January 3, 2023

Submitted electronically via https://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-0056-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-45 CFP Part 162, CMS-0056-P Proposed Rule – Comments

Dear Center for Medicare and Medicaid Services:

NCPDP is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the CMS-45 CFR Part 162; CMS-0056-P Proposed Rule.

NCPDP agrees the adoption of the NCPDP Telecommunication Standard Version F6 and Batch Standard Implementation Guide Version 15 will provide the benefits outlined by HHS and improve patient care. However, NCPDP recommends HHS name Telecommunication Standard Version F7 and Batch Standard Version 15 for healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and coordination of benefits (COB). Telecommunication Version F7 is necessary to align with regulatory and healthcare needs by creating the distinction between administrative gender and clinical sex at birth. Additional information is provided in the comments beginning on page three.

NCPDP also agrees with the adoption of NCPDP Batch Standard Subrogation Implementation Guide Version 10. However, the NCPDP DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard.

Additionally, NCPDP requests the compliance date be set 44-months after the final rule effective date for all covered entities to be supporting NCPDP Telecommunication Standard Version F7, Batch Standard Version 15 and Batch Standard Subrogation Implementation Guide Version 10. As outlined in the detailed comments on pages three to 17, the volume, complexity and co-dependency of the enhancements within

these Standards require an appropriate implementation period to ensure the objectives are delivered without impacting patient access to care.

NCPDP stands ready to assist the Office of Burden Reduction and Health Informatics (OBRHI) - National Standards Group (NSG) in the support of the next round of HIPAA. Thank you for the opportunity to respond to this NPRM.

For direct inquiries or questions related to this letter, please contact

Margaret Weiker
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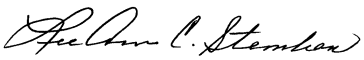
Sincerely,



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I. Executive Summary

B. Summary of the Major Provisions (page 67635)

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

NCPDP Response:

Please address the following typographical and content reference errors within the Final Rule:

- 'ruled' should be 'rule'
- 'NCPDP Pharmacy Subrogation Implementation Guide, Version 10' should be 'NCPDP Batch Standard Subrogation Implementation Guide Version 10'
- Remove 'for non-Medicaid health plans,', as the NCPDP Batch Standard Subrogation Implementation Guide is for Medicaid and non-Medicaid subrogation

As additional clarification to the NCPDP changes for subrogation, the NCPDP DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard.

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

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

NCPDP Response:

The Batch Standard Subrogation Implementation Guide Version 10 is the proper name of the standard, not Pharmacy Subrogation Implementation Guide for Batch Standard.

NCPDP's DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard. However, moving Medicaid subrogation to the Batch Standard Subrogation Implementation Guide Version 10 would allow the first step of administrative simplification by aligning all subrogation processes with one common standard.

NCPDP adapted the Medicaid Subrogation Implementation Guide v3.0 to incorporate data elements and use cases required for subrogation initiated by non-Medicaid payers, resulting in the Batch Standard Subrogation Implementation Guide Version 10. NCPDP developed the more universal subrogation standard format that would allow (not mandate) non-Medicaid plans to subrogate while using nearly the same standard that has been successfully working for the Medicaid use case.

There is a critical difference between Medicaid subrogation and non-Medicaid subrogation. Medicaid subrogation is supported by defined payer order rules, where Medicaid is usually the payer of last resort. However, the broader healthcare industry currently lacks payer order rules for non-government-funded programs, e.g., a patient having coverage with multiple commercial plans. Making the Batch Standard Subrogation Implementation Guide v10 available (not mandated) for non-Medicaid subrogation situations will allow the pharmacy industry to determine if there are additional data elements, use cases, payer order rules and other guidance that may be necessary. Maintaining this flexibility would accelerate the adoption of electronic transactions to replace paper exchanges and the improvement of the standard for the greater variety of non-Medicaid subrogation.

As submitted within DSMO Request 1202, NCPDP requests the Subrogation Implementation Guide for Batch Standard Version 10 be named in HIPAA to replace the Medicaid Subrogation Standard Implementation Guide, Version 3.0 for Medicaid use only.

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

NCPDP Response:

The general reference to the compliance dates in this section of the preamble is confusing, as it does not align to the timelines with the Proposed Compliance Date section. Please refer to section C: *Proposed Compliance and Effective Dates for NCPDP* requested timeline comments.

