewed toward smaller firms, with the very largest firms likely to have multiple pharmacy channel segments.

Based on conversations with a variety of industry representatives, we understand that these larger firms retain the technical staff and/or contractors that would undertake the Version F6 conversion efforts as an ongoing business expense. Consequently, in practice the cost estimates developed in this section do not represent new additional expenditures for these firms, but rather opportunity costs for these resources that would otherwise be deployed on other maintenance or enhancement projects.

As previously noted, industry estimates of the costs of a conversion

[15] NCVHS Hearing on NCPDP Standards and Updates—March 26, 2018 Virtual Meeting. *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-march-26-2018-hearing-on-ncpdp-standards-and-updates/.*

[16] CVS, Express Scripts, and the Evolution of the PBM Business Model. Drug Channels. May 29, 2019. *https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html.*

[17] The Pharmacist Is Out: Supermarkets Close Pharmacy Counters: *Regional grocery chains get squeezed by consolidation, shrinking profits in prescription drugs.* By Sharon Terlep and Jaewon Kang. Wall Street Journal. Updated Jan. 27, 2020 6:18 p.m. ET. Accessed 10/13/2020 at: *https://www.wsj.com/articles/the-pharmacist-is-out-supermarkets-close-pharmacy-counters-11580034600?mod=business_lead_pos3&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.*

[18] The Top 15 U.S. Pharmacies of 2019: Specialty Drugs Drive the Industry's Evolution. Drug Channels Institute. Published March 3, 2020. *https://www.drugchannels.net/2020/03/the-top-15-us-pharmacies-of-2019.html.*

from current Version D.0 to Version F6 have been in the form of multiples of the costs for the Version 5.1 to Version D.0 conversion. As a technical matter, we assume these informal multiples account for inflation. In a presentation to the NCVHS,[19] the NCPDP indicated that stakeholders' input indicated the level of effort and cost for Version F6 to be at least double that of implementing NCPDP D.0. In public comments to the NCVHS, a chain pharmacy association stated that implementation costs would vary significantly among different pharmacy chains based on size, scope of services provided, and business models, and that hardware, software, and maintenance costs allocated specifically to Version F6 are estimated to be in the tens of millions of dollars. One of the largest pharmacy chains estimated costs associated with Version F6 implementation to be three to four times higher than the implementation of Version D.0, also in the tens of millions of dollars. This commenter explained that much of these higher costs is related to the expanded dollar fields, the structure of new fields that require database expansion, and updates to many integrated systems. Another of the largest pharmacy chains with integrated PBM functions offered preliminary estimates in the range of two to three times greater than the Version D.0 conversion, and noted that the expanded dollar fields would impact all of the following systems: point of service claim adjudication, all associated financial systems, internal and external reporting programs, help desk programs, member/client portals, and integrated data feeds. This same stakeholder stated that the size of the transactions has also increased considerably due to the inclusion of new segments and repeating fields and would require new database storage hardware.

The 2009 Modifications final rule discussed receiving estimates of $1.5 million and $2 million from two large national pharmacy chains and elected to use an estimate of $1 million for large pharmacy chains and $100,000 for small pharmacy chains in the first implementation year. That rule also discussed a few public comments disputing these large chain estimates,[20] suggesting in one case an alternative $2 million estimate inclusive of Version 5010 costs, and, in another, a 2-year cost of $4.9 million without specification of which costs were included. Another retail pharmacy commenter that self-identified as neither a chain nor an independent estimated a cost of implementation of both standards of $250,000, with 90 percent of the cost attributable to Version 5010 and, thus, $25,000 attributable to Version D.0. Using these estimates, we develop a rough estimate of the true baseline D.0 conversion costs and then apply a Version F6 multiplier. We solicit comments on the appropriateness of this approach.

We believe that Version F6 conversion costs for chain pharmacies would be differentiated in three general categories: (1) the largest firms operating in multiple pharmacy channels; (2) other midsize retail pharmacy chain firms operating primarily in either the open-door retail and/or another single pharmacy channel; and (3) smaller chain pharmacy firms. Starting with the point estimates discussed in the Version D.0 rulemaking and making some upward adjustments to address potential underestimation, we estimate that—

- The two largest chain pharmacy firms incurred a baseline (D.0) cost of $2 million;
- The 23 midsize chain pharmacy firms, the VA and IHS pharmacy operations incurred a baseline cost of $1 million; and
- The 237 smaller chain pharmacy firms incurred a baseline cost of $25,000.

Based on the 2x–4x multiplier estimates described previously, we assume a midpoint 3x multiplier for the estimated 25 larger chain pharmacies and the VA that would finance and manage their system conversion requirements internally; consequently, we estimate that over the 2-year implementation period:

- Two chain pharmacy firms would incur all internal Version F6 conversion costs of (3*2 million), or $6 million each.
- The 25 chain pharmacy-sized firms (23 midsized chains, the VA and IHS) would incur all internal Version F6 conversion costs of (3*1 mil), or $3 million each.

Based on a CAMH environmental scan conducted with industry representatives, we understand that most pharmacy firms rely on their pharmacy management system vendor for conversion planning, development, implementation, testing, and initial (primary) training. CAMH suggested that pharmacies would likely need to make some investments in staff training, but would likely not have an increase in direct upfront software costs because system software updates are usually factored into the ongoing contractual fees for operating and maintenance costs of their pharmacy systems. Thus, we understand that HIPAA modification efforts are generally already priced into vendor maintenance agreements and fee structures, and we assume there would be no increases specifically due to the Version F6 conversion in these ongoing costs to pharmacies. We assume that primary training is developed or purchased at the firm level and may deploy at the establishment level in secondary employee in-service training slots. We assume that this training does not scale along with the conversion costs, but rather with the size of the organization in terms of locations and employees. As summarized in Table 2, using the generally uncontested estimates from the Version D.0 rulemaking adjusted for inflation,[21] we estimate that: 237 smaller chain pharmacy firms and 51 urban and tribal entity pharmacies (a total of 288 pharmacies) would incur Version F6 conversion training costs of ($25,000 × 1.20) or $30,000 each on average, generally in the second year of the 2-year implementation period.

We invite public comments on our general assumptions and request any additional data that would help us determine more accurately the impact on the pricing structures of entities affected by this proposed rule.

[19] NCVHS Full Committee Hearing, March 24–25, 2020. *https://ncvhs.hhs.gov/meetings/full-committee-meeting-4/.*

[20] 74 FR 3319 (January 16, 2009).

[21] Based on inflation from January 2010 to September 2020: *https://www.bls.gov/data/inflation_calculator.htm.*

TABLE 2. CHAIN PHARMACY COSTS OF CONVERSION TO VERSION F6

Version F6 Conversion Cost Category by Chain Size	D.0 Cost Baseline ($ in millions)	Inflation Adjustment to Baseline	Adjusted D.0 Baseline ($ in millions)	D.0 Cost Multiplier for Version F6	Conversion Cost Per Entity ($ in millions)	Number of Affected Entities	Total F6 Conversion Costs ($ in millions)
All (largest)	2.0	N/A	2.0	3	6.0	2	12.0
All (midsize)	1.0	N/A	1.0	3	3.0	25	75.0
User Training (smaller)	0.025	1.2	0.03	N/A	0.03	288	8.6
Total						315	95.6

(2) Independent Pharmacies

As noted previously, the 2019 IQVIA data included 88,181 pharmacies, of which 45 percent (39,985) were independently owned. We recognize that this classification is not identical to the use of the term independent community pharmacy; however, we are not aware of publicly available data to help us segment this market further. We know from Census business data that in 2017 there were 19,044 pharmacy firms with fewer than 500 employees, representing 20,901 establishments. Just as we assume that the firms with more than 500 employees represent chains, we assume that those with fewer than 500 employees represent independently owned open- or closed-door pharmacies.

