



July 30, 2021

Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted via email: NCVHSmal@cdc.gov

Re: National Committee on Vital and Health Statistics Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

Dear Mr. Landen and Ms. Love,

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, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to submit comments and looks forward to further discussion on ways we can assist the subcommittee. NCPDP is concerned with the current rulemaking process which impedes innovation, interoperability and industry speed to implementation. We offer the following comments to questions posed by the subcommittee and request NCVHS recommend revisions to the current processes to enable standards development organizations (SDOs) to name standards in a timelier manner and work with the industry to speed implementation of such standards.

NCPDP Comment Question #1: How can data sharing be improved between patients, providers, payers, public health systems, and other actors in health care? What are the barriers to these improvements?

NCPDP standards can be used to improve data sharing among patients, providers, payers, and public health systems. NCPDP standards support real-time communications between providers (prescribers and pharmacies), payers, public health systems and intermediaries. These standards include patient demographic, eligibility and specific clinical information as well as details related to the product and services provided to the patient. Real-time communication protocols and the use of shared code list terminology allows for expedited processes to be coordinated between the prescriber and the pharmacy, the pharmacy and the payer, and the payer and the prescriber. NCPDP standards are

available to support the communication of similar information between the provider and an intermediary or regulated agency such as Prescription Drug Monitoring Programs (PDMP) and state Health Information Exchanges (HIEs). As the industry moves forward in integrating the patient into the healthcare continuum, existing NCPDP standards can be used to create synergies in the development of new standards that provide interoperable solutions that include the patient.

The industry continues to merge clinical and administrative data for both pharmacy and medical services to achieve improved patient outcomes. This merged data provides an opportunity to streamline processes to achieve interoperability. There are, however, multiple barriers to reaching these goals resulting in increased healthcare costs and patient care risks. Below are examples of current barriers to interoperability and recommendations on how to improve the data sharing process.

<u>Barrier</u>	<u>Recommendation</u>
<ul style="list-style-type: none"> • Inconsistencies in patient matching processes 	<ul style="list-style-type: none"> • Explore implementation of a patient matching solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries • Support the use of a universal healthcare patient identifier • Harmonize data standards to support the use of a universal patient ID similar to the way the NCPDP standards are harmonized
<ul style="list-style-type: none"> • Disparate standards and the lack of harmonization of data dictionaries and code lists 	<ul style="list-style-type: none"> • Involve all healthcare standards in the United States Core Data for Interoperability (USCDI) data harmonization process • Support language translation and recognize specific situations of use by the impacted entities
<ul style="list-style-type: none"> • Inability to pilot new solutions for HIPAA mandated standards without risk of being non-compliant • Rigid structure and extensive timeline of the HHS rulemaking process inhibits technology innovation and ability to address current business needs 	<ul style="list-style-type: none"> • Update HIPAA regulations and if necessary, legislation, to support SDO determination of updated version implementations. • Align the United States Department of Health and Human Services, (HHS) with the Office of the National Coordinator for Health Information Technology (ONC) Standards Version Advancement Process (SVAP) structure • The Secretary should allow the SDOs that are responsible for the specific standards to update to newer versions of standards without rulemaking in order to encourage innovation and the adoption of new functionality that can improve interoperability and promote patient safety
<ul style="list-style-type: none"> • Federal and state regulations impacting healthcare processes and standards lack consideration of interoperable technical and operational workflows, creating costly administrative barriers and compromising patient care, for example: <ul style="list-style-type: none"> ○ RxNorm to NDC 	<ul style="list-style-type: none"> • Leverage the Health Standards Collaborative (HSC) as a consultative forum where federal and state business cases would be proactively reviewed to determine the applicable standards' optimal solution(s)

<u>Barrier</u>	<u>Recommendation</u>
<ul style="list-style-type: none"> ○ ICD-10 utilization ○ Consolidated Appropriations Act of 2021 (CAA) requirement for ID cards 	
<ul style="list-style-type: none"> ● Data reporting format inconsistency across states compromises efforts to leverage healthcare data at the patient level regardless of the patient or service location, creates unnecessary administrative costs, and leads to data integrity risks due to data duplication ● Lack of standardization, simplification and interoperability across PDMPs, HIEs and immunization data repositories. ● State data sharing restrictions based on certain disease states (e.g., mental illness, HIV) and sharing outside of entity jurisdictions compromise provider access to critical clinical data necessary to coordinate patient care. 	<ul style="list-style-type: none"> ● Influence state agencies with specific data reporting requirements to adopt the use of the specific standard as recommended by the applicable SDO, and/or SDO Collaborative, for example: <ul style="list-style-type: none"> ○ NCPDP PDMP Reporting Standard ○ NCPDP SCRIPT MedicationList ○ NCPDP State Medicaid Provider File ● Harmonize federal and state regulations related to information blocking, to establish the necessary data transparency across provider systems.

