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Karen B. DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2015 Draft Interoperability Roadmap
Hubert H. Humphrey Building
Suite 729D
200 Independence Avenue S.W.
Washington, D.C. 20201

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

Dear Dr. DeSalvo:

Aetna appreciates the opportunity to submit these comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the draft Nationwide Interoperability Roadmap (Roadmap). Assuring timely and robust execution of health information technology (Health IT) interoperability is essential to enabling a truly 21st century health care system that spans from coast to coast. In this letter, we set forth Aetna's core priorities for achieving meaningful interoperability and how these core priorities can be applied in the context of the Roadmap. We also provide an *Addendum* section, in which we offer detailed feedback on specific provisions of the Roadmap.

Aetna is one of the nation's leading diversified health care benefits companies, and for the past several years, we have been at the forefront of developing innovative delivery models, incorporating electronic health records (EHRs), as well as utilizing sophisticated clinical data support across our wide range of businesses and contracted providers. Aetna has invested $1.5 billion in establishing Healthagen, a major and fast-growing component of our family of companies dedicated to advancing the opportunities offered by effective Health IT. Healthagen, in turn, consists of a portfolio of innovative businesses, including Medicity, ActiveHealth Management, Health Data and Management Solutions (HDMS), and Accountable Care Solutions (ACS). Medicity, for example, offers connectivity and population health management solutions to enable providers across settings to share patient data securely, effectively, and confidentially, including during actual care delivery.

Nationwide, much has been achieved in recent years to advance Health IT, but persistent and very vexing challenges remain. Since passage of the 2009 HITECH Act and implementation of its Meaningful Use (MU) program, the U.S. health care system has made significant strides toward the increased collection and storage of health information by providers in electronic health records (EHRs).

However, the critical challenge today is to assure that these EHR systems are truly and freely interoperable – i.e., achieving an environment in which EHRs and other Health IT systems can effectively communicate and exchange data so that patient data are available whenever and wherever needed. Interoperability is also essential to making health care delivery more affordable in the long run, as well as improving population health and public health.

Aetna is encouraged by the work that ONC has undertaken to develop this Roadmap, and we believe that many of the steps it describes promise to advance the vision of nationwide interoperability. To do so, the Roadmap asserts a commitment to overcoming remaining technical and business barriers to interoperability. In Aetna's view, the most important of these remaining barriers are:

1) Lack of common standards;
2) Proprietary systems that block information flow;
3) Inability to locate health data (e.g., query-based discovery); and
4) Privacy concerns and inadequate information security, regrettably heightened by recent breaches of personal health information.

To overcome these barriers, Aetna believes that ONC can and should leverage the authority it currently holds pursuant to its certification program to assertively advance the goal of interoperability. ONC already performs the role of certifying EHR systems as a condition of provider participation in federal payment programs, federal procurement, and contracting. Going forward, demonstrated attainment of interoperability goals (such as those set forth in this Roadmap) should become embedded in the Health IT certification process.

As ONC works in coming months to finalize its proposed Roadmap, Aetna believes ONC should devote special care and attention to the following six core interoperability priorities.

1) *Adopt open standards for systems going forward;*
2) *Make today's remaining proprietary systems more open by curbing information blocking and using public APIs (Application Programming Interfaces);*
3) *Leverage existing Meaningful Use certification to drive interoperability;*
4) *Enable providers to better access data on a timely basis;*
5) *Assure that interoperability incentives developed in various segments of the health care system are aligned; and*
6) *Ensure interoperable networks are secure and protect patient privacy*

Aetna Core Interoperability Priorities:

1) ***Adopt open standards for systems going forward:*** The Roadmap correctly acknowledges that many EHRs and Health IT systems today use proprietary standards that inhibit the connection and sharing of data with other systems. In Aetna's view, this problem needs to be addressed by taking concrete steps to drive the adoption of open standards that are platform-independent in a vendor-neutral environment. This is essential to freeing data to move among systems and overcoming information blocking.

Aetna commends ONC's effort to promote adoption of common standards through the release of the Standards Advisory. However, we believe that ONC in its Roadmap needs to articulate very concrete steps for driving adoption of these open standards. We believe an opportunity exists to build on the proposed coordinated governance approaches already outlined in the Roadmap with an additional step – namely, the leveraging of ONC's

already existing statutory certification and testing authority to drive adoption of common and open standards, defined and adopted in a transparent process.