We understand that these smaller pharmacies predominantly rely on their pharmacy system vendors for upgrades, including HIPAA standard version conversion planning, development, implementation, testing, and primary training. In return, they pay ongoing maintenance and transaction fees. As discussed previously with respect to some chain pharmacies, we understand that Version F6 conversion efforts would already be priced into existing maintenance agreements and fee structures. Therefore, we do not assume increases in these ongoing costs to independent pharmacies as the result of the Version F6 conversion, and we estimate pharmacy direct costs would generally be comprised of training and other miscellaneous expenses. As with chain pharmacies, we assume that primary training is developed or purchased at the firm level and deployed at the establishment level in secondary employee in-service training slots. We further assume that this training does not scale along with the conversion costs, but, rather, with the size of the organization in terms of locations and employees. For this reason, we assume that the few system users in very small pharmacies would be trained directly by the pharmacy management system vendor, and no secondary training costs would be required for such small firms.

As noted previously, a commenter on the 2009 Modification proposed rule [22] that self-identified as neither a chain nor an independent pharmacy estimated implementation costs of both Version 5010 and Version D.0 standards of $250,000, with 90 percent of the costs attributable to Version 5010. Thus, one non-chain pharmacy estimated conversion costs for Version D.0 of about $25,000. Although we do not know the size or complexity of this organization, this level would not be inconsistent with our understanding that the costs of an NCPDP Telecommunication Standard conversion would be borne by the pharmacy management system vendors and that smaller pharmacy conversion costs would consist primarily of user training expense. Referring to the 2017 Census business data, almost 90 percent (17,016 out of 19,044) of these pharmacy firms had fewer than 20 employees, while the remainder (2,028) had between 20 and 499. Therefore, we assume that 17,016 small pharmacy firms would incur opportunity costs for employee time spent in training and 2,028 pharmacy firms would incur secondary training expenses. As summarized in Table 3, assuming baseline training costs per independent pharmacy with 20 or more employees of $25,000, and a cumulative inflation adjustment of 20 percent,[23] we estimate that 2,028 independently owned pharmacies would incur Version F6 conversion training costs of ($25,000 × 1.20) or $30,000 each on average, in the second year of the 2-year implementation period

TABLE 3. INDEPENDENT PHARMACY COSTS OF CONVERSION TO VERSION F6

Version F6 Conversion Cost Category	D.0 Cost Baseline ($ in millions)	Inflation Adjustment to Baseline	Adjusted D.0 Baseline ($ in millions)	D.0 Cost Multiplier for Version F6	Conversion Cost Per Entity ($ in millions)	Number of Affected Entities	Total F6 Conversion Costs ($ in millions)
User Training	0.025	1.2	0.03	N/A	0.03	2,028	61

(3) Health Plans and PBMs

We anticipate that health plans should see minimal changes in their operations and workflows between Version D.0 and Version F6. Health plans contract with processors/PBMs for conducting online eligibility verification, claim and service billing, predetermination of benefits, prior authorization, and information reporting transaction exchange types and transaction record storage. While health plans (or their other vendors) supply PBMs with eligibility records and receive data from PBMs containing data derived from claims, they are not typically parties to the exchange of the HIPAA pharmacy transactions. Based on NCVHS testimony with stakeholders and in development of an environmental scan on the impact of this update to the pharmacy standards, we understand that HIPAA standard conversion costs are already priced into

[22] 74 FR 3317 (January 16, 2009).

[23] Based on inflation from January 2010 to September 2020: *https://www.bls.gov/data/inflation_calculator.htm.*

ongoing contractual payment arrangements between health plans and PBMs and would not be increased specifically in response to the Version F6 conversion.

All PBMs would experience some impacts from the Version F6 conversion, involving IT systems planning and analysis, development, and external testing with switches and trading partners. One PBM commented to the NCVHS that the most significant impact would be the expansion of the financial fields to accommodate very expensive drug products with charges greater than $999,999.99. Another PBM processor representative indicated in a conversation that the impact on payer/processors would depend on the lines of business they support—that entities supporting Medicare Part D processing would have the most work to do, but would also get the most value from the transition. The extent to which these activities would be handled by in-house resources or contracted out may vary by organization. Based on other conversations, we understand that from the PBM perspective, the Version F6 conversion adds fields that increase precision and machine readability; rearranges some things to make processing more efficient and flexible in the long run; implements more efficient ways to accomplish work-arounds that payers already have in place (so the changes in the transactions would map to back-end system fields and logic already in place); and involves relatively few structural changes.

PBMs may manage prescription drug coverage for a variety of lines of business, including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, managed Medicaid plans, and others,[24] such as state Medicaid programs. While details on internal operating systems are proprietary, we assume that the three largest PBMs that controlled 75 percent of 2018 market share[25] (not including the VA) have contractual agreements supporting all or most drug coverage lines of business and host the most variants in legacy operating platforms, customer-specific processing requirements, and scope of customer service requirements—involving all the information exchange types supported by the NCPDP Telecommunications Standard. We assume that the remaining three of the top six PBMs, responsible for another 20 percent of market share, have lesser operating system complexity but also provide services for multiple lines of business and a full scope of information exchange types. We assume that the VA PBM is comparable to these midsize PBMs. We assume that the remainder of the PBM market is comprised of approximately 33 (40 − 7) smaller PBMs supporting one or more lines of business and information exchange types.

Public commenters to the 2009 Modifications proposed rule regarding the D.0 conversion, self-identifying as large PBMs, estimated that costs for their upgrades would be more than $10 million and $11 million, respectively. As a result of these comments, we revised our estimates up to $10.5 million for each large PBM company and maintained the original assumption of $100,000 in conversion costs for smaller specialty PBMs,[26] as we received no comments critical of that estimate. Based on updated data on market share, we now assume more segments in the PBM industry to account for the consolidation and growth of midsize entities that comprise the second tier of market share and assume their costs to be less than half those of the largest PBMs due to lesser complexity of structure and operations. Therefore, using the Version D.0 revised estimates as anchors, we estimate the following:

- The largest three PBMs incurred baseline (Version D.0) conversion costs of $10.5 million.
- The 3 next-largest PBMs and the VA PBM incurred baseline conversion costs of $4 million.
- The remaining 33 PBMs incurred baseline costs of $500,000.

