Input on the costs, benefits, pros and cons of changing the future
HIPAA named NCPDP Telecommunication Standard from Version F2 to Version F6

Received as of March 16, 2020

	Organization	**Signatory**
1.	VA/VHA Office of Community Care	Frank Annechini Deputy Director for Development (acting) eBusiness Solutions, Revenue Operations
2.	NCPDP	Lee Ann Stember President and CEO
3.	ADA	Paul R. Leary, DMD Chair, DeCC, and ADA Trustee
4.	CVS	Melissa Schulman Senior Vice President Government & Public Affairs
5.	NACDS	Steven Anderson President and Chief Executive Officer
6.	PDX, Inc.	Leann Lewis Director of Industry Relations
7.	PharMerica	Erica A. Cook, Manager of 3rd Party Operations and Reconciliation
8.	DST Pharmacy Solutions	Kathy Knapp Transaction and Code Set Compliance Regulatory Compliance | SS&C Health
9.	Prime Therapeutics	Jon Paladino Pharmacy Benefits Manager
10.	Walgreens	Michele V. Davidson Sr. Mgr. Pharmacy Technical Standards, Development and Policy

Lorraine,

Thank you for giving Department of Veterans Affairs (VA) an opportunity to comment on NCPDP F6 update. At this time, VA as a Provider, does not feel the need to submit any input. Katie Knapp will be physically present, and Debbie Wistuba will join the audio remotely, to hear these deliberations at the Full Committee meeting on March 24, 2020. Please continue to include VA on future testimony and comment opportunities for upcoming standards.

Thank you,

Frank

Chief, Payer EDI
Program Administration & Logistics
Systems Engineering Management
Program Improvement & Reporting

Deputy Director for Development (acting)
eBusiness Solutions
Revenue Operations (10D1C2)

VHA Office of Community Care
U.S. Department of Veterans Affairs

March 10, 2020

William Stead, MD, Chair
National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget and Legislation
3311 Toledo Road
Hyattsville, MD 20782
NCVHSmail@cdc.gov

RE: Questions for industry input: Impact of adopting the updated pharmacy standard
NCPDP Telecommunication Standard Version F6 – DSMO Request 1208

Dear Dr. Stead,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies 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 solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to submit comments to questions related to the implementation of the NCPDP Telecommunication Standard Implementation Guide Version F6 (hereinafter referred to as vF6) as the next HIPAA-named industry standard for eligibility verification, claim, and service billing, predetermination of benefits, prior authorization and information reporting transaction exchanges.

In closing, NCPDP supports the transition to vF6 within the enclosed recommended timeline. We thank NCVHS for the opportunity to comment on this important advancement for the pharmacy industry that is designed to increase patient safety, expedite patient access to care and improve operational execution.

For direct inquiries or questions related to this letter, please contact
    Margaret Weiker
    Vice President, Standards Development
    NCPDP
    E: mweiker@ncpdp.org

Sincerely,

Lee Ann C. Stember President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

cc: NCPDP Board of Trustees

1. What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response and indicate why HHS should adopt version F6.

   How version vF4 – vF6 Improve Functionality:
   - Coverage under prescription benefits of new innovative drug therapies with costs greater than $999,999.99 is available as a result of expanding all dollar fields to support up to $999 million.
   - Patient safety processes are enhanced through enabling pharmacy and prescriber system automation and interoperability of clinical information, as a result of replacing free text clinical and non-clinical information with codified fields.
   - IT development, testing and implementation burdens are reduced by eliminating intermediary qualified message solutions in prior versions and enhancing the use of the Other Related Benefit Information segment. Some examples include Qualified Medicare Beneficiary (QMB) identifiers, End-Stage Renal Disease and Hospice indicators, dates such as formulary alternative effective date and provider validation data source (e.g., OIG, Medicaid enrollment file, etc.).
   - Patient access to care is expedited through workflow interoperability between the payer, pharmacy and prescriber as a result of new response data elements to better communicate current and future effective date plan formulary alternative information and patient cost share amounts.

   Why vF6 should be adopted:
   VF6 offers enhancements that better support current and future business needs, which are anticipated to introduce advancements in the following areas:
   - Improves structure to support clinical evaluation of prescription products and plan benefit transparency which are key components in achieving expected healthcare outcomes related to value-based care, digital therapeutics, social determinants of health and other areas of healthcare innovation
   - Adds opportunities for system automation, harmonization of data and workflow interoperability across the care continuum
   - Enhances drug utilization/patient safety mechanisms by providing better tools to address health issues such as the opioid epidemic
   - Expedites patient access to care
   - Facilitates patient care coordination across distinct components of prescription and medical benefits
   - Expedites claim resolution through improved data analytics
   - Allows adjudication of claims for innovative drug therapies using industry standard processes leveraging expanded financial fields

2. When should HHS adopt and require implementation of F6?
   NCPDP recommends HHS name vF6 in a proposed rule as soon as possible and no later than December 2020, and the Final Rule be published no later than August 2021. This timeframe allows stakeholders to begin planning and allocating the applicable IT budget and development phases.

NCPDP recommends HHS adopt a compliance date no sooner than May 2025, which is based on stakeholder analysis indicating the development and testing effort for vF6 to be far greater than previous HIPAA-named versions.

If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address. If the Final Rule is not published in the recommended timeframe, industry will need to continue using NCPDP Telecommunication Standard Implementation Guide Version D.0 (hereinafter known as vD.0) and the associated work-arounds including manual claims processing, splitting of claims for million-dollar drugs and manual workflow steps to identify and act upon patient safety alerts. Furthermore, the future use of the 8-byte IIN (previously known as the BIN) is not supported by vD.0 and will prevent processing of claims. Other features such as medical and other related benefit information (e.g., substance abuse program enrollment) will simply not be available to trading partners for enhanced patient care coordination.

What is industry's desired implementation timeframe?
SNIP vF6 Timeline Recommendations:

Step #	Milestone	vF6 Timeline
1	NCVHS hearings Completed	4/1/2020
2	HHS releases NPRM	12/31/2020
3	NPRM comment period ends	02/28/2021
4	Final Rule is published	08/28/2021
5	IT business planning, development, informal and formal testing	
6	Trading partner certification, pilot use in production environment	
7	NCPDP recommended full use of vF6	08/28/2024
8	HHS Compliance Date	05/01/2025

3. We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?
The following processes are available when the drug is covered under the prescription benefit:
- Paper – Universal Claim Forms or CMS 1500 forms.
- Billing across multiple claims. E.g., for Luxturna, the blindness drug, there would be two vials, one for each eye. They can be billed separately to keep it under $1M per claim.
- Other as defined by trading partner agreements.

What is the latest date the standard must be officially available for use?
NCPDP is currently not aware of a hard date on which vF6 must be officially available for use, as the industry is supporting alternative solutions to address the new business cases. However, the health care industry is rapidly changing where business needs and regulatory requirements could quickly necessitate the implementation of enhancements in vF6 (e.g., Quantity Prescribed for CIII – CV). NCPDP recommends the timeline outlined above be supported by HHS and communicated as soon as possible to allow stakeholders to begin budgeting, planning, development work, and coordinating the necessary trading partner agreements.

4. What is industry's deadline for adoption?

NCPDP's timeline recommends full use of vF6 between trading partners as of 08/28/2024, and a compliance date of 05/01/2025 to allow for necessary system adjustments identified during the external testing, certification and production deployment phases.

5. Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?

