December 7, 2018

Alix Goss and Nick Coussoule, Co-Chairs
NCVHS Standards Subcommittee

Reference: Predictability Roadmap

Dear Ms. Goss and Mr. Coussoule,

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,400 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 health care 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. Through a consensus building process in collaboration with other industry organizations, our members develop these solutions to improve safety, privacy and healthcare outcomes for patients and healthcare consumers, while reducing costs in the system.

The NCPDP SNIP Committee reviewed the draft recommendations for the Predictability Roadmap and provides the following comments.

1. **Would these recommendations as a whole improve the predictability of the adoption of administrative standards and operating rules?**

NCPDP agrees there must be improvements in the adoption of standards and operating rules.

NCPDP believes a predictable, reliable and regular schedule for recommending rule adoption of new or revised standards would have the most beneficial industry impact. The total timeframe associated with the process must be condensed.

NCPDP does not agree with the recommendations as a whole and have outlined specific areas of concern below.

2. **What additional recommendations are critical to achieve predictability?**

NCPDP recommends HHS commit to meeting the timely promulgation of proposed and final rules and must publish reliable, accountable dates for release of final and proposed rules. In addition, NCPDP requests a new and abbreviated process for responding to the SDO's request for the adoption of incremental updates to the current HIPAA-named version of the standard.

In addition, NCPDP recommends HHS use the Interim Final Rule (IFR) process to adopt new or updated HIPAA standard transactions.

Recommendations

1. **HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry.**

   NCPDP Comment: No comment.

2. **HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.**

   NCPDP Comment: *No comment.*

3. **HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.**

   NCPDP Comment: *NCPDP agrees the DSMO has served its purpose and should be disbanded. In the beginning the DSMO performed an important function managing HIPAA standard change requests and coordinating activities of the standards bodies and data content committees. Currently this coordination happens among the standards bodies and data content committees with their respective liaisons and no longer needs this additional oversight.*

   Additional details around the transition need to be provided.

4. **HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities.**

   NCPDP Comment: *NCPDP is opposed to any created entity which would have any oversight and/or governance of our ANSI-accredited standards development processes. As an ANSI-accredited Standards Development Organization (SDO), NCPDP uses a consensus-building process to create national standards for real-time, electronic exchange of healthcare information. Even though the oversight criteria may take into account ANSI's Essential Requirements, such oversight could run counter to ANSI's Essential Requirements which can change annually. In addition, NCPDP is opposed to the creation of an entity that could elongate the process and increase administrative costs for implementation of a standard.*

5. **HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.**

   NCPDP Comment: *As stated in our response to item 4, NCPDP is opposed to any created entity which would have any oversight and/or governance of our ANSI-accredited standards development processes. As an ANSI-accredited Standards Development Organization (SDO), NCPDP uses a consensus-building process to create national standards for real-time, electronic exchange of healthcare information. Even though the oversight criteria may take into account ANSI's Essential Requirements, such oversight could run counter to ANSI's Essential Requirements which can change annually. In addition, NCPDP is opposed to the creation of an entity that could elongate the process and increase administrative costs for implementation of a standard.*

6. **SDOs and ORAE should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years.**

   - Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCVHS.
   - NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months.
   - HHS should adopt the NCVHS recommendations on a regular schedule.

   NCPDP Comment: NCPDP meets the publishing requirements of this recommendation as NCPDP's standards development process allows new versions to existing standards as well as new standards to be published twice per year. The determination to move an existing or new standard forward through the rule making process is managed through NCPDP's regular review process which includes input from NCPDP membership's evaluation of business needs and cost benefit analysis.

   If the intention of the predictability timeline is to support recommending standards and operating rules to NCVHS on a schedule that is not greater than 2 years, NCPDP would support an annual response from the SDOs to NCVHS to move or not move a new or updated version of a standard forward. NCPDP does not support an approach that would allow HHS to mandate the SDO move to a new version of a standard or a new standard every year or every two years.

