Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments

April 3, 2015

Office of the National Coordinator
Department of Health and Human Services
Hubert H. Humphrey Bldg., Suite 729D
200 Independence Ave., SW
Washington, DC 20201

Re: Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0

Dear Sir or Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding the proposed *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0.*

The Collaborative has been involved with the federal agencies developing the national health information technology (HIT) framework since 2010. The Collaborative is supportive of the proposed roadmap and recommendations to improve the safety of HIT through coordinated governance and safely designed and implemented systems, while maintaining and protecting patient privacy.

The Collaborative was pleased to see and appreciates the Office of the National Coordinator (ONC) recognizing pharmacists numerous times in various sections of the roadmap. These include specifically listing pharmacists as health care providers and users of health information exchanges; referencing the NCPDP-HL7 Pharmacist/Pharmacy Provider Functional Profile Task Group; and acknowledging patient-centered care services, such as comprehensive medication management (CMM) and medication therapy management (MTM), provided by pharmacists.

Pharmacists provide patient-centered care and services, maintain various secure patient care records, and as part of the integrated health care team, they are directly involved with other health care providers and patients in various practice settings.

Pharmacists are in a strategic position to help improve patient safety and patient privacy, especially, through HIT.

The following are our comments regarding the proposed roadmap:

A. *Shared governance of policy and standards that enable interoperability:* *Nationwide interoperability across the diverse health IT ecosystem will require stakeholders to make collective decisions between competing policies, strategies, standards in a manner that does not limit competition. Maintaining interoperability once established will also require ongoing coordination and collaborative decision-making about change.*

The Pharmacy HIT Collaborative (Collaborative) supports the ONC's role in establishing shared governance policy and standards that enable nationwide interoperability. The Collaborative agrees with the premise that there needs to be a single set of basic or common rules of the road for policy, operations, and technical standards. We believe the proposed governance principles outlined in the roadmap, as based on the initially established principles by the ONC in its Governance Framework for Trusted Electronic Health Information Exchange in 2013, are a good starting point for laying the governance foundation.

For these principles to be successful, however, agreement with them by the multi-stakeholders working with the ONC should be sought. In reviewing the principles and implementation timeframes presented in the roadmap (Table 1, page 34), seeking specific input on the proposed principles does not appear to be included. Under 2015-17, A1 Establishment of Coordinated Governance, Item 1 states that the ONC will define a nationwide governance framework with common rules of the road and a mechanism for identifying compliance with common criteria and that these rules will first focus on interoperability. The task listed with this timeframe does not appear to include input from the multi-stakeholders on the governance principles with which health care providers, data holders, HIT vendors, and others are "expected" to comply.

We request clarity on the compliance expectations with the proposed governance principles. First is whether compliance with these principles would be mandated or voluntary? Although one of the tasks the ONC is charged with is identifying a mechanism for recognizing organizations that comply with the common rules of the road, it is unclear whether there is an expectation that organizations must comply with them. Second is whether compliance is expected across the whole continuum of health care nationwide or will the focus be on health care involving existing or new federal programs (e.g., Medicaid/Medicare, Meaningful Use EHR Incentive Program, etc.). And third, if noncompliance occurs, what action will ONC take?

The Collaborative does not agree with unfunded regulatory requirements. We would agree with voluntary governance driven by business incentives, such as business agreements between parties to comply with the governance principles. The ONC in 2012 decided not to move forward with such regulation at that time. The roadmap does not indicate whether the ONC will reverse that decision and move forward with regulation.

Another compliance compatibility concern is noted in A1, Items 3 & 4, Call to Action. It appears that two different governance frameworks may be created by 2017. It is not clear if this was the ONC's intent or an oversight, and we recommend that it be reviewed and clarified.