NCPDP is not aware of any barriers specific to the implementation of vF6. As with any new version implementation, the following complications may exist:
   • Stakeholder financial constraints (e.g., state Medicaid programs, smaller stakeholders) may create barriers to meeting implementation timelines and the compliance date
   • A compliance date that coincides with annual prescription benefit implementations, (e.g., January, July) and the immunization season (e.g., August – March)

6. Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.

NCPDP defers to industry stakeholder comments on the implementation costs. Note, costs can vary significantly across the different stakeholders based on their business models and specific roles (e.g. payer, provider, vendor) within the telecommunication pathway.

7. Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing?

No, NCPDP is not aware of any testing between trading partners of vF6. Trading partners typically do not test until the final version has been named.

If no testing has taken place, what testing strategy should take place in advance of the implementation date?

NCPDP recommends full functionality testing occur internally and between trading partners prior to the use of vF6 in the production environment.

NCPDP requests NCVHS include a reminder in their letter to HHS that the following DSMO Requests be included in the NPRM and Final Rule as they would leverage vF6:
   • DSMO 1201 requests the Batch Standard Implementation Guide Version 15 be named under HIPAA.
   • DSMO 1202 requests the Subrogation Implementation Guide for Batch Standard Version 10 be named in HIPAA for Medicaid use to replace the Medicaid Subrogation Standard Implementation Guide Version 3.0.

March 10, 2020

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget, and Legislation
3311 Toledo Road
Hyattsville, MD 20782

Dear Doctor Stead:

On August 17, 2000, the Secretary of Health and Human Services (HHS) named six entities as the Designated Standards Maintenance Organizations (DSMO) under the Health Insurance Portability and Accountability Act (HIPAA) in § 162.910(a). The DSMO organizations work together on the maintenance and development of HIPAA adopted administrative simplification transaction standards.

The six organizations include three standard setting organizations (SSO):

- X12
- Health Level Seven (HL7)
- National Council for Prescription Drug Programs (NCPDP)

And three data content committees:

- Dental Content Committee of the American Dental Association (DeCC)
- National Uniform Billing Committee (NUBC)
- National Uniform Claim Committee (NUCC)

As a member organization of the DSMO, the Dental Content Committee is requesting that Change Request #1208 proceed through the regulatory process for industry adoption under HIPAA expeditiously.

Regarding Change Request #1208 (attached):

The NCPDP Telecommunication Standard provides a standard format for the electronic submission of third party drug claims and other transactions between pharmacy providers, insurance carriers, third-party administrators, and other responsible parties. The Telecommunication Standard includes transactions for eligibility verification, claim, and service billing, predetermination of benefits, prior authorization, and information reporting transaction exchanges. The Batch Standard uses the functionality, syntax, formatting, data set, and rules of the Telecommunication Standard to "wrap" in a detail record for an

implementer to use for coding. The batch header and trailer are included to support the batch method of submitting the transaction information.

Due to the cost of certain groundbreaking drugs exceeding $1 million, NCPDP saw no option but to implement a required expansion of a field length in the standard. This and several other changes in the standard necessitated a standards upgrade to Version F6, through versions F3, F4, and F5.

In answer to questions distributed prior to the hearing, the leadership of the Dental Content Committee has prepared the following responses.

1. What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt version F6.

    As stated in the submitter's rationale, F6 permits reporting drug costs in excess of $1 million. This is a necessary step to support prescription and billing of innovative new drugs and reduce administrative costs associated with their use by keeping the process completely electronic, whether batch or real time transactions are used.

2. When should HHS adopt and require implementation of F6? If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address? What is industry's desired implementation timeframe? Why?

    "As soon as possible" would be our recommendation on behalf of our health care provider colleagues and their patients who need to prescribe, and to use, these new drugs. Such drugs are not used in dentistry but dentists still treat the same patients as their physician colleagues, and a desire for the wellbeing of those patients requires us to recommend this timeline.

3. We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?

    We would defer to our colleagues at the NCPDP to recommend alternative solutions.

4. What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?

    Again, we defer to our NCPDP colleagues for these recommendations.

5. Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?

The DeCC is not aware of any barriers save the regulatory process itself.

6. Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.

    We are not in possession of any such data.

7. Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing? If not testing has taken place, what testing strategy should take place in advance of the implementation date?

    We defer to our NCPDP colleagues.

The Dental Content Committee thanks the NCVHS and NCHS for the opportunity to comment on this important matter.

Sincerely,

Paul R. Leary, DMD
Chair, DeCC, and ADA Trustee

PRL:jn:pc
Enclosure

cc: David M. Preble, DDS, JD, Senior Vice President, ADA Practice Institute

    Jean Narcisi, Director of Dental Informatics, ADA Practice Institute
    Patrick Cannady, MSHI, Manager, Dental Informatics, ADA Practice Institute

CRS 1208

Retail Pharmacy Claim

On August 17, 2017, NCPDP entered DSMO Change Request 1201 which requested Version F2 of the Telecommunication Standard Implementation Guide be named in HIPAA. NCVHS held a hearing in March of 2018 and sent a letter to the Secretary of HHS on May 17, 2018 recommending the Secretary adopt the new versions of the standards.

Since that time, the pharmacy industry has experienced several new drugs coming into the market with prices over $1 million dollars. Researchers expect three dozen new drugs with the potential price over $1 million dollars will come on the market over the next few years with hundreds more therapies under development. These new treatments include gene therapies, which target certain cancers and rare diseases.

The Telecommunication Standard Implementation Guide Version F2 does not support dollar fields greater than $999,999.99. NCPDP has modified the Telecommunication Standard to support dollar fields up to $999,999,999.99. Other enhancements have been made to the standard which are provided under separate cover.

The NCPDP membership is requesting Version F6 of the Telecommunication Standard Implementation Guide be named in HIPAA.

The Telecommunication Standard Implementation Guide supports the following processes:
1. Eligibility Verification
2. Claim
3. Service
4. Information Reporting
5. Prior Authorization
6. Predetermination of Benefits

Note: There is no change to the Batch Standard Implementation Guide Version 15 requested in Change Request 1201 as it supports the Telecommunication Standard Version F6 in a batch mode. There is no change to Change Request 1202 - 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.

March 13, 2020

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget and Legislation
3311 Toledo Road
Hyattsville, MD 20782

Submitted electronically via: NCVHSmail@cdc.gov

Re: Input on the costs, benefits, pros and cons of changing the future HIPAA named NCPDP Telecommunication Standard from Version F2 to Version F6 (HHS Document Citation # 85 FR 11375, Document Number 2020-03981)

Dear Dr. Stead,

CVS Health appreciates the opportunity to respond to NCVHS questions regarding the industry recommendation to implement NCPDP Telecommunication Standard version F6 as the next HIPAA named industry standard for eligibility verification, claim, and service billing, predetermination of benefits, prior authorization, and information reporting transaction exchanges. CVS Health is dedicated to becoming the most consumer-centric health company in the world. We're evolving based on changing consumer needs and meeting people where they are, whether in the community at one of our nearly 10,000 local touchpoints, in the home, or in the palm of their hand. Our newest offerings – from HealthHUB locations that are redefining what a pharmacy can be, to innovative programs that help manage chronic conditions, are designed to create a higher-quality, simpler and more affordable experience.

