Dear National Coordinator DeSalvo and ONC Team,

The Pennsylvania eHealth Partnership Authority applauds the work of the ONC in development of the Nationwide Interoperability Roadmap, and welcomes this opportunity to offer comment on the plan. The Authority believes that the overall tone of the Roadmap is excellent, and in particular supports the stakeholder-driven processes and citizen-centric approach evident throughout the Roadmap. We look forward to further work with ONC as they strive to advance national cooperative efforts under this roadmap and develop greater specificity in the areas of the Roadmap that are, by necessity, currently somewhat general.

Please note that our feedback below is provided in three categories. "Significant Modifications" describes those items that we believe to be the highest priority topics. "Other Brief Items" includes either relatively minor proposed changes as well as some items that may require significant effort but which we feel are second-tier priorities. Finally, "Other Feedback" includes lower-priority items or topics where we believe additional clarification within the Roadmap would be helpful.

Again, the Authority appreciates this opportunity to participate in the national conversation as we mutually strive toward effective modernization of our health care system. Please feel free to contact us with any questions.

Respectfully submitted,

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## **Significant Modifications:**

- **STATE GOVERNMENTS' ROLE IN GOVERNANCE**. In Figure 5: Stakeholder Perspectives (page 22), it is recognized that state governments, along with federal, tribal, and local governments, are the "organizations that support the public good". In the section on Supportive Business, Clinical, Cultural and Regulatory Environments (pages 37-44), state government are identified as a "key partner", particularly due to their governance of Medicaid programs. Throughout the roadmap, "states" are called upon to be part of the governance team to advance interoperability. It seems unusual, then that in Table 1 on page 34, there is not a call for ONC to partner with state government-lead eHIE initiatives to define the nationwide governance framework. Put more strongly, while we recognize the political benefits of treating stakeholders equitably in this kind of very large collaborative effort, we feel that in this effort to work towards interoperability and a citizen/patient-centric system, "organizations that support the public good" should be singled out as having particular responsibility and authority in advancing the discussion. Moreover, it should be called-out that while reform of this magnitude will not be possible without informed and affirmative participation by many (not all) stakeholders, our interest is first and foremost in reforming to a system that is cost effective and delivers high quality for citizens and patients.
- LIABILITY RISK. A major barrier to implementation and use of electronic health information exchange (eHIE) is liability risk to the providers using such systems. There is only one mention of this risk in the current document (page 38), and it is in a "background and current state" section. Moreover, this mention appears to focus only on liability risk associated with eHIE security and information protection. ONC should include in this roadmap a description of several liability risks, and include a process to examine, and possibly address specific liability risk issues such as when a provider reasonably relies on inaccurate information received via eHIE, resulting in erroneous clinical decisions harmful to the patient. Such inaccurate information could result from unintended inaccuracies by individuals or systems on the sending end of the exchange, or through inaccurate patient-matching. This examination should include definition of a set of best practices that can be applied by providers and vendors to reduce the possibility of inaccurate information being made available via eHIE (i.e. data entry validation protections), as well as appropriate practices for a recipient or a recipient's system to identify potentially inaccurate information (i.e. validation of medication and allergy lists with patients when possible).
- **PAYER PARTICIPATION**. Suggest that the classification of "the intersection of clinical and administrative electronic information" as out of scope (page 10) needs clarification. One of the major short-term value propositions of eHIE should be the ability of payers to access clinical information for routine treatment, payment and operations functions such as gathering clinical information to support claims adjudication, supporting case and disease management programs, and supporting HEDIS and similar quality programs. In cases where payers support accountable care organizations, patient centered medical homes, or similar patient centric/population health oriented risk sharing programs, ability for payers to participate in eHIE seems critical. It should be sufficient to make it clear that out of scope statement refers to integration of administrative data into eHIE-related data sources, but then also make it clear in the policy portion of the document that

treatment, payment and operations definitions include use of clinical data by payers; that such use should be permitted; and that organizations should not erect barriers based on artificial distinctions between functions performed by providers and those performed by payers. Where such restrictions are legally valid, organizations may restrict payer use of eHIE-derived data to only current members of the payer, and may impose limitations that exclude use of eHIE derived data for actuarial or coverage decision purposes.