Item 3 states that "public and private sector shareholders across the ecosystem should come together to establish a single coordinated governance process to establish more detailed policies regarding business practices", including policies for identifying and addressing bad actors and to identify the technical standards that will enable interoperability for specific use cases. We also note that this item is not required to be aligned with the nationwide governance framework, which in all likelihood it should be. This seems to run counter to the ONC's goal of establishing a single set of governance principles, especially since, Appendix H, Priority Interoperability Use Cases, also includes federal use, and that Item 4, Call to Action, charges federal agencies that provide or pay for health services to align their policies for interoperability with the nationwide governance framework.

B. ***A supportive business and regulatory environment that encourages interoperability:*** *Rules that govern how health and care are paid for must create a context in which interoperability is not just a way to improve care, but is a good business decision*.

The Pharmacy HIT Collaborative supports this objective and agrees that rules governing how health and care are paid for need to create a context in which interoperability is a good business decision to further improve the health and care of patients. We recommend that the 2015-17 timeframe for this section include an action for the ONC and the Center for Medicaid and Medicare Services (CMS) to provide prescriptive and educational components so that interoperable health IT can be expanded for achieving this type of interoperability to move toward a value-based health care system providing person-centered care. This recommendation is supported by the overall HHS move toward improving the use of evidence-based strategies for producing positive outcomes as discussed in the Office of the Assistant Secretary for Planning and Evaluation's February 2013 research brief – *Core Intervention Components: Identifying and Operationalizing What Makes Programs Work*.

It appears that the roadmap presumes that all private payers and purchasers are fully knowledgeable and understand how interoperability health IT supports value-based payments in delivering high-value health care that is safe, timely, effective, efficient, equitable, and person-centered. We believe this may not necessarily be the case. As there are federal value-based payment programs, the ONC and other federal agencies, such as CMS, are in a unique position to provide information to help private payers and purchasers increase their knowledge and understanding to move toward improved care coordination through interoperable health IT that supports a value-based payment system. Increasing knowledge is part of the learning health system that is being promoted.

Additionally, as patient-centered health care providers, pharmacists can improve outcomes in value-based payment models and should be included in these quality-based incentives. Many quality measures required currently by CMS, as well as the recently announced

HHS goals for fee-for-services in Medicare, focus on medication use and will be influenced by pharmacists. Some examples include safe and appropriate medication use, adherence, and the use of high-risk drugs for the elderly.

C. ***Individuals are empowered to be active managers of their health****: A learning health system is person-centered, enabling individuals to become active partners in their health by not only accessing their health information, but also providing and managing health information through mobile health, wearable devices and online services.*

The Pharmacy HIT Collaborative supports the intent of this objective. As health care providers of patient-centered and patient-centric care, pharmacists provide their patient-centered services to individual patients in a person-centered manner. The Collaborative agrees that moving further toward a person-centered vision, especially in engaging the individual as an active partner and providing their caretakers the tools and educational resources to access wellness and health care services, is important to improving health and health care outcomes.

Concerning an individual's use of mobile health, wearable devices, and online services to provide and manage health information, it is important that producers of mobile medical devices, mobile medical apps, and online services be encouraged to certify that their products follow and meet acceptable health IT standards and platforms for the collection, exchange, and protection of patient health information, as well as ensuring patient security, safety, and well-being in use of these devices and information. Protecting patient information collected via mobile medical devices or other electronic means is paramount. Development of an HIT framework in this area needs to ensure that any patient information transmitted to or received by a mobile device and using mobile medical apps or online services is protected and patient privacy secured.

Table 3, C1, page 47, raises a question. Does the ONC plan to develop a nationwide campaign during the 2015-17 timeframe to have "a majority of individuals demand access to their electronic health information in a format they can use"? As these calls to action are written, it can be interpreted that such a campaign is being planned, though it is not specifically stated in the roadmap. If no such campaign is planned, then we suggest that the calls for action in Items 1 and 2 be redrafted to better reflect their intent. It is important to keep in mind that not all health care providers may be prepared to provide health information electronically to patients or caregivers. As the roadmap states, challenges also persist for some individuals, particularly in underserved communities, because of "disparities in technology access and digital literacy," which need to be addressed.

