April 2, 2015

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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W., Suite 729-D
Washington, D.C. 20201

RE: ONC Nationwide Interoperability Roadmap

Dear Dr. DeSalvo:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 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 supports interoperability among stakeholders and looks forward to continuing to work with ONC on achieving this critical healthcare objective. We appreciate the references to pharmacy and pharmacists and encourage efforts to more fully include them in the roadmap and associated efforts. As the care models continue to evolve, pharmacists will play an increasingly important role in the care and safety of patients.

Thank you for your consideration of our input. NCPDP welcomes the opportunity to work with ONC representatives in advancing interoperability.

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

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Sincerely,

Lee Ann C. Stember
President
National Council for Prescription Drug Programs
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cc: NCPDP Board of Trustees

Nationwide Interoperability Roadmap (General Comments):

- NCPDP and other ANSI-accredited Standards Development Organization(s) (SDO) are stakeholders in the interoperability process and must continue to be identified as such. While we appreciate the references to pharmacy/pharmacists, more needs to be done to include them in these interoperability efforts. Pharmacists today play a key role in providing care in various settings and that role will expand as they gain provider status.

- A mechanism to validate new standards/new versions of standards that are named in HHS regulations prior to their mandated implementation needs to be developed. Metrics, use cases prioritized by stakeholders, and feedback loops are critical to the success of adoption and use. One possible mechanism is to allow trading partners to pilot these before being named or required. This will assist the industry in identifying issues prior to widespread use.

- Many of the points raised in the roadmap presume the data gathered will be available for use in a timely and effective manner. This presumption deserves to be expanded so it is clear that this is an expectation for developers and users.

- As an ANSI-accredited SDO, we would like clarification on how the processes that we comply with for standards development and maintenance are envisioned to integrate with some of the proposed processes for standards development and modification that are mentioned repeatedly. Please clarify who ONC considers to be an SDO – those with ANSI-accreditation, those named by other regulation (i.e. Affordable Care Act)?

Specific Comments

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Page 7	Care Providers is Broadly Inclusive of the Care Continuum, Including, but not Limited to:	Please clarify if home and community-based services include educational institutions and if other authorized individuals and institutions include correctional facilities.
Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability		
A1.1	ONC will define a nationwide governance framework with common rules of the road for trust and interoperability and a mechanism for identifying compliance with common criteria. These rules will first focus on interoperability of a common clinical data set for purposes of treatment.	The coordinated governance process needs further definition, including identification of stakeholders, the relationship with existing organizations and processes.
A1.2	ONC will identify a mechanism for recognizing organizations that comply with the common rules of the road.	The recognition of the organizations who comply with the common rules should be done publicly. Please provide clarification around the mechanism, the criteria/measurements used for recognizing the organizations and what organization will be applying the criteria.
A.1.3	Call to action: Public and private sector stakeholders across the ecosystem should come together to establish a single coordinated governance process to establish more detailed policies regarding business practices, including	Please provide additional clarification as to the role of the stakeholder relative to the historical role of HHS staff who previously identified technical standards. What will happen if the stakeholders do not come together to establish the single coordinated governance process? Please provide

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	policies for identifying and addressing bad actors and to identify the technical standards that will enable interoperability for specific use cases (see Appendix H for Priority Interoperability Use Cases).	clarification as to how you would define a bad actor and how this affects existing processes and trading partner agreements. NCPDP recommends a single organization such as WEDI, or the SCO be appointed as the organization to organize the stakeholders.
A.1.5	ONC and stakeholders participating in the coordinated governance process should establish metrics for monitoring and assessing nationwide interoperability and methods for data collection.	NCPDP and other ANSI-accredited Standards Development Organization(s) (SDO) are stakeholders in the interoperability process and must continue to be identified as such.
A.1.6	The coordinated governance process will continue to operate and update policies for business practices/operations and technical standards to enable interoperability as needed.	Each ANSI-accredited SDO has a process that allows stakeholders to request updates to the standards. The coordinated governance process should feed into the ANSI-accredited SDO process, but must not override the process. Please confirm that the existing processes and policies for standards management (for ANSI-accredited SDOs) will be honored.
A1.8	The coordinated governance process will continue to operate and update policies for business practices/operations and technical standards to enable interoperability as needed.	As stated in A1. 6., should feed into the ANSI-accredited SDO process, but must not override the process. This would also apply to other organizations and processes named in federal/state regulation, i.e. CAQH CORE.
A2.3	ONC will work with the established coordinated governance process to identify or modify criteria and implementation specifications to address an expanded data set and uses of health information beyond treatment, including but not limited to payment and health care operations and patient-generated health data.	As stated in the concerns from A1, the SDOs already have a process in place to modify criteria and implementation specifications. If the standard is a named standard (i.e. HIPAA or MMA), the regulatory process must be followed to move the industry to a new standard or version.
A2.4	ONC and stakeholders participating in the coordinated governance process, human service providers and health-related device overseers should define policies for interoperability of health information from non-clinical sources.	Please provide a definition of non-clinical sources.
A2.6	ONC will work with the coordinated governance process to identify or modify criteria and implementation specifications to address the needs of a	Each ANSI-accredited standard has a process that allows stakeholders to request updates to the standard. The coordinated governance process should feed into the ANSI SDO accreditation

