NCVHS Hearing
Industry implementation of new HIPAA Standards
NCPDP Telecommunication Standard Version F.2, NCPDP Batch Standard Implementation Guide Version 15
and Subrogation Implementation Guide for Batch Standard Version 10
https://www.ncpdp.org/NCPDP/media/pdf/StandardsMatrix.pdf

Questions for testifiers on the NCPDP proposals. Additional details on return on investment and burden reduction may be provided in written testimony.

Telecommunications vF2 Questions:
Please incorporate answers to the questions below as they pertain to your business or industry.

1. What are the anticipated changes to the administrative, technical, business, operational, or workflow processes when the new standard becomes mandatory for use?
   ➤ *While vF2 leverages the technical foundation established within NCPDP Telecommunication vD0, there are some enhancements that will require coordination across various business processes to facilitate a seamless transition. For example:*
      ▪ *Administrative processes may include contractual negotiations as they relate to enhanced methods of billable services such as medication compounding. Administrative processes will also be impacted though pro-active coordination in identifying lines of business as they will relate to the Adjudicated Program Type data element.*
      ▪ *Changes in technical processes will be based on trading partner business agreements as well as support of mandatory data elements and regulatory requirements. For example, payers will be required to return the Adjudicated Program Type, where the pharmacy would submit this information to downstream payers. However, based on pharmacy business decisions, additional technical changes could be incorporated to improve workflow processes and patient outcomes. It's important to note, that from a pharmacy perspective, we need to be ready to support the technical solutions for all business cases/situations added to vF2, to which any of our trading partners may implement.*
      ▪ *The level of operational changes would be dependent on each entities business needs. Many of the major components of the vF2 standard are the result of business needs brought forward by specific stakeholders, but gained support of the industry through the consensus building process.*
      ▪ *Workflow processes will benefit from vF2, where manual steps could be replaced with automation. This ties to the business decisions and level of technical changes that can be supported within the budget.*

2. What are the anticipated benefits to business, operational or workflow processes of implementing this new version of the pharmacy standard?
   ➤ *As outlined by NCPDP SNIP, and based on the level of business and technical changes incorporated through project implementation, below are benefits from vF2 enhancement examples:*

Enhancement	Benefits
1. *New Claim Segment fields to better support controlled substance claims processing. Improved transparency of details within the prescription to the claim billing transaction*	▪ *Streamline processes to maintain compliance* ▪ *Enhanced patient safety mechanisms* ▪ *Increase interoperability*
2. *New Prescriber segment fields to enhance prescriber validation, e.g. DEA number and Prescriber Place of Service to identify Telehealth*	▪ *Streamline processes to maintain compliance* ▪ *Increase interoperability* ▪ *Improved patient access to care*

3. New COB segment fields to improve the identification of the previous payer, allowing pharmacy providers and COB payers to enhance system rules for regulatory compliance	• Streamline processes to maintain compliance • Enhances the availability of information allowing the pharmacy to better communicate to the patient • Increase interoperability • Improved analytics
4. New Pricing Segment fields in the request and response to improve the identification and flexibility of changes related to tax and regulatory fees	• Streamline processes to maintain compliance • Enhances reimbursement methodologies • Enhances the availability of information allowing the pharmacy to better communicate to the patient
5. New Response Claim Segment fields to improve transparency of plan formulary information to facilitate actionable pharmacy and prescriber workflow processes	• Enhances the availability of information allowing the pharmacy to better communicate to the patient • Improves workflow automation • Improved patient access to care
6. New Claim Request fields to mitigate use of manual entry of overrides, allow system automation based on claim submission type and better placement of short cycle dispensing values	• Improves workflow automation • Improved LTC patient access to care • Streamline processes to maintain compliance
7. New Claim Request fields to improve multi-ingredient compound claims processing, harmonizing clinical identifiers with USP	• Improves workflow automation • Improved LTC patient access to care • Streamline processes to maintain compliance
8. New Claim Response and Claim request field to better support transaction matching criteria for claim reversals	• Enhances reimbursement methodologies • Improved analytics
9. New segments to support FDA REMS intermediary processes	• Streamline processes to maintain compliance • Enhanced patient safety mechanisms • Increase interoperability
10. Transition of codified message fields to distinct response fields, facilitating transparency of plan benefit information	• Improves workflow automation • Enhances the availability of information allowing the pharmacy to better communicate to the patient
11. Updated structure of response Patient Pay component fields to align with COB request format and ECL flexibility	• Streamline processes to maintain compliance • Improved analytics • Increase interoperability
12. Harmonized format of demographic attributes across the NCPDP standards, eliminating truncation risks and cleaner identification processes	• Improves workflow automation • Improved analytics • Increase interoperability
13. New response fields that enhance the target plan benefit and other plan benefit information detail associated to the patient (similar to TPL processes)	• Streamline processes to maintain compliance • Improved patient access to care • Improves workflow automation • Improved analytics • Increase interoperability

3. What are the anticipated barriers to implementing the new version of the pharmacy standard?
   - Lack of awareness resulting in budget constraints, deficient coordination and un-timely implementations
   - Timely coordination with updated trading partner agreements

4. What if anything, would be difficult about implementing version F2 for small pharmacies? What about the new version would be difficult for small pharmacies to adjust to?
   ➢ *From a chain pharmacy perspective, the business SMEs generally work directly with the IT technical staff through-out the project development life-cycle, prioritizing and facilitating expected outcomes. The panelist from the vendor community can best speak to their processes in managing the implementation of a new version for 'small' pharmacies.*

5. The HIPAA statute provides for a two year implementation window for health plans and providers after publication of a final rule.