D. ***Care providers partner with individuals to deliver high value care:*** *Providers share and use information from multiple sources as they transform the way they provide care and engage with patients to routinely assess and incorporate patient preferences and goals into care plans that achieve measurable value for individuals and the population.*

The Pharmacy HIT Collaborative supports this concept. As health care providers, pharmacists provide patient-centered care and services; maintain various secure patient care records; and as part of the integrated health care team, they are directly involved with other health care providers and patients in various practice settings. Pharmacists are in a strategic position to help improve usage, patient safety, and protect patient privacy through HIT. To achieve this objective, however, bidirectional communication via health IT among health care providers is critical, especially for pharmacists. In health care settings today, bidirectional communication through HIT has not fully achieved its promise and should be considered a priority. Therefore, we recommend that a bidirectional communication call to action be included in this section of the roadmap.

The best health care outcomes happen with an integrated team approach of health care providers delivering coordinated and comprehensive care. Pharmacists' unique experiences, expertise, and access to medication information that others may not have bring enormous value to physicians and other health care providers in caring for patients, as noted in the Collaborative's case study, *Pharmacists Working in Collaboration with Physicians and Other Health Care Professionals*.[1] Pharmacists' expertise and patient-care services include, but are not limited to, medication management therapy; immunization administration; medication reconciliation and the resolution of medication-related issues in many health care settings; medication adherence; evaluation of medication errors; coordination of care, including care transitions; and programs for controlling diabetes, high blood pressure, and high cholesterol.

As noted in the roadmap's discussion for this section, pharmacists use clinical decision support (CDS) tools. The Collaborative agrees that close integration of CDS into health IT systems will improve dissemination of new knowledge to support the use of best evidence in the care of all patients. Also as presented in the discussion, "CDS based on availability of pharmacist 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 abuse of controlled substances."

The Collaborative believes that CDS functionalities that operate without a health care provider's direct involvement should be subject to the health management health IT framework and FDA oversight. If a health care provider is directly involved in the decision-making and recommended action, then FDA oversight would not be needed. For example, if a medical device (e.g., home blood pressure) displays a measurement and from that measurement the CDS is alerting the patient to take some action (e.g., lower or increase medication dosage) without getting advice from a health care provider, then FDA should have oversight.

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[1] *Case Study Examples: Pharmacists Working in Collaboration with Physicians and Other Health Care Professionals*, Pharmacy Health Information Technology Collaborative, http://www.pharmacyhit.org/pdfs/workshop-documents/WG1-Post-2015-01.pdf, accessed March 26, 2015.

The Collaborative agrees that integration of this information will support distributed models of care management, comprehensive medication management, and medication therapy management.

E. ***Ubiquitous, secure network infrastructure****: Enabling an interoperable, learning health system requires a stable, secure, widely available network capability that supports vendor-neutral protocols and a wide variety of core services.*

The Pharmacy HIT Collaborative supports this objective, especially the establishment of a cybersecurity Information Sharing and Analysis Center (ISAC). Cybercrime is a fast-growing challenge. We hope, however, that the ISAC will be more than just a center for bidirectional information sharing about cyber threats and vulnerabilities between the private sector health care industry and the federal government. As we stated in our February 6, 2015 comments on the ONC's proposed *Federal Health IT Strategic Plan 2015-2020*[2], we believe a digital crime center should also proactively research new areas of cybercrime and solutions to these threats.