The NCPDP Telecommunication Standard supports real-time transactions, allowing pharmacy providers, insurance carriers and third-party administrators to communicate at the point-of-care and meet patient care needs. Effective, efficient and timely communication is critical at this point in the industry where there are evolving medication therapies, plan benefit structures being developed to improve healthcare outcomes and lower administrative costs. While the anticipated costs to implement version F6 are much higher than previous versions, we support the benefits these changes will offer. The following comments represent the broad scope of the CVS Health enterprise, considering retail, LTC, mail and specialty pharmacy as well as our PBM and health plan unique business needs, while collectively helping our patients on their path to better health.

1. ***What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt version F6.***

Improvements to Functionality

The changes incorporated into NCPDP Telecommunications versions F3 through F6 offer new functionality to support new and future business needs. The enhancements outlined below are critical as the healthcare industry strives to achieve greater transparency between stakeholders and the consumer and improve patient safety mechanisms.

- Replacement of free text clinical and non-clinical information with codified fields to enable pharmacy and prescriber system automation and interoperability of clinical information as a foundation to enhance patient safety
- Replacement of intermediary qualified message solutions in versions F2 through F5, with distinct codified fields and new segments in version F6 to reduce IT development, testing and implementation burdens; for example Qualified Medicare Beneficiary (QMB) identifiers, End-Stage Renal Disease and Hospice indicators and dates, formulary alternative effective date, and provider validation data source (e.g. OIG, Medicaid enrollment file, etc.).
- Addition of new response data elements to communicate current and future effective date plan formulary alternative information and updated data elements to clearly identify the patient cost share amount will facilitate workflow interoperability between the payer, pharmacy and prescriber, expediting patient access to care
- Expansion of all dollar fields to support up to $999 million in order to facilitate prescription benefit coverage of new innovative drug therapies with costs greater than $999,999.99

Why version F6 should be adopted
CVS Health is a healthcare innovation company that relies on industry standards to reduce administrative burdens and enhance interoperability, with the ultimate goal to improve healthcare outcomes. NCPDP Telecommunication Standard version F6 offers enhancements that better support current and future business needs, replacing the use of free text messaging with codified fields to facilitate system automation, harmonization of data elements and workflow interoperability across the care continuum. CVS Health is eager to see the following benefits from the enhancements available in version F6:

- Increased interoperability, promoting transparency of information shared between the payer, pharmacy, prescriber and patient;
- Advanced workflow automation;
- Enhanced patient safety mechanisms;
- Expedited patient access to care;
- Simplified patient care coordination across distinct components of prescription and medical benefits; and
- Accelerated problem solving opportunities through improved data analytics.

2. When should HHS adopt and require implementation of F6?

CVS Health recommends that HHS name version F6 as soon as possible, to allow stakeholders as much time as possible for planning and budgeting activities. Corporate IT budgets and timelines are dependent on the rule making process. In order to plan accordingly and balance with other product development initiatives, HHS processes need to be timely. CVS Health aligns with NCPDP SNIP recommendations, where the Notice of Proposed Rule Making should be released no later than December 2020, and the Final Rule published no later than August 2021.

As noted above, version F6 offers the necessary enhancements to support new and future business needs, however our initial analysis indicates the work to be far greater than previous HIPAA named versions. As a result, CVS Health recommends HHS allow a 44 month period from the date of the final rule to the compliance date, where the compliance date is no sooner than May 01, 2025 and does not interfere with the pharmacy benefit welcome season (e.g.: January).

What is industry's desired implementation timeframe?

CVS Health aligns with NCPDP SNIP implementation timeline recommendations as outlined below.

Step #	Milestone	Version F6 Timeline
1	NCVHS hearings Completed	4/1/2020
2	HHS releases NPRM	12/31/2020
3	NPRM comment period ends	02/28/2021
4	Final Rule is published	08/28/2021
5	IT business planning, development, informal and formal testing	
6	Trading partner certification, pilot use in production environment	
7	Recommended full use of new version	08/28/2024
8	HHS Compliance Date	05/01/2025

If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address.

CVS Health will align with NCPDP guidance and leverage existing processes to ensure patient access to care is not compromised. The pharmacy industry as a whole however, may struggle with manual processes to provide plan benefit transparency details, ensure

accurate routing to new IIN's, communicate necessary expanded product identifiers (e.g. universal device identifier) and high dollar financial values.

3. ***We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?***

Currently instances of individual claims for drugs costing over $999, 999.99 are rare, however as an industry leader in specialty pharmacy, CVS Health is ready to support the needs of all of our customers as these unique patient care opportunities are presented. CVS Health has done extensive research in this area, outlining barriers and opportunities to reducing patient financial impacts, within our 'Gene Therapy Keeping Costs from Negating Its Unprecedented' white paper.

The technical enhancements to support the dollar field expansion are a significant investment, impacting multiple systems beyond point of service adjudication. Additionally, the interim solutions using current industry standards and best practices, present barriers that will require uniquely defined solutions to meet all of our customer's needs. For example:

- High dollar therapies where single drug unit exceeds current dollar limitation ($999,999.99), splitting orders becomes more complex and requires CVS Specialty alignment across all the PBMs/Clients served to successfully manage workaround processes. This option will not be scalable and sustainable as new therapies become available and individual package costs prevent claim splitting.
- High dollar therapies are expected to have very limited or exclusive distribution dispensing networks, creating complexity to manage due to variability across manufacturers and unique payer needs.
- Payers may not share a consistent approach in medical vs. pharmacy benefit for a specific drug, creating complexity in billing requirements and variations in patient out of pocket costs.

CVS Health anticipates the use of the following high level options to meet the needs of our patients and clients prior to the availability of the expanded dollar fields in version F6.

- When coverage is coordinated under the pharmacy benefit the following options could apply:
    - Pharmacy submits multiple claims using the NCPDP Telecommunication version D.0 Standard, (e.g. Luxturna would result in 2 claims, 1 vial for each eye);
    - Pharmacy submits Universal Claim Form;
    - Pharmacy submits special handling invoice.
- When coverage is coordinated under the medical benefit, the following would apply:

o Pharmacy submits the claim for the drug and shipping costs; and the administering provider would submit a claim for the drug administration service.

4. **What is the latest date the standard must be officially available for use?**

CVS Health recommends the timeline outline above be supported by HHS and communicated as soon as possible, to allow stakeholders to begin IT budget, planning and development work, and coordinate the necessary trading partner agreements.

What is industry's deadline for adoption?

CVS Health supports NCPDP's recommendation where trading partners target August 2024 for full use of version F6, and achieve compliance prior to May 2025.

5. **Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?**

CVS Health, as a multi-faceted healthcare enterprise believes the following implementation barriers impact payers, providers and vendor/intermediaries, where the level of impact is based on individual business models.
- Stakeholders who may not be impacted by million-dollar drug use cases may incur barriers with implementation timeline and costs associated to dollar field expansion
- Stakeholder IT budget constraints (e.g. state Medicaid programs) may create barriers to meeting implementation timelines
- Compliance dates that conflict with prescription benefit welcome seasons, e.g. January

It is also important to note, that as the healthcare industry moves forward in developing innovative solutions to improve patient outcomes, the current HIPAA process may also need to evolve to allow more timely and cost effective implementations. The industry is not in need of just smaller more frequent changes to the standard, but rather changes to reduce the size of the payload, the legacy systems behind it and the rigid HIPAA process. These barriers prevent industry stakeholders from being innovative, building and piloting solutions prior to the changes becoming a new version named under HIPAA.