As previously noted, industry estimates of the costs of a conversion from Version D.0 to Version F6 have been expressed as multiples of two to four times the costs for the Version 5.1 to Version D.0 conversion. However, several PBM commenters to the NCVHS suggested the lower end of this range. This would be consistent with our understanding that many of the changes involve mapping current back-end work-around systems to newly codified data, as opposed to building substantial new functionality from scratch. However, expansion of all existing financial fields to accommodate larger numbers would involve changes to many interrelated systems. As summarized in Table 4, using a 2x multiplier, we estimate that over the 2-year implementation period:

- The largest 3 PBMs would incur Version F6 conversion costs of (2*10.5 mil), or $21 million each.
- The next 3 midsize PBMs and the VA PBM or four firms, would incur Version F6 conversion costs of (2*4 mil), or $8 million each.
- The remaining 33 PBMs would incur Version F6 conversion costs of (2*500,000), or $1 million each.

TABLE 4. PBM COSTS OF CONVERSION TO VERSION F6

Version F6 Conversion Cost Category by PBM Size	D.0 Cost Baseline ($ in millions)	Inflation Adjustment to Baseline	Adjusted D.0 Baseline ($ in millions)	D.0 Cost Multiplier for Version F6	Conversion Cost Per Entity ($ in millions)	Number of Affected Entities	Total F6 Conversion Costs ($ in millions)
All (largest)	10.5	N/A	10.5	2	21	3	63
All (midsize)	4.0	N/A	4.0	2	8	4	32
All (smaller)	0.5	N/A	0.5	2	1	33	33
Totals						40	128

[24] Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers. Prepared for the Pharmaceutical Care Management Association (PCMA). February 2020. *https://www.pcmanet.org/wp-content/uploads/2020/02/Pharmacy-Benefit-Managers-Generating-Savings-for-Plan-Sponsors-and-Consumers-2020-1.pdf.*

[25] CVS, Express Scripts, and the Evolution of the PBM Business Model. Drug Channels. May 29, 2019. *https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html.*

[26] 74 FR 3320 (January 16, 2009).

(4) Vendors

As previously discussed, pharmacies that do not internally develop and maintain their pharmacy management systems contract with technology vendors for these services. We believe there are approximately 30 technology firms providing computer system design, hosting, and maintenance services in this market, with different companies serving one or more market segments, such as retail, mail, long-term care, or specialty pharmacy. Software vendors often have commitments to their clients to maintain compliance with the latest adopted pharmacy transaction standards. They must incorporate these standards into their software systems; otherwise, they would not be able to sell their products competitively in the marketplace. These systems cannot properly support their users using outdated standards or missing key functionalities which the industry has identified as essential to business operations. We understand that vendors anticipate upgrades to these standards, and the cost of updating the software is incorporated into the vendor's routine cost of doing business and product support pricing. As discussed in the context of independent pharmacies, based on conversations with a variety of industry representatives, we understand that future HIPAA standard conversion efforts are often already priced into existing maintenance agreements and fee structures for their customers. However, the marginal costs of the conversion would be borne by these vendor entities.

We understand from conversations with industry representatives that system update costs are usually embedded into operating costs, where they represent opportunity costs for vendors that offset the resources to add new features (system enhancements) that their clients may request. Updating systems would take some, but not all, resources currently doing system enhancements and improvements and move them over to ensuring compliance with the new standards. In the 2009 Modifications final rule,[27] we explained that we received no comments from pharmacy software vendors in response to the solicitation of comments on expected Version D.0 conversion costs, actual costs for vendor software upgrades, and any downstream impact on covered entities. We believe it is likely that firms would continue to decline to share this type of proprietary and market-sensitive data. Thus, we do not have comparable anchors from prior impact analyses for cost estimates. However, in the public comments submitted to the NCVHS, one pharmacy software vendor with multiple product lines provided a preliminary estimate of approximately 50,000 man-hours to make the Version F6 changes. We are not aware of publicly available data segmenting this industry, so we assume this one estimate is representative of the industry on average. Using this estimate and a mean hourly wage rate of $54 from BLS data [28] and rounding to the nearest million, we estimate that over the 2-year implementation period: 30 pharmacy management system firms would incur Version F6 conversion costs of approximately $3 million each for software planning, development, and testing.

We further estimate that these pharmacy system vendor firms would incur 80 hours of training costs for each pharmacy client firm at a mean hourly wage rate of $28.51 (also from the BLS data), the product rounded to $2,300. Thus, we estimate that in the third year of the 2-year implementation period: 30 pharmacy management system firms would incur Version F6 training costs of $2,300 for 2,265 clients (237 small chain pharmacy and 2,028 independent pharmacy firms), or $5,210,000 in total for this industry segment.

In addition, both pharmacies and PBMs contract with telecommunication switches for transaction validation and routing. Based on conversations with industry representatives, we believe there are three switches in this segment of the market. We are not aware of any data to help us estimate their costs of system upgrades, but believe their costs are less than those of chain pharmacies and PBMs. We estimate that over the 2-year implementation period three telecommunication switching vendors would incur Version F6 conversion costs of $1.5 million each. These other vendor costs are summarized in Table 5.

TABLE 5. OTHER VENDOR COSTS OF CONVERSION TO VERSION F6

Version F6 Conversion Cost Category	Conversion Cost Per Entity ($ in millions)	Number of Affected Entities or Sites	Total F6 Conversion Costs ($ in millions)
Pharmacy Management System IT Implementation	3.0	30	90.0
Pharmacy Management System User Training	0.0023	2265	5.2
Subtotal			95.2
Telecommunication Switches	1.5	3	4.5
Total			99.7

In summary, total estimated Version F6 conversion costs are summarized in Table 6.

[27] 74 FR 3320 (January 16, 2009).

[28] Bureau of Labor Statistics. May 2019 National Occupational Employment and Wage Estimates United States. Mean hourly rates for Computer Network Architects, Software Developers and Software Quality Assurance Analysts and Testers, and Computer Support Specialists. *https://www.bls.gov/oes/current/oes_nat.htm#15-0000.*

TABLE 6. TOTAL INDUSTRY COSTS FOR CONVERSION TO VERSION F6

Conversion Cost Category	Number of Affected Entity (firms)	Total F6 Conversion Costs ($ in millions)
Chain Pharmacies	315	95.6
Independent Pharmacies	19,044	61.0
Health Plans	772	---
PBMs	40	128.0
Pharmacy Management System Vendors	30	95.2
Telecommunication Switches	3	4.5
Total		384.3

c. Benefits

Industry commentary on benefits related to the Version F6 conversion is available in two segments: first, the 2018 NCVHS testimony and industry representative interviews related to the proposed intermediate Version D.0 to Version F2 conversion, and second, the 2020 NCVHS testimony and public comments related to the revised Version F6 proposal. Both sets of evidence portray industry consensus that updating the HIPAA pharmacy standards is necessary for current and future business needs at a significant, but unavoidable, cost. Commentaries describe numerous non-quantifiable benefits, such as to enable compliance with regulatory requirements, to facilitate the transmittal of additional codified and interoperable information between stakeholders that would benefit patient care and care coordination, and to power advanced data analytics and transparency. Some changes would result in operational efficiencies over manual processes, but would also entail greater manual effort to collect information and input data at an offsetting cost. We are not aware of any assertions or estimates of industry cost savings attributable to the Version F6 conversion, and we solicit comment on whether there are significant savings that should be accounted for in our analysis. For pharmacy management system vendors and switches, we assume upgrading existing systems for the Version F6 conversion is a cost of doing business and retaining customers and does not involve cost savings.