C. Summary of Costs and Benefits (page 67635)

We estimate that the overall cost for pharmacies, pharmacy benefit plans, and chain drug stores to move to the updated versions of the pharmacy standards and the initial adoption of the pharmacy subrogation transaction standard would be approximately $386.3 million. The cost

estimate is based on the need for technical development, implementation, testing, initial training, and a 24-month compliance timeframe. We believe that HIPAA covered entities or their contracted vendors have already largely invested in the hardware, software, and connectivity necessary to conduct the transactions with the updated versions of the pharmacy standards.

NCPDP Response:

The NCPDP Strategic National Implementation Process (SNIP) committee, which has representation from all sectors of the pharmacy industry, has indicated new investments have not occurred yet. Companies typically rely on the release of the final rule before beginning the budgeting process for analysis and development. Many organizations have a calendar year fiscal cycle and budgets are approved before fourth quarter. Please refer to section C: *Proposed Compliance and Effective Dates for NCPDP* requested timeline comments.

III. Provisions of the Proposed Rule

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

3. Batch Standard, Version 15 (Version 15) for Retail Pharmacy Transactions ***(page 67638)***

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

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

NCPDP Response:

NCPDP agrees the adoption of Version F6 and Batch Standard Version 15 will provide the benefits outlined by HHS and improve patient care. However, NCPDP recommends HHS name Telecommunication Standard Version F7 and Batch Standard Version 15 for healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and COB. Telecommunication Version F7 is necessary to align with regulatory and healthcare needs by creating the distinction between administrative gender and clinical sex at birth.

In alignment with Health IT interoperability objectives, NCPDP and HL7® have identified the need to support both administrative gender and sex at birth data attributes within their standards. NCPDP Telecommunication Standard vF6 supports the Patient Gender Code (305-C5) field, used to support eligibility verification tied to enrollment processes, formulary coverage rules and clinical patient safety edits. In order to align with various state regulatory requirements as it relates to gender identity, "Non-Binary" was added as Patient Gender Code value and available for use under Telecommunication versions D.0 and F6. While the value of Non-Binary can be supported within eligibility verification processes, it creates a challenge with gender specific formulary rules and clinical patient safety edits. To address this gap, NCPDP added the Sex Assigned at Birth (F32-W8) field to Telecommunication Standard vF7.

The ONLY modification between Telecommunication Standard vF6 and vF7 is the addition of the Sex Assigned at Birth (F32-W8) field. NCPDP is required to move to a new version of a standard when a field is added. NCPDP believes there is minimal additional administrative and IT effort for stakeholders to include this new field within their enhancements without compromising expected timelines. NCPDP also believes not including this attribute within this current HIPAA version naming process will create significant gaps within healthcare interoperability. The pharmacy industry will be at a disadvantage if the Sex Assigned at Birth field is not available for multiple years. The NCPDP Telecommunication Standard Version F7 Implementation Guide may be obtained from the National Council for Prescription Drug Programs (NCPDP), 9240 East Raintree Drive, Scottsdale, AZ 85260; phone: (480) 477-1000; fax: (480) 767-1042; website: www.ncpdp.org.

At a minimum, NCPDP requests HHS name NCPDP Telecommunication Standard Version F6. However, NCPDP strongly recommends HHS recognize the critical need for the additional field of the Sex Assigned at Birth (F32-W8) field for interoperability and equity goals, as well as statutory and regulatory compliance. To that end, NCPDP requests HHS name NCPDP Telecommunication Standard vF7 (instead of naming vF6) within §§ 162.1102, 162.1202, 162.1302 and 162.1802 for use in healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and COB. NCPDP also requests HHS leverage the same compliance date and implementation timeline as NCPDP recommends in section C: *Proposed Compliance and Effective Dates* and not restart the HIPAA process to adopt a new version of the named standard.

B. Proposed Modifications of the Pharmacy Subrogation Transaction Standard for State Medicaid Agencies and Initial Adoption of the Pharmacy Subrogation Standard for Non-Medicaid Health Plans (page 67640)

1. Proposed Modification to the Definition of Medicaid Subrogation Transaction (page 67640)

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

request for reimbursement of a pharmacy claim from a health plan that paid the claim, for which it did not have payment responsibility, to the health plan responsible for the claim.

