



National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Discussion: Request to Recommend Adoption of NCPDP F6

Subcommittee on Standards

March 24, 2020



Agenda: Discussion of NCPDP F6

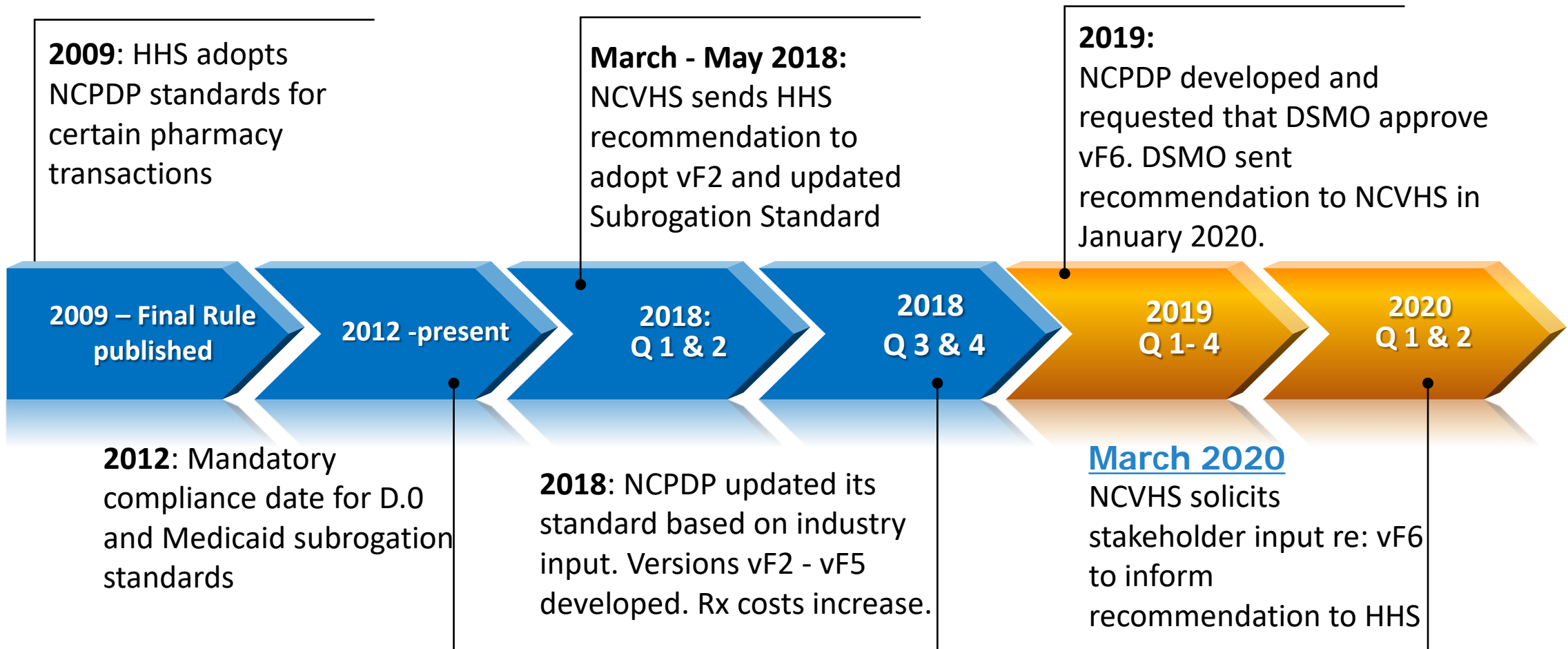
1. Purpose for today's discussion – Act on a request to recommend adoption of an updated NCPDP standard as a HIPAA-mandated national standard
2. Review of standards adopted for pharmacy transactions under HIPAA
3. Overview of NCPDP Version F6 and summary of changes between F2 and F6 (Margaret Weiker)
4. Process for obtaining stakeholder feedback
5. Committee Discussion
6. Public Input
7. Next steps

Request from NCPDP to adopt Version F6



- January 2020: the Designated Standards Maintenance Organization Steering Committee (DSMO) submitted letter asking NCVHS to recommend NCPDP Version F6 to HHS for adoption as a HIPAA standard to replace version D.0.
 - This replaces the request submitted in February 2018 to adopt NCPDP version F2.
- Key factor for new request: new drugs coming to market have price points over \$1 million dollars.
 - Dozens more with such costs are anticipated in the near future with hundreds more therapies under development, including gene therapies for certain cancers;
 - NCPDP Version F2 does not support dollar fields greater than \$999,999.99.
- NCPDP has made modifications in version F6 to accommodate the drug costs, in addition to other enhancements requested by industry.
 - F6 includes all modifications since D.0, not just the changes between F2 and F6.