(1) Pharmacies

Initial automation of pharmacy coordination of benefits transactions was a large part of the previous Version 5.1 to D.0 conversion. Further refinement of this type of information is included in the Version F6 conversion. Additional fields are expected to improve the flow of information between pharmacies and payers and allow for more accurate billing to the correct entity. However, better information does not translate into savings as directly as the initial transition from manual to fully electronic processes. Moreover, commenters to the 2009 Modifications proposed rule suggested that even those minor levels of savings (1.1 percent of pharmacist time) may have been overestimated.[29] Some of the less quantifiable benefits include enabling more integration with back-office systems, more informative data analytics, better forecasting, and stronger internal controls over both proper payments and compliance with contractual requirements. For instance, better information on adjudicated payer types allows pharmacies to identify and apply insurance program-specific coverage requirements more accurately.

Other changes, such as more structured communication between pharmacies and payers to resolve prescriber-identifier validation activities at the point of sale, or to better enable compliance with federal and state limitations on filling and refilling controlled substance prescriptions, would enable better compliance with Drug Enforcement Administration and CMS rules without PBMs having to resort to claim rejections. In general, many of these changes are expected to support pharmacy efficiency improvements, reduce some manual workflow processes related to Food and Drug Administration mandated Risk Evaluation and Mitigation Strategy (REMS) data collection and use, reduce the time required to resolve claim rejections and transaction attempts, and reduce recoupment risk on audits.[30] However, these efficiencies may not necessarily translate directly to cost savings for pharmacies, as other changes require more data collection, greater pharmacy staff communication with prescribers, and inputting more coding than required previously. We are not aware of any estimates of quantifiable savings related to these efficiencies. Improvements like the expanded financial fields would avoid future manual processes needed to enter free text, split claims, or prepare and submit a paper Universal Claim Form; however, million-dollar claims are quite rare today, and, thus, it seems this change may not represent significant cost savings over current processes. But, as noted earlier, their numbers are expected to increase, and, without this functionality, the risk of billing errors could potentially increase. Moreover, these types of drugs would likely be dispensed by a small percentage of pharmacies, so the benefits would likely not be generally applicable to all pharmacies.

Pharmacy and pharmacy vendor commenters to the NCVHS noted that other types of changes would benefit patients by enhancing pharmacy and payer patient care workflows through the replacement of many clinical free text fields with discrete codified fields. This would enable automation that can trigger real-time workflows that could aid in goals such as combatting the opioid crisis or communicating relevant therapy-related information for at-risk patients. Improvements would support better patient care and safety through more accurate patient identification and enhanced availability and routing of benefit and drug utilization review information. For instance, new response fields for drug utilization review messaging and Formulary Benefit Detail help to convey clinical information such as disease, medical condition, and formulary information on covered drugs. This would enable the pharmacist to have more informative discussions with patients and provide valuable information about alternative drug or therapy solutions. We assume that some of this data exchange would eliminate manual processes and

[29] 74 FR 3320 (January 16, 2009).

[30] S. Gruttadauria. (March 26, 2018). ''NCPDP Telecommunications Standard vF2 Written Testimony.'' Available: *https://ncvhs.hhs.gov/wp-content/uploads/2018/05/Session-A-Gruttadauria-Written.pdf.*

interruptions, and would also enable additional required pharmacist interventions to be added contractually which could not occur previously. Thus, we conclude that the changes available through the Version F6 conversion would allow pharmacies to improve the accuracy and quality of services they provide but may not generate significant cost savings from a budgeting perspective.

(2) Health Plans and PBMs

The benefits that could accrue to health plans and PBMs mirror the improvements that could accrue to pharmacy efficiencies discussed previously. Better information flows and interoperability could enable more efficient benefit adjudication, enhanced communications with trading partners and patients, and better data. Better data could improve payment accuracy, regulatory compliance, and advanced analytics for forecasting, coordination of care, and patient safety. For instance, better information on adjudicated payer types could support more accurately identifying other payers involved in the transaction. Improved information on other payers could result in cost avoidance by avoiding duplication of payment and/or by preventing Medicare from paying primary when it is the secondary payer. However, improved patient and alternative payer identification could also increase the transparency of the identification of payers secondary to Medicare and increase costs from other payers' subrogation in some circumstances. The ability to automate the processing of very expensive drug claims would avoid more cumbersome processes, but the absolute volume of such claims may not be enough to generate significant savings. We are not aware of any studies or estimates of cost savings for health plans or PBMs attributable to the Version F6 conversion, nor are we aware of public comments describing any such cost savings. Furthermore, in testimony to the NCVHS, the NCPDP noted the importance of Version F6 for achieving broader (but difficult-to-quantify) healthcare transformation goals: it improves the structure to support the clinical evaluation of prescription products and planned benefit transparency, which are key components for achieving expected healthcare outcomes related to value-based care, digital therapeutics, social determinants of health, and other areas of health innovation.[31] Thus, we conclude that while the benefits of adopting Version F6 are necessary for meeting current and future business needs and policy goals, we are unable to monetize these benefits in the form of cost savings. We solicit comments on whether there are significant quantifiable benefits or cost savings that should be included in our analysis.

2. Adoption of Version 10

a. Introduction

Subrogation occurs when one payer has paid a claim that is subsequently determined to be the responsibility of another payer, and the first payer seeks to recover the overpayment directly from the proper payer. Such erroneous payments may occur as the result of retroactive changes in patient coverage or because of the lack of information on other payers or correct payer order at the point of sale. Subrogation avoids putting the pharmacy in the middle of the corrective action by avoiding the alternative burdensome process of the first payer recovering the overpayment from the pharmacy and, thus, forcing the pharmacy to attempt reversing the claim and rebilling the proper payer.

The current HIPAA subrogation transaction standard addresses federal and state requirements for state Medicaid agencies to recover reimbursement from responsible health plans but does not address similar requirements for other payers, such as Medicare Part D, State Pharmaceutical Assistance Programs (SPAPs), state AIDS Drug Assistance Programs (ADAPs), or other private insurers. Replacing this standard with initial adoption of Version 10 would extend the standard to all third-party payers. Insurers, employers, and managed care entities are generally referred to as health and/or drug plan sponsors, or, more generally, as third-party payers. Their health plans generally provide some coverage for outpatient prescription drugs, but do not generally directly manage coordination of pharmacy benefits and subrogation (also known as third-party liability services). Instead, health plans and other third-party payers generally contract with PBMs or with specialized payment integrity/financial recovery vendors for these services. The subrogation technical standard is based on the batch telecommunications standard and may utilize any field in an approved standard.

b. Affected Entities

Medicare Part D requires real-time coordination of benefits, and we understand that these processes, as well as responsibility for managing subrogation (primarily for Medicaid retroactivity), are generally contracted through PBMs. Other payers, such as state Medicaid agencies and commercial insurers, are more likely to contract with payment integrity/financial recovery vendors. As of March 2018, there was evidence that some states managed this activity directly,[32] but we are not aware of publicly available information on whether this is, or would still be, the case for the Version 10 implementation timeframe. Likewise, we understand the VA PBM does not coordinate benefits in real time but contracts with a payment integrity/financial recovery firm for retrospective subrogation in some circumstances. We believe there are four firms in the specialized pharmacy benefit payment integrity/financial recovery industry, with the majority of business volume concentrated in one firm.