6. **Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.**

As previously noted, the enhancements within version F6 benefit the healthcare industry by improving patient outcomes. This is critical as we move forward with new business models and patient care programs. It does come with a price, as the implementation of version F6 is estimated to be significant, impacting hundreds of internal systems and coordination with external systems and processes. As an example, the expanded dollar fields not only impact point of service claim adjudication systems, but will also require enhancements to all

associated financial systems, internal and external reporting programs, help desk programs, member/client portals, integrated data feeds, etc. The size of the transactions have also increased considerably, with the inclusion of new segments and repeating fields, requiring new hardware to support data base storage needs. While comprehensive evaluations are still in progress, initial reviews indicate the costs to be 2-3 times greater than the implementation of version D.0.

7. ***Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing?***

CVS Health has not conducted any formal or informal testing of version F6.

If no testing has taken place, what testing strategy should take place in advance of the implementation date?

CVS Health will coordinate internal and external testing based on the NCPDP implementation timeline and trading partner agreements, as we have done with NCPDP Telecommunications version 5.1 and D.0.

In summary, CVS Health supports the transition from D.0 to F6 within the timeline proposed by NCPDP. We thank NCVHS for the opportunity to comment on this important advancement for the pharmacy industry that is designed to increase patient safety, expedite patient access to care, and improve operational execution.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

Enclosures: (number and/or name of each document)

CC:

March 13, 2020

Via Email: NCVHSmail@cdc.gov

Lorraine Doo
Senior Policy Advisor
Centers for Medicare & Medicaid Services
National Standards Group
Office of Enterprise Information
7500 Security Boulevard
MS S2-25-15
Baltimore, MD 21244-1850

Re: Input on the costs, benefits, pros and cons of changing the future HIPAA-named NCPDP Telecommunication Standard from Version F2 to Version F6

Dear Ms. Doo:

The National Association of Chain Drug Stores (NACDS) thanks the National Committee on Vital and Health Statistics (NCVHS) and its Standards Subcommittee for the opportunity to present our views on changing the implementation of the HIPAA-named NCPDP Telecommunication Standard from Version F2 to Version F6.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and health care affordability.

The NCPDP Telecommunication Standard ("Standard") is the major HIPAA-named standard used by our pharmacy members today. The Standard is a real-time transaction standard that allows pharmacies to verify eligibility, determine insurance coverage, learn if alternative medications are on the patient's drug formulary, inform a patient of their required copay, and submit the claim, all in under three seconds. Since this is a real-time transaction at the point-of-care, patient care and the patient experience are heavily dependent upon the utilization of the most current standard with the functionality needed to meet the needs of today's medication therapies and drug benefit plans, as well as near-term anticipated needs.

In providing input to NCVHS, NACDS worked with our members to obtain their viewpoints on the necessity of moving from Version F2 to Version F6 of the Telecommunication Standard. Although a much more costly transition than the move to Version F2 would be, our members are supportive of moving to Version F6 of the NCPDP Telecommunication Standard. Our answers to NCVHS' questions are provided below.

1.   *What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt NCPDP version F6.*

The following needed Version F6 features and benefits are not found in Version F2:

- An increase in financial field lengths by three digits to accommodate the growing number of drugs and therapies to treat cancer and rare diseases with claim costs of $1 million of higher (up to $999 million). Expanding the dollar field ensures the claim transaction is adjudicated without errors and with all the other benefits of a real-time transaction, including patient eligibility verification and drug utilization review edits and alerts. It also avoids workarounds and an inferior patient experience at the pharmacy.

- The new Patient ID Count field in the Claim Request transaction so that more than one Patient ID can be sent on a single transaction. Transmission of more than one Patient ID will improve patient care by allowing for enhanced patient identification across the healthcare ecosystem including in Prescription Drug Monitoring Programs (PDMPs).

- New Claim Response transaction data elements that better communicate both current and future effective dates of plan formulary information, including therapy alternatives and patient cost share amounts. This information assists the pharmacy personnel in communicating with the patient.

- A new Claim Response transaction segment for payers to communicate information on another patient benefit/program (e.g. hospice, disability, substance abuse treatment) on a paid claim, enhancing coordination of care between the pharmacy and other patient care providers or benefit programs.

- Enhancements to the drug utilization review (DUR) fields in the Claim Response transaction to more effectively communicate information from the payer for pharmacy action.

2.   *When should HHS adopt and require implementation of F6? If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address? What is industry's desired implementation timeframe? Why?*

NACDS recommends that HHS name Version F6 as soon as possible to allow for the implementation process to proceed without further delay. Because our members' IT budgets and timelines are impacted by the rulemaking process, quick action is necessary for industry to develop and finalize plans and budgets, and to accommodate other development initiatives. HHS' HIPAA rulemaking processes must be timely.

NACDS and many of our individual member companies have been actively engaged in the NCPDP implementation planning process to arrive at what our industry sector believes is a suitable timeframe and transition period. NCPDP has taken industry concerns into account in their proposed implementation plan and we are recommending that the Subcommittee and HHS follow NCPDP's proposed timeline. The proposed rule should be released no later than December 2020, and the Final Rule be published no later than August 2021.

As noted above, Version F6 offers the necessary enhancements to support new and future business needs. However, initial analysis indicates the development work to be far greater than previously HIPAA-named versions, including the planned Version F2. NACDS recommends that HHS adopt a Compliance Date no sooner than that recommended by NCPDP. It is also critical not to set important milestones, or compliance dates, during those times of year when industry resources are stretched due to the cold and flu season and annual benefit change activity. We suggest avoiding November 15 – March 3, and support considering the second calendar quarter of the year.

If a final rule is not published in the recommended timeframe, industry will need to continue using NCPDP Version D.0 and the associated work-arounds, including manual claims processing, splitting of claims for million-dollar drugs, and manual workflow steps to identify and act upon patient safety conditions. Other features of Version F6 and their related benefits would simply not be available for trading partners and patients.

3.   *We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?*

The options are limited at this time for high cost medications. The industry trading partners will need to work among themselves to agree on method for billing such claims.

Although non-electronic methods, such as paper claims, are an option, utilizing the paper claim process is much more labor intensive. Another potential option could be to determine ways to split up the high-value claims and associated costs among two or more claims and electronic transmissions. This may negatively impact drug utilization review, duplicate claim logic, patient pay amount calculations, and other claim components.

4.   *What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?*

Rather than a deadline for adoption, we would more likely recommend moving on to yet another future version of the standard if a proposed rule for Version F6 is not published by the timeframe set forth above. The healthcare industry is rapidly evolving, and industry is currently employing alternative and/or manual workarounds to address the limited functionality of Version D.0. However, these workarounds are costly to industry and unnecessarily impact patient experience.

The current HIPAA process of naming and implementing new standards or versions of existing standards must evolve to support new and emerging business needs in a timelier manner, thus allowing industry to be more agile and innovative.

5.   *Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?*

At this time, no unique barriers are known. Typical barriers to such an implementation process include resource competition with other priority development activities, technical learning curves for employees, possible lost or delayed opportunities due to limited resources, time constraints, and coordinating quality assurance and user acceptance testing resource availability. Throughout the development and rollout timeframe, it is of prime importance that the implementation process remains seamless from the patient perspective and that patients do not experience any gaps in care.

6.   *Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP Version F6.*

Qualitatively speaking, pharmacies must be able to provide these high cost therapies to patients. Not expanding the financial fields of the standard ultimately limits pharmacies' abilities to provide these medications in a timely manner.

Actual costs of implementation will vary significantly among different pharmacy chains based on their size, scope of services provided, and business models. Thousands of labor hours will be needed from various business teams to plan, develop, and test Version F6 before it can be fully implemented.