There are a few notable differences between the current and proposed transaction definitions. First, the current definition defines the transaction such that it only applies to state Medicaid agencies, in their role as health plans, as the sender of the transaction. Because we are proposing to broaden the scope of the transaction to apply to all health plans, not just state Medicaid agencies, the Pharmacy subrogation transaction definition would specify that the sender of the transaction is "a health plan that paid the claim" instead of a "Medicaid agency."

In addition, the current definition identifies that the sender of the transaction is requesting "reimbursement for a pharmacy claim the state has paid on behalf of a Medicaid recipient." To align this aspect of the current definition with the broadened scope that would apply to all health plans, the proposed definition identifies that the sender health plan has paid a claim "for which it did not have payment responsibility."

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

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

NCPDP Response:

NCPDP disagrees with broadening the scope of the Medicaid subrogation transaction as defined at § 162.1901. Maintaining the current terminology allows the industry to advance administrative simplification for non-Medicaid health plans by not imposing HIPAA restrictions and mandates.

NCPDP's DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard.

2. *Proposed Initial Adoption of the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, for Non-Medicaid Health Plans (page 67640)*

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

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

NCPDP Response:

NCPDP DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. Naming the Batch Standard Subrogation Implementation Guide Version 10 for non-Medicaid health plans impedes the industry advancement of administrative simplification by imposing HIPAA restrictions and mandates. NCPDP requests the scope of subrogation transactions remain specific to Medicaid Subrogation as defined in the 2009 Final Rule.

3. *Proposed Modifications of the Pharmacy Subrogation Transaction Standard for State Medicaid Agencies (page 64671)*

We are proposing to replace the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0, with the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10 as the standard for Pharmacy subrogation transactions at § 162.1902(b). For state Medicaid agencies, this proposal would be a modification from Version 3.0. While Version 10 is called the "Pharmacy Subrogation Implementation Guide" rather than the "Medicaid Subrogation Implementation Guide," Version 10 still applies to subrogation transactions originating from Medicaid agencies and preserves the data elements in Version 3.0

except in the following instances, the purpose of which is to accommodate non-Medicaid plans' use of the modified standard:

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

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

NCPDP Response:

Please incorporate within the Final Rule the below corrections to the document name, as well as the status and use of the data elements listed above.

Replace "NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10" with "NCPDP Batch Standard Subrogation Implementation Guide, Version 10."

The 'Not Used' situation within the NCPDP transaction matrices for the below two fields is specific to real-time non-subrogation transactions such as claim billing and eligibility. These fields are required in the Batch Standard Medicaid Subrogation Implementation Guide Version 3.0 and are retained for Medicaid situational use in the Batch Standard Subrogation Implementation Guide Version 10.

- Field 116-N6 – Medicaid Agency Number – A number assigned by the processor to identify the Medicaid benefit, coverage criteria, or Agency.
- Field 115-N5 – Medicaid ID Number – Unique ID Number the Medicaid Agency assigns to the member. This information may be required on the claim when one of the subrogation trading partners is Medicaid.

The below fields available for use in the Batch Standard Medicaid Subrogation Implementation Guide Version 3.0 were sunset and replaced by other fields in the Batch Standard Subrogation Implementation Guide Version 10:

- Field 114-N4 – Medicaid Subrogation Internal Control Number/Transaction Control Number (ICN/TCN) – is replaced with the Reconciliation ID (B98-34) and will be used to represent the Medicaid unique claim identification number. This information is required on the claim submitted and the response received for the original adjudicator to identify the claim within their system. The information would be echoed in the Subrogation Requestors Reconciliation ID (D15-KY) field.
- Field 113-N3 – Medicaid Paid Amount is replaced with the Subrogation Amount Requested (D14-KX) to represent the amount paid by the Original Adjudicator.

NCPDP supports the adoption of the NCPDP Batch Standard Subrogation Implementation Guide Version 10 under § 162.1902(b) as a replacement to the NCPDP Medicaid Subrogation Implementation Guide Version 3.0 for Medicaid Subrogation.

NCPDP's DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard. However, moving Medicaid subrogation to the Batch Standard Subrogation Implementation Guide Version 10 would allow the first step of administrative simplification by aligning all subrogation processes with a common standard.

NCPDP requests covered entities have the ability to begin using Batch Standard Subrogation Implementation Guide v10 for non-Medicaid subrogation without violating the HIPAA mandate that only the single named version is permitted. Maintaining this flexibility would accelerate the adoption of electronic transactions to replace paper exchanges and the improvement of the standard for the greater variety of non-Medicaid subrogation.

