TABLE 3 TO PARAGRAPH (d)—Continued

Category	CAS No.	Special exemptions	Effective date	Sunset date
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 162

[CMS–0056–F]

RIN 0938–AU19

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

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

ACTION: Final rule.

SUMMARY: This final rule adopts 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 are 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. This final rule also adopts a modification to the standard for the Medicaid pharmacy subrogation transaction.

DATES:

Effective Date: This final rule is effective on February 11, 2025. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register beginning February 11, 2025. The incorporation by reference of certain other publications listed in the rule was approved by the Director as of March 17, 2009.

Compliance Date: Compliance with this final rule is required beginning February 11, 2028.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Severability

A. Purpose

We published a proposed rule titled ''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'' (hereafter referred to as the November 2022 proposed rule) that appeared in the November 9, 2022, **Federal Register** (87 FR 67634). In that rule, we proposed to adopt modifications to the retail pharmacy and Medicaid subrogation standards. This final rule adopts modifications to standards for electronic retail pharmacy transactions and the Medicaid pharmacy subrogation transaction adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

1. Need for the Regulatory Action

The modified standards adopted in this rule will benefit the health care industry by offering more robust data exchange and workflow automation, enhanced patient safety, improved coordination of benefits, and expanded financial fields, so that entities may not have to manually enter free text, split claims, or prepare and submit a paper Universal Claim Form. The current retail pharmacy standards adopted in 2009 remain unchanged. In 2018, the National Committee on Vital and Health Statistics (NCVHS) recommended that HHS adopt more recent standards to address evolving industry business needs. Consistent with the NCVHS recommendations and collaborative industry and stakeholder input, we believe the updated retail pharmacy standards we are adopting are sufficiently mature for adoption and that covered entities are ready to implement them.

2. Legal Authority for the Regulatory Action

Through subtitle F of title II of HIPAA, Congress added to title XI of the Social Security Act (the Act) a new Part C, titled ''Administrative Simplification,'' which requires 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. More specifically, 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, thus providing the legal authority for this regulatory action.

B. Summary of the Major Provisions

The provisions in this final rule adopt the following modifications: 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 Subrogation Implementation Guide, Version 10 (Version 10). These updated standards will 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, Release 0 (Version 3.0).

Version 3.0 was adopted to support Federal and State requirements for State Medicaid agencies to seek reimbursement from the health plan responsible for paying the pharmacy claim after the State Medicaid agency has paid the claim on behalf of the Medicaid recipient.

In the November 2022 proposed rule, we proposed to broaden the scope of the subrogation transaction to apply not only to State Medicaid agencies but to

all health plans, such as Medicare Part D, State assistance programs, and commercial health plans, attempting to recover reimbursement from the responsible payer, and to rename the transaction the Pharmacy subrogation transaction. At § 162.1902(b), we proposed to adopt Version 10 to replace Version 3.0 as the standard for the subrogation transaction. This would have been a modification for State Medicaid agencies, and for non-Medicaid health plans this would have been the adoption of an initial standard.

However, compelling comments to the November 2022 proposed rule persuaded us to adopt Version 10 solely for State Medicaid agencies. While we are not adopting Version 10 for non-Medicaid health plans in this final rule, they are permitted to use the standard

C. Summary of Effective and Compliance Dates

The policies adopted in this final rule are effective 60 days after publication of the final rule in the **Federal Register**.

In the November 2022, proposed rule, we proposed that all covered entities would need to comply with Version F6, Version 15, and Version 10 beginning 24 months after the effective date of the final rule. For Version F6 and Version 15, we are adopting a later compliance date than we had proposed, and are including an 8-month transition period:

- Starting August 11, 2027, all covered entities, as agreed to by trading partners, may use either Version D.0 and Version 1.2 or Version F6 and Version 15 for 8 months as a transition period prior to full compliance, which begins 36 months after the effective date of the final rule.
- All covered entities must be in compliance with Version F6 and Version 15 beginning February 11, 2028.

As noted previously and discussed in section III. of this final rule, we are adopting Version 10 to apply solely to State Medicaid agencies. This final rule adopts a compliance date for State Medicaid agencies to comply with Version 10 that aligns with the compliance date for Version F6 and Version 15:

- Starting August 11, 2027, State Medicaid agencies, as agreed to by trading partners, may use Version 3.0 or Version 10 for 8 months as a transition period prior to full compliance, which begins 36 months after the effective date of the final rule.
- State Medicaid agencies must be in compliance with Version 10 beginning February 11, 2028.

D. Summary of Costs and Benefits

The overall cost for affected HIPAA covered entities—independent and non-independent pharmacies, pharmacy benefit plans, and State Medicaid agencies—to move to the updated versions of the retail pharmacy transaction standards and the Medicaid pharmacy subrogation transaction standard will be approximately $386.3 million. The cost is based on the need for such entities to engage in technical development, implementation, testing, and initial training to be prepared to meet a compliance date beginning February 11, 2028. As discussed in the November 2022, proposed rule, 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 retail pharmacy standards and the Medicaid pharmacy subrogation standard.

E. Severability

This final rule adopts updated versions of currently adopted standards for numerous provisions under aspects of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Subtitle F of Title II of HIPAA added a new Part C to Title XI of the Social Security Act (sections 1171 through 1179 of the Act, 42 U.S.C. 1320d through 1320d–8). These updated versions are 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. This final rule also adopts a modification to the standard for the Medicaid pharmacy subrogation transaction. The provisions adopted would be distinct provisions. We believe these distinct processes may function independently of each other. To the extent a court may enjoin any part of a final rule, the Department of Health and Human Services (HHS) intends that other provisions or parts of provisions should remain in effect, ensuring the continuity of the regulations. We intend that any provision of the requirements described in this section or in another section held to be invalid or unenforceable by its terms or as applied to any person or circumstance would be construed so as to continue to give maximum effect to the provision permitted by law unless such holding is one of utter invalidity or unenforceability, in which event we intend that the provision would be severable from the other finalized provisions described in this section and in other sections and would not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

II. Background

A. Legislative Authority for Administrative Simplification

This background discussion presents a history of statutory and regulatory provisions that are relevant for the purposes of this final 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 final 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 (Affordable Care Act), Pub. L. 111–148), further addresses the goal of uniformity by requiring the Secretary to adopt a single set of operating rules for each HIPAA transaction. Section 1171(9) of the Act defines operating rules as ''the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications.'' Section 1173(g)(1) of the Act requires operating rules 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 in accordance with 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 Affordable Care Act additionally required the Secretary to adopt 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)(1)(A) of the Act prohibits health plans from refusing to conduct a transaction as a standard transaction. Section 1175(a)(1)(B) 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 provisions. 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) of the Act 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 of the Act 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

We published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' that appeared in the August 17, 2000, **Federal Register** (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 Standard Version 5.1 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'' that appeared 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 Telecommunication Standard Version 5.1 and equivalent Batch Standard Implementation Guide Version 1, Release 1, to Telecommunication Standard Version D.0 and Version 1.2. In that rule, we also adopted Version 3.0 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 (65 FR 50322). Maintenance changes are typically corrections that are obvious to readers of the implementation guides, not controversial, and essential to implementation as such, in the February 20, 2003 final rule (68 FR 8334) titled, ''Health Insurance Reform: Security Standards''.

Maintenance changes to Telecommunication Standard Version

D.0 were identified by the industry, balloted and approved through the NCPDP, and are contained in a document titled ''Telecommunication Version D and Above Questions, Answers and Editorial Updates,'' that can be accessed free of charge from the NCPDP website's HIPAA Information Section, at *https://member.ncpdp.org/Member/media/pdf/VersionDQuestions.pdf.* In an October 13, 2010, **Federal Register** notice 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 Telecommunication Standard Version D.0 Editorial and how it then could be obtained. The document is a consolidated reference for questions that have been posed based on the review and implementation of 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,'' that appeared in the January 24, 2020 **Federal Register** (85 FR 4236) (hereafter referred to as the 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 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 for a Schedule II drug for the following 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 published an updated telecommunication standard implementation guide, the October 2017 Telecommunication Standard Implementation Guide, Version F2 (Version F2), that, among other changes, revised the situational use of a not used field to specify an even broader use of the Quantity Prescribed (460–ET) field. The change described the Quantity Prescribed (460–ET) 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 evaluate the impact of a new version on covered entities.

C. Standards Adoption and Modification

The law generally requires at section 1172(c) of the Act 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), and specifically mentions the NCPDP (the SSO associated with this final 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, *http://www.ncpdp.org.*

1. Designated Standards Maintenance Organizations (DSMOs)

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 a notice titled ''Health Insurance Reform: Announcement of Designated Standard Maintenance Organizations'' (65 FR 50373), which appeared in the August 17, 2000 **Federal Register** concurrently with the Transactions and Code sets final rule, 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.

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

As noted previously, 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 standards modifications finalized in this rule, which stemmed from the following change requests the NCPDP submitted to NCVHS: (1) DSMO request 1201 that requested replacing Version D.0 and Version 1.2 with the Version F2 and Version 15; (2) DSMO request 1202 that requested replacing Version 3.0 with Version 10 to be used by Medicaid plans only; and (3) DSMO request 1208 that updated DSMO request 1201, and requested adopting Version F6, instead of Version F2.