7. **HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.**

   NCPDP Comment: *NCPDP agrees HHS should regularly make guidance available as long as the guidance is issued in conjunction with the SDO responsible for the development of the standards and operating rules. Additionally, in the communications, HHS should reference the guidance published by the SDOs.*

8. **HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with what is permitted in §1174 of the Act).**

   NCPDP Comment: *NCPDP agrees HHS must commit to an established timeframe for publication of regulations. NCPDP is not clear as to what the one-year recommendation contains. Is it the NPRM and the Final Rule? NCPDP requests the published regulation incorporates the number of months recommended by the SDO for implementation and compliance after the final rule is published.*

   In addition, NCPDP recommends HHS use the Interim Final Rule (IFR) process to adopt new or updated HIPAA standard transactions.

9. **HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.**

   NCPDP Comment: *NCPDP agrees.*

10. **HHS should adopt incremental updates to standards and operating rules. In accordance with Sec 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCVHS, and if updates are available.**

    NCPDP Comment: *NCPDP agrees HHS should adopt incremental updates on a reliable, predictable schedule. A process that abbreviates the regulatory requirements for incremental updates would be supported. SDOs need an incremental update process to appropriately respond to new legal/regulatory changes as well as unanticipated industry wide business needs that require immediate attention.*

11. **HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation.**

    NCPDP Comment: *NCPDP recommends further investigation and analysis regarding this recommendation.*

12. **HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.**

    NCPDP Comment: *NCPDP agrees with this recommendation*.

Call to Action

A. **Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases.**

   NCPDP Comment: NCPDP consistently promotes the effective use of the NCPDP transactions through the NCPDP SNIP Committee, Frequently Asked Questions

and best practice guides. NCPDP encourages health plans, vendors and providers to consult with the appropriate SDOs or ORAE regarding any barriers and issues.

B. The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.

NCPDP Comment: *WEDI creates white paper and guidance for the medical and dental industries. NCPDP identifies issues, solutions and publishes white papers advising on agreed upon policy implications and best practices related to the use of NCPDP standards and operating rules for prescribing, dispensing, monitoring, managing and paying for medications and pharmacy services crucial to quality healthcare.*

C. HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3rd parties to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.

NCPDP Comment: *NCPDP agrees based on the successful precedents established by ONC's joint collaboration with NCPDP (the SDO).*

D. HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.

NCPDP Comment: *NCPDP is opposed to this action if it would elongate the process and increase administrative costs for implementation of a standard. NCPDP is not opposed to a cost benefit analysis of standards and operating rules after implementation to determine return on investment.*

E. SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.

NCPDP Comment: *NCPDP actively recruits stakeholders to address specific industry concerns to ensure that interested parties are aware of and represented in the standards development process.*

F. Leadership from the public and private sector should commit to membership in Standards Development Organizations, assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs.

NCPDP Comment: *NCPDP agrees.*

G. **Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable policies regarding business practices, including policies for identifying and implementing best practices in such an organization.**

NCPDP Comment: *Without further clarification, NCPDP has no comment.*

H. **HHS should continue to publish a universal dictionary of clinical, administrative, and financial standards that are or will be available for use, e.g. the ONC Interoperability Standards Advisory (ISA).**

NCPDP Comment: *NCPDP agrees.*

Recommendations for Measurement

M1. HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.

NCPDP Comment: *No comment.*

M2. HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance.

NCPDP Comment: NCPDP is opposed to any created entity which would have any oversight and/or governance of our ANSI-accredited standards development processes. As an ANSI-accredited Standards Development Organization (SDO), NCPDP uses a consensus-building process to create national standards for real-time, electronic exchange of healthcare information. Even though the oversight criteria may take into account ANSI's Essential Requirements, such oversight could run counter to ANSI's Essential Requirements which can change annually.

M3. NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

NCPDP Comment: *NCPDP agrees.*

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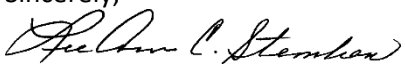
Sincerely,



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