Hardware, software, and maintenance costs allocated specifically to Version F6 implementation are estimated to be in the tens of millions of dollars. The greater share of these costs is associated with the expanded dollar fields enhancement as this change requires expansion of financial fields in other databases used in the many integrated systems carrying financial information.

The benefits of an updated Standard include greater ability to support the rapidly changing healthcare delivery and payment systems. Benefits also include the ability to support new therapies that, while costly, often can result in cures for conditions previously untreatable.
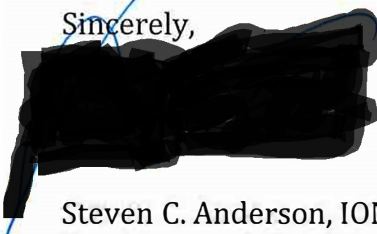
7.   *Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing? If no testing has taken place, what testing strategy should take place in advance of the implementation date?*

We are not aware of any testing that has taken place for Version F6. Over 3 billion prescription drug claims utilize the Standard each year. Our members' implementation project plans for the transition to a new standard include contingency plans that put patient access to care as the highest priority.

We believe an implementation will be successful if there is adequate time for (1) voluntary transition to the new standard between willing trading partners, (2) pharmacy rollout, and (3) the ability for trading partners to revert back to Version D.0 if something unforeseen occurs to reduce potential impact on patient access to care. During the transition period, it is likely both versions of the standard will be used concurrently by claim processors/PBMs and pharmacies, depending upon whether both trading partners are ready to transition to Version F6.

In closing, NACDS supports the transition from Version D.0 to Version F6 within the timeline proposed by NCPDP. We thank NCVHS for the opportunity to comment on this important issue. We look forward to working to ensure that these standards enhance pharmacy operations as well as increase patient safety and patient access to healthcare.

Sincerely,

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

March 13, 2020

William Stead, MD Chair,
National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget, and Legislation
3311 Toledo Road
Hyattsville, MD 20782
NCVHSmail@cdc.gov

RE: Questions for industry input: Impact of adopting the updated pharmacy standard NCPDP
Telecommunication Standard Version F6 – DSMO Request 1208

Dear Dr. Stead,

PDX, Inc. welcomes the invitation to submit comments related to the adoption the NCPDP
Telecommunication Standard Version F6 (hereafter referred to as vF6) as the next HIPAA named
standard for eligibility verification, claim and service billing, predetermination of benefits, prior
authorization, and information reporting transaction exchanges.

PDX, Inc. is a technology company built on a foundation of and a commitment to Community Pharmacy.
For over 30 years, we have provided innovative solutions and an integrated comprehensive suite of
products and services to meet the needs of pharmacy. The approximately 6,000 pharmacies that
subscribe to PDX software and services operate in all 50 states, the District of Columbia, Puerto Rico, US
Virgin Islands, and Guam. Our system-partners include both independent pharmacies and chain
pharmacies, with one chain having over 1,800 pharmacies.

PDX appreciates the opportunity to comment on this important rulemaking. Our answers to the
forwarded questions are attached.   Thank you for your thoughtful consideration of our comments.

For direct inquiries or questions related to these comments, please contact Leann Lewis.

Respectfully,

Leann Lewis
Director of Industry Relations
PDX, Inc.
Email: llewis@pdxinc.com

1. **What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response and indicate why HHS should adopt NCPDP version F6.**

    The main enhancements between version vF2 and vF6 include:
    a. Claims processing of innovative drugs is supported under prescription benefits by increasing dollar fields for drugs priced at more than the current 1 million dollar limit.
    b. Pharmacy and payer workflow are enhanced and optimized by replacing many clinical and non-clinical free text fields with discrete codified fields. The discrete fields can trigger workflows which can aid in combatting the opioid crises or communicating relevant information for at risk patients.
    c. Overall interoperability between the payer and pharmacy is improved with the ability by expanded communication of plan information. These efficiencies could reduce delays in therapy and improve patient adherence. Some examples include plan effective dates, formulary Qualified Medicare Beneficiary (QMB) identifiers, End-Stage Renal Disease and Hospice indicators and their related dates, formulary alternative effective date, and data sources used to validate prescriber eligibility for a specific plan (e.g. OIG, Medicaid enrollment file).

    NCPDP vF6 should be adopted in part due to the industry is currently working on the HIPAA named NCPDP Telecommunications Version D.0. It was approved by NCPDP in 2007. Healthcare and pharmacy have changed dramatically in the last 13 years. The Affordable Care Act, the opioid crisis, million dollar drugs, and changes to Medicare Part D and Medicaid policy are just a few examples of these changes. The industry must move forward and vF6 is the latest version which NCPDP as an organization has approved to address many of these changes and embrace the efficiencies provided in vF6.

2. **When should HHS adopt and require implementation of F6?**

    PDX concurs with the NCPDP comments that recommend HHS name vF6 in a proposed rule as soon as possible and no later than December 2020. A Final Rule should be published no later than August 2021.

    Assuming there is a final rule by August 2021, PDX recommends that HHS adopt a compliance date no sooner than April 2025.

    If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address?

    PDX would have to recommend that if the Final Rule is not published in the recommended timeframe, the industry will need to continue to use NCPDP Version D.0. The costly and inefficient workarounds employed today will continue to delay access to care and could impact patient safety.

What is industry's desired implementation timeframe? Why?

PDX concurs with NCPDP that the implementation period should be an estimated 36 months, with a final compliance date no later than 48 months from final rule.

Given that many systems, particularly legacy systems, could be greatly impacted due to the increased dollar field change, the development cycle for vF6 is estimated to be greater than previous HIPAA versions. Therefore, PDX believes the timeframe of 4 years from final rule to compliance date is justified.

PDX respectfully requests that if existing legislation allows, a final compliance date would not be scheduled between October 1 and March 1. A compliance date during this time frame would avoid common "code freeze" periods between November 1 and February 1. A code freeze is imposed by many entities during this time which prohibits any system changes from being deployed.   This action is taken so as to minimize potential workflow issues and patient access to care disruptions during the holidays through the first of the year when many plan, coverage, and compliance changes occur.   The October to March time frame allows for a code freeze time period as well as a buffer period to accommodate system changes that could conflict with a successful HIPAA implementation.

3. **We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?**

There are currently workarounds for this that would continue to be used including:
- Billing across multiple claims. E.g. for Luxturna, gene therapy for the treatment of Leber's congenital amaurosis, is delivered in two vials, one for each eye. The vials can be billed separately to keep each claim under $1 million.
- Billing of Paper Claims on Universal Claim Forms, or CMS 1500 forms
- Other trading partner agreements, both related to NCPDP standards or possibly billing using the ASC X12 837P claim through an intermediary.

4. **What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?**

PDX is unaware of any date where the standard must be officially available for use or a deadline for adoption. As time passes, there is an increased probability that current workarounds may no longer be effective. For example, full implementation of the transition from the 6 digit BIN (Banking Identification Number) to an 8 digit IIN (Issuer Identification Number) could at minimum create claim routing issues. Full implementation of UDI (Unique Device Identifiers) exceeding the current 19 characters allowed by the existing standard, could result in an inability to continue with claims processing for some devices.

PDX encourages that the timeframes previously proposed be adopted to avoid industry disruption.

5. **Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect**?