3. NCVHS Recommendations

The NCVHS, which was established by statute in 1949, 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 2 days of hearings seeking the input of health care providers, health plans, clearinghouses, vendors, and interested stakeholders regarding Version F2 as a potential replacement for Version D.0, and Version 15 as a potential replacement for Version 1.2. Testimony was also presented in support of replacing Version 3.0 with Version 10. In addition to the NCPDP, organizations submitting testimony included the Centers for Medicare & Medicaid Services on behalf of the 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 dated May 17, 2018, the NCVHS recommended that the Secretary adopt Version F2 to replace Version D.0, Version 15 to replace Version 1.2, and Version 10 to replace Version 3.0.[2] As discussed in section III.B. of this final rule, we did not propose to adopt Version F2 based on that NCVHS recommendation in our proposed rule titled ''Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard'' that appeared in the **Federal Register** on January 31, 2019 (84 FR 633) because we believed that proposing a modification to the retail pharmacy standards 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.

The NCVHS held a later hearing, on March 24, 2020, to discuss Change Request 1208 that recommended that Version F6 supplant Version F2, in regard to the NCVHS's prior recommendation that the Secretary adopt Version F2. During the hearing, the NCPDP noted that Version F6 had resolved several key limitations of Version F2. Significantly, with respect to the number of digits in the dollar field, Version F2 did not support dollar fields of $1 million or more. Since 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 of likely high-priced therapies, including 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 more than, $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 March 24, 2020, NCVHS meeting transcript and testimony 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, provide a 3-year pre-implementation window allowing, but not requiring, covered entities to use Version F6 beginning at the end of the 3 years, and allowing both Versions F6 and D.0 to be used for an 8-month period until a compliance date of May 1, 2025, when only Version F6 and Version 15 could be used. 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 recommended that the Secretary adopt Batch Standard Versions 15 and 10, as it had previously recommended in May 2018. The NCVHS has not, as of publication of this final rule, recommended that the Secretary adopt any other version of the NCPDP Telecommunication Standard, such as Version F7, which is discussed in section III. A. of this final rule.

III. Provisions of the Final Rule and the Analysis of and Responses to Public Comments

In response to the November 2022 proposed rule, we received 25 timely pieces of correspondence, which resulted in over 47 unique comments from a variety of commenters, including a pharmacy standards development organization, data content committees, health plans, health care companies, professional associations, technology companies, and individuals.

In this section of this final rule, we present our proposals, a summary of the comments received, and our responses to the comments. Some of the public comments received in response to the November 2022 proposed rule were outside of the scope of the proposed rule and are not addressed in this final rule.

A. Adoption of the NCPDP Telecommunication Standard Implementation Guide Version F6 (Version F6) and Equivalent Batch Standard Implementation Guide, Version 15 (Version 15) for Retail Pharmacy Transactions

In the November 2022 proposed rule, we proposed to adopt a modification to the current HIPAA retail pharmacy standards for the following transactions: (1) health care claims or equivalent encounter information; (2) eligibility for a health plan; (3) referral certification and authorization; and (4) coordination of benefits. We indicated that moving to Version F6 and Version 15 would: allow for the accommodation of drug therapies priced at or in excess of $1 million; include information needed for prior authorizations and enhancements to the drug utilization review (DUR) fields; include new coordination of benefits segment fields that would improve the identification of the previous payer and its program type, such as Medicare, Medicaid, workers compensation, or self-pay programs, which would eliminate the need to use manual processes to identify this information; and accommodate business needs to comply with other industry requirements, among other benefits. For the full discussion, we refer readers to the November 2022 proposed rule (87 FR 67638 and 67639).

We proposed that 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)—Retail pharmacy drugs.

We note that, as is the case with Version D.0, Version F6 is specifically designed for communication between retail pharmacies and health plans, as described in the NCPDP Version F6 Telecommunication Standard Implementation Guide[4] and equivalent NCPDP Version 15 Batch Standard Implementation Guide. Specifically, the implementation guides for Version F6

[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.*

[4] The Telecommunication Standard Implementation Guide Version F6 (Version F6), January 2020 and equivalent Batch Standard Implementation Guide, Version 15 (Version 15) October 2017, National Council for Prescription Drug Programs.

and Version 15 specify that those standards support transmissions to and from ''providers'' and indicate that a provider ''may be a retail pharmacy, mail order pharmacy, doctor's office, clinic, hospital, long-term care facility, or any other entity, which dispenses prescription drugs.'' This means the use cases for the retail pharmacy drugs transactions addressed in this Final Rule, including the HIPAA requirements for the use of Version F6 and Version 15 we are finalizing here, apply only to providers that dispense prescription drugs. That is, they do not apply to providers that do not dispense prescription drugs.

Comment: A number of commenters supported HHS's proposal to modify the currently adopted retail pharmacy standards from Version D.0 and Version 1.2 to Version F6 and Version 15. Commenters remarked that it has been over 10 years since Version D.0 was adopted for retail pharmacy transactions and agreed that the enhancements in the updated standards will better meet the present business needs of pharmacies and payers, thereby reducing administrative burden. While most commenters agreed that adopting Version F6 is appropriate, several suggested that HHS instead adopt an even more recently updated NCPDP Telecommunication Standard, Version F7 (Version F7). Commenters remarked that the only difference between Version F6 and Version F7 is the addition of a field that distinguishes between administrative gender (used to indicate the sex a person has listed with their insurance company) and clinical sex at birth. Commenters noted that the Patient Gender Code field (305–C5) in Version F6 includes ''Non-Binary'' as an optional value. While the ''Non-Binary'' value can be used to support various eligibility and enrollment business functions, it does not support gender-specific coverage rules or clinical patient safety functions. To address this clinical concern, the NCPDP updated Version F6 to Version F7 by adding a new field called Sex Assigned at Birth (F32–W8). Commenters urged HHS to consider the need for this field and adopt Version F7 in this final rule.

Response: We thank the commenters for their support of our proposal to adopt Version F6. While we appreciate comments urging us to adopt Version F7 instead of Version F6, as of the publication date of this final rule there is no DSMO recommendation to adopt Version F7 in accordance with the processes specified in § 162.910(c), nor has the NCVHS been asked to consider updating its prior recommendation to adopt Version F6. While we did not discuss adopting Version F7 in the November 2022 proposed rule, we may address it in future rulemaking. therefore, covered entities will be required to use Version F6 only.

Comment: A commenter acknowledged that adoption of Version F6 would reduce industry burden by replacing several free text fields with discrete data fields, thus allowing the industry to automate additional pharmacy workflows. However, another commenter expressed concern that the replacement of free text fields with discrete data fields in Version F6 would result in the permitted information being too limited or not well-defined. The commenter noted that poorly designed discrete data fields potentially lead to unclear communication and confusion, which has patient-safety implications. The commenter said that before deploying the discrete data fields, the standard should be broadly tested by both physicians and pharmacists to ensure clear communication.

Response: HHS consulted with the NCPDP, the SSO associated with this rulemaking, and was advised that the free text fields were not removed from Version F6. Rather, the free text fields still exist in Version F6 and can be used when additional text is needed for clarification or detail or when a discrete data field does not exist. But, Version F6 provides a format to convey situational plan benefit information, previously sent using free text fields, in discrete data fields. The discrete data fields, which are on the claim response from the payer or PBM to the pharmacy, enable the plan benefit information to be better communicated to the pharmacy, which in turn enables the pharmacy to better communicate to the patient and the prescriber. The use of discrete data fields improves communication of the plan benefit information because it does not rely on the pharmacist reading and interpreting free text. The types of plan benefit information that are communicated via free text fields in Version D.0 and that will be sent in discrete data fields in Version F6 are dates (for example, next available fill date and prior authorization date), minimum/maximum ages, minimum/maximum quantity, minimum/maximum day supply, minimum/maximum dollar amounts, and maximum or remaining fills. Additional detail about formulary alternatives, if applicable, will be communicated via the new discrete data fields rather than via free text. Such detail includes the required duration of therapy and plan benefit tiers.

It is also important to note that since the new discrete data fields are not codified, the information conveyed is not limited to, or defined by, a set of values. A codified field is one that that requires a value that is defined either in NCPDP's External Code List (ECL) or a code set maintained by a non-NCPDP organization (for example SNOMED CT values or ICD–10 code values), where only those values may be included in the data field. The new discrete data fields do not require a defined set of values—they are date fields or fields for a number representing, for example, an age, quantity, or dollar amount.

In light of these updates, we continue to agree with the NCPDP's assessment that replacing free text fields with discrete data fields for clinical and non-clinical information will enhance patient safety processes because there will be less room for interpretation, and, therefore, likely less room for the error and confusion that can occur with free text fields. By ensuring standardization and enabling pharmacy and prescriber system automation and interoperability of clinical information, critical pharmacy information will thus be more readily identifiable and actionable. Lastly, we believe that adopting a later compliance date, including an 8-month transition period, than what we had proposed, will allow for the standard to be broadly tested by health plans, pharmacies, and pharmacy benefit managers (PBM) to ensure clear communication. We discuss the compliance dates in section III.C. of this final rule.

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

In the November 2022 proposed rule (87 FR 67640), we discussed that the 2009 Modifications final rule adopted Version 3.0 as the standard for the Medicaid pharmacy subrogation transactions. We discussed how State Medicaid agencies sometimes pay claims for which a third party may be legally responsible, and where the State is required to seek recovery. For the full 2009 Modifications final rule discussion, please refer to 74 FR 3296.

1. Modification to the Definition of the Medicaid Pharmacy Subrogation Transaction

The November 2022 proposed rule (87 FR 67640) proposed to broaden the scope of the pharmacy subrogation transaction to apply to all health plans, not just State Medicaid agencies. In doing so, we proposed to modify the name and definition of the transaction to reflect the proposed amended requirements. The transaction at 45 CFR 162.1901 is presently known as the

Medicaid pharmacy subrogation transaction and is described 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. The proposal would have changed the name of the transaction to the Pharmacy subrogation transaction and defined it 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.