   Is this time frame sufficient for your industry sector?
   ➢ *Based on the implementation timeframe needed for v5.1 and cD0, 2 years is insufficient and would create significant barriers for industry stakeholders if applied to vF2. At a minimum, and as outlined by NCPDP SNIP, the industry would require at least 3 years from the final rule publication date to the compliance date. This time period is needed to support business planning, IT development, internal and external testing, and coordination with trading partners, training and deployment with all trading partners.*

   Does the pharmacy industry want or need an overlap of the current and new standards?
   ➢ *A transition period where either vD0 or vF2 can be used is necessary. While the real-time environment used within the pharmacy industry can technically support a hard cut-over date, this would be a significant risk factor to patients and providers. The natural back-up plan is to be able to fall back to the current version to address coordination with prescription refills, coordination of benefits, claim reversals, etc.*

   Thinking about the changes in health care, is there an ideal time frame for the adoption of new versions of standards, and of their implementation?
   ➢ *Annual benefit election periods incur significant increase in transaction volume, create resource constraints and align education and training efforts on plan benefit changes. In order to avoid additional change management risks, the ideal timeframe for vF2 implementation compliance date would be towards the end of the second quarter.*

6. Which industry stakeholders are impacted by implementing a new version of this pharmacy standard? Can you offer a verbal or pictorial description of the flow of the transaction, e.g. prescribers, health plans (including self-funded health plans and Flexible Spending Accounts if relevant), pharmacy benefit managers, pharmacies, pharmacy management programs, and other parties?

   ➢ *All pharmacy industry stakeholders will be impacted in some manner. The NCPDP membership categories address the coordination across the different stakeholder groups, by ensuring consensus between providers, payers/processors and vendors. Each stakeholder entity can identify based on their specific business processes, their upstream and downstream business partners who may be impacted. As a pharmacy provider stakeholder, our business partners would include:*

     ▪ *Payer/processors – claim billing, pre-determination of benefits, eligibility*

     ▪ *Vendors/Intermediaries - e.g. REMS Administrator, Switch, Medicare Part D Facilitator, TPL vendors, Remittance Processing, Data Feeds, Analytics, etc.,*

     ▪ *EHR vendors – as vF2 enhances interoperability with the NCPDP SCRIPT standard*

7. Please provide evidentiary information (qualitative or quantitative) to support the need for a recommendation to adopt version F2 at this time. If you wish to send this under separate cover because it is proprietary, that is acceptable. Should NCVHS render an affirmative recommendation to the Secretary,

cost benefit data will be necessary for the regulatory process to move forward by HHS in accordance with requirements of the Office of Management and Budget?

> *As outlined in the chart above, NCPDP vF2 offers numerous qualitative benefits with better tools to maintain compliance, improve patient healthcare outcomes, increase automation and reduce administrative costs.*

8. What are the costs involved in implementing a new version of a standard, and by whom and to whom are they paid? For example, hardware system and software upgrades, vendor fees, real time or batch transaction fees, processing fees, clearinghouse or PBM charges, etc. Do these costs place burdens on any individual stakeholder group?

> *Based on the vD0 implementation, the estimated cost areas would include software development and the entire project lifecycle, training, and external vendor fees. Since the business planning stage has not yet been initiated for vF2, it is difficult to identify any additional costs that may occur. For example, expanded field lengths may incur additional hardware costs, or business objectives may require additional vendor relationships.*

9. What are the patient service and care impacts to implementing version F2? For example, are there patient service and care impacts version F2 will solve/resolve, or are there potential service issues the new standard could create?

> *As outlined in the chart above, the impetus of vF2 is to deliver qualitative changes that will improve patient outcomes. A sufficient implementation period is necessary in order to eliminate any impacts to care.*

10. What are the consequences to industry if NCVHS does not recommend adoption of Version F2 to the Secretary?

> *If vF2 is not recommended to the Secretary, patient safety initiatives will be impaired, streamlined claim adjudication processes will be compromised and transparency of plan benefit information will be hindered. One of the key benefits of vF2 is the ability to improve the harmonization between e-prescribing and claim billing transactions, specifically as it relates to controlled substances. If vF2 is not implemented timely, the industry will lose the benefits of interoperability and fall behind current business and compliance needs.*

11. Is there any opposition to the upgrade to Version F2?

> *Through NCPDP's consensus building process, the pharmacy industry has already agreed on these business needs and transaction changes to support current and future objectives. Any opposition to proposed changes were vetted out through the process and adjustments made to ensure industry support.*

12. What is the burden reduction to your stakeholder group for use of Version F2?

> *Reduction in manual workflow processes*
> *Reduction in time to resolve claim rejections, reduction in transaction attempts*
> *Reduction in lack of transparency and inability to address patient plan benefit questions*
> *Reduction in audit risks*

Telecommunications vF2 and Subrogation Standard Questions:
1. Is there anything else you deem relevant, important and appropriate to inform the committee and HHS about adoption and implementation for each of these standards?

> Not at this time.

2. What testing has been done of the standards to demonstrate that they are ready for use?
   ➢ *NCPDP vF2 is an iterative version built on the framework of vD0, where the industry has experienced these transactions since 2010. The moving external code list that was implemented with vD0 allows stakeholders to continuously implement changes. For example, the message field within the response supports qualified values for designated information to be returned. All values created in vD0 have were added to vF2 as new fields. As a result, changes in vF2 are currently being tested/used within vD0.*