PDX believes that no technological or standards related barriers exist with vF6 that can't be solved with two things: time and money.   These two barriers affect every aspect of the industry but are likely more impactful to state Medicaid programs and smaller plans and vendors. With other HIPAA transitions, it has generally been the Medicaid programs who have either not implemented by the compliance date or have implemented through a hard cutover on the compliance date.   This created claims processing delays that could have been isolated and resolved during the transition period.

PDX respectfully requests that HHS, CMS, or other appropriate entity provide outreach to the pharmacy industry (payers, vendors, Medicaids, switches, etc.) on the importance of meeting the compliance deadline. This outreach could help to limit costs incurred by compliant trading partners due to the noncompliance of other trading partners.   Continued outreach could also limit the impact to patient access to care.

6. **Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.**

PDX had estimated during its vF2 testimony that the project would take approximately 40,000 man hours. Although we have not completed our full analysis, but given, the differences between vF2 and vF6, our expanded product line, enhancements to existing products and interfaces, that the vF6 changes would likely increase that estimate by about 25% to approximately 50,000 man hours.

7. **Are you aware of any testing that has taken place with the NCPDP Version F6 standard between partners, and the outcome of that testing? If no testing has taken place, what testing strategy should take place in advance of the implementation date?**

PDX has neither performed nor is it aware of any testing which has taken place with vF6. However, it is worth noting, that previous HIPAA versions were named without testing being performed.

The industry has demonstrated successful transitions in previous implementations of HIPAA named NCPDP standards.   However, a transition period up to 12 months is critical for that success. Testing prior to the naming of the new standard is not required, nor would it impact the outlier entities that are unable to meet the compliance date.

Finally, in NCVHS's letter to HHS asking for approval of a new standard, PDX reiterates a request from NCPDP that NCVHS include a reminder of two other DSMO (Data Standard Maintenance Organization) requests related to a new HIPAA standard.

The letter should state that the following DSMO requests be included in the NPRM and Final Rule as they leverage the NCPDP Telecommunication Standard vF6:

- DSMO 1201 requests the Batch Standard Version 15 be named under HIPAA
- DSMO 1202 requests the Subrogation Implementation Guide for Batch Standard v10 be named in HIPAA for Medicaid use to replace the Medicaid Subrogation Standard Implementation Guide, version 3.0.

Dear Leaders of NCVHS,

PharMerica would like to thank you for this opportunity to submit written testimony and represent Long Term Care pharmacies as it relates to NCPDP's transition from Telecommunication version F2 to F6. We were proud to work alongside other industry partners and submit comments previously related to the Telecom F2 transition and hope you will continue to seek our input for future industry changes as well.

Before discussing F2 to F6 we'd like to quickly touch on the benefits contained in F2 as they would at this point be contained in the F6 release and are still essential needs of the industry. Some of the major benefits within the F2 standard were (a) new request fields created related to Short Cycle, Split Bill, and other claim types that are prevalent in LTC (b) new fields added to the response segment that help facilitate the transfer of information from PBM to pharmacy and help provide better patient care, including specific phone numbers for prior authorization and other areas. (c) Introduction of "Adjudicated Program Type"- a mandatory response field that will let pharmacies know if the claim adjudicated as Medicaid, Medicare, Managed Medicaid, etc. (d) Enhancements to the E1 response that will provide additional benefit information to LTC pharmacies, including Hospice plan names, effective dates, and termination dates, as well as ESRD effective and termination dates.

As with F2, version F6 introduces new request and response data elements to better communicate between the pharmacy and PBM, and thus to the patient. The biggest change between F2 and F6 is, as you noted in your reach out to the industry, the expansion of dollar fields due to million dollar drugs now available in the market. There are a limited number of drugs involved now, but as time goes on and science evolves, the expansion of dollar fields to accommodate proper billing is greatly needed. Without this, pharmacies are forced to comply with whatever methods are required by plans to bill for these drugs. Varying requirements per plan/payer inevitably cause confusion at the pharmacy, and may result in billing errors which may cause pharmacies to lose reimbursement, or have unintended financial burden on LTC facilities or patients.

Version F6 also offers many new response fields for DUR messaging and Formulary Benefit Detail that help to convey potential drug, disease/condition, and other information to the pharmacy that we may otherwise not know about the patient. This allows the pharmacist to have more informative discussions with the patients and provide valuable information about alternative drug or therapy solutions. Version F6 also removes the "CMS Part D Qualified Facility ID" from the request fields, which had caused claim editing issues for LTC pharmacies when version D0 was originally required in 2012. Since then, many plans have removed their edits and focused on Patient Residence Code and Pharmacy Service Type, and no longer edit upon this field, making it extraneous.

As a consensus organization, NCPDP unanimously voted to move to version F6. There is no contention to moving to this version and many industry partners have been waiting for years on the solutions contained in versions above D0. Version F6 offers (a) enhancements that better support current and future business needs, (b) promotes transparency of information shared between the payer, pharmacy, prescriber and patient, (c) improves workflow automation, (d) enhances patient safety mechanisms, (e) expedites patient access to care, and (f) improves data analytics.

Without adoption of the new version, the industry continues to have unsolved business needs, including the ability to respond to ANSI requirements to Bank Identification Number, now known as Issuer Identification Number, from 6 to 8 digits. Additionally, we are not able to comply with FDA

requirements for Unique Device Identifiers as the UDI is up to 40 characters in length and our current standard only allows for a product length of 11.

Based on implementations of previous versions, the industry would like to stay away from mandating compliance in January and July, as those months typically experience heavy new member enrollment/eligibility and formulary updates. We recommend a compliance date of April 28th, 2026, which is based on previous implementation timelines and includes an estimated Final Rule being published in August, 2021. From there, the industry would need a minimum of 36 months for IT resource planning, budgeting, and development, followed by trading partner testing and certification. If the recommended timelines are not met, then industry will default to "trading partner agreements" to mitigate issues as a result. Historically, being held to trading partner agreements can have negative results, as many plans and PBMs force their requirements on pharmacies and pharmacies cannot realistically meet the requirements.

Barriers for F6 would be similar to F2. Pharmacies, PBMs, and other entities may need to re-contract with each other. Technical changes between the existing and new versions will need to be defined, coded, and tested, which requires dedicated resources and prioritization over other projects. It also requires considerable development and training costs that need to be budgeted.

PharMerica is not aware of any testing that has already taken place, but understand that due to the fluidity of the standard, most industry stakeholders wait until government mandates are in place before coding any changes. Following the above referenced timeline and allowing ample time for testing and certification between the final rule and the mandated implementation date is key to the industry's adoption of F6. The testing phase is critical, this is when trading partners communicate most, find and unanticipated implementation issues and create collaborative solutions for a smoother standard process.

Thank you again for this opportunity. We appreciate NCVHS's interest in the Long Term Care perspective and look forward to being involved in the advancement of pharmacy standards.

Sincerely,

Erica A. Cook,
Manager of 3rd Party Operations and Reconciliation

350 Myles Standish Boulevard, Suite 104, Taunton, MA 02780

Written Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL
COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

March 13, 2019
DST Pharmacy Solutions, Inc.

Members of the Subcommittee, DST Pharmacy Solutions, Inc. appreciates the opportunity to present written testimony concerning the adoption of the NCPDP Telecommunication Standard version F6. The new version of the Telecommunication Standard is being requested as a replacement for the current version D.0 named as a part of the Transactions and Code Sets Rule for HIPAA.

There continues to be a need for expanding the telecommunication standards to support healthcare industry efforts to reduce financial and safety burdens and to improve information exchange necessary to streamline pharmacy processes.