Comment: Several commenters responded to our proposal to require all health plans, not just State Medicaid agencies to use the HIPAA standard for pharmacy subrogation transactions. Most of those commenters disagreed with the proposal, but a few supported it and specifically expressed support for our proposal to change the name and definition of the transaction.

Response: We appreciate the commenters' input. As discussed in section III. B.2. of this final rule, we are not finalizing our proposal to require all health plans to use the HIPAA standard for pharmacy subrogation transactions, and, therefore, we are not finalizing our proposal to change the name and definition of the transaction at § 162.1901.

2. Application of NCPDP Batch Standard Subrogation Implementation Guide, Version 10 to Non-Medicaid Health Plans

As discussed previously, the current HIPAA standard, Version 3.0, only applies to State Medicaid agencies seeking reimbursement from health plans responsible for paying pharmacy claims. In the November 2022 proposed rule (87 FR 67640), we stated that Version 3.0 does not address business needs for other payers and that adopting a more broadly applicable subrogation transaction standard would facilitate the efficiency and effectiveness of data exchange and transaction processes for all payers involved in post-payment of pharmacy claims and support greater payment accuracy across the industry.

Comment: The majority of those who commented on our proposal to adopt Version 10 for all health plans expressed support for the adoption of Version 10 to replace Version 3.0 for State Medicaid agencies but opposed our proposal to adopt the standard to apply to all health plans. Commenters believe there are differences between Medicaid subrogation and non-Medicaid subrogation that Version 10 does not address, such as the different payer order rules that are required for non-Medicaid subrogation. They asserted that making Version 10 available, but not required, for non-Medicaid subrogation transactions would allow the pharmacy industry to determine if there are additional data elements, use cases, payer order rules, and other guidance needed for different subrogation transactions.

Response: We thank the commenters for their input. As noted in the November 2022 proposed rule (87 FR 67640 and 67641), during the March 2018 NCVHS hearing, several testifiers noted that there was a need to expand the use of the subrogation transaction beyond State Medicaid agencies based on other payers'—such as Medicare Part D, State assistance programs, or private health plans—business needs to seek similar reimbursement that could not be accommodated by Version 3.0. A testifier noted that a subrogation standard that addresses all payers would allow the industry to have a standardized approach to subrogation, which ultimately would reduce the manual processes that health plans and pharmacies currently use. The testifier added that requiring use of a subrogation standard by all health plans would allow for better tracking of subrogation efforts, which would improve payment accuracy and support cost containment efforts. Another testifier advised that expanding the requirement for non-Medicaid health plans to use the transaction standard would allow for any PBM to use the standard. For these reasons, we proposed that all health plans would be required to use Version 10 for pharmacy subrogation transactions.

Nonetheless, we have decided to adopt Version 10 for State Medicaid agencies only and are not requiring non-Medicaid health plans to use a subrogation standard for pharmacy subrogation transactions. While reviewing commenters' concerns and suggestions, we consulted with the NCPDP, the SSO associated with the rulemaking, and found that Version 10 does not address requirements for all non-Medicaid subrogation situations, especially when these situations involve multiple commercial health plans. In the ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' August 2008 proposed rule (73 FR 49751), we explained that Federal law requires, with some exceptions, that Medicaid be the payer of last resort, which means that health plans that are legally required to pay for health care services received by Medicaid recipients are required to pay for services primary to Medicaid. However, Medicaid agencies will sometimes pay claims for which a third party is legally responsible. This occurs when the Medicaid agency is not aware of the existence of another coverage, and there are also specific circumstances for which State Medicaid agencies are required by Federal law to pay claims and then seek reimbursement afterward.

Payer order rules are critical in subrogation transactions since they determine the primary or secondary insurer, and, in the case of subrogation, a payer needs to know which insurer to bill for the payment it incorrectly made. In retrospect, since payer order rules aside from Medicaid are not well developed, we believe that Version 10 is not ready for adoption beyond State Medicaid agency subrogation transactions. Although we are not adopting Version 10 for all health plans in this rule, we note that the standard is available for use, meaning covered entities may use it for non-Medicaid subrogation transactions between willing trading partners.

3. Modification of the NCPDP Batch Standard Subrogation Implementation Guide, Version 10 Transaction Standard for State Medicaid Agencies

In the November 2022 proposed rule (87 FR 67641), we proposed to replace Version 3.0 with Version 10 as the standard for Pharmacy subrogation transactions at § 162.1902(b).

Comment: As noted previously, commenters agreed that Version 10 should replace Version 3.0 for Medicaid subrogation transactions but opposed requiring its use by non-Medicaid health plans.

Response: We thank commenters for their input and suggestions. As previously discussed, we are adopting the NCPDP Batch Standard Subrogation Implementation Guide, Version 10 as the standard for Medicaid pharmacy subrogation transactions at § 162.1902(b) to apply only to Medicaid pharmacy subrogation transactions.

C. Compliance and Effective Dates

1. 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, though

the compliance date may not be sooner than 180 days after the effective date of the final rule. In the November 2022 proposed rule, we proposed that covered entities would need to be in compliance with Version F6 and 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 the November 2022 proposed rule (87 FR 67641), we acknowledged that in its April 22, 2020, recommendation letter to the Secretary, the NCVHS recommended the following implementation timelines and dates for Version F6 and Version 15: [5]

- A 3-year pre-implementation window following publication of the final rule, allowing (but not requiring) industry use beginning at the end of the 3 years (or 36 months).
- Allow both Versions D.0 and F6 and their equivalent batch standards, Version 1.2 and Version 15, to be used for an 8-month period after the 36-month pre-implementation window, which the NCVHS suggested would enable an effective live-testing and transition period.
- Require full compliance, that is, exclusive use of Version F6, after the 8-month transition period, following the 36-month pre-implementation window.

The NCVHS also recommended a compliance date in May, as opposed to January, due to: seasonal organizational burdens associated with the end-of-year timeframe, such as processing burden for annual benefit plan changes, which are typically effective January 1; unavailability of full staff during the holiday season preceding January 1; competing administrative obligations requiring information technology (IT)/operations and corporate resources such as closing out annual books and compiling reports; and annual flu season peaks affecting both providers and IT/operations staff.

After carefully considering the NCVHS's recommendation and industry testimony on implementation timelines and dates, as well as the potential benefits that would be derived from implementing Version F6 and Version 15 (discussed in section III.A.1. of the November 2022 proposed rule and section III. of this final rule) as soon as possible, we chose not to propose a 3-year pre-implementation compliance window or an 8-month transition period. Instead, we proposed a 24-month compliance date. We believed that the industry was capable of implementing the changes necessary to comply with the updated standards by 24 months from the effective date of the final rule, in light of: (1) limited industry testimony on any barriers specific to the implementation of Version F6; (2) industry testimony on the similarities between the level of effort necessary to implement Version F2 and Version F6, as discussed in the NCVHS's 2018 recommendation; (3) and the limited scope of the modification to only retail pharmacy transactions.

Comment: The majority of commenters opposed the proposed 24-month compliance date requirement for Version F6 and Version 15. In response to our solicitation for information on barriers the industry may face that would require additional time for implementation, commenters noted that there were fewer than 100 data element changes between Version 5.1 and Version D.0, but more than 300 data element changes between Version D.0 and Version F6 and their equivalent batch standards, a greater than 300-percent increase when comparing the two standards. Commenters described that the volume of changes affect multiple business functions, including, for example, transaction routing, pricing, controlled substance billing, Medicare Part D long term care dispensing frequencies, coordination of benefits, Medicare eligibility response, and reversals, which require expansion of internal databases and system updates to build the new data elements into automated claims adjudication processes. Commenters noted the updates will require extensive internal IT development and testing and external trading partner testing across multiple databases and systems before covered entities can conduct real-time exchanges in compliance with the requirements.

In addition to the volume of required data element changes, several commenters provided detailed information about the complexity of the changes. For example, as discussed in section III. of the November 2022 proposed rule, Version F6 supports drugs priced at and in excess of $1 million. This change is specific to Version F6 and, therefore, was not accounted for in any of the earlier industry testimony regarding appropriate timeframes for moving from Version D.0 to Version F2. Commenters noted that, to accommodate drugs priced at $1 million and up, Version F6 includes 31 expanded pricing fields. To comply with these changes, covered entities must ensure that their own systems and/or their business associates' systems increase database capacity to store the expanded field length and have the ability to recognize when a ninth digit may be missing across all 31 expanded pricing fields.

Additionally, Version F6 eliminated 13 distinct patient pay fields in Version D.0 and combined them into one qualified, repeating field. Commenters suggested that changes necessary to move 13 distinct patient pay fields into one pose complex implementation challenges. As a result of these financial field changes, commenters believe that the coding tasks required to ensure that accurate pricing data is included within Version F6 and Version 15-compliant transactions will require additional time. Further, commenters noted that should pricing fields associated with coordination of benefits transactions not be coded correctly as a result of rushed attempts to comply with Version F6 and Version 15, it could result in communicating incorrect patient co-insurance and out-of-pocket calculations to pharmacy providers.

Some commenters also raised concerns regarding the required changes necessary for moving from Version 3.0 to Version 10. Version 10 uses an 8-digit Issuer Identifier Number (IIN) in place of the 6-digit Bank Identification Number (BIN) required by Version 3.0.[6] As discussed in section III. of the November 2022 proposed rule (87 FR 67639), within a pharmacy transaction the BIN is a field in the Telecommunication Standard that is used for the routing and identification in pharmacy claims. These commenters believed that there will need to be system updates in order to recognize and process 8-digit IINs, and systems will also need to be updated to map all 8-digit IINs to the former 6-digit BINs. At one time, both Version 5.1 and Version D.0 required the use of the BIN in a 6-digit, mandatory, fixed-length field located in the header section of the transaction. However, since the adoption of Version D.0, the International Organization for Standardization (ISO) created the IIN, which was expanded to 8 digits (as opposed to the 6-digit BIN) to increase the pool of possible identifiers. Version F6 includes an 8-digit, mandatory, fixed-length field to accommodate 8-digit IINs and represents the first change to the header section of the NCPDP Telecommunication standard since the adoption of Version 5.1 in 2002. However, commenters were concerned that, should system changes to accommodate the new header

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

[6] *https://www.ncpdp.org/NCPDP/media/pdf/Resources/NCPDP-Processor-ID-(BIN).pdf?ext=.pdf.*

information not be implemented properly, it could result in transactions being routed to the wrong PBMs, delaying patient access to care.