Based on a CAMH environmental scan conducted with industry representatives, we understand that the demand for subrogation today differs by third-party line of business. Third-party payers for governmental programs (Medicaid, Medicare Part D, and SPAPs/ADAPs) drive most of the subrogation demand. This is in large part due to their retroactive eligibility rules and potential overlaps in enrollment. Third-party commercial payer contracts are less likely to have a comparable retroactivity-of-coverage issue and, due to the rising cost of health insurance, are increasingly less likely to have enrollees covered under more than one insurance program or policy. For these reasons, we understand that third-party commercial payers are more likely to subrogate with workers' compensation, auto insurance, or other non-healthcare insurance-related parties, rather than with other healthcare payers.

While pharmacies are not users of the subrogation standard, they are potentially affected by any further expansion of the standard from Medicaid to all third-party payers. This is because one alternative to subrogation involves the payer that paid in error recouping funds from pharmacies and transferring the effort and risk of rebilling the appropriate payer to the pharmacy.

[31] National Committee on Vital and Health Statistics Transcript March 24, 2020, 10:00 a.m.—5:30 p.m. ET. *https://ncvhs.hhs.gov/wp-content/uploads/2020/05/Transcript-Full-Committee-Meeting-March-24-2020.pdf.*

[32] NCVHS Hearing on NCPDP Standards and Updates—March 26, 2018 Virtual Meeting. *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-march-26-2018-hearing-on-ncpdp-standards-and-updates/.*

c. Costs

(1) Third-Party Payers (Includes Plan Sponsors and PBMs)

The bulk of the work to implement Version 10 for many third-party payers has been previously addressed in costs associated with implementing Version F6, specifically its equivalent batch standard. Based on conversations with industry representatives familiar with the subrogation standards, we understand that the changes in Version 10 have been undertaken to preserve the integrity of the standard for Medicaid purposes while allowing for the collection of a limited number of new data elements to assist with other payer subrogation, particularly for Part D payers. We understand that the changes between Version 3.0 and Version 10 are not extensive, so we believe this change would not have significant effects on state Medicaid agencies or their vendors. However, we are not aware of data or public comments to help us confirm this assumption.

We also assume that payers that desire to pursue prescription drug claim subrogation have already contracted with PBMs or other contractors that have implemented the Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, or some variation on this standard, on a voluntary basis. However, testimony provided in the March 2018 NCVHS hearing indicated that some payers had not yet implemented the batch processing software, and would have additional IT system, administrative, and training costs to convert to Version 10. We are not aware of the specific payers to which this remark referred, and, thus, several years later, we have no basis on which to estimate the number of additional payers or state Medicaid agencies that could potentially adopt the standard for the first time with Version 10. Nor do we know if any such payers might instead contract with a vendor to manage this function on their behalf during the course of the Version 10 implementation. As with PBM and vendor contractual arrangements discussed previously, we assume that HIPAA standard conversions have been priced into ongoing contractual payment arrangements and would not increase costs to third-party payers as the result of converting to Version 10. We solicit comments to help us understand the impacts of converting to Version 10 on any payers or state Medicaid agencies that have not previously implemented NCPDP batch standards and/or Subrogation Version 3.0. We also solicit comments on our assumptions on the impacts on state Medicaid agency vendors in general, as well as data with which to quantify any additional impacts beyond the Version F6 conversion estimates provided previously.

Based on conversations with industry representatives, we further understand that payers already engaged in subrogation, particularly Part D PBMs, have already, albeit inconsistently, implemented Version 3.0 for other payers. Version 10 provides more requirements for use of the standard and how to populate the fields to increase standardization. Thus, we assume that the incremental effort required to transition to Version 10 largely consists of a mapping exercise from current PBM or vendor operating systems, rather than an initial build and migration from manual to automated processes. We are not aware of any studies or public comments to help us quantify these incremental costs.

(2) Vendors

As noted previously, state Medicaid agencies, commercial third-party payers, and the VA generally contract with four payment integrity/financial recovery firms for subrogation. We believe, based on conversations with industry representatives, that these firms generally utilize Subrogation Version 3.0 today, and would have to invest in Version F6 batch standard upgrades to implement Version 10 and prepare to potentially accept subrogation from other third-party payers. These firms were not included in the previous vendor estimates. We are not aware of studies or public comments that describe costs related to their activities and requirements. We assume these vendors would incur a minority of the costs associated with the Version F6 conversion and some internal data remapping expense. Therefore, as summarized in Table 7, we estimate that that over the 2-year implementation period:

Four payment integrity/financial recovery vendors would incur Version F6, equivalent Batch Standard, Version 15 and other Version 10 conversion costs of $500,000 each.

TABLE 7. OTHER VENDOR COSTS OF CONVERSION TO VERSION 10

Conversion Cost Category	Conversion Cost Per Entity ($ millions)	Number of Affected Entities	Total F6 Conversion Costs ($ millions)
Payment Integrity/Financial Recovery Vendors	0.5	4	2.0

d. Benefits

(1) Third-Party Payers

The primary benefits for third-party payers are the opportunity to reduce claims costs when another party is also responsible for the claims and the avoidance of cumbersome manual processes. However, we are not aware of studies or public comments that help us estimate the frequency and size of this benefit. Prescription drug claims tend, on average, to be for much smaller amounts than medical claims, such as those for hospital admissions, and we believe many payers may pursue subrogation only on the more expensive claims. Discussion at the March 2018 NCVHS hearing indicated that about 5 percent of patients had multiple insurances. It is estimated that national drug expenditures, the volume of claim reconciliation, and that the savings opportunity could easily exceed a billion dollars (as the subrogation transaction standard proposal was not revised in 2020, we do not have more recent testimony updating this estimate). However, additional testimony at that same hearing [33] suggested there is not a huge cost savings opportunity left for commercial subrogation, but, instead, an occasional need that would be facilitated by a standardized approach. It seems that we do not have enough information to quantify the incremental benefits of extending Version 10 to non-Medicaid

[33] Transcript-Standards Subcommittee Hearing—NCPDP Standards Updates—March 26, 2018. Accessed 05/14/2021 at: *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-march-26-2018-hearing-on-ncpdp-standards-and-updates/*.

third-party payers. We seek comment on our assumptions.

(2) Pharmacies

As noted previously, while pharmacies are not users of the subrogation transactions standard, they could potentially benefit from further expansion of the standard from state Medicaid agencies to all third-party payers if additional payers that are currently recouping overpayments from pharmacies instead were to transition to a subrogation approach. However, we are not aware of any studies or public comments that would help us estimate the likelihood or size of a potential change of this nature. We solicit comments to help us understand the extent to which the adoption of Version 10 may have an effect on pharmacies.

E. Alternatives Considered

We considered a number of alternatives to adopting Version F6 and Version 10, but chose to proceed with the proposals in this in this rule after identifying significant shortcomings with each of the alternatives.