Adoption of Pharmacy Standards Under HIPAA



2018 NCPDP Recommendation to NCHVS: Adopt Version F2 to replace D.0



- F2 contained enhancements to address the opioid crisis (eligibility and drug utilization review, prescription drug monitoring programs, enhanced coordination of benefits).
- Improvements in F2 addressed industry business needs not met in D.0:
 - Changes in reimbursement methodologies;
 - Information allowing the pharmacy to better communicate alternative therapy availability with the patient;
 - Workflow automation.
- Enhanced patient safety mechanisms (improved identification of medication contraindications).
- Improved ability to communicate information to patients about services.
- Increased opportunities for interoperability.

NCVHS Recommendation to HHS to adopt NCPDP F2



- NCVHS Recommendations in its [May 17, 2018 letter](#) to HHS:
 1. **Adopt updated versions of the Standards**
 - Version F2 to replace Version D.0
 - Adopt the Batch Standard Implementation Guide Version 15
 - Adopt the updated Medicaid Subrogation Implementation Guide, Version 10 to replace Version 3.0
 2. **Implementation timing**
 - Expedite rulemaking to the extent feasible and publish a final rule by the end of calendar year 2019
 - Provide for a two-year implementation timeline following publication of the final rule
 - Use June as the compliance month
 - Require that the updated version of the standard be used by the compliance date, but allow both versions of the standards be used for a one-year period after the compliance date
 - Require full compliance by the end of the third year, and only allow use of the new versions of the updated standards (F2, Batch Version 15 and Subrogation Version 10)
- HHS has not yet proposed adoption of NCPDP Version F2, Batch Version 15 or Medicaid Subrogation Version 10

New Proposal from NCPDP: Adopt Version F6



Presentation:
Margaret Weiker, NCPDP

Public Comment Period



To Submit Public Comment:

- On Zoom, click “raise your hand” to have your audio unmuted
- By phone, press *9 to request unmuting of phone
 - If you are muted on the phone and have permission to speak, press *6 to unmute yourself
- Or send comment by email to NCVHSmail@cdc.gov

Please include your name, title, and organization

Process for obtaining stakeholder input



- Federal Register Notice (2/27/20) invited stakeholders to submit written input.
- Additional industry outreach to subject matter experts from NCVHS and NCPDP requested written response to this list of questions:
 1. What are the main enhancements between vF2 and vF6 that improve functionality of the standard?
 2. When should HHS adopt and require implementation of vF6? What is industry's desired implementation timeframe/timeline? Why?
 3. What is the latest date the standard must be available for use? What is the industry's deadline for adoption?
 4. How will industry accommodate cost of \$1 million drugs until standard is adopted/mandated for use?
 5. What are the barriers to implementing vF6? What parts of industry are affected by these?
 6. Provide any qualitative or quantitative costs and benefits for implementing vF6.
 7. Are you aware of any testing that has taken place with vF6 between trading partners? What testing strategy should take place in advance of the implementation date?

The Principles of Updating or Adopting Standards under HIPAA



1. Lead to cost reductions through efficiency and effectiveness.
2. Meet the needs of the health data standards user community.
3. Be uniform/consistent with other adopted standards.
4. Have low development costs relative to the benefits of using the standards.
5. Be supported by ANSI accredited Standard Setting Organization (SSO) or other organization that would maintain the standard over time.
6. Have timely development testing, implementation and updating procedures to achieve administrative simplification benefits faster.
7. Be technically independent of the computer platforms and transmission protocols used in electronic transactions unless explicitly part of the standard.
8. Be precise, unambiguous and as simple as possible.
9. Result in minimum data collection and paper work burdens.
10. Incorporate flexibility to adapt more easily to changes in health care infrastructure (e.g. new services, organizations and provider types).

Themes from Stakeholder Input (1)



NCVHS received input from diverse stakeholder organizations including national organizations representing thousands of pharmacies, pharmacy benefit managers, community pharmacies, chain pharmacies, technology providers, vendors, and health plans.

1. General support for adoption of NCPDP version F6 based on its accommodation of the changing landscape of health care operations and technology.
 - No opposition to the proposal.
2. Timely adoption of the standards by HHS is critical.
3. Industry will not start development work or testing without a Federal rule.
4. Implementation date should not interfere with pharmacy change periods or peak influenza spikes.

Themes from Stakeholder Input (2)



5. Version F6 brings incremental improvements over F2:
 - Opportunities for greater automation and interoperability between systems;
 - Less manual effort required due to increased use of codes;
 - Improves patient care.
6. F6 is a real time transaction. The patient experience is dependent on use of current standards with functionality that meets needs of today's medication therapies and drug benefit plans.
 - NCPDP does have a batch equivalent transaction.
7. Level of lift and cost at least double that of NCPDP D.0.
 - Transformation is from D.0 to F6 (10+ years of change).

Summary of Responses to Questions

Q1: What are the Main Enhancements of vF6?