F. Verifiable identity and authentication of all participants*: Legal requirements and cultural norms dictate that participants be known, so that access to data and services is appropriate. This is a requirement for all participants in a learning health system regardless of role (individual/patient, provider, technician, etc.)*

The Pharmacy HIT Collaborative supports the intent of this objective. Establishing common identity proofing practices and requiring multi-factor authentication for all patient and provider access to health IT systems is important, particularly with regard to the various electronic means of accessing health IT systems. Access to health IT systems via mobile phones, email, online services, etc., is becoming more commonplace. With that in mind, this objective appears to be missing a component to ensure the security of the devices/products used when accessing health IT systems. Although security may be implied, it would be helpful to have that indicated as part of this objective, particularly in today's environment. Protecting patient information collected or transmitted via any electronic means and allowing patients to control their information are paramount, particularly with the increase in cybercrime.

G. ***Consistent representation of permission to collect, share and use identifiable health information****: Though legal requirements differ across the states, nationwide interoperability requires a consistent way to represent an individual's permission to collect, share and use their individually identifiable health information, including with whom and for what purpose(s).*

The Pharmacy HIT Collaborative supports the intent of this objective. Protecting information authorized by the patient to be collected or transmitted to the patient or health care provider via any electronic means and allowing patients to control their information are paramount, particularly with the increase in cybercrime. It is critical to ensure that any health IT

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[2] *Pharmacy HIT Collaborative's Federal Health IT Strategic Plan 2015-2020 comments February 6, 2015*, http://www.pharmacyhit.org/pdfs/collaborative-outreach/FINAL%20Pharmacy%20HIT%20Collaborative%20-ONC%202015-2020%20Strategic%20Plan%20v1.pdf, accessed March 26, 2015.

system used not only allows and shows that the individual authorized the collection, use, and release of any identifiable information but that such collection, use, and release are fully compliant with all appropriate state and federal laws pertaining privacy protections.

A particular barrier to interoperability regarding this objective is the various state laws concerning privacy, data collection, and security, especially as they pertain to individually identifiable information. According to the National Conference of State Legislatures (NCSL), 32 states and Puerto Rico have enacted laws that require entities to destroy, dispose, or otherwise make personal information unreadable or undecipherable. All of these laws apply to businesses, and in 14 of the states, they also apply to government agencies. Because of outdated contracts, some state health information exchanges (HIEs) have excluded pharmacists from accessing data through HIEs. Pharmacists should not be precluded from accessing health information.

Given the sensitivity to states rights and the fact that states may be more restrictive than federal laws and regulations, as well as the roadmap's timeframe indicated on page 69 for suggesting that states revise their regulations and policies to align with federal definitions of permitted uses for data under HIPAA and the ONC standard on what constitutes Basic Choice, we encourage the ONC to work with the NCSL and the Council of State Governments (CSG) on this particular area. NCSL and CSG are national public policy organizations comprised of the 50-state legislatures and territories. These organizations' standing committees adopt policies, which become the backbone of their federal advocacy efforts on behalf of the states' legislatures, particularly in areas in which states feel their authority and autonomy are threatened.

H. ***Consistent representation of authorization to access health information****: When coupled with identity verification, this allows consistent decisions to be made by systems about access to information.*

The Pharmacy HIT Collaborative supports this objective; however, there appears to be a disconnect between the two action items proposed in Table 8, page 73, and the intent of this objective. To move this objective forward, it does not appear that the action items pertain to the objective for representation of authorization to access health information and the discussion outlined in this section of the roadmap. We would ask that the ONC clarify how the proposed workshops on data sharing that may be required to support value-based purchasing relates to the specifications for the Authorization Framework. This same question may be applied to the action item pertaining to the HHS Office for Civil Rights and the guidance it may need to provide for value-based purchasing. As noted previously, pharmacists should not be precluded from accessing health information. Because of outdated contracts, some state health information exchanges (HIEs) have excluded pharmacists from accessing data through HIEs.