C. Proposed Compliance and Effective Dates

1. Proposed Compliance Date for Version F6 and Version 15 (page 67641)

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

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

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

After carefully considering the NCVHS's recommended implementation timelines and dates, for the following reasons we are not proposing a 3-year pre-implementation compliance window or an 8-month transition period. While industry feedback on which the NCVHS relied to make its recommendations did include some discussion on specific changes necessary to implement Version F6 (for example, the expansion of the financial fields), the majority of feedback was not specific to Version F6, but, rather, concerned general challenges that would be associated with implementing any standard modification. For example, feedback related to concerns about general budget

constraints, as well as compliance dates that conflict with other pharmacy industry priorities such as the immunization season or times of year where prescription benefits plans typically experience heavy new member enrollment. In addition, several industry stakeholders, including the NCPDP, stated that they were not aware of any significant implementation barriers specific to Version F6. In its May 17, 2018 letter industry testimony asserted, and the NCVHS agreed, that the process to implement Version F6 would be similar to the process necessary to implement Version F2. Therefore, we are proposing a 24-month compliance timeframe that aligns with the recommendation that the NCVHS made in its May 17, 2018 letter to implement Version F2.

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

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

NCPDP Response:

NCPDP agrees with HHS to implement the requested versions of the Telecommunication and Batch Standards as soon as possible to take advantage of the significant improvements. As outlined above in section A: *Proposed Modifications to NCPDP Standards*, NCPDP requests HHS name Telecommunication Standard Version F7 within §§162.1102, 1621202, 162.1302 and 162.1802 for use in healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and COB. The following comments related to the implementation period and compliance dates are not impacted by the request to name Version F7 over Version F6. NCPDP does not agree with the compliance date, 24 months from the date of the Final Rule as proposed by HHS. NCPDP requests a compliance date 44 months after the effective date of the final rule. This recommendation is based on NCPDP and stakeholder testimony addressing the major changes between version D.0 and F2, then F6.

While this is a change to an existing named standard, it is important to call out the number and complexity of changes that have been necessary to meet rapidly changing healthcare business and regulatory needs since Telecommunication Standard Version D.0 was published. Just from a data element and structural transaction perspective, there were less than 100 data element changes between Telecommunication Version 5.1 and D.0, and over 300 data element changes between Version D.0 and F7. As a reminder, there is only one data element change between Version F6 and F7. The changes between Versions D.0 and F7 impact many claims processing conditions such as transaction routing, pricing, controlled substances, compounds, Medicare Part D Long Term Care dispensing frequencies, 340B, COB, Medicare eligibility responses, reversals and codified plan benefit

detail. The November 2022 NCPDP Telecommunication Educational Summit provides an overview of these major changes. These presentations may be obtained from the National Council for Prescription Drug Programs (NCPDP), 9240 East Raintree Drive, Scottsdale, AZ 85260; phone: (480) 477-1000; fax: (480) 767-1042; website: www.ncpdp.org.

The addition and removal or change in use of data elements not only requires changes to the electronic transaction, but also requires expansion of internal data bases to store the data and business rules that determine when and how to use the data elements within the claim adjudication process. This requires extensive internal IT development and testing, before trading partner testing, certification and production exchange can occur in real-time.

It is also important to note the complexity associated to a number of the data element changes. One of the major impacts to transitioning to Version F7 that was not a concern with Version D.0, is the number of ancillary system and processes impacted by data element changes. These changes to the Telecommunication transactions were the result of business processes outside of the prescription claim adjudication process. For example, as a result of the evolution of new drug therapies all pricing fields were expanded to support dollar amounts up to $999,999,999.99. This change requires stakeholders to ensure real-time pricing logic accuracy across the 31 expanded pricing fields, recognize when the ninth digit may be missing, increase database capacity to store the expanded field length and update any internal or external claim data exchange processes. In addition to the expanded length of the pricing fields, enhancements were made to tax/regulatory fees. Also, 13 distinct patient pay fields were deleted and moved into one qualified repeating field. The coding to transfer accurate pricing data to designated entities will require additional time where extensive testing will be imperative. These changes are particularly critical to Medicare Part D COB claims processing. If the pricing fields associated to COB transactions are not handled correctly, the impact to Medicare Part D beneficiaries will be incorrect co-insurance and True Out-of-Pocket (TrOOP) calculations.