DST Pharmacy Solutions, Inc. LLC (Pharmacy Solutions) is a wholly owned subsidiary of SS&C Technologies, Inc. Pharmacy Solutions provides an extended suite of pharmacy health management solutions supporting various lines of business including commercial, Health Insurance Marketplace, Medicaid and Medicare Part D. Pharmacy Solutions supports a wide range of clients and key healthcare organizations including managed care health plans, pharmacy benefits managers and pharmaceutical manufacturers. Established in 1983, Pharmacy Solutions was a pioneer in electronic claims processing and has continued to evolve to help clients navigate the complexity of the healthcare industry.

The responses below represent our perspective on adoption of the NCPDP Telecommunication Standard version F6 (vF6) as a healthcare information management services provider and as members of the group identified at NCPDP as a "Pharmacy Benefit Management/Admin Company". Pharmacy Solutions supports the timelines and recommendations of NCPDP and are providing our specific responses to the questions posed by NCVHS on February 6, 2020 below.

1. What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt version F6.

    Moving beyond vF2, Pharmacy Solutions has identified the most significant impact to be the expansion of the financial fields, which is required to process high-cost drugs with an electronic point-of-service (POS) claim transaction.

2. When should HHS adopt and require implementation of F6? If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address? What is industry's desired implementation timeframe? Why?

    Pharmacy Solutions supports NCPDP's recommended timeline (shown below). We agree that the multi-year implementation period is needed due to the complexity and scope of changes involved with successfully migrating from version D.0 to version F6. This timeline must allow for extensive planning, development, internal and trading partner testing, pharmacy and switch certification as

Written Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL
COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

March 13, 2019
DST Pharmacy Solutions, Inc.

well as administrative processes that include communication and coordination with pharmacies, health plans, and vendors.

NCPDP vF6 Timeline Recommendations:

Step #	Milestone	vF6 Timeline
1	NCVHS hearings Completed	4/1/2020
2	HHS releases NPRM	12/31/2020
3	NPRM comment period ends	02/28/2021
4	Final Rule is published	08/28/2021
5	IT business planning, development, informal and formal testing	
6	Trading partner certification, pilot use in production environment	
7	NCPDP recommended full use of version F6	08/28/2024
8	HHS Compliance Date	05/01/2025

3. We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?

Pharmacy Solutions requires the submission of high-cost drugs via the Universal Claim Form (UCF) as a workaround for the current inability of the pharmacy industry to process point-of-service (POS) transactions submitted for any amount greater than $999,999.99. This requirement aligns with NCPDP's recommendation, published as a Frequently Asked Questions (FAQ) in May 2019, which referenced using the Universal Claim Form (UCF) as an interim solution until vF6 is available for production use.

4. What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?

Pharmacy Solutions supports NCPDP's timeline that recommends full use of vF6 in the industry as of 08/28/2024, and a compliance date of 05/01/2025. We request that HHS work with the industry to ensure all entities are ready by the published compliance date to avoid any date extensions. Extending compliance dates can have negative results by causing ongoing, duplicate updates and testing required to support multiple versions of the standard after the original compliance date. In addition, delaying compliance will continue the burden of manual work-arounds on high-dollar medications for any impacted pharmacies not meeting the compliance date.

We also support an implementation date that is outside of the open enrollment implementation periods of January and July in order to avoid patient access to care issues.

Written Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL
COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

March 13, 2019
DST Pharmacy Solutions, Inc.

5. Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?

Pharmacy Solutions has not identified barriers to implementing vF6. We join NCPDP in making the point that any government entities and/or pharmacies that are not ready by the compliance date could create member access to care issues and continue the burden of manual processes and work-arounds.

6. Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.

Pharmacy Solutions has not quantified the total cost associated with implementing vF6 but anticipates the cost to be a significant investment that will impact all stakeholders, including pharmacies, payers, patients/members, pharmacy benefit managers, claims processors, network switches, software vendors and NCPDP. Initial estimates put the effort to implement vF6 for Pharmacy Solutions and others in the industry at nearly double the work that was required to implement D.0.

7. Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing? If no testing has taken place, what testing strategy should take place in advance of the implementation date?

Because vF6 has not been named as a HIPAA standard, Pharmacy Solutions supports NCPDP's position that there is typically not testing until a standard has been named in regulation and testing timelines have been published. We support NCPDP's timeline for vF6 adoption and will continue to participate within NCPDP to develop the industry testing timelines for vF6 and, when those testing dates are available, work to meet those timeframes.

Testimony Before the NCVHS Subcommittee on Standards on Updated Versions of NCPDP Standards

March 13, 2020

By Jon Paladino, MBA

On behalf of Prime Therapeutics LLC

<u>Background on Prime Therapeutics</u>

Prime Therapeutics is a privately held, full service pharmacy benefit management (PBM) company that serves 21 Blue Plans and more than 20 million members.

What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response and indicate why HHS should adopt version F6.

The move forward in the NCPDP Telecommunication standard from version D0 to version F6 is the result of many years of pharmacy industry consensus building. Versions F3-F6 provide many enhancements in transmitting data to better support the ever-changing business environment. Among the benefits this more recent version brings:

- Support for claims with costs that are $1 million dollars or more
- Dedicated new fields for drug utilization information
- New fields that contain information on different benefit programs, such as Qualified Medicare Beneficiaries (QMB), End Stage Renal Disease (ESRD), and hospice patients

These changes will avoid inefficient workarounds, such as splitting up claims (where possible), or manual claims processing. The dedicated claims fields will allow for automated solutions and enhance abilities for reporting.

When should HHS adopt and require implementation of F6?

Prime supports the timeline developed by the NCPDP Strategic National Implementation Process Committee. The key features of this timeline are:

- Timely initiation and movement through the federal regulatory process
- Sufficient planning and implementation time based on the milestones in the regulatory process
- Avoidance of the peak implementation times at the beginning and mid-year
- Avoidance of the compliance day in the middle of immunization season

- High level milestones of the NCPDP SNIP proposed timeline
  - Proposed Rule out by the end of 2020.
  - Final Rule published by August 2021
  - Recommended full use by August 2024
  - Compliance date of May 2025

Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.

The expansion of most of the financial fields will increase the implementation costs by up to twice the estimates from the previous HIPAA administrative transactions final regulation for a large health plan.

On behalf of Prime Therapeutics, I appreciate the opportunity to provide these comments to the Committee.

March 13, 2020

William Stead, MD, Chair
National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget and Legislation
3311 Toledo Road
Hyattsville, MD 20782
NCVHSmail@cdc.gov

RE: NCPDP Telecommunication Standard Version F6 Questions

Dear Dr. Stead,

Walgreens is pleased to submit comments to questions from the National Committee on Vital and Health Statistics (NCVHS) regarding the implementation of the NCPDP Telecommunications Standard Guide Version F6 (hereinafter referred to as vF6) as the next HIPAA-named industry standard for eligibility verification, claim, and service billing, predetermination of benefits, prior authorization and information reporting transaction exchanges. Walgreens supports the transition to vF6 within the timeline recommended in comments submitted by the National Council of Prescription Drug Programs (NCPDP), we write separately to further highlight issues important to community pharmacy. We thank NCVHS for the opportunity to provide comments on this important advancement for the pharmacy industry that is designed to increase patient safety, expedite patient access to care and improve operational execution.