I. ***Stakeholder assurance that health IT is interoperable:*** *Stakeholders that purchase and use health IT must have a reasonable assurance that what they are purchasing can interoperate with other systems.*

The Pharmacy HIT Collaborative supports this objective and encourages interoperability testing and standards adoption for use in assessments. In some areas, this is a common practice, especially on the payer side. Pharmacy business partners who exchange payment information must test scenarios and claims information transitions. One of the reasons for this testing is to ensure the safety and validity of the medication information being exchanged. The pharmacy profession is moving toward this direction with clinical information transmission. Like many other health care providers, pharmacists document patient care services in many different ways, including, but not limited to, hand-written notes and non-standard electronic processes. Through standards development work (NCPDP, HL7)[3], standardized technology solutions have been developed to exchange patient health information.

Another example of this is electronic prescribing. Electronic prescribing systems (e-prescribing) must be able to handle the information being tested. DEA's Electronic Prescribing of Controlled Substances (EPCS) audit/certification process and rules for pharmacy systems and physician EHR software companies became effective in June 2010, with DEA approving several categories of third-party audit/certification organizations, as well as the subsequent addition of individual eligible audit/certification organizations.

Pharmacists also capture and monitor their patients' health information through mobile medical devices. It is important that the producers of mobile medical devices and mobile medical apps be encouraged to certify that their products follow and meet acceptable HIT standards and platforms for the collection, exchange, and protection of patient health information, as well as ensuring patient security, safety, and well-being in use of these devices and information. Protecting patient information collected via mobile medical devices or other electronic means is paramount. Development of an HIT framework in this area needs to ensure that any patient information transmitted to or received by a mobile device and using mobile medical apps is protected and patient privacy secured.

J. *Consistent Data Formats and Semantics*: *Common formats (as few as necessary to meet the needs of learning health system participants) are the bedrock of successful interoperability. Systems that send and receive information generate these common formats themselves or with the assistance of interface engines or intermediaries (e.g., HIOs, clearinghouses, third-party services.) The meaning of information must be maintained and consistently understood as it travels from participant to participant. Systems that send and receive information may or may not store standard values natively and therefore may rely on translation services provided at various points along the way.*

The Pharmacy HIT Collaborative supports this objective. The private sector is currently using third party resources, such as OSCAR and OASIS, for garnering consensus on standards, security, and rating health IT systems and making those results available for public viewing. The pharmaceutical and IT communities, including Health Level 7 (HL7), announced a collaboration in

[3] National Council for Prescription Drug Programs (NCPDP) Recommendations for Use of the HL7 Consolidated CDA Templates for Pharmacy Version 1. Ø, http://www.ncpdp.org/NCPDP/media/pdf/NCPDP_Recommedations_for_Use_CCDA.pdf , accessed February 26, 2015.

March 2014 on OASIS clinical trial data standard for content management systems to advance interoperability for exchanging clinical trial content in the cloud.[4] The Collaborative supports the use of HL7, as well as Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)[5], and the National Council of Prescription Drug Programs (NCPDP) within pharmacy HIT. The Collaborative recommends exploring such third party resources further for use in health IT and by the Health IT Safety Center that will be established.

The Collaborative is also supportive of the National Library of Medicine (NLM), particularly with its role in helping to standardize information collection and dissemination of vocabulary data. RxNorm and the maintenance of DailyMed, including RxNorm coding, are especially useful to physicians and pharmacists who use e-prescribing. It is important to the pharmacy profession to have up-to-date maintenance of usable normalized medication nomenclature when documenting medication orders and electronic prescriptions. Such normalization will help to standardize data between codified and proprietary systems, thus substantially reducing errors during transmission to a pharmacy and adverse events that may result from errors.

Pharmacy's technological needs and its terminology are rapidly becoming adopted by clinical coding terms for medicine, such as SNOMED CT, for clinical documentation by pharmacists. This includes clinical documentation for medication therapy management services[6] and comprehensive medication management using SNOMED CT. [7] The NLM plays an important role in providing free access to these standard vocabularies to assure proprietary compendia and system vendors do not adopt their own set of values.