NCPDP Comment Question #2: *Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.*

NCPDP has been waiting since NCVHS made their recommendation to HHS on April 22, 2020 to name the Telecommunication Standard Version F6. NCPDP requests NCVHS' support in expediting the rulemaking process for NCPDP's Telecommunication Standard Version F6. This version includes multiple enhancements to improve interoperability across standards by harmonizing field formats, field lengths, and patient demographic information. The ability to link data at the patient and product/service level is critical to achieving interoperability advancements.

NCPDP has many other existing standards published and ready for use, supporting interoperable communication between the designated stakeholders. Similar to the ONC SVAP, NCPDP recommends NCVHS endorse new standards as needed and allow the SDO of each standard to support pilots and implementation of new versions of previously named standards.

NCPDP recommends that NCVHS support the advancement and endorsement of these standards. Such support could be through demonstration projects or rulemaking that facilitates piloting of these standards and messages.

The list below includes examples of the most recent developments.

- Specialty Medication Enrollment Implementation Guide
 - NCPDP worked with HL7® to improve the enrollment process associated with the prescribing and dispensing of specialty medications.
 - The resulting Specialty Medication Enrollment Implementation Guide will reduce current administrative barriers and delays in patient access to care.
- Real Time Prescription Benefit Standard (RTPB) Version 12
 - This standard provides prescribers and pharmacists access to plan benefit coverage rules and, where applicable, alternative options for the patient.

- The RTPB Standard is a critical tool in reducing workflow barriers and patient care delays, as it provides the necessary transparency at point of care, mitigating retrospective actions that cause care delays.
- State Medicaid Provider File Standard
 - This standard provides practical guidelines for state Medicaid agencies or entities producing federal and state required provider enrollment files used in the pharmacy industry to leverage a standardized file layout.
 - The standardized layout allows for interoperable implementation and use of the data between the Medicaid agency, Managed Care Organizations (MCOs), Pharmacy Benefit Managers (PBMs), pharmacies and prescribers, enabling consistency in communication to the patient.
- Post Adjudication Standard
 - Enables processors/payers to supply the qualified receiving entity, in a consistent format, detailed drug or utilization information post claim adjudication.
- Prescription Drug Monitoring Program Reporting Standard
 - Provides a consistent format for providers to report prescription data to PDMPs.
- NCPDP SCRIPT 2019071 and higher
 - MedicationList Message
 - Enables pharmacies to communicate dispensed medication lists to HIEs and other entities.
 - Referral Message
 - Enables providers and payers to request referrals electronically from other providers.

NCPDP Comment Question #3: How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

NCPDP cannot speak to the standards process and business needs of non-healthcare related industries reliant on interoperability of data. NCPDP can, however, emphasize the broad number of stakeholders and processes that are supported within the healthcare industry and how the current regulatory process often hinders advancement. NCPDP recommends regulators replace the current HIPAA/HHS rulemaking process with a method similar to ONC's Standards Version Advancement Process (SVAP). SVAP allows developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use approved newer versions of standards that are adopted in regulation so long as certain conditions are met. This supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

NCPDP Comment Question #4: What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term: As noted under the response to question #2, NCPDP stresses the immediate need for HHS to complete the HIPAA rulemaking process for NCPDP Telecommunication Standard Version F6.

Mid-term: While COVID has hindered many timelines and initiatives, the industry is eager to establish new mechanisms to expedite the HHS rulemaking process to allow the use of current versions of named standards. NCPDP recommends the HIPAA/HHS rulemaking process be modified to better support the implementation speed necessary to address business needs and regulatory requirements.

The combination of eliminating or reducing rigid regulations and establishing SDOs as the industry experts for proactive solutions will allow the industry to pilot innovation more quickly. Government program incentives that support these pilots will further increase stakeholder participation to validate viability and expected outcomes.

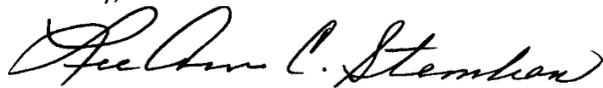
Long-term: The past 20 years of experience has made it evident that the current rulemaking process for HIPAA Transactions and Code Sets needs to be streamlined. This process and the associated Transaction Standards rule no longer support the speed of change happening in the healthcare industry.

NCPDP looks forward to working with NCVHS to streamline the current rulemaking process and improve the advancements of standards for the industry.

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

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Sincerely,



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