Walgreens operates more than 9,200 stores in all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. More than 8 million customers and patients interact with Walgreens each day in communities across America, many of them in rural areas. In fact, two-thirds of the 123 million people living in medically underserved areas (MUAs) are within a 15-minute drive time of a Walgreens[1]. Through our locations, customers are experiencing convenient, multichannel access to trusted, cost-effective pharmacy, health and wellness services and advice, as well as health and well-being focused consumer goods and services.

The answers to the questions below are grounded in our core purpose to champion the health and well-being of every community in America. Further, Walgreens is committed to serving patients with integrity and in compliance with all Federal health care program requirements. As such, we are encouraged that NCVHS is requesting industry feedback on implementation of the next version of the NCPDP Telecommunication Standard to lessen barriers in order to allow pharmacists and other healthcare professionals to spend more time on their primary mission—improving their patients' health.

---

[1] MUA data is from https://data.hrsa.gov/data/download as of January 2018.

1. **What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt NCPDP version F6.**

Main enhancements between vF2 and vF6
The clinical evaluation of prescription products and plan benefit transparency will be key components in achieving expected healthcare outcomes as the industry moves forward with miracle drug therapies, value-based care, digital therapeutics, social determinants of health, and other areas of healthcare innovation. NCPDP Telecommunication Standard vF6 offers enhancements that better support current and future business needs, replacing the use of free text messaging with codified fields to facilitate system automation, harmonization of data elements and values and workflow interoperability across the care continuum. The changes include, but are not limited to;

- Allows coverage under prescription benefits of new innovative drug therapies with costs greater than $999,999.99 as a result of expanding all dollar fields to support up to $999 million.
- Enhances patient safety processes by enabling pharmacy and prescriber system automation and interoperability of clinical information, as a result of replacing free text clinical and non-clinical information with codified fields.
- Reduces IT development, testing and implementation burdens as a result of eliminating intermediary qualified message solutions in prior versions and enhancing the use of the Other Related Benefit Information segment. Some examples include Qualified Medicare Beneficiary (QMB) identifiers, End-Stage Renal Disease and Hospice indicators and dates, formulary alternative effective date, provider validation data source (e.g. OIG, Medicaid enrollment file, etc.).
- Expedites patient access to care and facilitates workflow interoperability between the payer, pharmacy and prescriber, as a result of new response data elements to better communicate current and future effective date plan formulary alternative information and patient cost share amounts.

Why vF6 should be adopted
VF6 offers enhancements that better support current and future business needs, which are anticipated to introduce advancements in the following areas:
- Improves structure to support clinical evaluation of prescription products and plan benefit transparency which are key components in achieving expected healthcare outcomes related to value-based care, digital therapeutics, social determinants of health and other areas of healthcare innovation
- Adds opportunities for system automation, harmonization of data and workflow interoperability across the care continuum
- Enhances drug utilization/patient safety mechanisms by providing better tools to address health issues such as the opioid epidemic
- Expedites patient access to care
- Facilitates patient care coordination across distinct components of prescription and medical benefits
- Expedites claim resolution through improved data analytics
- Allows adjudication of claims for innovative drug therapies using industry standard processes leveraging expanded financial fields

2. **When should HHS adopt and require implementation of F6? If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address.**

Timeline Recommendations
Walgreens recommends that HHS name vF6 as soon as possible, to allow stakeholders to begin planning and allocating the applicable IT budget and development phases. Our corporate IT budgets and timelines are dependent on the rule making process and in order to plan accordingly and balance with other product development initiatives, HHS processes need to be timely.

Walgreens aligns with NCPDP implementation timeline recommendations, where the Notice of Proposed Rule Making is released no later than December 2020, and the Final Rule is published no later than August 2021.

Walgreens recommends HHS adopt a compliance date no sooner than May 2025, which is based on stakeholder analysis indicating the development and testing effort for vF6 to be far greater than previous HIPAA-named versions.

Step #	Milestone	vF6 Timeline
1	NCVHS hearings (completed)	4/1/2020
2	HHS releases NPRM	12/31/2020
3	NPRM comment period ends	02/28/2021
4	Final Rule is published	08/28/2021
5	IT business planning, development, informal and formal testing	
6	Trading partner certification, pilot use in production environment	
7	NCPDP recommended full use of vF6	08/28/2024
8	HHS Compliance Date	05/01/2025

Operational/and or technical actions needed if timeline is not met

If the Final Rule is not published in the recommended timeframe, industry will need to continue using NCPDP Telecommunication Standard Implementation Guide Version D.0 (hereinafter known as vD.0) and the associated work around(s) including manual claims processing, splitting of claims for million dollar drugs and manual workflow steps to identify and act upon patient safety alerts. Furthermore, the future use of the 8-byte IIN (previously known as the BIN) is not supported by vD.0 and will prevent processing of claims. Other features such as medical and other related benefit information (e.g., substance abuse program enrollment) will simply not be available to trading partners for enhanced patient care coordination.

3. **We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?**

The following processes are available when drugs are covered under the prescription benefit:

- Paper – Universal Claim Forms, or CMS 1500 forms (the old HCFA forms)

- Billing across multiple claims. E.g. Luxturna®, the blindness drug, there would be two vials, one for each eye. Bill them separately to keep it under $1M per claim.
- Other as defined by trading partner agreement agreements

4. **What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?**

Walgreens is currently not aware of a hard date in which vF6 must be officially available for use, as we are currently supporting alternative solutions to address the new business cases. However, the health care industry is rapidly changing where business needs and regulatory requirements could quickly necessitate the implementation of enhancements in vF6 (e.g., Quantity Prescribed for CIII – CV). We recommend the timeline outlined above be supported by HHS and communicated as soon as possible to allow stakeholders to begin budgeting, planning, development work, and coordinating the necessary trading partner agreements.

The current HIPAA process of naming and implementing new standards or versions of existing standards must evolve to support new and emerging business needs in a more timely manner, thus allowing industry to be more agile and innovative.

5. **Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?**

Walgreens is not aware of any barriers specific to the implementation of vF6. As with any new version implementation, the following complications may exist:

- Stakeholder financial constraints (e.g., state Medicaid programs, smaller stakeholders) may create barriers to meeting implementation timelines and the compliance date
- A compliance date that coincides with annual prescription benefit implementations, (e.g., January, July) and the immunization season (e.g., August – March)

6. **Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.**

Hardware, software and maintenance costs associated to vF6 implementation are estimated to be three to four times higher than the implementation of the current vD.0 NCPDP Telecommunication Standard, in the $$ millions. Much of these costs are associated to the expanded dollar fields and structure of new fields that require data base expansion and updates to many integrated systems, while these costs are high they are essential to our operations.

7. **Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing? If not testing has taken place, what testing strategy should take place in advance of the implementation date?**

Walgreens is not aware of testing to date, however the industry will need to extensively test prior to implementation.

Testing strategy

Historically, software vendors and /intermediaries will begin external testing/certification with individual PBMs as soon as internal testing is completed.   Along with internal testing and development, the industry has required approximately 36 - 43 months to complete the implementation process. This timeline has spearheaded successful adoption of previous versions of the NCPDP Telecommunication schedule.

In closing, Walgreens supports the transition to vF6 within the enclosed recommended timeline. We thank NCVHS for the opportunity to comment on this important advancement for the pharmacy industry that is designed to increase patient safety, expedite patient access to care and improve operational execution.

Sincerely,

Michele V. Davidson, R.Ph
Sr. Mgr. Pharmacy Technical Standards, Development and Policy