Another example is with the change to the Bank Identification Number (BIN), now called Issuer Identifier Number (IIN). The IIN's primary use in Telecommunication transactions is transaction routing. It determines which entity will receive the transaction request for processing. In Version D.0, the IIN is a fixed length of six-digits. International Organization for Standardization (ISO) standards were updated in 2017 to expand the IIN to eight-digits to avoid running out of IINs. Since the IIN used for transaction routing is a mandatory fixed length field, the transition to eight digits will occur with the new version of the standard. This impacts the Header Segment of the NCPDP transactions. The fixed format of the header segment which has been in place since 2002 when HIPAA named Telecommunication Standard Version 5.1 is changing to support the increased size of the IIN. The testing to ensure trading partners can exchange this data is significant, ensuring protected health information (PHI) is only disclosed to the intended entity. If the IIN is not implemented and tested properly, transactions will reject at point of service which will delay patient access to care. The change in the IIN format also impacts eligibility inquiry transactions as IIN is a component of the critical 4RX for these services. IIN, Processor Control Number, Group ID and Cardholder ID make up the 4RX data returned on eligibility transaction responses. This information is also included in the Third-Party Liability files used by Medicaid programs to identify other payer information for point of service coordination of benefits claims and subrogation processes. Routing of the Telecommunication Standard information reporting transaction as well as the Financial

Information Reporting Standard transactions will also be impacted by the changes to the IIN. All of the impacted systems will need to be updated to recognize, consume and map eight-digit IINs to former six-digit IINs to ensure accuracy of real-time data exchange. The changes to the IIN will also impact beneficiary ID cards, where health plans and Medicaid programs will need to ensure their IIN is accurately reflected and available to beneficiaries as of the transition to the updated version.

While there are several other data element changes that will incur similar implementation complexity, NCPDP believes the above detail explains the need for the compliance date to be 44-months from the final rule effective date. This offers stakeholders time to coordinate business decisions and budgets, IT development and internal testing, external testing and certification, and then begin production deployment.

Due to the number of providers and processor/payers in the pharmacy industry, trading partner software certification and production deployment can take eight months to complete. This allows trading partners to identify gaps within specific use cases, requiring recoding and testing efforts prior to the compliance date. During this period, trading partners may need to revert to Telecommunication Standard Version D.0 to ensure patient access to care.

In addition to the significant level of effort associated to new versions of these HIPAA named standards, the pharmacy industry will be challenged with coordinating budgets, resources and timing for the NCPDP SCRIPT and Real Time Pharmacy Benefit Standards as proposed under CMS-4201-P Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare, RIN 0938-AU96.

NCPDP requests the compliance date be set 44 months after the final rule effective date for all covered entities to be supporting NCPDP Telecommunication Standard Version F7 and Batch Standard Version 15.

2. *Proposed Compliance Dates for the Batch Standard Subrogation Implementation Guide, Version 10 (Version 10), September 2019, National Council for Prescription Drug Programs (page 67642)*

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

We are proposing to align the compliance dates for state Medicaid agencies and all other health plans (except small health plans) to comply with Version 10. Should we not to do this, some health plans would need to use Version 10 at the same time as state Medicaid agencies in order to conduct Pharmacy subrogation transactions with those state Medicaid agencies, while other health plans could use different standards. Aligning the compliance timeframes would reduce

confusion and administrative burden that would arise were there concurrent standards in effect. Thus, we propose to require all health plans (except small health plans) to comply at the same time. The alignment of compliance dates also makes it more feasible for state Medicaid agencies and non-Medicaid health plans to invest in system upgrades to accommodate one specific standard rather than divide resources to maintain two concurrent transaction standards. Therefore, we propose to revise §162.1902(b) to reflect that all health plans, except small health plans, would be required to comply with Version 10 for Pharmacy subrogation transactions 24 months after the effective date of the final rule. We would also revise § 162.1902(a) to reflect that state Medicaid agencies would be required to comply with the current standard, Version 3.0, until the compliance date of Version 10.

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

NCPDP Response:

NCPDP's DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard. The implementation timeline for Batch Standard Subrogation Implementation Guide Version 10 needs to align with the timeline adopted for the Telecommunication Standard Version F7 implementation.

