March 31, 2015

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National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
United States Department of Health and Human Services

Dear Dr. DeSalvo:

The Capital Region Care Transitions Coalition (CRCTC) would like to express support for the content and implementation timeline of the proposed Interoperability Roadmap. Improved communications and data sharing between providers and care settings are critically necessary if we as a nation are to achieve and sustain meaningful improvements in healthcare quality and outcomes, and the Office of the National Coordinator is effectively leading improvements in these key areas.

The Capital Region Care Transitions Coalition is comprised of numerous healthcare providers including but not limited to hospitals, long-term care facilities, home healthcare agencies/services, local department of health representatives, adult homes/assisted living, behavioral health, primary care, pharmacies, patient advocacy organizations, community-based organizations, emergency medical services, the NYS Quality Improvement Organization (QIO) and others.

In evaluating the proposed Roadmap, the CRCTC would like to make recommendations that we believe will enhance the quality and impact of Roadmap implementation in the following areas:

1. General

We loudly and enthusiastically applaud the Roadmap vision seeking to create an environment in which all pertinent health-related data can be shared electronically between providers. We would want the Roadmap to also harness the opportunities presented through existing Care Transition Coalitions (CTC). Formal, mature CTC's exist in every state as the result of the Centers for Medicare & Medicaid Services QIO initiatives to improve the quality of patient care during cross-setting transitions and decrease hospital admissions and readmissions, which have been proven effective (Brock et al, JAMA, 2013). The ideal safe patient transfer requires communication of concise, clinically relevant, and timely information bi-or multi-directionally through Direct electronic exchange of C-CDA clinical summaries across the entire care continuum. The CRCTC is actively engaged in identifying role-based workflow for care transition communication, both manual (as healthcare organizations become "live" with Direct interoperability) and electronic (as increasing organizations are Direct electronically exchange enabled), across the community care settings. The power of the CTC for enabling rapid improvement is its local nature as a forum for negotiation and alignment of priorities through cross-setting, consensus building relationships. We believe that Federal and State based policies, incentives, and value based payment models should leverage the strengths of CTCs for innovative learning health system projects.

2. Supportive Business, Cultural, Clinical and Regulatory

The Roadmap acknowledges on page 39 that "EHR Incentive programs were not designed to include all providers across the continuum of care, such as long-term care and behavioral health providers, which are some of the most significant cost drivers in the care delivery system" and

that policy levers should be applied to encourage "1) new incentives to adopt and use interoperable health information systems to create additional demand for interoperability; and 2) requirements/penalties that raise the costs of not moving to interoperable systems".

- ***Recommendations***: All healthcare providers including but not limited to hospitals, long-term care facilities, home healthcare agencies/services, local departments of health, adult homes/assisted living, behavioral health, primary care, pharmacies, and emergency medical services should have the opportunity to participate in EHR Incentive Programs and value-based payment models. Incentivized meaningful use-like programs should be developed to encourage the use of interoperable certified electronic health record technologies for the health care providers/organizations in these service areas. Likewise, disincentives should be applied for failure to use interoperable certified electronic health record technologies. However, it should be recognized that the current Federal and State reimbursement structures for home healthcare have been reduced and continue to be reduced, decreasing the home healthcare agency's ability to obtain and sustain needed technology. Also, current payment structure and reimbursement in different care settings allow for inconsistencies in treatments/medications, type of DME, etc. and can impact standards of care. Regulations and conditions of participation can be developed or amended to assure care settings are given the same incentives. Incentivized technologies for all providers should have the capability to send, receive, push, find and use a common clinical data set via electronic C-CCDA's according to direct protocol and be able to integrate discrete data based on the use of standardized data vocabularies.

The Roadmap on page 40 provides examples of Federal HHS policies that have increased interoperability demand including the promotion of "interoperability as a core element of delivery system reform" through a new billable payment for chronic care management where "physicians will be required to utilize certified health IT to furnish certain services" and "accountable care programs…are designed to reward more effective care coordination".

- ***Recommendation***: Care is not delivered in a vacuum and although we agree that primary care should coordinate and orchestrate care, all provider services (hospitals, long-term care, home healthcare, behavioral health, pharmacists/pharmacies, etc.) should be included in innovative billing and shared savings models to improve overall healthcare value by improving outcomes and decreasing cost.

The Roadmap on page 41 states, "as part of managed care organization requests for proposals…states can require payers to ensure that provider networks use interoperable health IT or electronically support care coordination as a condition of participation".

- ***Recommendation:*** Payers must be obliged to send clinical data through interoperable technology using a defined standardized vocabulary such that providers can incorporate this data into EHRs to ensure accurate clinical quality measure reporting. Examples are: when a payer is informed that a primary or secondary prevention test or study such as a mammogram in a woman older than 50 years of age or an annual retinal ophthalmologic exam for a diabetic is performed that the primary care provider is informed. Payers must provide transparency and information regarding value based care such that providers and consumers can identify which providers of comparable services offer the best value care, e.g. primary care providers should know prior to referral the quality and cost of specialist care.