One alternative we considered was to not propose to adopt Version F6 and continue to require the use of Version D.0. We also considered waiting to adopt Version F6 at a later date since we recently published a final rule in 2020 modifying the requirements for the use of Version D.0 by requiring covered entities to use the 460–ET field for retail pharmacy transactions denoting partial fill of Schedule II drugs. We did not proceed with either alternative because we believe that, were we to do so, the industry would continue to use a number of work arounds that increase burden and are contrary to standardization. We also believe that the number of these work arounds, as well as use of the work arounds, would continue to increase if we were not to propose adoption of Version F6 at this time. For example, NCPDP has advised that several new drugs priced at, or in excess of, $1 million are already on the market, and researchers and analysts anticipate that over the next several years, dozens of new drugs and therapies priced similarly or higher may enter the market. As the number of drugs and therapies in the market priced at, or in excess of, $1 million increases, the total burden associated with manual work arounds would also increase.

We invite public comments on these assumptions and request any additional data that would help us to more accurately quantify the time and resource burdens associated with the existing, and, potentially, future work arounds should Version F6 not be adopted. We also chose not to proceed with these alternatives because, as discussed in section III.A. of this proposed rule, we believe adoption of Version F6 would support interoperability and improve patient outcomes.

We considered proposing a compliance date longer than 24 months for covered entities to comply with Version F6. However, as discussed in section III.C. of this proposed rule, we chose to propose a 24-month compliance date because we believe the benefits to be derived from implementing Version F6 as soon as possible are significant. We also considered proposing staggered implementation dates for Version F6, whereby covered entities using the retail pharmacy transactions would have different compliance dates. We believe this alternative would not support standardization since pharmacies, PBMs, and health plans all rely on the information transmitted in the retail pharmacy transactions, and if any one of these three entities would not be using the same standard version at the same time, the information needed to process claims and check eligibility would be deficient. Pharmacies need the most current eligibility data from the plans to determine correct coverage and payment information, and health plans and PBMs need the most current information to be reflected in the claims data to maintain the beneficiaries' most current benefits.

Concerning the proposed adoption of Version 10, we considered not adopting that updated version and continuing to require the use of Version 3.0. Such alternative would continue to permit non-Medicaid health plans that engage in pharmacy subrogation transactions to continue using the proprietary electronic and paper formats currently in use. We chose not to proceed with this alternative because we believe it is important to adopt standards that move the industry toward uniformity among all payers.

F. Regulatory Review Cost Estimate

One of the costs of compliance with a final rule is the necessity for affected entities to review the rule in order to understand what it requires and what changes the entity will have to make to come into compliance. We assume that 104 affected entities will incur these costs, as they are the entities that will have to implement the proposed changes, that is, those entities that are pharmacy organizations that manage their own systems (27), pharmacy management system vendors (30), PBMs (40), telecommunication switch vendors (3), and payment integrity/financial recovery vendors (4). The particular staff involved in such a review will vary from entity to entity, but will generally consist of lawyers responsible for compliance activities and individuals familiar with the NCPDP standards at the level of a computer and information systems manager. Using the Occupational Employment and Wages for May 2020 from the BLS for lawyers (Code 23–1011) and computer and information system managers (Code 11–3021),[34] we estimate that the national average labor costs of reviewing this rule are $95.56 and $113.12 per hour, respectively, including other indirect costs and fringe benefits. We estimate that it will take approximately 4 hours for each staff person involved to review this final rule and its relevant sections and that on average two lawyers and two computer and information manager-level staff persons will engage in this review. For each entity that reviews the rule, the estimated costs are therefore $1,669.44 (4 hours each × 2 staff × $95.56 plus 4 hours × 2 staff × $113.12). Therefore, we estimate that the total cost of reviewing this rule is $171,953 ($1,669.44 × 103 affected entities).

G. Accounting Statement and Tables

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table 8 we present an accounting statement showing the classification of the annualized costs associated with the provisions of this final rule. Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized benefits and non-budgetary costs are presented as discounted flows using 3 percent and 7 percent factors.

[34] Bureau of Labor Statistics. May 2020 National Occupational Employment and Wage Estimates United States. Mean hourly rates for Computer Network Architects, Software Developers and Software Quality Assurance Analysts and Testers, and Computer Support Specialists. Accessed 5/14/2021 at: *https://www.bls.gov/oes/current/oes113021.htm#top.*

TABLE 8. ACCOUNTING STATEMENT

(Accounting Statement: Classification of Estimate Costs and Benefits from FY 2023 to FY 2032 ($ in millions)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source
Benefits				
Annualized monetized benefits:				
7% Discount	n/a			
3% Discount	n/a	n/a	n/a	RIA
		n/a	n/a	RIA
Qualitative (un-quantified benefits	Wider adoption of standards; increased productivity due to decrease in manual processing; reduced delays in patient care.			
Benefits will entail enhanced abilities for health plans, other third-party payers, and pharmacies to achieve regulatory compliance and other business needs, such as greater potential for operational efficiencies through transmission of codified data, improved access to information that may improve patient care, more detailed information for coordination of benefits, and other non-quantified benefits that exceed the costs.				
Costs				
Annualized monetized costs:				
7% Discount	60			
3% Discount	50	40	70	RIA
		30	60	RIA
Qualitative (un-quantified costs	None			
Opportunity costs will be borne by the entities that will have to implement the proposed changes, that is, those entities that are pharmacy organizations that manage their own systems, pharmacy management system vendors, PBMs, telecommunication switch vendors, and payment integrity/financial recovery vendors. Some marginal user training costs will be borne by other pharmacies.				
Transfers				
Annualized monetized transfers: "on budget".	None	None	None	
Annualized monetized transfers: "off budget".	None	None	None	

H. Regulatory Flexibility Analysis (RFA)

The RFA requires agencies to prepare an initial regulatory flexibility analysis that describes the impact of a proposed change on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a small entity as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of a small entity. For the purpose of the proposed rule, we estimate that a change in revenues of more than 3 to 5 percent would constitute the measure of significant economic impact on a substantial number of small entities.

SBA size standards have been established for types of economic activity or industry, generally under the North American Industry Classification System (NAICS). Using the 2019 SBA small business size regulations and Small Business Size Standards by NAICS Industry tables at 13 CFR 121.201, we have determined that the covered entities and their vendors affected by this proposed rule fall primarily in the following industry standards:

TABLE 9. SBA SIZE STANDARDS FOR APPLICABLE NAICS INDUSTRY CODES

NAICS Code	NAICS U.S. Industry Title	SBA Size Standard ($ mil)
446110	Pharmacies and Drug Stores	30.0
524114	Direct Health and Medical Insurance Carriers (Health Plans)	41.5
621491	HMO Medical Centers (Health Plans)	35.0
524292	Third Party Administration of Insurance and Pension Funds (PBMs)	35.0
541512	Computer Systems Design Services (Pharmacy Management System Vendors)	30.0
518210	Data Processing, Hosting, and Related Services (Telecommunication Switches)	35.0
524298	All Other Insurance Related Activities (Payment Integrity/Financial Recovery)	16.5

This change in retail pharmacy transaction standards would apply to many small covered entities in the Pharmacy and Drug Store segment (NAICS code 446110). However, based on information obtained by CAMH during its conversations with industry experts, we understand that small pharmacies generally rely on ongoing arrangements with certain specialized computer system design services vendors (a subset of NAICS code 541512) to integrate the standards into their pharmacy management software and systems as a routine cost of doing business. Therefore, these covered entities may not bear the bulk of the costs attributable to the proposed changes. Instead, as detailed later in this RIA, generally, the costs applicable to small pharmacies are expected to be a portion of the costs for user training for some firms. The pharmacy management system vendors are not covered entities, and we are not aware of publicly available data to comprehensively identify these entities and, where applicable, parent firm size. Other types of covered entities providing pharmacy services, such as the subset of grocery stores with pharmacies, cannot be clearly identified within NAICS data, as such data are not collected in this detail, but are included in our estimates for larger entities. Conversely, institutions with outpatient pharmacies (for example, hospitals) also cannot be clearly identified by NAICS data but are not included in our analysis, since we believe such institutions are generally part of larger organizations that do not meet the SBA definition. One exception to this assumption are the IHS urban and tribal facilities with pharmacies that bill prescription drug plans, which we address later in this analysis.