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	learning health system.	process, but must not override the process.
A2.7	ONC and stakeholders participating in a coordinated governance process should define criteria and implementation specifications for interoperability of clinical data to support research and big data analyses nationwide.	Each ANSI-accredited standard has a process that allows stakeholders to request updates to the standard. The coordinated governance process should feed into the ANSI SDO accreditation process, but must not override the process.
A3.1	The coordinated governance process should support three main functions related to technical standards: prioritization of use cases for which standards are needed, selection of standards to support priority use cases based on ONC's Interoperability Advisories and coordination across SDOs and implementers as standards are developed and refined (see Appendix H for Priority Interoperability Use Cases).	The Use Cases provided appear to be statements of goals/objectives and not true Use Cases. Some of the items listed include those that have existing solutions, although these have not been widely adopted. Use Cases should be fully developed for those items that are ranked as the highest priority. Support from ONC to drive adoption of available solutions would be appreciated.
A3.2	The coordinated governance process should support a holistic lifecycle process for technical standards that enable care providers and individuals to send, receive, find and use a common clinical data set. This involves establishing clear feedback loops between SDOs and implementers, as well as supporting non-certification-related testing of technical standards.	ONC should align with the regulatory authorities for naming of new versions/new standards to be used. It is our assumption that the last sentence will allow for testing/piloting of new version/standards before implementation is required.
A3.3	The coordinated governance process should establish an ongoing evaluation process for the efficacy of standards and testing tools.	The development of widely available testing tools is needed. We encourage ONC to work with the SDOs and other stakeholders to develop and distribute these tools. Each ANSI-accredited standard has a process that allows stakeholders to request updates to the standard. The coordinated governance process should feed into the ANSI SDO accreditation process, but must not override the process.
A3.4	The coordinated governance process should work with SDOs to identify or develop additional standards for new learning health system priority functions as part of the holistic lifecycle process.	Each ANSI-accredited standard has a process that allows stakeholders to request updates to the standard. The coordinated governance process should feed into the ANSI SDO accreditation process, but must not override the process.
Table 2: Critical Actions for a Supportive Business and Regulatory Environment that Encourages Interoperability		
B2.2	Call to action: All states should take appropriate steps to implement policies	Not only should states align with the roadmap, they should not have policies that are in contradiction.

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	that are in alignment to the national, multi-stakeholder approach to coordinated governance for interoperability.	
Table 3: Critical Actions for Individuals That Are Empowered, Active Partners in the Health and Health Care		
C1.3	Call to action: Individuals should contribute clinically relevant patient-generated health data and request corrections to their electronic health information to effectively manage their interactions with the care delivery system and to manage their health and wellness where they live, work and play.	There needs to be a standard and a mechanism that facilitates an individual to contribute clinically relevant health data, such as biometric data.
C2.6	Call to action: Providers and technology developers should support the incorporation of patient-generated health data in health care delivery, which may include advance directives, remote monitoring, glucose levels and other data individuals are tracking.	Patient-generated health data, such as biometric data, should be incorporated into health records via a standard. ONC should provide guidance as to whether patient-generated data should be incorporated if manually tracked (i.e. not from a device).
C2.9	Call to action: Providers and health IT developers should provide a majority of individuals/caregivers the ability to contribute as needed to their electronic health information and support the incorporation of patient-generated health data.	The use of a national standard should be used for the exchange of patient generated data. The source of the data should also be tracked.
C3.2	C3. 2 Call to action: Providers should provide individuals with secure access to their own behavioral health information in a manner that is easy to use and enables them to make choices about disclosure of specific information that is sensitive to the individual and/or legally protected.	NCPDP recommends ONC, EHR vendors and SDOs evaluate this call to action and provide guidance to the industry prior to any decision or action being taken.
Page 51: Moving Forward and Critical Actions		
	For example, CDS based on wide availability of pharmacy prescribing and fill data will enable patient education, prevention of adverse drug events, tracking and improvement of medication adherence and, through linkages to Prescription Drug Monitoring Program (PDMP) systems, enable interventions to prevent the abuse of controlled substances. Further, the integration and wide availability of this information will support distributed	NCPDP agrees that integration and wide availability of pharmacy prescribing and fill data is beneficial, but this presumes the data will be available for use in a timely and effective manner. This presumption deserves to be expanded so it is clear that this is an expectation for developers and users.