The Collaborative also believes that the NLM's leadership role as the steward of nationally recognized codes for the U.S. helps in the adoption of vocabulary standards for health information technology for interoperability. In this regard, standardized nomenclature or terminology is critical for the exchanging of information between computer systems, as pointed out in the roadmap discussion. As national HIT initiatives take place, expanding the NLM's role in authorizing standardized value sets of codes in the U.S. is important.

K. ***Standard, secure services****: Services should be modular, secure and standards-based wherever possible.*

The Pharmacy HIT Collaborative is supportive of this objective to implement a coordinated approach to developing and standardizing a targeted set of public application programming interfaces (APIs) for nationwide interoperability. The Collaborative agrees with the

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[4] *Pharmaceutical and IT Communities Collaborate on OASIS Clinical Trial Data Standard for Content Management Systems*, Oasis, https://www.oasis-open.org/news/pr/pharmaceutical-and-it-communities-collaborate-on-oasis-clinical-trial-data-standard-for-cont, accessed March 26, 2015.

[5] *Documenting Comprehensive Medication Management in Team-Based Models Using SNOMED CT Codes*, Pharmacy HIT Collaborative, http://www.pharmacyhit.org/pdfs/workshop-documents/WG2-Post-2014-03.pdf, accessed March 8, 2015.

[6] *Medication Therapy Management Services, Clinical Documentation: Using a Structured coding System – SNOWMED* CT, http://www.pharmacyhit.org/pdfs/workshop-documents/WG2-Post-2014-02.pdf, March 26, 2015.

[7] *Documenting Comprehensive Medication Management,* op.cit.

HIT Policy Committee task force's recommendation calling for a coordinated architecture.

Additionally, the Collaborative agrees that health IT developers should work with standard development organizations (SDOs) to develop interoperable electronic health devices and that such devices should be certified to show that their products follow and meet acceptable health IT standards and platforms for the collection, exchange, and protection of patient health information, as well as ensuring patient security, safety, and well-being in use of these devices an information.

L. ***Consistent, secure transport technique(s)****: Interoperability requires transport techniques that are vendor-neutral, easy to configure and widely and consistently used. The fewest number of protocols necessary to fulfill the needs of learning health system participants is most desirable.*

The Pharmacy HIT Collaborative is supportive of this objective and agrees that a suite of transport standards also should be consistent with core Internet technologies that are deployed. Such transport techniques also need to be secure and tested.

M. ***Accurate identity matching****: Whether aggregated in a repository or linked "just in time," health information from disparate sources must be accurately matched to prevent information fragmentation and erroneous consolidation. As a learning health system evolves, more than individual/patient-specific information from health records will be matched and linked, including provider identities, system identities, device identities and others to support public health and clinical research.*

The Pharmacy HIT Collaborative is supportive of this objective and agrees that patient identity matching needs to be consistent and accurate. This is critical for clinical care, especially when an individual's health information may be stored in multiple systems. Take into consideration NCPDP work in this area. As an example, ONC in partnership with the Substance Abuse and Mental Health Services Administration worked on the PDMP in recognizing recommended data elements.[8] This work continued with NCPDP and S&I Framework initiative with national pilot tests.

We agree that through coordinated governance, the ONC and SDOs, as well as other public and private shareholders, including health IT developers, should work collaboratively to standardize the minimum recommended data elements that would be consistently included in all queries for patient clinical health information that would be used to link patient clinical health information from disparate systems.

[8] *Enhancing Access to Prescription Drug Monitoring Programs Using Health Information Technology: Work Group Recommendations*, http://www.healthit.gov/sites/default/files/work_group_document_integrated_paper_final.pdf, accessed March 26, 2015.

N. *Reliable resource location**: The ability to rapidly locate resources, including provider, individuals, APIs, networks, etc. by their current or historical names and descriptions will be necessary for a learning health system to operate efficiently.*

The Pharmacy HIT Collaborative supports this objective. As health care providers, pharmacists provide patient-centered care and services and would view reliable, secure, resource location a valuable asset for connecting individuals with providers and their health care services.