Several commenters also suggested that additional time to comply with Version F6 and Version 15 is needed to accommodate competing regulatory demands on stakeholder resources. Specifically, commenters identified the need to implement updated electronic prescribing standards as proposed in the Medicare Program; Contract Year 2024 Policy and Technical Changes proposed rule,[7] to develop Application Programming Interfaces to support prior authorization transactions as proposed in CMS's Advancing Interoperability and Improving Prior Authorization Processes proposed rule,[8] and to implement pharmacy changes required under the Inflation Reduction Act of 2022.

Finally, most commenters suggested that the Secretary re-consider and adopt the NCVHS's recommended implementation timeline, which included an additional 8-month period after a 36-month compliance timeframe, during which use of both Version D.0 and Version F6 and their equivalent batch standards would be allowed. Ultimately, this suggestion would result in a 44-month compliance timeframe. Commenters explained that this type of flexibility would allow trading partners to revert to Version D.0 should initial attempts to comply with Version F6 reveal gaps within specific use cases that require recoding and testing efforts prior to a final compliance date. A commenter stated that before finalizing the modification, HHS should consider permitting more testing time between physicians and pharmacists to ensure clear communication. Another commenter identified that the additional 8-month period would be especially beneficial to small, independent pharmacies and State health programs, which have traditionally had the most difficulty in achieving compliance with new standards.

Response: We continue to believe that it is prudent to expedite compliance with the updated standards to ensure that the industry can realize value as soon as possible. However, commenters' detailed explanation of the increased level of complexity in moving from Version D.0 and Version 1.2 to Version F6 and Version 15, as compared to moving from Version 5.1 and Version 1.1 to Version to D.0 and Version 1.2, offered in response to the compliance timeframe proposals, persuaded us to reconsider whether we were allowing sufficient time for covered entities to make system and process updates to accommodate the changes in the standards.

After carefully considering the public comments and reconsidering the NCVHS's recommended implementation timelines and dates, we are attempting to strike a balance by finalizing a longer compliance timeline than we proposed, though not as long as that advocated by some commenters, and also including a transition period. We are finalizing a 36-month compliance date, which includes an 8-month transition period during which covered entities may use both Version D.0 and Version F6. We premised our decision on the fact that most commenters echoed the NCVHS's recommendations and suggested that HHS should 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 3 years and allowing both Versions D.0 and F6 to be used for an 8-month period after the 3-year pre-implementation window, which would enable an effective live testing and transition period. We anticipate that, in order to enable covered entities to use both standards during the permitted 8-month transition period, trading partner agreements will have to be implemented so health plans, processors, PBMs and pharmacies, and software vendors can set up the appropriate editing and formatting of the transactions. With the exception of the requirements set forth in § 162.915, regarding certain specifics that may not be included in them, we do not dictate the terms of trading partner agreements but expect that health plans and pharmacies will continue to collaborate on processes to adjudicate these claims during the permitted 8-month transition.

Finally, it is important to note that HHS received comments stressing the importance of covered entities taking steps as soon as possible to become prepared to move to the updated versions of the Telecommunication and Batch Standards so as to be ready soon to take advantage of their significant improvements.

The 2009 Modifications final rule provided covered entities approximately 36 months from the final rule's effective date to comply with Version D.0 and Version 1.2, though the proposed rule had proposed a 24-month compliance date. In support of the increased compliance timeframe that we finalized, we stated that the competition for resources to make system and business process changes necessary to comply with both the modified pharmacy transactions standard and Version 5010 at the same time necessitated the additional 12 months. While we acknowledge that the level of complexity and volume of changes between Version D.0 and Version F6 and their equivalent batch standards far exceed those between Version 5.1 and Version D.0 and their equivalent batch standards, they do not far exceed the volume and complexity of changes necessary to concurrently comply with updated pharmacy and X12 standards. As such, we do not believe these changes necessitate a compliance timeframe exceeding 36 months. Therefore, we disagree with commenters that a total of 44 months is necessary to comply with the modified pharmacy transaction standards finalized in this rule. Additionally, we are persuaded by commenters, and now agree with the April 22, 2020, NCVHS recommendation letter, which was based on consideration of industry feedback, that advised the Secretary to consider an 8-month transition period. The NCVHS suggested that an 8-month transition period is necessary and sufficient to support a successful and timely transition, stating in its recommendation letter that, should covered entities identify errors in their systems and processes after moving Version F6 and Version 15 into production, the transition period would allow them, if needed, to revert to Version D.0 and Version 1.2 to avoid stops in business functions and delays in patient access to care.

As stated at the beginning of this preamble, this final rule is effective 60 days after publication in the **Federal Register**. The effective date is the date on which the policies set forth in this final rule take effect. The compliance date is the date on which covered entities are required to implement the policies adopted in this rule. The final transition and compliance dates for Version F6 and Version 15 at §§ 162.1102, 162.1202, 162.1302 and 162.1802 are as follows:

- All covered entities may, as agreed to by trading partners, use either Version D.0 and Version 1.2 or Version F6 and Version 15 beginning August 11, 2027.
- All covered entities must comply with only Version F6 and Version 15 beginning February 11, 2028.

[7] *https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.*

[8] *https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.*

2. Compliance Dates for Version 10

As discussed in section III.B. of this final rule, we are not finalizing our proposal to broaden the scope of the Medicaid pharmacy subrogation transaction to apply to all health plans. Therefore, we discuss here only the compliance date for State Medicaid agencies to comply with Version 10.

As previously noted, with respect to State Medicaid agencies, Version 10 is a modification of the currently adopted standard, Version 3.0. Section 1175(b)(2) of the Act requires the Secretary to set the compliance date for a modification to a standard at such time as the Secretary determines appropriate, but no sooner than 180 days after the effective date of the final rule in which we adopt that modification. We proposed to align the compliance date for Version 10 with the compliance date for Version F6 and Version 15 to reduce confusion and administrative burden. Therefore, we proposed to reflect at § 162.1902(b) that State Medicaid agencies would be required to comply with Version 10 beginning 24 months after the effective date of the final rule.

Comment: A majority of commenters agreed that the implementation timeline for Version 10 needs to align with the implementation timeline for the NCPDP Telecommunication Standard. Commenters suggested a longer implementation timeframe for Version F6 and Version 15 (described earlier), they suggested the Secretary implement a 36-month compliance timeframe, followed by an 8-month period where both Version 3.0 and Version 10 could be used as agreed to by trading partners.

Response: HHS agrees that it is important to align the transition period and compliance date for Version 10 and for the NCPDP Telecommunication standard. We understand that without employing burdensome workarounds it would be difficult for State Medicaid agencies to comply with Version 10 for Medicaid subrogation transactions prior to complying with F6 and Version 15. As such, we believe that aligning the compliance timeframes will reduce confusion for, and burden on, State Medicaid agencies. This includes establishing an 8-month transition period where State Medicaid agencies may, as agreed to by trading partners, use either Version 3.0 or Version 10. The changes required for State Medicaid agencies to comply with Version 10 are minimal, as discussed in section III.B.3. of the November 2022 proposed rule.

After careful consideration of the comments received, at § 162.1902, we are finalizing the compliance date for Version 10 as beginning February 11, 2028, which aligns with the timeline we are adopting for Version F6 and Version 15. In addition, at § 162.1902, we are finalizing that beginning August 11, 2027, which is 8 months before the compliance date, State Medicaid agencies may, as agreed to by trading partners, use either Version 3.0 or Version 10 for Medicaid pharmacy subrogation transactions.

D. Incorporation by Reference

This final rule incorporates by reference the following implementation guides at 45 CFR 162.920: (1) the Telecommunication Standard Implementation Guide Version F6, January 2020, National Council for Prescription Drug Programs; (2) the Batch Standard Implementation Guide, Version 15, October 2017, National Council for Prescription Drug Programs; and (3) the Batch Standard Subrogation Implementation Guide, Version 10, September 2019, National Council for Prescription Drug Programs.

The Telecommunication Standard Implementation Guide Version F6 provides a standard format that addresses data format and content, transmission protocol, and other applicable requirements, for the electronic submission between pharmacy providers, insurance carriers, third-party administrators, and other responsible parties of the following transactions, eligibility verification, claim and service billing, prior authorization, predetermination of benefits, and information reporting (the latter two categories are not HIPAA transactions).

The Batch Standard Implementation Guide Version 15 provides practical guidelines and ensures consistent implementation throughout the industry of a file submission standard to be used between pharmacies and processors, or pharmacies, switches, and processors, when using the Telecommunication Standard framework.

The Batch Standard Subrogation Implementation Guide Version 10 provides the guidelines and process for payers and PBMs to communicate to other payers' reimbursement requests for covered services paid to pharmacy providers for which the other payers are responsible.[9] This implementation guide uses the Telecommunication Standard and the Batch Standard as frameworks for exchange.

The materials we 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. The implementation specifications for the retail pharmacy standards, and for the batch standard for the Medicaid pharmacy subrogation transaction, may be obtained from the NCPDP, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the internet at *http://www.ncpdp.org.* NCPDP charges a fee for all of its Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards.