D. *Proposed Incorporation by Reference (page 67642)*

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

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

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

The materials we propose to incorporate by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, 21244-1850. Copies may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477-1000; FAX (480) 767-1042. They are also available through the Internet at https://www.ncpdp.org. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of

other publishers of standards. If we wish to adopt any changes in this edition of the Code, we would submit the revised document to notice and comment rulemaking.

NCPDP Response:

NCPDP requests the following NCPDP Standards be incorporated by reference:

(1) Telecommunication Standard Version F7
(2) equivalent Batch Standard Implementation Guide Version 15
(3) Batch Standard Subrogation Implementation Guide Version 10

NCPDP also clarifies the Telecommunication Standard Implementation Guide, Version F7 contains the formats, billing units, and operating rules used for real-time pharmacy claims submission. Implementation guides do not contain the Data Dictionary.

NCPDP requests the incorporation by reference of the Batch Standard Subrogation Implementation Guide Version 10 for the Medicaid subrogation transaction as defined by HHS in its 2009 final rule.

V. Regulatory Impact Analysis

D. Anticipated Effects

2. Adoption of Version 10

d. Benefits

(2) Pharmacies (page 67655)

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.

NCPDP Response:

NCPDP's DSMO Request 1202 is specific to naming the Batch Standard Subrogation Implementation Guide Version 10 as the replacement to the currently named Batch Standard Medicaid Subrogation Implementation Guide Version 3.0. NCPDP is not looking to change the business case for Medicaid subrogation purposes or requesting CMS alter the scope of the transactions it defined in the 2009 Final Rule when naming the initial subrogation standard. However, moving Medicaid subrogation to the Batch Standard Subrogation Implementation Guide Version 10 would allow the first step of administrative simplification by aligning all subrogation processes with a common standard. NCPDP believes pharmacies are not impacted by subrogation as it is a transaction exchanged between payers.

E. Alternatives Considered (page 67655)

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

One alternative we considered was to not propose to adopt Version F6 and continue to require the use of Version D.0. We also considered waiting to adopt Version F6 at a later date since we recently published a final rule in 2020 modifying the requirements for the use of Version D.0 by requiring

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

NCPDP Response:

NCPDP agrees with HHS that the use of Telecommunications Standard Version D.0 work arounds to support current business and regulatory needs is inefficient, burdensome and creates risk for unintended errors that impact the patient. While drug therapies in excess of $1 million is one of the major changes since version D.0, it is important to call out the IIN used for claim transaction routing requires a new version to be named to support the necessary changes to the Header Segment. The current work arounds for the IIN increased length are not sustainable and will result in claim routing errors and unresolved point of care rejections. As noted previously, NCPDP recommends Telecommunication Standard Implementation Guide Version F7 be named, to support harmonization with other healthcare standards, comply with gender identity regulatory requirements and maintain the necessary clinical review processes related to Patient Gender Code (305-C5) and Sex Assigned at Birth (F32-W8) code values.

We also chose not to proceed with these alternatives because, as discussed in section III.A. of this proposed rule, we believe adoption of Version F6 would support interoperability and improve patient outcomes.

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

NCPDP Response:

NCPDP agrees with HHS to adopt the requested versions of the Telecommunication and Batch Standards as soon as possible to take advantage of the significant improvements. As outlined above in section A: *Proposed Modifications to NCPDP Standards*, NCPDP requests HHS name Telecommunication Standard Version F7 within §§162.1102, 1621202, 162.1302 and 162.1802 for use in health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and COB.

The following comments related to the implementation period and compliance dates are not impacted by the request to name Version F7 over Version F6.

NCPDP does not agree with the compliance date, 24 months from the date of the Final Rule as proposed by HHS. NCPDP requests a compliance date 44 months after the effective date of the final rule. This recommendation is based on NCPDP and stakeholder testimony addressing the major changes between version D.0 and F2, then F6.

In summary, NCPDP requests the adoption of the below NCPDP Standards versions for retail pharmacy transactions and Medicaid subrogation, with a compliance date 44 months from the Final Rule Effective Date:

(1) Telecommunication Standard Version F7:
For: healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and coordination of benefits

(2) Equivalent Batch Standard Implementation Guide Version 15
For: healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and coordination of benefits

(3) Batch Standard Subrogation Implementation Guide Version 10
For: Medicaid Subrogation