- Specifically suggest addition to the "Private Payer" critical actions (page 42) to encourage payer participation in eHIE to streamline appropriate administrative functions, specifically those where they already request and receive clinical information, usually via mail and fax, such as claims adjudication, HEDIS chart reviews, and case/disease management functions. This could work as either a query-based eHIE use case or DIRECT use case.
- Suggest adding the HEDIS chart review and case/disease management use cases to Appendix H (already covers claims adjudication under Appendix H item 53).
- While we understand the need to focus the scope of the Roadmap, we believe that at least initial planning efforts for integration administrative information into eHIE should be included in this Roadmap.
- MISSING ELEMENTS FOR CLINICAL DATA SET. In the "Common Clinical Data Set" (page 12, page 80) suggest the following elements are missing:
  - "Other allergies" as distinct from medication allergies (i.e. food allergies)
  - Minimum metadata elements to identify source and date of information (and possibly date of exchange)
- **FEDERAL ALIGNMENT**. While we understand that the Interoperability Roadmap is meant to be an overarching national plan and not specifically a federal government plan, we feel that the document is incomplete without a mention of at least some specific federal actions to demonstrate active support for the plan. For instance, we believe the roadmap should include a process to ensure, or at least encourage alignment by federal agencies with the various contents of the plan. This could take the form of letters of support from the Executive Branch, key members of the Legislative Branch, and such agencies as the Department of Defense and the Department of Veterans Affairs. While we understand that gaining such public commitments may be politically and administratively difficult, they would send a clear message that the federal government is united in its intention to "walk the talk".
- ACCOUNTING OF DISCLOSURES. The current document does not discuss accounting of disclosures, but of course this is a key HIPAA right. Suggest a use case for the citizen's ability to request an eHIE accounting of disclosures be added to Appendix H, and suggest that this important topic be added at least to the "Privacy and Security Protections for Health Information" section, and possibly to the Individual Empowerment section or other sections.
- VALUE ORIENTED USE CASES. While there are many references throughout the roadmap to the importance of the value that can be achieved from an interoperable healthcare system, and the

close tie between the viability of emerging value-based programs and eHIE, there is remarkably little discussion regarding specific quality improvements based on interoperable eHIE. In fact, reduced readmissions are mentioned only twice and reduction of redundant care is mentioned only a single time, all on two pages in the "Measuring and Evaluating Impacts" section (pages 108-109). Not only should the roadmap include specific activities to identify cost and quality factors that eHIE and interoperability can influence, but it should then include work to tie these factors to specific use cases and specific measurable quality and cost outcomes. These efforts should lead to the development and adoption of evidence-based guidelines, protocols, and best practices that produce these improvements. Such adoption should be massively incentivized, if not mandated, at least across entities that receive public sector funding.

## **Other Brief Items:**

- The document states (page 11): "While each electronic health information sharing arrangement may continue to use its own policies, service agreements and technical standards to support participant priorities and needs..." Suggest "standards" in above sentence should be "specifications", "agreements", or some other term so as to distinguish locally-adopted policy from true industry or national standards.
- Suggest addition to the last paragraph in the "Current Context" section (page 11): "The goal of such HHS consideration will be to respect patient privacy while removing artificial barriers to electronic exchange."
- In the LHS Requirements (page 23), under "Rules for engagement and governance": "... standards in a manner that does not limit competitions." Suggest clarification is required to specify "other than competition based on limiting interoperability". Same consideration required on page 27.
- In the LHS Requirements (page 24), under "Core technical standards and functions" item J: "... therefore may rely on translation services provided at various points along the way." Suggest there needs to be a distinction between legitimate translation services (i.e. customization based on workflow needs and legacy system compatibility), and illegitimate translation that is introduced into systems, particularly newly-designed systems, to make interoperability more challenging and/or expensive.
- In the second paragraph of "Non-Governmental Governance" (page 29) suggest second paragraph, last sentence "And most (but not all) operate some level of technical infrastructure to identify participants in the trust community." Consider adding to end of sentence "and/or create joint infrastructures to manage patient consent".
- In the list outlining "individual choice" (page 32), suggest adding another bullet: "Entities that facilitate the interoperability of electronic health IT should provide individuals with easily used and accessible electronic processes that permit individuals to express their consent to and desire for disclosure."
- In the first bullet under "open exchange" (page 33), suggest clarification to "...applications will not prevent a user from using health information exchange applications developed by competitors." to specify "either through user agreements or technical means".