We recommend the following addition to Table 2, Category B2. State Actions, 2015-2017 goals on page 44:

- ***Recommendation:*** Call to action: All states should encourage the formation of or leveraging of existing care transition coalitions that encourage interoperability across a section of providers, patients, patient advocacy organizations, public health, and community based service organizations to serve as models of implementing a patient centered medical neighborhood. Providers include but are not limited to: hospitals, long-term care facilities, home healthcare agencies/services, local departments of health, adult homes/assisted living, behavioral health, primary care, pharmacies, emergency medical services, etc.

The Roadmap on page 45 states, "A learning health system is person-centered, enabling individuals to become active partners in their health by…managing health information through mobile health, wearable devices and online services", and on Table 3, Category C2, page 48, number 6, "Providers and technology developers should support the incorporation of patient-generated health data in health care delivery".

- ***Recommendation:*** Blood pressure machines and "health care kiosks" are entering public spaces making patient self monitoring of chronic disease states highly accessible. However, the vast majority of devices are not FDA validated for clinical use, not accessible for all patients (e.g. typical retail pharmacy blood pressure cuff is not adjustable to fit very large or very small individuals and is not often accessible to the disabled or wheelchair bound) and the data is not shared with providers via interoperable electronic technology. We recommend that health technologies presented to patients within the public domain for the presumptive use of improved self care be of valid clinical use, be accessible to all patients and enter the medical neighborhood data stream through interoperable connection to primary care electronic health records. Incentives for public placement of clinically validated patient self-monitoring devices that are interoperable with primary care electronic health records is recommended as a longer term goal (5-10 years).

Regarding consumer access to their electronic health records on page 45, the Roadmap states, "…the data of those who reside in long-term, post-acute care settings are still often unavailable electronically".

- ***Comment:*** This reinforces the need for all healthcare provider organization types, including long-term care, to able to push and receive data in a standard vocabulary based on C-CDA using direct interoperable protocols via certified electronic health record technology.

The following phrase is often utilized throughout the Roadmap and also appears on page 50: "individuals, their families, and caregivers".

- ***Recommendation:*** We suggest that the Roadmap verbiage be changed to: "individuals, their families or designees, and caregivers" to recognize and accommodate patient preferences or legal rights for determining who has access to the patient or their health information.

The Roadmap on page 50 acknowledges that "team-based care, strong care coordination and effective patient engagement are fundamental to an efficient care delivery system. However, coordinating care and engaging with multidisciplinary, cross-organization care teams has been incredibly difficult with the tools available today".

- ***Recommendation:*** Multidisciplinary, cross-organization care teams must have the ability to share an ambulatory standardized vocabulary based care plan that is maintained and updated by the primary care provider. This care plan can then become part of the pushed C-CDA to the receiving provider during care transitions.

The Roadmap on page 51 states, "data will be created and collected automatically during the routine provision of care… (and) will support secondary uses of data that help to achieve important advances in population health management, public health and the generation of new biomedical knowledge".

- ***Recommendation:*** Public health agencies require access to local provider clinical data in a useable format to perform community assessments, identify and understand the prevalence of emerging and existing public health issues, and prioritize interventions at the local level through provider and community collaborations that help link patients to community resources. We recommend that within Table 4, Category D2 a Call to Action be added to improve interoperability between providers and public health agencies, so that public health agencies can produce a clinically driven analysis of local public health. We also recommend that a Call to Action be added within Category D3, number 1 that local public health findings be utilized by providers as part of the data providers should leverage beyond their internal systems that support value based payment systems.

The Roadmap on page 51 states, "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 the linkages to Prescription Drug Monitoring Program (PDMP) systems, enable interventions to prevent the abuse of controlled substances", and "…integration and wide availability of this information will support distributed models of care management, comprehensive medication management and medication therapy management across multiple healthcare disciplines and sites of care such as community pharmacies".

- ***Comments:*** Community pharmacies largely operate in an electronically siloed, passive fashion. Electronic interoperability is usually limited to the following:
  a. Receipt of electronic prescription from prescriber
  b. Sending prescriber notification of need for prescription refill, renewal, or payer restriction (prior authorization, step down therapy, etc.) through internal fax server
  c. Access to Prescription Drug Monitoring Programs where available

  Community pharmacies do not have easy or electronic access to, nor are they receivers or senders of, clinically relevant patient data. Pharmacists must communicate telephonically with providers to receive the clinically relevant patient data (e.g. past medical history, laboratory, imaging or diagnostic tests, etc.) required for the safe provision of CMM, MTM, or post-discharge medication management. Lack of easy or electronic access to patient clinical data is a barrier for the provision of high quality CMM and MTM services, and a significant barrier for the identification of medication related

problems resulting in adverse drug events, particularly in vulnerable patient populations during care transitions. Identification and amelioration of prescriber errors, EHR eRx errors, and medication related problems that occur during patient transitions are not covered services by any payers. MTM Part D programs do not address or pay for resolution of technical or clinical prescription related problems that are frequently encountered by pharmacists during patient care transitions. Community pharmacies are not included in the incentive programs built around quality measures that are important to the larger healthcare communities in which they are embedded such as reduction of re-hospitalization rates.