IV. Out of Scope Comments

We received several comments on subjects that were outside the scope of the November 2022 proposed rule. We do not directly respond to those types of comments, but we acknowledge them. They are summarized in the following list:

- A commenter suggested that HHS consider expanding the Referral Certification and Authorization transaction (§ 162.1301) in order to provide a clear breakdown of the contractual cost of medication before a rebate or the patient cost (copay or deductible) is paid by the health plan. Another commenter expressed that, in order to address these costs, pharmacies should be able to disclose to the patient the lowest cost option for the prescribed medication at the pharmacy, which should include available discounted prescription drug programs resulting in reduced patient cost that is sometimes lower than when using the consumer's health insurance prescription drug benefit. Another comment suggested that HHS should review drug costs first and then consider streamlining drug dispensing.
- A commenter encouraged HHS to work with Congress to allow Medicare beneficiaries to use pharmaceutical discount cards and coupons the same way commercially insured consumers may.
- A few commenters expressed concern that retail pharmacies and health plans may pass the cost of implementing Version F6 to consumers by increasing the costs consumers pay for prescription drugs, thereby increasing the cost of health insurance premiums.
- A commenter was concerned that the costs associated with the proposals

[9] The September 2019 version is a republication to correct a field name—433–DX Patient Paid Amount Reported field name corrected to Patient Pay Amount Reported. We will make a reference to this information in the ''incorporate by reference'' section.

will raise taxes at a time when inflation is at an all-time high.

• A commenter requested that the cost to update electronic health records and e-prescribing platforms to reflect these changes not be passed on to physicians.

• A commenter expressed concern that if the updated pharmacy standards are adopted, it will limit the use of paper that some retail pharmacies continue to utilize. The commenter explained that pharmacies that do not have access to ample technology, or those that are unfamiliar with the use of technology, would be disadvantaged by these proposals. Therefore, the commenter recommended that the best solution would be to allow pharmacies the flexibility to choose whether to use Version F6 or paper-based claims based on their business practice or customer base.

V. 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 required 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 rule, we are finalizing the sections 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 final 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). In the November 2022 proposed rule, we assumed each entity will have four designated staff members who will review the entire final rule, meaning there would be 416 total reviewers. 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. We did not receive any comments and are finalizing this rule based on our assumptions.

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 final rule is $99.93 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 would take each such individual approximately 4 hours to review this final rule. The estimated cost per entity would therefore be $799.44 (4 hours × $99.93 × 2 staff), and), and the total cost borne by the 104 affected entities would be $83,142 ($799.44 × 104 entities).

We are also assuming that an entity would have two lawyers reviewing this final rule. Using the wage information from the BLS for lawyers (code 23–1011), we estimate that their cost of reviewing this final rule would be $100.47 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 each for two lawyers to review this final rule. The estimated cost per entity would therefore be $803.76 (4 hours × $100.47 × 2 staff), and the total cost borne by the 104 affected entities would be $83,592 ($803.76 × 104 entities).

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 final rule 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 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 will be limited to the review and approval of initial standards and to changes in industry standards that will substantially reduce administrative costs (see 65 FR 50350 (August 17, 2000)). This document, which finalizes updates to adopted electronic transaction standards that are being used, will constitute an information collection requirement because it will require third-party disclosures. However, because of OMB's determination, as previously noted, there is no need for OMB review under the PRA.

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

VI. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes modifications to standards for electronic retail pharmacy transactions and the Medicaid pharmacy subrogation transaction adopted under the Administrative Simplification subtitle of HIPAA. Under HIPAA, the NCVHS recommends standards to the Secretary following review and approval of standards or updates to standards from the applicable SSO—in this case, the NCPDP. The 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 Version F2 to replace Version D.0, Version 15 to replace Version 1.2, and Version 10 to replace Version 3.0. On April 22, 2020, the NCVHS recommended that the Secretary adopt Version F6 in lieu of Version F2, as well as the two batch standard recommendations set forth in the May 2018 letter. 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 Version D.0 and associated workarounds, including manual claims processing and claims splitting for drugs priced at, or in excess of, $1 million.

B. Overall Impact

We have examined the financial impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980; Pub. L. 96–354), 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 (CRA) (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). Executive Order 14094 amends section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule: (1) that may have an annual effect on the economy of $200 million or more in any one year, or adversely affecting in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order.

Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is 3(f)(1) significant as measured by the $200 million or more in any 1 year and meets the criteria under 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act). Accordingly, we have prepared an RIA and Regulatory Flexibility Analysis (RFA) that, to the best of our ability, presents the revised costs and benefits from the November 2022 proposed rule and the impact it will have on small entities.

We did not receive any comments on the RIA or RFA presented in the proposed rule. We adjusted our previous calculations to accommodate a 3-year implementation timeframe and updated our summary of the RFA using updated business data. OMB has reviewed these final regulations and provided an assessment of their impact. For details, we refer readers to the discussion provided as follows.

C. Detailed Economic Analysis

While significant efforts were taken to ensure that the cost and benefits captured for this rule were accurate, there are a few key uncertainty factors that should be considered in reviewing the regulatory impact analysis:

1. Data Sources

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 will 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 the RFA and RIA are based on the interviews conducted by CAMH, unless otherwise noted.

Because the industry has not conducted entity-specific financial impact analyses for the adoption of the modified standards in this rulemaking, the analysis relies on preliminary assessments from industry stakeholders that the conversion to Version F6 will 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. 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. In addition, we did not receive any comments on assumptions in the November 2022 proposed rule. We are finalizing this RIA using the estimates provided in public comments reported in the 2009 Modifications final rule to develop estimates of the true baseline Version D.0 conversion costs applying 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 modified standards subject to this rulemaking.

2. Interpreting Cost

To implement Version F6, pharmacies and vendors will likely hire coders, software development and testing specialists, and/or consultants to modify their production code and will likely conduct employee training to facilitate the use of the new version. These one-time, out-of-pocket expenditures constitute a cost attributable to the final rule. Costs to transmit transactions using the Version F6 standard after business systems have been modified to implement the adopted standard, as well as costs to maintain those systems for compliance with the standard, were not factored into the 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, we do not anticipate any costs attributable to this final rule after the completion of the final 3-year compliance timeframe.

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. We believe Version F6 implementation will shift the priorities of technical staff at large pharmacy firms, potentially delaying other improvements or projects. In this scenario, the opportunity cost consists of the time-value of delayed projects. Other pharmacies 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.

Further, the RIA in the November 2022 proposed rule used average costs to assess costs to each industry stakeholder because of their availability and verifiability. We did not receive any responses to our solicitation for comments related to these assumptions and cost interpretations.

3. Anticipated Effects

The RIA summarizes the costs and benefits of adopting the following standards:

- Telecommunications Standard Version F6, replacing Version D.0, including equivalent Batch Standard Version 15 for health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits transactions.
- Batch Standard Subrogation Implementation Guide, Version 10 replacing Batch Standard Medicaid Subrogation Implementation Guide, Version 3, for Medicaid Pharmacy Subrogation Transactions.

This RIA amends the RIA from the November 2022 proposed rule, while acknowledging any changes made in this final rule, to reflect a 3-year compliance date following the effective date of this final rule. All other information regarding the details supporting the cost-benefit analysis for each of the standards listed previously remains unchanged.

Table 1 is the compilation of the estimated costs for all of the standards adopted in this final rule. To allocate costs over the 3-year implementation period, we use a 30–40–20–10 percent allocation of IT upgrades and training expenses across the 3-year implementation period. We believe that since the effective date of this final rule will be in the latter part of 2024, costs will start at that time and go into 2027.

TABLE 1—ESTIMATED COSTS ($ MILLIONS) FOR YEARS 2024 THROUGH 2033 FOR IMPLEMENTATION OF VERSIONS F6 AND VERSION 10 (V10)

Cost type	Industry	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
F6	Non-Independent Pharmacy	2,828.68	3,838.24	1,919.12	9.56							95.6
	Independent Pharmacy	18.3	24.4	1,212.2	6.1							61.0
	Health Plan											
	PBM	3,838.4	5,151.2	2,525.6	12.8							128.0
	Vendors*	2,929.91	3,939.88	1,919.94	9.97							99.7
SV10	Health Plan											
	Medicaid Agency											
	PBM											
	Vendors	0.66	0.8	0.4	0.2							2.0
	Annual Total	115.89	154.52	77.26	38.63							386.3

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

4. 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.

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-standard transactions). 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.

Based on the business data from the CAMH, 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 pharmacy corporations represent over 28,000 locations, and the two largest corporations each exceed 9,000 locations.[10] However, the business data from the Pharmacy and Drug Store segment (NAICS code 456110) may not capture all pharmacy firms affected by this final rule.

Pharmacies are typically classified by ownership as either not-independent or independents. Health data analytics company IQVIA estimated [11] in 2021 that there were 66,083 pharmacies, of which 70 percent (46,964) were not-independent and 30 percent (19,119) were independents. Retail pharmacies, which provide access to the general public, comprised the clear majority of pharmacy facility types at 91 percent (59,395). The five largest pharmacy corporations owned about 40 percent (close to 29,000) 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, 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 corporations are increasingly likely to operate multiple pharmacy business segments (channels), such as retail, mail, specialty, and long-term care. We did not receive any responses to our solicitation for comments on whether there are meaningful distinctions in cost structures or data sources to assist in quantifying entities in these segments.