- Suggest "Individuals Are Empowered, Active Partners in Their Health and Health Care" (pages 45-49) be modified to include the suggestion that payers offer incentives to patients who do take an active role. Could be tested first with Medicaid MCO members to determine effectiveness and value of such incentives.
- NSTIC alignment is mentioned in the narrative for "Verifiable Identity and Authentication of All Participants" (pages 58-61), but not in the critical actions table. Believe it is appropriate to include ONC action, in cooperation with other federal agencies and NSTIC, to encourage/incentivize participation by vendors and state-level HIE initiatives.
- Believe that methods to identify and take action against bad actors needs to be included in "Certification and Testing to Support Adoption and Optimization of Health IT Products and Services" narrative and critical actions chart (pages 74-76). This could include the creation of a formal EHR/eHIE user feedback mechanism to ONC, with subsequent follow-up processes, to help identify bad actors.
- In the discussion of the potential benefits of "data-centric ways of exchanging information" (page 82), believe it is worth noting the potential for data-centric exchange to limit redundancy of exchange across multiple documents in document-centric exchange. Such redundancy can bloat records contained in EHR systems and create unnecessary "noise" in the information an eHIE-using provider needs to review in order to find information relevant to the clinical situation.
- Believe critical actions table for "Consistent Data Formats and Semantics" (pages 84-85) should include a more phased approach to the inclusion of "best available" standards to certification programs. Could initially take the form of a special recognition program, perhaps even monetary incentives, for vendors who are early adopters of "best available" standards, then gradually morph into an absolute certification requirement.
- Suggest the use of the term "With their consent" be added to the start of use cases 16 and 32 in Appendix H. Suggest further emphasis on the patient's ability to decide for themselves by changing "participation" to "voluntary participation" in use case 16, and "participate" to "voluntarily participate" in use case 32.
- Suggest use case 43 be modified to include either federated or centralized provider directory information in Appendix H. This demonstrates a willingness to recognize different solutions that may already exist.
- While use case 37 covers patient contribution to electronic health records, believe a separate new use case is warranted for ability of individuals to contribute and manage advance directives, POLST, and healthcare-related powers of attorney.

## **Other Feedback:**

- Plan notes that "data quality, usability and workflow" are out of scope (page 10) but in the very next paragraph discusses "approaches to send, receive, find and use". Suggest that having "use" in scope and "usability" out of scope is confusing.
- Suggest some of the roadmap may need evaluation on timing. For example, in the critical actions for a coordinated governance framework and process (Table 1, page 34), the call to action for public

and private stakeholders (item 3) may not yield robust response if people perceive that they need to wait for the results of federal action (such as those in item 1).

- Suggest another possible approach (moving forward and critical actions) for "Supportive Business, Clinical, Cultural and Regulatory Environments" (page 39-42) would be for vendors to develop lower-cost "plug and play" EHR systems that integrate HIE into the EHR workflow, then educate providers on the economic benefits of adopting these more standardized systems and workflows.
- There is a typographical error on page 45 "four in10shared".
- Table 15 "Measurement Actions", item 5 states "ONC will work with relevant grantees...", but it is unclear what grantees are being discussed SIM participants? EHR Incentive Program participants? Former State HIE Cooperative Agreement participants?