With regard to adverse drug event prevention, The National Action Plan for Adverse Drug Event Prevention (http://www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf Pgs. 72, 73, 80) addresses the problems of a lack of interoperability between hospitals and primary care with long-term care facilities and home health settings. Anticoagulant drugs are the most common causes of drug-related hospital admissions in older Americans. Congressional members and HHS have recently identified anticoagulant adverse drug event (ADE) prevention as a national patient safety priority and EHR coordination as a critical area for improvement for patients receiving these drugs. The National Action Plan for ADE Prevention, a collaborative effort of a multitude of HHS agencies, the Veterans Health Administration, and other Federal agencies, identified limitations in the current health information exchange infrastructure, including lack of interoperability, as one of the foremost barriers to anticoagulant ADE prevention efforts. The National Action Plan calls for improvements to EHR interoperability between acute care settings and long-term care facilities and home health settings. Communication challenges may be one of the foremost barriers to delivering optimal anticoagulation management in LTC settings. Limited accessibility to EHRs outside a particular facility and the challenge of transmitting pertinent anticoagulation-related data elements in an efficient manner to a remote provider that can manage patients' anticoagulation may complicate anticoagulation services in LTC settings. In addition, significant lag time in reporting laboratory results to laboratory portals for home healthcare nurses or long-term care consultant pharmacists to review may result in delayed action taken for anticoagulation management. For this reason, there may be a need for more centralized EHR tools that promote data exchange and facilitate provider access to real-time, linked pharmacy–laboratory data.

Electronic exchange of health information, such as laboratory results and care (e.g., discharge) summaries, has been identified as a critical component of delivering optimal patient care; however, several barriers remain in health information exchange infrastructure. For anticoagulation management specifically, improving bidirectional communication among multiple health care providers caring for the same patient may have a very important role in improving care transitions for patients, especially those most vulnerable to anticoagulant ADEs (e.g., patients undergoing transitions across health care settings). Health information exchange, as it relates to interoperability between pharmacy and laboratory systems, also affects safe delivery of anticoagulation. In spite of the recognition that enhanced laboratory–pharmacy linkages are key to improving the safety of medications such as anticoagulants, challenges remains in the ability of diverse EHR products to exchange this information so as to allow for delivery of more coordinated, effective, and efficient care. Moving forward, policies and standards that better facilitate health information exchange will also facilitate improvement in care delivery, as it pertains to high-risk medications such as anticoagulants.

- ***Recommendations:*** Community and long-term care pharmacies should be encouraged to participate in EHR Incentive Programs and value-based payment models for meeting improved individual and population health outcomes through clinically relevant eCQMs. Community and long-term care pharmacy EHRs/medication profile systems should utilize interoperable certified electronic health technology and have send, receive, push, find and use capability of a common clinical data set as those of other health care providers, including receipt of C-CDA from primary care and the last care provider. We recommend that ONC prioritize and accelerate interoperability requirements for clinical data elements that are directly associated with anticoagulant and other high risk drug use and clinical monitoring and management.

  The following Call to Action items are recommended for inclusion in Table 4:

  1) Category D2, number 1: add community pharmacy notification or receipt of electronic patient discharge information from hospitals, at minimum PAMI for 2015-2017 and including the medication reconciliation, patient discharge instructions and discharge summary within 5 years (number 7).
  2) Category D2, number 10: add community pharmacy and post-acute care setting (e.g., long-term care) electronic access to clinical patient data through laboratory linkages, provider EHR, and regional health information exchange with feedback loop to provider EHR regarding recommended medication management interventions
  3) Category D3, number 1-6: add development and leveraging of adverse drug event prevention eCQMs (i.e. anticoagulants, hypoglycemics, opioids) that align with the National Action Plan for Adverse Drug Event Prevention and support value based payment models
  4) Category D4, numbers 1-3: add bidirectional/multidirectional secure laboratory data communications across continuum of care between primary care and/or hospital providers and post-acute care settings, including long-term care (e.g., nursing homes) and home health.
  5) Category D4, number 1: add bidirectional/multidirectional secure clinical communications between community pharmacies and providers
  6) Category D4, number 2: add prescribers should receive push notifications of all prescriptions filled, refilled and never filled

The Roadmap on page 59 states, “OMB M-04-04 defines four levels of assurance (LOA) as a means to weigh the risks associated with authentication errors and misuse of credentials. Level 1 is the lowest assurance level and Level 4 is the highest”.

- ***Recommendation:*** We recommend a minimum of LOA 3 for providers and a minimum LOA 2 for consumers. We also recommend that electronic personal health record companies be required to have a business associate agreement with the HIPAA covered entities they are interacting with to ensure consumer protection.

The Capital Region Care Transitions Coalition applauds the work of the ONC, and eagerly awaits the widespread enhancements that will accompany the effective implementation of the Roadmap. Thank you for the opportunity to provide comments. We believe that leveraging the strengths of the care transition coalition model and providing the opportunity for all healthcare providers to participate in incentive programs and value based payment models will accelerate local, regional, state and national electronic health record interoperability.

Thank you,

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On behalf of the Capital Region Care Transitions Coalition