Questions on the Roadmap

In response to the questions posed by the ONC, the Collaborative's comments are as follows:

General

- *Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?*

  Comment: The Pharmacy HIT Collaborative believes these are the right actions for the long term.

- *What, if any, gaps need to be addressed?*

  Comment: The Collaborative believes pharmacists need to be included in incentive programs. As meaningful users of health IT, pharmacists have to identify business needs that will drive adoption of HIT, although pharmacists are not eligible for incentives (e.g., CMS EHR Incentives Program).

- *Is the timing of specific actions appropriate?*

  Comment: The timing is appropriate for those receiving incentives. Those who have not been using because they are not required by regulation to do so may lag behind. There must be help with the return on investment for those who have to adopt usage without receiving incentives.

- *Are the right actors/stakeholders associated with critical actions?*

  Comment: As long as pharmacists continue to be included as part of this process and not excluded, then we believe they are the right actors/stakeholders for critical actions.

2. Priority Use Cases A

- *Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further*

prioritization. ***Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.***

Comment: Of the 56 use cases provided by the ONC for review, the Collaborative recommends the following three as important to pharmacists:

3. The status of transitions of care should be available to sending and receiving providers to enable effective transitions and closure of all referral loops.

35. Individuals have electronic access to an aggregated view of their health information including their immunization history.

44. Providers have ability to access information in PDMP systems before prescribing narcotics to patients.

3. Governance

- *The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?*

Comment: The Collaborative believes governance has to be supported by federal and state processes. If industry leads, there would need to be some regulatory activity at the federal and state levels to drive compliance with the governance. These could include self-reporting or business driven compliance models through certification or business agreements.

As noted in our comments in Section A, for these principles to be successful, agreement with them by the multi-stakeholders working with the ONC should be sought.

4. Supportive Business, Cultural, Clinical and Regulatory

- *How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?*

Comment: Providers including pharmacies and pharmacists have provider agreements with multiple private and government health plans. In order to drive standardization of data exchange and not to overburden providers, it is essential for these plans through adoption of ANSI accredited standards agree on common clinical data elements and standard means of exchange.

As with previous value-based payment plan commentary above, private health plans and purchasers need provider participation in clinical data exchange. In order to encourage that health IT be adopted across all in an interoperable way, private health plans may want to

help providers with their return on investment. A focus on each party's return on health IT investment would be helpful.

It is absolutely critical that sharing clinical data across the care continuum through financial incentives align with federal policies.

It is important to align information goals with payment goals to achieve the envisioned outcome of improved health and reduced costs. If not, then the goals set by HHS for having 30% of Medicare health care reimbursements through value-based models by the end of 2016 and 50% of these reimbursements by the end of 2018 may not be reached.

5. Privacy and Security Protections for Health Information

- *What security aspects of RESTful services need to be addressed in a standardized manner?*

Comment: Security measures have to be put in place at the level of secured networks. It cannot be at the level of just the Internet. There will need to be more secure connections. A level of authentication so that one partner knows who the other partner is and has authority to send/receive information also will need to be built in.

6. Core Technical Standards and Functions

- *Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?*
- *Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?*

Comment: The Collaborative suggests the following changes to the common clinical data set list:

- Smoking status change to social substance status (smoking, alcohol, marijuana, illicit drugs).
- Medications should include dietary/herbal supplements and nonprescription drugs.
- Medication allergies should include all substances (e.g. food, environmental substances), not just medications, and allergic reactions to the allergen.

In order to achieve *Accurate Individual Data Matching* and address the industry's needs and current barriers, the ONC should not "reinvent the wheel". The ONC should take into consideration work from other initiatives such as NCPDP's work in PDMP and e-prescribing.