2) ***Make today's remaining proprietary systems more open by curbing information blocking and using public APIs (Application Programming Interfaces):*** The proposed Roadmap asserts that it is unreasonable in the short-term to expect providers to fully abandon their existing proprietary EHR systems and switch over to fully interoperable systems – and we agree. It is for this reason that we believe it is essential to prioritize the use of public APIs as an indirect but effective way to achieve connectivity and data exchange, even among otherwise disparate and proprietary EHRs. Unfortunately, the Roadmap's proposed public-private effort to develop and standardize a targeted set of public APIs is important, but not sufficient. Equally important, we believe, is identifying and penalizing those bad actors whose actions, whether intentional or otherwise, block meaningful seamless information sharing across systems. Without tackling this problem head-on, the effectiveness of open APIs cannot be fully realized.

3) ***Leverage existing Meaningful Use certification to drive interoperability:*** Aetna believes that ONC should proactively leverage its existing testing and certification authority established in HITECH for MU to *also* ensure true interoperability of all existing and emerging Health IT systems. We hope that the recent issuance of the MU 3 regulations will facilitate this process. Moreover, we believe ONC's testing and certification authority to drive interoperability should be applied to all important aspects of interoperability, including data creation, transmission, and consumption of data for the purpose of population health management. Simply moving data from one system to another will be pointless if the recipient cannot understand, store, and use that data. To that end, we encourage ONC to drive towards end-to-end testing for usability of Health IT systems.

4) ***Enable providers to better access the data they need for patient care on a timely basis:*** Today, most health information exchange efforts are ad hoc, untimely, and involve sending massive amounts of data (e.g., lengthy care summaries) that are difficult for receiving providers to review and use. The Roadmap correctly acknowledges this information overload and proposes a standardized, common clinical dataset that providers would have to share during transitions of care. This dataset is necessary to reduce information overload when pushing information to the next provider. However, pushing information (i.e. push-based exchange) doesn't equate to true interoperability.

   To make health data relevant, accessible, and usable, Aetna believes that providers should also be able to access data proactively (e.g., using search functions) and receive timely notifications after important events (e.g., hospital admission). Toward this end, we propose that public APIs be required to encompass a set of rigorously defined core data services, which include provider directories, to locate data stored in provider EHRs for care delivery, population health management, and research. Further, APIs should also enable timely notification of providers as certain information is created (i.e., publish-subscribe models).

5) ***Assure that interoperability incentives developed in various segments of the health care system are aligned:*** We are pleased that the Roadmap recognizes the power and potential that value-based payment and delivery models (e.g., Medicaid managed care, bundled payments, and accountable care organizations) hold in making investments in interoperability commercially attractive for providers. These models can offer payment

incentives and, in some cases, make provider participation conditional on adoption of interoperable Health IT systems.

However, we are concerned that well-intentioned but uncoordinated efforts to incentivize interoperability by various state Medicaid programs (or by Medicare or large commercial accountable care organizations) could inadvertently create new barriers to interoperability -- even as they seek to lessen it. That is, if various segments of the system separately seek to address interoperability only within their silos -- by defining different interoperability requirements and adding new compliance burdens -- the long-term goal of a seamlessly interoperable health care system could be undermined. Such a web of different regulations and requirements could be especially challenging for stakeholders like Aetna that increasingly operate across state lines on a regional or national platform. There is unlikely to be a perfect solution to this challenge, but we urge the Roadmap's authors to produce a final version that more squarely confronts this issue and identifies potential public-private strategies for addressing it.

6) ***Ensure interoperable networks are secure and protect patient privacy:*** We applaud ONC for clearly articulating the importance of interoperable networks that are secure, protect patient privacy, verify the identities of users, and only permit access to authorized individuals. Names, addresses, employment information, Social Security Numbers ("SSNs"), and more are at risk of theft when not properly protected at rest and in transmission. Recognizing these threats, information security vigilance and controls are a business necessity and should classify SSNs in the highest risk category, eliminating their use wherever possible. Privacy and security of patient data are of upmost importance and without them, all efforts to advance interoperability through incentives, standardization and certification will fail to achieve the trust necessary for patients, providers, plans, and other industry actors to share and use data.

Aetna believes that the ONC's proposed Roadmap offers a very thoughtful foundation for addressing the challenges facing Health IT interoperability. Through careful attention to the six core priorities identified above, an improved final Roadmap can serve as a clear and robust guide for policymakers, payers, providers, and consumers to achieve a truly interoperable health care system.

The *Addendum* section that follows offers additional and more detailed recommendations concerning specific components of the proposed Roadmap, some of which expand upon the core priorities emphasized above, and some of which address additional questions and concerns.