For purposes of this RIA, the definition of an entity most closely resembles the federal statistical agencies' concept of a firm.[35] A firm consists of one or more establishments under common ownership. An establishment consists of a single physical location or permanent structure.[36] Thus, a chain drug store or chain grocery store constitutes a single firm operating multiple establishments. Using the 2017 Census Bureau Annual Business Survey estimates of firms, sales, and receipts by NAICS sector (available at *https://www.census.gov/programs-surveys/abs.html,* and hereafter referred to as Census business data), we have attempted to estimate the number of small pharmacy entity firms and provide a general discussion of the effects of the proposed regulation. We solicit industry comment on these assumptions.

1. Initial Regulatory Flexibility Analysis (IRFA)

a. Number of Small Entities

Based on Census business data records indicating that in 2017 there were a total of 19,234 total pharmacy firms, we estimate that just over 19,000 pharmacy firms qualify as small entities, though communications with industry representatives suggest that figure may overestimate the current industry small entity landscape. Available data does not permit us to clearly distinguish small pharmacy firms from firms that are part of larger parent organizations, but we use employee size as a proxy for the firm size subject to the SBA size standard. For purposes of this analysis, we assume the firms with more than 500 employees (190) represent chain pharmacies and those with fewer than 500 (19,044) employees represent independently owned open- or closed-door pharmacies. The 19,044 firms with fewer than 500 employees represented 20,901 establishments and accounted for total annual receipts of $70.9 billion and average annual receipts of $3.7 million—well below the SBA standard of $30 million. By contrast, the 190 firms with 500 or more employees represented 27,123 establishments and accounted for over $211 billion in annual receipts, and thus, average annual receipts of $1.1 billion. Therefore, we assume 19,044 pharmacy firms qualify as small entities for this analysis.

For 2017, the Census Bureau counts 745 entities designated as Direct Health and Medical Insurance Carriers and 27 as Health Maintenance Organization (HMO) Medical Centers. We assume that these 772 firms represent health plans that sponsor prescription drug benefits. Of the 745 Carriers, those with fewer than 500 employees (564) accounted for $35 billion in total and over $62 million in average annual receipts, exceeding the SBA size standard of $41.5 million. Comparable data on the eight smaller HMO Medical Centers is not available due to small cell size suppression. Although health plan firms may not qualify as small entities under the SBA receipts size standard, they may under non-profit status. However, we are not aware of data that would help us understand the relationship between health plan firm and ownership tax status to quantify the number of such firms. In any case, as explained in more detail later in this RIA, we do not estimate that health plans would generally bear costs associated with the changes in this proposed rule, as their contracted transaction processing vendors (generally PBMs) would be responsible for implementing the changes, and, generally, based on conversations with the industry we do not believe their contractual terms would change as the result. Therefore, although we cannot estimate the number of health plan firms that may meet the small entity definition using non-profit status, generally we do not believe such entities would bear costs attributable to the proposed changes.

In addition to the covered entities, we estimate 30 pharmacy management system vendors, 40 PBM vendors, three telecommunications switching vendors, and four payment integrity/financial recovery firms would be affected by the proposed changes to their clients. We

[35] *www.bls.gov/opub/mlr/2016/article/establishment-firm-or-enterprise.htm.*

[36] *www.census.gov/programs-surveys/susb/technical-documentation/methodology.html.*

are not aware of comprehensive publicly available data detailed enough to quantify the size of these remaining entities, but we believe that the affected firms are, generally, part of larger organizations. We solicit comments with respect to our assumptions.

b. Cost to Small Entities

To determine the impact on small pharmacies, we used Census business data on the number of firms with fewer than 500 employees and user training cost estimates developed using public comments on prior rulemaking and updated for inflation. As discussed earlier in this RIA, we assume that the clear majority of pharmacy firms are small entities that rely on their contracted pharmacy management system vendors to absorb HIPAA standard version conversion costs in return for ongoing maintenance and transaction fees. We assume that pharmacy firms would have direct costs related to Version F6 user training that would vary in relation to employee size; that the vast majority (90 percent) of small pharmacy firms with fewer than 20 employees would receive all necessary user training from vendors; and that the remaining 10 percent of small pharmacy firms (2,028) with 20 or more employees would have additional staff user training expense totaling $30,000 on average in the second year of the implementation period. As displayed in Table 10, the resulting total impact of approximately $61 million represents approximately 0.1 percent of small pharmacy annual revenues. Therefore, we conclude that the financial burden would be less than the 3 percent to 5 percent of revenue threshold for significant economic impact on small entities.

TABLE 10. ANALYSIS OF IMPLEMENTATION BURDEN ON SMALL COVERED ENTITIES

NAICS	Entity Type	Number of Small Entities	Revenue ($ in billions)	Implementation Costs ($ in millions)	Cost percentage of revenues
446110	Pharmacies and Drug Stores	19,044	71	61	0.1%

Source for number and revenue: Census Bureau. 2017 Economic Census.

As stated in section V.F. of this proposed rule, we considered various policy alternatives to adopting Version F6. Specific to reducing costs to small entities, we considered staggering the implementation dates for Version F6 among the affected entities that utilize the NCPDP transaction standard. But we chose not to propose this alternative because pharmacies, PBMs, and health plans all rely on the information transmitted though the retail pharmacy transactions, and if any one of these three entities would not be using the same standard version at the same time, the information needed to process claims and check eligibility would be deficient. Pharmacies need the most current eligibility data from the plans to determine correct coverage and payment information. Plans and PBMs would suffer because they would not have the most current information reflected though the claims data to maintain the beneficiaries' most current benefits.

2. Conclusion

As referenced earlier in this section, we use a baseline threshold of 3 percent to 5 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. The small pharmacy entities do not come close to this threshold. Therefore, the Secretary has certified that this proposed will not have a significant economic impact on a substantial number of small entities. Based on the foregoing analysis, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would not affect the operations of a substantial number of small rural hospitals because these entities are not involved in the exchange of retail pharmacy transactions. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

I. Unfunded Mandates Reform Act of 1995 (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending more in any 1 year than threshold amounts in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule does not contain mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, in excess of more than $165 million in any 1 year. In general, each state Medicaid agency and other government entity that is considered a covered entity would be required to ensure that its contracted claim processors and payment integrity/financial recovery contractors update software and conduct testing and training to implement the adoption of the modified versions of the previously adopted standards. However, information obtained by CAMH during its conversations with industry experts supports that the costs for these services would not increase as a result of the proposed changes. Our understanding is that HIPAA standard conversion costs are already priced into ongoing contractual payment arrangements between health plans, contracted claim processors, and payment integrity/financial recovery contractors.