7. Certification and Testing

- *In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)*

Comment: Semantic interoperability should be tested through certification, usability, and performance measures. Testing needs to consistently certify different versions and updates

and make sure they are meeting all of the standard terminology. There also needs to be standard protocols and some governance over verification and testing.

8. Measurement

- *Does the measurement and evaluation framework cover key areas? What concepts are missing?*

  Comment: We believe the key areas are covered.

- *Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?*

  Comment: The Collaborative believes outcomes are important to measure; process measures drive adoption, but outcomes measures will be a result of adoption and value.

- *Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g., encounter, patient, provider, organization)?*

  Comment: Population health allows for better outcomes measures (e.g., immunizations). We also believe that anything pertaining to medications and immunizations provides an appropriate focus for measurement.

- *What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?*

  Comment: Metrics that show movement from process to outcomes measures. An example of an outcomes-related measure could be the number of reductions in medication errors by using electronic prescribing for prescription drugs. This can also be used as a metric that measures the process (i.e., how many physicians send X number of electronic prescriptions). Another example of a process measure is counting the number of Medication Therapy Management (MTM) service provided by pharmacists. This could be used to show how many Medicare beneficiaries receive MTM services. It could also be used as an outcomes measure for a particular disease state (e.g., diabetes). In this example, the outcomes measure could indicate how many Medicare beneficiaries receiving pharmacist provided MTM services saw a reduction in their A1C levels to normal. Though, at the moment, pharmacists don't have standard systems to capture these types of outcome measures.

- *What measurement gaps should be prioritized and addressed quickly?*

  Comment: Outcome measurements need to be developed and the gaps between them and process measurements closed. The examples noted in the previous question pertaining to the types of metrics need to be developed further with systems developed

to capture such outcomes measures.

- *What other available data sources at the national level could be leveraged to monitor progress?*

  Comment: Pharmacists' recommendations during comprehensive medication management (CMM)[9], especially during transitions of care coordination; medication adherence, and medication synchronizations programs are ways to measure appropriateness for medication use. Prescription drug monitoring programs as an outcomes measurement can be shown to reduce drug abuse. Immunizations also can be used under outcomes of population health (e.g., effectiveness of that vaccine).

- *Are the potential mechanisms for addressing gaps adequate? What are other suggestions?*

  Comment: The Pharmacy HIT Collaborative generally agrees with the potential mechanisms for addressing gaps including those outlined in Table 15 (page 112). It is important to assure all mechanisms would include the ability for pharmacists to report key metrics when obtaining national data.

- *How should data holders share information to support reporting on nationwide progress?*

  Comment: Sharing through registries would be one way to support reporting.

- *What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?*

  Comment: Quality organizations should drive the development of these measurements to make clinical data usable rather than relying on billing and claims data. Quality organizations, such as the Pharmacy Quality Alliance (PQA), should be developing quality measures based on clinical data and move toward using SNOMED CT for capturing health information for these quality measures. An example of a non-claims based data source for quality measurement is demonstrated by CMS using minimum data set (MDS) data from long-term care skilled nursing facilities for capturing antipsychotic medication use managed by consultant pharmacists.[10]

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[9] *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management (CMM) to Optimize Patient Outcomes*., http://www.accp.com/docs/positions/misc/cmm%20resource%20guide.pdf, accessed March 26, 2015.

[10] *Minimum Data Set (MDS) Resources*, American Society of Consultant Pharmacists, https://www.ascp.com/articles/minimum-data-set-mds-resources, accessed March 26, 2015.

The Pharmacy HIT Collaborative's vision and mission are to assure the nation's health care system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The Collaborative was formed in the fall of 2010 by nine pharmacy professional associations, representing 250,000 members, and also includes seven associate members from other pharmacy-related organizations. The Pharmacy HIT Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing and health information networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. For additional information, visit www.pharmacyhit.org.

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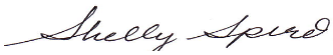
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0..*

For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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