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

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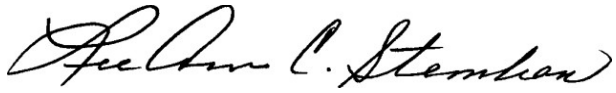
Sincerely,



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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.