J. Federalism

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. This proposed rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication because, even though state Medicaid agency contractors would be converting to a modified version of an existing standard with which they are already familiar, we believe that any conversion costs, would, generally, be priced into the current level of ongoing contractual payments. State Medicaid agencies, in accordance with this proposed rule, would have to ensure that their contracted claim processors or PBMs successfully convert to Version F6 and that their payment integrity/financial recovery contractors make relatively minor updates to subrogation systems to collect and convey some new fields to conduct subrogation initiated by other payers using Version 10. With respect to subrogation for pharmacy claims, this proposed rule would not add a new business requirement for states, but rather would replace a standard to use for this purpose that would be used consistently by all health plans.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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 proposes to amend 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 Public Law 111–148, 124 Stat. 146–154 and 915–917.

■ 2. Section 162.920 is amended by—

■ a. Revising the introductory text of the section and the introductory text of paragraph (b).

■ b. Adding paragraphs (b)(7) through (9).

The revisions and additions read as follows:

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under *5 U.S.C. 552(a)* and *1 CFR part 51.* To enforce any edition other than that specified in this section, the Centers for Medicare & Medicaid Services (CMS) must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at CMS and the National Archives and Records Administration (NARA). Contact CMS at: Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244; email: *AdministrativeSimplification@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(b) National Council for Prescription Drug Programs (NCPDP), 9240 East Raintree Drive, Scottsdale, AZ 85260; phone: (480) 477–1000; fax: (480) 767–1042; website: *www.ncpdp.org.*

* * * * *

(7) The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020; as referenced in § 162.1102; § 162.1202; § 162.1302; § 162.1802.

(8) The Batch Standard Implementation Guide, Version 15 (Version 15), October 2017; as referenced in § 162.1102; § 162.1202; § 162.1302; § 162.1802.

(9) The Batch Standard Subrogation Implementation Guide, Version 10 (Version 10), September 2019, as referenced in § 162.1902.

* * * * *

■ 3. Section 162.1102 is amended by—

■ a. In paragraph (c), removing the phrase ''For the period on and after the January 1, 2012,'' and adding in its place the phrase ''For the period from January 1, 2012, through [date TBD],''.

■ b. In paragraph (d) introductory text, removing the phrase ''For the period on and after September 21, 2020,'' and adding in its place the phrase ''For the period on and after September 21, 2020, through [date TBD],''.

■ c. Adding paragraph (e).

The addition reads as follows:

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

* * * * *

(e) For the period on and after [date TBD], the following standards:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020 and equivalent Batch Standard Implementation Guide, Version 15 (Version 15) October 2017 (incorporated by reference, see § 162.920).

(2) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1 (incorporated by reference, see § 162.920).

(3) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222 (incorporated by reference, see § 162.920).

(4) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1 (incorporated by reference, see § 162.920).

(5) *Retail pharmacy supplies and professional services claims.* (i) The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020 and equivalent Batch Standard Implementation Guide, Version 15 (Version 15) October 2017 (incorporated by reference, see § 162.920).

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3-Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222 (incorporated by reference, see § 162.920).

■ 4. Section 162.1202 is amended by—

■ a. In paragraph (c), removing the phrase ''For the period on and after January 1, 2012,'' and adding in its place the phrase ''For the period from January 1, 2012, through [date TBD],''.

■ b. Adding paragraph (d).
The addition reads as follows:

§ 162.1202 Standards for eligibility for a health plan transaction.

* * * * *

(d) For the period on and after [date TBD], the following standards:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020, and equivalent Batch Standard Implementation Guide, Version 15 (Version 15), October 2017 (incorporated by reference, see § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279 (incorporated by reference, see § 162.920).

■ 5. Section 162.1302 is amended by—

■ a. In paragraph (c), removing the phrase ''For the period on and after January 1, 2012,'' and adding in its place the phrase ''For the period from January 1, 2012, through [date TBD],''.

■ b. In paragraph (d) introductory text, removing the phrase ''For the period on and after September 21, 2020,'' and adding in its place the phrase, ''For the period on and after September 21, 2020, through [date TBD],''.

■ c. Adding paragraph (e).
The addition reads as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(e) For the period on and after [date TBD], the following standards:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020, and equivalent Batch Standard Implementation Guide, Version 15 (Version 15), October 2017 (incorporated by reference, see § 162.920).

(2) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1 (incorporated by reference, see § 162.920).

■ 6. Section 162.1802 is amended by—

■ a. In paragraph (c), removing the phrase ''For the period on and after January 1, 2012,'' and adding in its place the phrase ''For the period from January 1, 2012, through [date TBD],''.

■ b. In paragraph (d) introductory text, removing the phrase ''For the period on and after September 21, 2020,'' and adding in its place the phrase ''For the period on and after September 21, 2020, through [date TBD],''.

■ c. Adding paragraph (e).
The addition reads as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(e) For the period on and after [date TBD], the following standards:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020 and equivalent Batch Standard Implementation Guide, Version 15 (Version 15) October 2017 (incorporated by reference, see § 162.920).

(2) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1 (incorporated by reference, see § 162.920).

(3) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222 (incorporated by reference, see § 162.920).

(4) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1 (incorporated by reference, see § 162.920).

■ 7. Revise the heading of subpart S to read as follows:

Subpart S—Pharmacy Subrogation

■ 8. Section 162.1901 is amended by—

■ a. Revising the section heading.

■ b. Designating the text of the section as paragraph (a) and adding paragraph (b).

The revision and addition read as follows:

§ 162.1901 Pharmacy subrogation transaction.

* * * * *

(b) The pharmacy subrogation transaction is the transmission of a request for reimbursement of a pharmacy claim from a health plan that paid the claim, for which it did not have payment responsibility, to the health plan responsible for the claim.

■ 9. Section 162.1902 is revised to read as follows:

§ 162.1902 Standards for pharmacy subrogation transaction.

(a) The Secretary adopts the following standards for the Medicaid pharmacy subrogation transaction, described in § 162.1901(a), for the period from January 1, 2012, through [date TBD], The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, as referenced in § 162.1902 (incorporated by reference, see § 162.920).

(b) The Secretary adopts the following standard for the pharmacy subrogation transaction, described in § 162.1901(b), The Batch Standard Subrogation Implementation Guide, Version 10 (Version 10), September 2019, as referenced in § 162.1902 (incorporated by reference, see § 162.920).

(1) For the period on and after [date TBD], for covered entities that are not small health plans.

(2) For the period on and after [date TBD], for small health plans.

Dated: November 1, 2022.

Xavier Becerra

Secretary, Department of Health and Human Services.

[FR Doc. 2022–24114 Filed 11–7–22; 4:15 pm]

BILLING CODE 4150–28–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 18–143, 10–90; FCC 22–79; FR ID 112958]

The Uniendo a Puerto Rico Fund and the Connect USVI Fund, Connect America Fund

AGENCY: Federal Communications Commission

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) seeks comment on proposals to ensure that mobile carriers continue to implement advanced telecommunications services and that fixed providers have sufficient