[10] 2021 ''U.S. National Pharmacy Market Summary.'' IQVIA. *https://www.iqvia.com/-/media/iqvia/pdfs/us/publication/us-pharmacy-market-report-2021.pdf.*

[11] 2021 ''U.S. National Pharmacy Market Summary.'' IQVIA. *https://www.iqvia.com/-/media/iqvia/pdfs/us/publication/us-pharmacy-market-report-2021.pdf.*

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 identified 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.[12]

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 identified three telecommunication switches in this segment of the market for consideration in the RIA.

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 the 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 believe even the relatively 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.

In the CAMH report, there were 745 Direct Health and Medical Insurance Carriers and 27 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 estimated that approximately 40 firms conduct some PBM functions involved with processing some pharmacy claim transactions. For the RIA, we assumed 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) Not-Independent Pharmacies

Pharmacies either internally develop or externally purchase pharmacy management information systems to bill and communicate with PBMs. 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. However, 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. The RIA identified the top 25 firms, based on 2021 IQVIA data, as well as the VA and the Indian Health Service (IHS), as financing and managing their pharmacy system conversion requirements internally, and the remainder of chain pharmacy firms relying on their technology vendor for technical development, implementation, testing, and initial training.

Although they are not legally considered ''not-independent pharmacies,'' we grouped IHS, tribal, and urban facilities with them based on conversations with representatives from IHS that suggested their costs would be roughly similar to those of not-independent pharmacies. 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 as 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 3-year implementation timeframe. We estimated that IHS would incur implementation costs at a level roughly equivalent to the VA system, and that this expense will 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 believe that about 60 percent of these smaller IHS, tribal, and urban entities (51) will rely on existing maintenance agreements with commercial vendors for implementation and, like smaller not-independent pharmacies, will incur direct implementation costs to support user training costs. We solicited comments on our assumptions and did not receive any to the contrary.

Based on the data from the CAMH report, 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.[13] The business data from the CAMH report includes 72 firms classified as Supermarkets and Other Grocery (except Convenience) Stores with more than 5,000 employees, which we assumed 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, the RIA assumed 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 estimated the remainder of 237 (262–25) would rely upon their technology vendor.

Based on conversations with a variety of industry representatives, we understand that these larger firms retain the technical staff and/or contractors that will undertake the Version F6 conversion efforts as an ongoing business expense. Consequently, in

[12] 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/.*

[13] 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-.*

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 conversion 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 assumed these informal multiples account for inflation. In a presentation to the NCVHS,[14] 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 retail pharmacy association stated that implementation costs would vary significantly among different pharmacy corporations 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 corporations 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 corporations 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 corporations and elected to use an estimate of $1 million for large pharmacy corporations and $100,000 for small pharmacy corporations in the first implementation year. That rule also discussed a few public comments disputing these large chain estimates,[15] 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 not-independent 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 developed a rough estimate of the true baseline Version D.0 conversion costs and then applied a Version F6 multiplier. Comments were not received on our approach.

We believe that Version F6 conversion costs for pharmacies corporations will be differentiated in three general categories: (1) the largest retail pharmacies operating in multiple pharmacy channels; (2) other midsize retail pharmacies operating primarily in either the open-door retail and/or another single pharmacy channel; and (3) smaller retail pharmacies. 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 retail pharmacy corporations incurred a baseline (Version D.0) cost of $2 million;
- The 23 midsize retail pharmacy corporations, the VA, and IHS pharmacy operations incurred a baseline cost of $1 million; and
- The 237 smaller retail pharmacy corporations incurred a baseline cost of $25,000.

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

- Two retail pharmacy corporations will incur all internal Version F6 conversion costs of (3*$2 million), or $6 million each; and
- The 25 retail pharmacy-corporations (23 midsized chains, the VA, and IHS) will incur all internal Version F6 conversion costs of (3*$1 million), 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's environmental scan suggested that pharmacies would likely need to make some investments in staff training but will 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 will be no increases specifically due to the Version F6 conversion in these ongoing costs to pharmacies. We believe that primary training is developed or purchased at the firm level and may be deployed at the establishment level in secondary employee in-service training slots. We believe 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,[16] we estimate that: 237 smaller retail pharmacies 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 3-year implementation period.

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

[15] 74 FR 3319 (January 16, 2009).

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

TABLE 2—PHARMACY CORPORATIONS' 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 2021 IQVIA data included 66,083 pharmacies, of which 30 percent (19,119) 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 the data in the CAMH environmental scan there were 19,044 pharmacy firms with fewer than 500 employees, representing 20,901 establishments. Since we did not receive any comments on our assumptions, for the purposes of this final rule, firms with more than 500 employees represent chains, and 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 will already be priced into existing maintenance agreements and fee structures. Therefore, we do not believe there will be increases in these ongoing costs to independent pharmacies as the result of the Version F6 conversion, and we believe pharmacy direct costs would generally be comprised of training and other miscellaneous expenses. As with retail pharmacies, we believe 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 assumed 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 believe that the few system users in very small pharmacies would be trained directly by the pharmacy management system vendor, and no secondary training costs will be required for such small firms.

As noted previously, a commenter on the 2009 Modification proposed rule [17] 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 will be borne by the pharmacy management system vendors and that smaller pharmacy conversion costs will 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 believe that 17,016 small pharmacy firms will incur opportunity costs for employee time spent in training and 2,028 pharmacy firms will 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,[18] we estimate that 2,028 independently owned pharmacies will incur Version F6 conversion training costs of ($25,000 × 1.20) or $30,000 each on average, in the first and second year of the 3-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 believe 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 the 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 ongoing contractual payment arrangements between health plans and PBMs and will not be increased specifically in response to the Version F6 conversion.

[17] 74 FR 3317 (January 16, 2009).

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

All PBMs will experience some impacts from the Version F6 conversion, involving IT systems planning and analysis, development, and external testing with switches and trading partners. A PBM commented to the NCVHS that the most significant impact will 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 payers/processors would depend on the lines of business they support—that entities supporting Medicare Part D processing will have the most work to do but will also get the most value from the transition. The extent to which these activities will 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 workarounds 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, State Medicaid agencies, and other [19] fee-for-service entities. While details on internal operating systems are proprietary, we believe that the three largest PBMs that controlled 75 percent of 2018 market share [20] (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. In the November 2022 proposed rule, we assumed 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 also assumed that the VA PBM is comparable to these midsize PBMs. We assumed 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. Since we did not receive comments, we are moving forward with our assumptions.

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,[21] as we received no comments critical of that estimate. Based on updated data on market share, we believe more segments in the PBM industry will 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 believe 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 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 will involve changes to many interrelated systems. As summarized in Table 4, using a 2x multiplier, we estimate that over the 3-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; and
- The remaining 33 PBMs would incur Version F6 conversion costs of (2*$500,000), or $1 million each.

The following comments were received on the subject, followed by our responses to those comments.

Comment: A commenter noted that the assumption about lesser operating system complexity is not valid for all smaller PBMs. The commenter noted that many mid-sized and smaller PBMs support multiple lines of business—commercial, health plan, Medicare Part D, Medicaid, labor, etc. and have complexity on par with larger PBMs, such that the assumptions that mid-size PBMs' cost would be 38 percent less than that of a large PBM and that smaller PBMs' cost would be only 4.7 percent of the cost of the largest PBMs is not valid. These changes represent a similar burden for midsize and smaller PBMs and, the commenter noted, was the main rationale for its requesting that HHS consider an extended implementation timeframe.

Response: We recognize that some mid-size and smaller PBMs do support multiple lines of business and may incur costs above those estimated in the RIA. As the commenter recommends, we have finalized a compliance date beyond the proposed compliance timeline. However, the commenter did not provide cost estimates that would justify amending the estimates within the RIA.

Comment: A commenter asserted that the assumption that HIPAA standard conversion costs are already priced into ongoing contractual arrangements between health plans and PBMs and SaaS vendors is also not valid. The commenter indicated that a set of changes as significant as Version F6 presents is not a business-as-usual change that can easily be absorbed into mid-size or small PBM or SaaS routine operations.

Response: While we recognize that, outside of pre-existing contract rates, nothing prevents a mid-size or small PBM from charging pharmacies for conversion to Version F6, this does not contradict information that CAMH gathered from industry representatives confirming that generally these costs are factored into ongoing contractual fees and will likely not result in an increase

[19] 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.*

[20] 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.*

[21] 74 FR 3320 (January 16, 2009).

in direct, upfront software costs to pharmacies.

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

(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 will 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 will 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,[22] 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. In addition, we did not receive comments on the November 2022 proposed rule. Therefore, we believe it is likely that firms will continue to decline to share this type of proprietary and market-sensitive data. Thus, we continue to 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 [23] and rounding to the nearest million, we estimate that over the 3-year implementation period: 30 pharmacy management system firms will incur Version F6 conversion costs of approximately $3 million each for software planning, development, and testing.

We further believe that these pharmacy system vendor firms will 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 believe that in the fourth year of the 3-year implementation period: 30 pharmacy management system firms will incur Version F6 training costs of $2,300 for 2,265 clients (237 small pharmacies and 2,028 independent pharmacy corporations), 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 3-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	2,265	5.2

[22] 74 FR 3320 (January 16, 2009).

[23] 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 5—OTHER VENDOR COSTS OF CONVERSION TO VERSION F6—Continued

Version F6 conversion cost category	Conversion cost per entity ($ in millions)	Number of affected entities or sites	Total F6 conversion costs ($ in millions)
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.

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 then-proposed 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 enabling compliance with regulatory requirements, facilitating the transmittal of additional codified and interoperable information between stakeholders that would benefit patient care and care coordination, and powering advanced data analytics and transparency. Some changes will result in operational efficiencies over manual processes, but will 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 did not receive any comments on our assumptions. For pharmacy management system vendors and switches, we believe 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 Version 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 final rule suggested that even those minor levels of savings (1.1 percent of pharmacist time) may have been overestimated.[24] 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.[25] 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 did not receive any comments on our estimates

[24] 74 FR 3320 (January 16, 2009).