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	models of care management, comprehensive medication management (CMM) and medication therapy management (MTM) across multiple healthcare disciplines and sites of care, such as community pharmacies. See Appendix F for more Background information on Medication Use and Management.	
Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value		
D2.6	Call to action: Providers should routinely populate key data when E-prescribing in support of unambiguous prescription for verification, counseling, monitoring and activities of comprehensive medication management.	Use of and compliance with NCPDP standards will ensure that unambiguous prescriptions are created to support patient care. NCPDP welcomes input regarding key data elements to ensure the standards support the exchange of that information.
D3.2	Call to action: Providers and other stakeholders should use standard metrics of interoperability to monitor and track improvement.	The standard metrics of interoperability need to be defined and agreed to by all stakeholders before they can be used.
D4.1	Call to action: Providers should routinely leverage standards- based health IT to support prioritized workflows including: • Closed loop transitions of care • Secure clinical communications • Prior authorizations, medication co-pays and imaging appropriateness • CPOE for services and diagnostic testing • e-prescribing of controlled substances with concurrent availability of PDMP data	NCPDP recognizes the use of standards-based health IT is necessary. Support from ONC to encourage adoption of the NCPDP Prior Authorization standard would be beneficial. NCPDP continues its efforts to provide medication copay information and PDMP data in a real time electronic manner to the prescriber.
D7.1	Call to action: Providers should work together with purchasers of care to have access to patient out-of-pocket costs and those of payers and purchasers. Providers are engaged in regional efforts to measure quality and maximize value.	NCPDP welcomes the input of other entities as we continue to develop standards for the exchange of patient prescription benefit information.
Table 5: Critical Actions for Ubiquitous, Secure Network Infrastructure		
E1.3	HHS will continue to support, promote and enhance the establishment of a single health and public health cybersecurity Information Sharing and Analysis Center (ISAC) for bi-directional	NCPDP supports the collaboration of ONC with NIST in creating a framework and we recognize NIST as an authoritative entity on cybersecurity threats. We recommend NIST be an advisor in this effort.

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	information sharing about cyber threats and vulnerabilities between private health care industry and the federal government.	
E1.4	ONC will work with NIST and OCR to finalize and publish the NIST Critical Infrastructure Cybersecurity Framework and Health Insurance Portability and Accountability Act (HIPAA) Security Rule Crosswalk.	
E1.5	HHS will work with the industry to develop and propose a uniform approach to enforcing cybersecurity in healthcare in concert with enforcement of HIPAA Rules.	
E2.1	ONC will work with OCR and industry organizations to develop "at rest" standards for data encryption and provide technical assistance. OCR will consider whether additional guidance or rulemaking is necessary.	Recommend working with NIST which developed The Advanced Encryption Standard (AES), also referenced as Rijndael (its original name), which is a specification for the encryption of electronic data. NIST will be able to suggest minimum standards, while industry would give valuable insight to what can be done reasonably.
E2.2	ONC will work with OCR and industry organizations to develop "in transit" standards for data encryption and provide technical assistance. OCR will consider whether additional guidance or rulemaking is necessary.	
Table 6: Critical Actions for Verifiable Identity and Authentication of All Participants		
F1.2	ONC will identify and undertake (where necessary) work to harmonize other standards with those adopted for multi-factor authentication.	ONC needs to work with the industry in this harmonization effort. The industry has invested heavily in multi-factoring technologies. Making changes or rules that force changes to existing authentication methods, without regard to the existing frameworks effectiveness could be short sighted.
F2.2	SDOs will work with health IT developers to conduct Pilots using RESTful approaches for authentication.	Current encryption technologies that are widely used are heavy and require large infrastructures for very high volumes. RESTful approaches for authentication will reduce network overhead, and if successful, lower IT costs.
Table 7: Critical Actions for Consistent Representation of Permission to Disclose Identifiable Health Information		
G2.2	adopt technical standards regarding how to ensure individuals are offered Basic Choice in a manner that can be captured electronically and in a manner in which the individual’s choice persists over time and in downstream environments, unless the individual makes a different choice.	Input from the industry is necessary before policies and regulations are adopted.