- Removes free text fields and replaces them with codified fields.
- Improves interoperability through use of codified fields.
- Mitigates needs to split claims for high dollar claims.
- Provides more data that can be used between Long Term Care providers and Pharmacy Benefit Managers (PBMs), including information needed for prior authorizations.
- Enhancements to the drug utilization review (DUR) fields in the claim response transaction (improves communication from payer for pharmacy action).

Q2: When Should vF6 be Adopted and Required for use?



Steps	Milestone	VF6 Timeline
1	HHS Release NPRM	12/31/2020
2	NPRM comment period ends	2/28/2021
3	Final Rule is published	8/28/2021
4	IT business planning development, informal and formal testing	
5	Trading partner certification, pilot use in production environment	
6	NCPDP recommended full use of vF6	8/28/2024
7	HHS compliance date	5/01/2025

- Timely rulemaking announcement of adoption supports IT budget and development process.
- Support for compliance date during second calendar quarter of the year.

Q3: What is the Latest Date the Standard Should be Available for Use?



- HHS should adopt the standard by December 2020.
- Delays in timeline, may necessitate work-arounds, such as:
 - manual claims processing;
 - splitting of claims for million- dollar drugs and manual workflow steps to identify and act upon patient safety alerts.
- One submitter proposed moving to the next version of the standard if VF6 is not adopted in accordance with the proposed timeline.
- Ongoing delays in adoption of standards hamper industry ability to meet continually changing/emerging business needs.

Q4: How Will Industry Accommodate High Cost Medications (over \$1 million)?



Submitters identified the following issues with increasing medication costs:

- The technical enhancements to support the dollar field expansion will require significant financial investments and impact multiple systems beyond point of service adjudication.
- Interim solutions using current industry standards and best practices will present barriers that require unique solutions for each organization.
- Some options will not be scalable and will preclude claim splitting.
- Some high dollar medication therapies may have limited or exclusive distribution dispensing networks. This will create complexity due to the variability of manufacturers and unique payer needs.

Submitters provided several solutions that could be implemented if F6 is not adopted:

- Pharmacy will submit multiple claims using NCPDP Version D.0. (“split claims”).
- Pharmacy will submit Universal Claim Form.
- Pharmacy could submit special handling invoice.
- For coverage coordinated under the medical benefit, pharmacy submits drug claim, provider submits claim for drug administration.

Q5: Are There Implementation Barriers for vF6? Who Could be Impacted?



- Compliance dates could conflict with other prescription benefit implementation.
- Field expansion will have significant workload and financial impact on systems.
- Technical and operational learning curves for employees.
- Possible lost or delayed opportunities due to limited resources and time constraints, coordination of quality assurance and user acceptance testing resource availability.
- All organizations will have to do significant planning and development. Some organizations may have more challenges than others, such as State Medicaid programs and small entities.

Q6: Provide Qualitative and Quantitative Cost Benefit Information



- Some submitters estimate the expense to be between 2 to 4 times that of implementing D.O.
- Thousands of labor hours will be needed from various business teams to plan, develop and test vF6 prior to full implementation.
- Costs will vary among different pharmacy chains based on size, scope of services provided and business models.
- Hardware, software, and maintenance costs allocated specifically to vF6 implementation are estimated to be in the tens of millions of dollars.
- Benefits include improved patient care and greater ability to support changing health care delivery and payment systems.

Q7: Has the Updated Standard Been Tested? Suggest Strategies for Testing?



- Testing of the updated standard will first be conducted internally by covered entities, followed by testing between trading partners.
- Submitters reported that development and testing is typically not done until a standard is named in regulation and the timeline published.

Additional Comments from Stakeholders



Barriers

- The current HIPAA process may 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 from being innovative, building and piloting solutions prior to the changes becoming a new version named under HIPAA.

Value

- NCPDP 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 (3) seconds.

Additional Comments from Stakeholders (2)



- Public Comments

Next Steps



- Consolidate input from stakeholders.
- Decide whether to make recommendation to HHS.
- Draft letter for HHS and secure approval from Full Committee.



National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Questions & Discussion

Draft Recommendation to HHS



The Standards Subcommittee recommends that the Full Committee make two recommendations to HHS:

1. Adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6 (to replace version D.0).
2. Promulgate and implement according to recommended timeline
 - Proposed Rule (NPRM) to be published by the end of calendar year 2020
 - Assuming favorable NPRM public comment, a Final Rule published by September 1, 2021
 - A 3-year pre-implementation window following publication of the final rule, allowing (but not requiring) industry use beginning September 1, 2024 (*This will allow sufficient time for planning and completion of necessary budget cycles.*)
 - Allow both versions (D.0 and F6) to be used for a 9-month period beginning September 1, 2024 and ending April 30, 2025 (*This will enable an effective live-testing and transition period that allows the use of either the D.0 or F6.*)
 - Require full compliance by the end of the third year (i.e., F6 only beginning May 1, 2025)