[25] 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.*

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 will likely be dispensed by a small percentage of pharmacies, so the benefits will likely not be generally applicable to all pharmacies.

Pharmacy and pharmacy vendor commenters to the NCVHS noted that other types of changes will benefit patients by enhancing pharmacy and payer patient care workflows through the replacement of many clinical free text fields with discrete codified fields. This will 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 will support better patient care and safety through more accurate patient identification and enhanced availability and routing of benefit and DUR information. For instance, new response fields for DUR messaging and Formulary Benefit Detail help to convey clinical information such as disease, medical condition, and formulary information on covered drugs. This will enable pharmacists to have more informative discussions with patients and provide valuable information about alternative drug or therapy solutions. We believe that some of this data exchange will eliminate manual processes and interruptions and will 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 will allow pharmacies to improve the accuracy and quality of their services 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 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.[26] 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 solicited comments on whether there were significant quantifiable benefits or cost savings that should be included in our analysis and did not receive any feedback on our assumptions.

5. Adoption of Batch Standard Subrogation Implementation Guide, Version 10

a. Introduction

As mentioned earlier, Version 3.0 was adopted to support Federal and State requirements for State Medicaid agencies to seek reimbursement, when they had made payment first, from the correct responsible health plan. We proposed to replace Version 3.0 with Version 10 as the standard for Pharmacy subrogation transactions at § 162.1902(b). We indicated that, for State Medicaid agencies, adopting Version 10 would be a modification from Version 3.0. We proposed to adopt Version 10 for all health plans based on industry stakeholders' reports that there was a need to expand the use of the subrogation transaction because the adopted standard only applied to State Medicaid agencies and did not address the business needs for non-Medicaid agencies such as Medicare Part D, State assistance programs, or private health plans that would seek similar reimbursement. Stakeholders also stated that a broader subrogation transaction 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.

However, in this final rule we have decided that we will adopt Version 10 but will only require State Medicaid agencies, not all health plans, to use it.

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 state Medicaid agencies managed this activity directly,[27] 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 most of the business volume concentrated in one firm.

Based on a CAMH environmental scan conducted with industry representatives, we understand that the

[26] 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.*

[27] 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/.*

demand for subrogation today differs by third-party line of business. 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.

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, Version 15. Based on conversations with industry representatives familiar with the subrogation standards, we understand that the changes in Batch Standard Subrogation 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 sponsors. The changes between Version 3.0 and Version 10 are not extensive, so we believe this change will not have significant effects on State Medicaid agencies or their vendors.

We also believe that health plans that desire to pursue prescription drug claim subrogation have already contracted with PBMs or other contractors that have implemented Version 3.0, or some variation on this standard, on a voluntary basis. However, testimony provided at 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 while implementing Version 10. As with PBM and vendor contractual arrangements discussed previously, we assume that HIPAA standard conversions have been priced into ongoing contractual payment arrangements and will not increase costs to third-party payers as a result of converting to Version 10. We solicited comments to help us understand the impacts of converting to Version 10 on State Medicaid agencies or any health plans that have not previously implemented NCPDP batch standards and/or Subrogation Version 3.0. We also solicited 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 and did not receive any comments.

Based on conversations with industry representatives, we further understand that health plans already engaged in subrogation, particularly Part D PBMs. Version 10 provides more requirements for use of the standard and how to populate the fields to increase standardization.

(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 Version 3.0 today, and will 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 believe these vendors will incur a minority of the costs associated with the Version F6 conversion and some internal data remapping expense. Table 7 summarizes the other vendor costs of conversion over the 3-year implementation period. In the November 2022 proposed rule, we estimated that 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. We did not receive any comments based on our assumptions; and therefore, we are finalizing the other vendor costs.

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 health care memberships across the country have multiple insurance coverage. By using national drug expenditures, the volume of claim reconciliation and savings opportunities could easily exceed a billion dollars and the need for this subrogation standard is critical for effective processing (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 [28] suggested there is not a huge cost savings opportunity left for commercial subrogation but, instead, an occasional need that will be facilitated by a standardized approach. We did not receive comments to quantify the incremental benefits of extending Version 10.

(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 solicited but did not receive any comments to help us understand the extent to which the adoption of Version 10 may affect pharmacies.

E. 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 believe that 104 affected entities will incur these costs, as they are the entities that will have to implement the adopted 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 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. Using the Occupational Employment and Wages for May 2022 from the BLS for lawyers (Code 23–1011) and computer and information system managers (Code 11–3021),[29] we believe that the national average labor costs of reviewing this rule are $100.47 and $99.93 per hour, respectively, including other indirect costs and fringe benefits. We believe that it will take approximately 4 hours to review this rule. The estimated costs per entity would therefore be $1,603.20 (4 hours each × 2 staff × $100.47 plus 4 hours × 2 staff × $99.93), and the total cost borne by the 104 affected entities would be $166,733 ($1,603.20 × 104 affected entities), which sums to $1 different from the identical math at section V.A. because the two calculations are rounded separately.

F. Accounting Statement and Tables

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-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. Monetary annualized non-budgetary costs are presented at the 2 percent discount rate.

TABLE 8—ACCOUNTING STATEMENT

[Classification of estimate costs and benefits from FY 2024 to FY 2033 ($ in millions)]

Category	Primary estimate	Source
Qualitative (un-quantified benefits)	Wider adoption of standards; increased productivity due to decrease in manual processing; reduced delays in patient care.	RIA.
Annualized monetized costs: * 2% Discount	$97	RIA.

* 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.

G. Regulatory Flexibility Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. Furthermore, the economic impact assessment of small entities is based on HHS's practice in interpreting the RFA to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. Using the 2022 SBA small business size regulations and Small Business Size Standards by NAICS Industry tables at 13 CFR 121.201, we have presented in Table 9 the covered entities and their vendors affected by this final rule.

TABLE 9—SBA SIZE STANDARDS FOR APPLICABLE NAICS INDUSTRY CODES

NAICS code	NAICS U.S. industry title	SBA size standard ($ in millions)
456110	Pharmacies and Drug Stores	37.5
524114	Direct Health and Medical Insurance Carriers (Health Plans)	47.0
621491	HMO Medical Centers (Health Plans)	44.5
524292	Third Party Administration of Insurance and Pension Funds (PBMs)	45.5
541512	Computer Systems Design Services (Pharmacy Management System Vendors)	34.0

[28] 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/.*

[29] Bureau of Labor Statistics. May 2022 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 9/12/2023 at: *https://www.bls.gov/oes/current/oes113021.htm#top.*

TABLE 9—SBA SIZE STANDARDS FOR APPLICABLE NAICS INDUSTRY CODES—Continued

NAICS code	NAICS U.S. industry title	SBA size standard ($ in millions)
518210	Data Processing, Hosting, and Related Services (Telecommunication Switches)	40.0
524298	All Other Insurance Related Activities (Payment Integrity/Financial Recovery)	30.5

This change in retail pharmacy transaction standards will apply to many small, covered entities in the Pharmacy and Drug Store segment (NAICS code 456110). 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 adopted 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 belief is 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.[30] A firm consists of one or more establishments under common ownership. An establishment consists of a single physical location or permanent structure.[31] 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 solicited industry comments on these assumptions and did not receive any.

1. Number of Small Entities

Based on the CAMH environmental scan that found a total of 19,234 total pharmacy firms, we believe 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 do 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 believe 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 $70.69 billion and average annual receipts of $3.7 million per firm. This is well below the SBA standard of $37.5 million. By contrast, the 190 firms with 500 or more employees represented 27,123 establishments and accounted for over $210.97 billion in annual receipts, and thus, average annual receipts of $1.1 billion. Therefore, we believe 19,044 pharmacy firms qualify as small entities for this analysis.

In 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 believe 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 $44.5 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 will generally bear costs associated with the changes in this final rule, as their contracted transaction processing vendors (generally PBMs) will be responsible for implementing the changes, and, generally, based on conversations with the industry, we do not believe their contractual terms will 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 will bear costs attributable to the 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 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 solicited comments with respect to our assumptions and did not receive any feedback.

2. Cost to Small Entities

To determine the impact on small pharmacies, we used data obtained in the development of the CAMH environmental scan 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 assumed that the clear majority of pharmacy firms are small entities that

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

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

rely on their contracted pharmacy management system vendors to absorb HIPAA standard version conversion costs in return for ongoing maintenance and transaction fees. We believe that pharmacy firms will have direct costs related to Version F6 user training and that it will vary in relation to employee size; that the vast majority (89 percent) of small pharmacy firms with fewer than 20 employees will receive all necessary user training from vendors; and that the remaining 10 percent of small pharmacy firms (2,028) with 20 or more employees will have additional staff user training expense totaling $30,000 on average in the second year of the implementation period. As shown in Table 10, the overall impact on small covered entity pharmacies and drugstores (NAICS 446110) with less than 500 employees reflects an estimated cost percentage of revenue per firm of 0.81 percent. Pharmacies and drug stores with less than 500 employees represent approximately 99 percent of all pharmacies and drug stores, including large pharmacies and drug stores with greater than 500 employees. Further analysis shows that pharmacies and drugstores with less than 100 employees represent 98 percent of all pharmacies and drugstores. These pharmacies and drugstores, with less than 100 employees, are estimated to have a cost percentage of revenue per firm of 0.86 percent. Also, pharmacies and drugstores with less than 20 employees represent 89 percent of all pharmacies and drugstores. These pharmacies and drugstores, with less than 20 employees, are estimated to have a cost percentage of revenue per firm of 1.10 percent. The highest cost percentage of revenue per firm of 2.25 percent is estimated to impact pharmacies and drugstores with less than 5 employees, which represents 36 percent of all pharmacies and drugstores. All other small entity pharmacy and drugstore enterprise sizes show a cost percentage of revenue per firm below 1 percent. Therefore, as shown in Table 10, the implementation cost of this final rule on small, covered entity pharmacies and drugstores falls below HHS's practice in interpreting the RFA to be economically ''significant,'' since it does not reach the threshold of 3 to 5 percent or more of total revenues.