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G4.1	ONC, standards development organizations, health IT developers and appropriate stakeholders harmonize technical standards and implementation guidance for consistently capturing, communicating and processing basic choice across the ecosystem.	SDOs should participate in the discussion to ensure communication of the basic choice information is provided in the same framework for health information interoperability.
G4.2	Technology developers begin implementing harmonized standards that document and communicate an individual's basic choice.	SDOs should participate in the discussion to ensure communication of the basic choice information is provided in the same framework for health information interoperability.
G5.1	ONC, standards development organizations, health IT developers, health care providers and appropriate stakeholders harmonize technical standards and develop implementation guidance for associating individual choice with data provenance to support choice.	NCPDP recommends the time frame be expanded.
G5.2	Technology developers begin to implement technical standards for associating individual choice with data provenance to support choice.	
Table 9: Critical Actions for Stakeholder Assurance that Health IT is Interoperable		
I2.1	Health IT Developers, ACBs, ATLs and other stakeholders will analyze, identify gaps and provide feedback to ONC regarding certification criteria that should be added to the ONC HIT Certification Program. Specifically, criteria that would support ONC's desire to expand the scope of the certification program to support health IT used in a broader set of health care settings, such as criteria for long-term and post-acute care, home and community based services in non-institutional settings and behavioral health settings. Additionally, criteria related to accessibility and usability of health IT.	While NCPDP believes that a set test criteria and continual improvement of the test criteria is needed; too much test criteria can stifle and slow implementation of newer standards that have more functionality and content. A balance or classification of test non-negotiable, strongly recommended, recommended, and optional should be considered.
Table 10: Critical Actions for Consistent Data Formats and Semantics		
J1.1	ONC will annually publish and update a list of the best available standards and implementation guides supporting interoperability in order to enable priority functions in a learning health system, to be used by technology developers and to inform coordinated	The process that facilitates competition between standards for selection must be defined with stakeholder input and all measurements must be objective.

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	governance efforts. ONC will create this list through an open and transparent process that facilitates competition between standards for selection. To the extent possible, the updates to this list will be done in a manner to minimize unnecessary sunk costs and to promote the entry of innovative standards.	
J2.3	Through coordinated governance, public and private stakeholders will define a necessary set standards activities that support the prioritized use cases and functional requirements and the agreed upon architecture.	The coordinated governance must be defined. ANSI-accredited SDOs operate where members or non-members bring forward business needs for revising a standard or creating a new standard. The SDO meets the business need through their accredited consensus process. The term architecture needs to be defined as well.
J3	Develop and pilot new standards for priorities	A mechanism to validate new standards/new versions of standards that are named in HHS regulations prior to their mandated implementation needs to be developed. Metrics, use cases prioritized by stakeholders, and feedback loops are critical to the success of adoption and use. One possible mechanism is to allow trading partners to pilot these before being named or required will assist the industry in identifying issues prior to widespread use.
J3.4	Health IT developers and SDOs should advance systems in support of human-centered design for systems, including the ability to provide information to individuals with varying levels of health literacy so individuals can understand their electronic health information and ability to provide information in their primary language.	NCPDP standards enable the exchange of an individual's primary language and structured data than can be translated.
J4.1	Through coordinated governance, public and private stakeholders will work with SDOs to define a standard approach to federated distribution of centrally maintained code sets.	What code sets does this reference? The standards have both internal code sets (maintained by the SDO) and external code sets (maintained by an external entity but referenced in the standard). License fees, frequency of updates, distribution methods formats of the list must all be defined and taken into account.
J4.2	Health IT developers will provide accurate translation and adapter services where needed in order to support priority learning health system use cases (see Appendix H for Priority	Please provide a definition of the term translation.

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	Interoperability Use Cases).	
J5.1	Through coordinated governance, public and private stakeholders will advance the development and maintenance of data format and vocabulary standards and implementation guidance necessary to support priority learning health system use cases.	This is being accomplished by NCPDP and is at the core of our mission.
J6.1	Through coordinated governance, public and private stakeholders will advance the development and maintenance of data format and vocabulary standards and implementation guidance necessary to support priority learning health system use cases.	Layers of governance does not lend to rapid development. The usefulness and the life cycle of a product must be considered.
Table 11: Critical Actions for Secure, Standard Services		
K1.1	Through the coordinated governance process, health IT developers, SDOs, ONC and others should implement a coordinated approach to developing and standardizing a targeted set of public APIs for nationwide interoperability.	Through the development and distribution of public APIs, an SDO's standard will effectively be free of charge. In addition, the conversion cost and training of systems staff must be factored into retrofitting systems to support public APIs. The revenue from SDO standards documents contributes to the financial sustainability of the organization. New sources of revenue would need to be developed and it would likely lead to an increase in membership dues.
K1.4	SDOs should advance and accelerate the development of standardized RESTful APIs.	NCPDP would support this effort.
K.1.5	Health IT developers should work with SDOs to develop standards for interoperable electronic health devices.	NCPDP would support this effort.
Table 12: Critical Actions for Consistent, Secure Transport Techniques		
L1.1	SDOs should update standards and health IT developers should adopt standards as needed.	NCPDP agrees that the SDOs that create transport standards should update those according to their process and adoption should occur based on industry need.
L2.1	Public health agencies should converge on the use of standardized web services to support data submission as well as	NCPDP needs to understand the benefit and the cost involved in changing from an existing effective process to a new model.

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	data query from registries and other systems.	
L2.2	Providers (including hospitals, ambulatory providers, long-term care centers and behavioral health providers) should adopt and use DIRECT to reach critical mass.	NCPDP needs to understand the benefit and the cost involved in changing from an existing effective process to a new model. Why call out DIRECT? DIRECT is useful for asynchronous use cases. SOAP and RESTful are useful in synchronous use cases. All three can be used either way, but allowing the right protocol for the right job should be determined by the entity. Please define critical mass.
L2.3	Providers and health IT developers should provide individuals with the ability to easily and securely transport their health data to a destination of their choice.	Providers should be allowed to deny choice when the choice is risking a provider's ability to keep this information safe and secure.
L3.4-6	Health IT developers should widely implement national standards for query. Health IT developers should widely implement national standards for publish/subscribe. Health IT developers should implement national standards for RESTful web services as they are available.	NCPDP needs to understand the benefit and the cost involved in changing from an existing effective process to a new model.
Table 13: Critical Actions for Accurate Individual Data Matching		
M1.1	ONC and SDOs should standardize the minimum recommended data elements to be consistently included in all queries for patient clinical health information, and to be used to link patient clinical health information from disparate systems.	SDOs should participate in any effort to standardize data elements for improving data quality.
M1.8	As evidence suggests, ONC and SDOs should standardize additional, required elements for identity matching.	SDOs should participate in any effort to standardize data elements for improving data quality.

Appendix H: Priority Interoperability Use Cases

NCPDP submits the following priority use cases:

1. (24) Benefits communication needs to be standardized and made available on all plans through HIT to providers and patients as they make health and healthcare decisions, in a workflow convenient to the decision-making process.
2. (25) Payer/purchaser requirements for payment, such as prior authorization, are clear to the provider at time of order and transacted electronically and timely to support efficient care delivery.

3. (22) Those who pay for care use standardized transactions and interoperability to acquire data needed to justify payment.
4. (44) Providers have ability to access information in PDMP systems before prescribing narcotics to patients
5. (4) Federal, State, provider and consumer use of standardized and interoperable patient assessment data to facilitate coordinated care and improved outcomes.
6. (10) Quality measures are based on complete patient data across multiple sources.
7. (33) Providers have the ability to query data from other sources in support of care coordination (patient generated, other providers, etc.) regardless of geography or what network it resides in.
8. (6) Providers and their support staff should be able to track all orders, including those leaving their own organization and EHR, to completion.