TABLE 10—ANALYSIS OF THE IMPLEMENTATION COST ON SMALL COVERED ENTITY PHARMACIES AND DRUG STORES
[NAICS 446110]

Enterprise size	Firms	Receipts ($1,000)	Cost percentage of revenue per firm
<5 employees	6,940	9,232,985	2.25
5–9 employees	5,776	16,700,443	1.04
10–14 employees	2,963	12,978,849	0.68
15–19 employees	1,337	7,599,680	0.53
<20 employees (separate category)	17,016	46,511,957	1.10
20–24 employees	661	4,673,350	0.42
25–29 employees	380	3,464,669	0.33
30–34 employees	224	2,324,169	0.29
35–39 employees	151	1,759,613	0.26
40–49 employees	204	2,610,831	0.23
50–74 employees	185	2,942,040	0.19
75–99 employees	77	1,509,958	0.15
<100 employees (separate category)	18,898	65,796,587	0.86
100–149 employees	59	2,060,372	0.09
150–199 employees	28	806,821	0.10
200–299 employees	33	1,190,264	0.08
300–399 employees	15	480,045	0.09
400–499 employees	11	353,254	0.09
<500 employees (separate category)	19,044	70,687,343	0.81

Source: Census Bureau. 2017 Economic Census.

As stated in section V.F. of the November 2022, proposed rule, we outlined the various alternative policy considerations 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 that alternative because pharmacies, PBMs, and health plans all rely on the information transmitted through the retail pharmacy transactions, and if any one of these three entities will 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 through the claims data to maintain the beneficiaries' most current benefits.

3. Conclusion

As referenced earlier in this section, the RFA is considered economically significant only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We conclude that the cost impact from this final rule on small pharmacy entities does not exceed this threshold. In Table 10, we illustrate that small covered entity pharmacies and drugstores with less than 500 employees may experience a cost percentage of revenue per firm of 0.81 percent, pharmacies and drugstores with less than 100 employees may experience a cost percentage of revenue per firm of 0.86 percent, pharmacies and drugstores with less than 20 employees may experience a cost percentage of revenue per firm of 1.10 percent, and finally pharmacies and drugstores with less than 5 employees may experience a cost percentage of 2.25 percent. Based on the foregoing analysis, we invited public comments on the analysis and requested any additional data that would help us determine more accurately the impact on the various categories of entities affected by this final rule but did not receive any. Therefore, the Secretary has certified that this final rule will not

have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. 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 2024, that threshold is approximately $183 million. This final rule does not contain unfunded mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, in excess of more than $183 million in any 1 year. In general, each State Medicaid agency and other government entity that is considered a covered entity will 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 will 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.

I. 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 final rule will 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 will be converting to a modified version of an existing standard with which they are already familiar, we believe that any conversion costs, will, generally, be priced into the current level of ongoing contractual payments. State Medicaid agencies, in accordance with this final rule, will 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 final rule will not add a new business requirement for States, but rather will update a version of the standard to use for this purpose that will be used consistently by all health plans.

J. Alternatives Considered

As stated in the November 2022 proposed rule (87 FR 67643), we considered a number of alternatives to adopting Version F6 and Version 10 and chose to proceed with the provisions 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 workarounds that increase burden and are contrary to standardization. We also believe that the number of, and use of, these workarounds will continue to increase if we do not adopt Version F6. Therefore, we choose not to proceed with these alternatives because we believe the adoption of Version F6 would support interoperability and improve patient outcomes.

In the November 2022 proposed rule, we considered proposing a compliance date longer than 24 months for covered entities to comply with Version F6. However, we chose to propose a 24-month compliance date with an 8-month transition period based on industry suggestions for implementing Version F6 as soon as possible in a manner that would be more feasible. 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 pic in pharmacy subrogation transactions to continue using the proprietary electronic and paper formats currently in use. We chose not to proceed with this alternative due to industry concerns regarding uniformity among all payers.

Finally, based on industry feedback, in this final rule, we decided to adopt the standards proposed in the November 2022 proposed rule with a compliance date of 3 years after the effective date. The compliance timeframe will include an 8-month transition. However, we are not requiring the use of Version 10 (Medicaid subrogation) for all health plans.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 7, 2024.

List of Subjects in 45 CFR Part 162

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

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

PART 162—ADMINISTRATIVE REQUIREMENTS

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

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

■ 2. Section 162.920 is amended by—

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

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

The revision 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 Department of Health and Human Services (the Department) 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 the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786–6597; email: *administrativesimplification@cms.hhs.gov*. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*. The material may be obtained from the following sources:

* * * * *

(b) *Retail pharmacy specifications and Medicaid pharmacy subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction 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 *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. The transaction implementation specifications are as follows:

* * * * *

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

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

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

■ 3. Section 162.1102 is amended by—

■ a. In paragraph (c), by 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 August 11, 2027,'';

■ b. In paragraph (d), by 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 August 11, 2027,''; and

■ c. Adding paragraphs (e) and (f).

The additions read as follows:

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

* * * * *

(e) For the period from August 11, 2027 through February 11, 2028, both of the following:

(1) The standards identified in paragraphs (c) and (d) of this section.

(2) The following standards:

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

(ii) *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 (both incorporated by reference in § 162.920).

(iii) *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 in § 162.920).

(iv) *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 (both incorporated by reference in § 162.920).

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

(f) For the period on and after February 11, 2028, the standards identified in paragraph (e)(2) of this section.

■ 4. Section 162.1202 is amended by—

■ a. In paragraph (c), by 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 August 11, 2027,''; and

■ b. Adding paragraphs (d) and (e).

The additions read as follows:

§ 162.1202 Standards for eligibility for a health plan transaction.

* * * * *

(d) For the period from August 11, 2027 through February 11, 2028, both of the following:

(1) The standards identified in paragraph (c) of this section.

(2) The following standards:

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

(ii) *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 in § 162.920).

(e) For the period on and after February 11, 2028, the standards identified in paragraph (d)(2) of this section.

■ 5. Section 162.1302 is amended by—

■ a. In paragraph (c), by 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 August 11, 2027,'';

■ b. In paragraph (d), by 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 August 11, 2027''; and

■ c. Adding paragraphs (e) and (f).

The additions read as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(e) For the period from August 11, 2027 through February 11, 2028, both of the following:

(1) The standards identified in paragraph (c) and (d) of this section.

(2) The following standards:

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

(ii) *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 (both incorporated by reference in § 162.920).

(f) For the period on and after February 11, 2028, the standards identified in paragraph (e)(2) of this section.

■ 6. Section 162.1802 is amended by—

■ a. In paragraph (c), by 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 August 11, 2027'';

■ b. In paragraph (d), by 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 August 11, 2027''; and

■ c. Adding paragraphs (e) and (f).

The additions read as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(e) For the period from August 11, 2027 through February 11, 2028, both of the following:

(1) The standards identified in paragraphs (c) and (d) of this section.

(2) The following standards:

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

(ii) *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 (both incorporated by reference in § 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 in § 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 in § 162.920).

(f) For the period on and after February 11, 2028, the standards identified in paragraph (e)(2) of this section.

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

§ 162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the following standards for the Medicaid pharmacy subrogation transaction:

(a) For the period from January 1, 2012 through August 11, 2027—The NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, July 2007 (incorporated by reference at § 162.920).

(b) For the period from August 11, 2027 through February 11, 2028—

(1) The standards identified in paragraph (a) of this section; and

(2) The NCPDP Subrogation Implementation Guide for Batch Standard, Version 10, September 2019 (incorporated by reference at § 162.920).

(c) For the period on and after February 11, 2028, the standard identified in paragraph (b) of this section.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–29138 Filed 12–12–24; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Parts 302, 303, 304, and 309

RIN 0970–AD00

Employment and Training Services for Noncustodial Parents in the Child Support Program

AGENCY: Office of Child Support Services (OCSS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS or the Department).

ACTION: Final rule.

SUMMARY: In an effort to make the child support program more effective, OCSS (or the Office) issues this final rule to allow State and Tribal child support agencies the option to use Federal financial participation (FFP) available under title IV–D of the Social Security Act to provide the following employment and training services to eligible noncustodial parents: job search assistance; job readiness training; job development and job placement services; skills assessments; job retention services; work supports; and occupational training and other skills training directly related to employment.

DATES: This rule is effective on January 13, 2025.

FOR FURTHER INFORMATION CONTACT: Chad Edinger, Program Specialist, OCSS Division of Regional Operations, at mail to: *ocss.dpt@acf.hhs.gov* or (303) 844–1213. Telecommunications Relay users may dial 711 first.

SUPPLEMENTARY INFORMATION:

Statutory Authority

This rule is published under the authority granted to the Secretary of Health and Human Services by section 1102 of the Social Security Act (the Act) (42 U.S.C. 1302). Section 1102 of the Act authorizes the Secretary to publish regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is responsible under the Act.

This rule is also authorized by sections 452(a)(1) and 454(13) of the Act (42 U.S.C. 652(a)(1) and 654(13)). Section 452(a)(1) of the Act expressly delegates authority to the Secretary's designee requiring the designee to ''establish such standards for State programs for locating noncustodial parents, establishing paternity, and obtaining child support . . . as he