Thank you for considering our comments. Should have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

Steven B. Kelmar
Executive Vice President, Corporate Affairs

Addendum Supplementing Aetna Comment Letter on Draft ONC Interoperability Roadmap

In addition to the core interoperability priorities articulated in the first portion of our comments, the following supplemental comments and recommendations either expand upon our priorities or address additional aspects of the Roadmap.

Recommendations:

I. More fully identify the current factors and stakeholder sectors that pose barriers to achieving effective interoperability, and more clearly spell out ONC's prescriptions for overcoming these barriers:

The Roadmap commendably provides a vision for nationwide interoperability and it does discuss some of the barriers to and means to achieving this vision. However, we believe it overlooks or underplays other very significant barriers. These barriers include: (1) lack of Health IT adoption across all care settings in the continuum, (2) inability of current value-based payment models to fully drive nationwide interoperability, instead of just fostering data exchange on a community or regional level; and (3) the increasing amount of data captured through remote monitoring devices and other mobile platforms that lack a path to interoperability with EHRs and other Health IT systems.

As ONC finalizes this Roadmap, Aetna recommends that the authors directly spell out all of the current barriers to interoperability, as well as how the actions of current stakeholders contribute to such barriers. Without a comprehensive understanding of all the problems, ONC runs the risk of developing a Roadmap that fails to achieve its stated vision of nationwide interoperability.

Aetna also believes that the final Roadmap should better identify and define actions, actors, milestones, accountability, and sequencing for addressing the identified barriers – including the ways in which ONC's existing certification and testing authority could be leveraged to more firmly drive interoperability adoption among all participating stakeholder sectors.

Finally, we are concerned that the proposed Roadmap proposes EHR-to-EHR interoperability goals for 2017, but these goals are published in advance of and without discussion of how these goals may or may not align with the next version of certified EHRs to be required under the Meaningful Use program. We hope that the final Health IT Certification regulation and the final version of this Roadmap will address the critically important alignment between the two.

II. Focus ONC's efforts on leveraging certification and adoption of standards:

The proposed Roadmap correctly acknowledges the need for private-public partnership and involvement of a variety of stakeholders to realize an interoperable nationwide learning health system. Aetna commends ONC for its vision and articulation of short-, medium-, and long-term goals for enabling this interoperability vision. However, to maintain a proper balance between official guidance and the flexibility needed to foster innovation, we recommend that ONC focus its Roadmap's implementation strategy on actively leveraging ONC's already potent certification

authorities to drive stakeholder adoption of common standards – and leave it to the marketplace to create the business case and trust infrastructure for effective data exchange.

We believe that this leveraging opportunity should be applied chiefly in the following contexts:

a) ***Certification:*** Inter-system interoperability is still a major challenge that requires resolution through certification programs and adoption of open standards. ONC should expand the existing testing and certification infrastructure established for MU to ensure interoperability of all existing and emerging Health IT systems. Moreover, future testing and certification requirements should include all aspects of interoperability — data creation, exchange, and usability of data for the purposes of population health management. It is important not only to make sure that a system is capable of demonstrating exchange capabilities during testing, but also that it is able to meet the exchange requirements in actual use by providers.

However, ONC also must strike a balance to assure that its testing and certification requirements are not overly prescriptive and rigid, but rather scalable and able to accommodate a variety of Health IT systems and vendors and their related service offerings. We encourage ONC to establish meaningful guardrails by creating a set of optional requirements alongside a core set of testing and certification requirements that would apply to all Health IT systems. At the same time, ONC should also clearly articulate incentives and interoperability standards for those categories of providers that are not currently within the scope of the MU standards (e.g., long-term and post-acute care providers)

b) ***Standards and Specifications:*** Simply moving data from one system to another is not sufficient; recipients of exchanged data should be able to store, understand, and use that data as needed – that is the essence of interoperability and for that we need adoption of common vocabulary, content, and transport standards. ONC's release of the 2015 Standards Advisory is a great start to cataloging the best available Health IT interoperability standards and specifications. However, Aetna believes ONC also needs to drive adoption of these standards to achieve interoperability. To that end, promoting the use of open standards that are platform-independent in a vendor-neutral environment is essential to enabling data to flow freely and securely among systems.

Moreover, we encourage ONC to take a cautious approach in promoting standards like the so-called FHIR standards (Fast Healthcare Interoperability Resources) until they are adequately mature for universal adoption. Undoubtedly, FHIR offers the promise of an expedient solution to many of the challenges associated with interoperability between proprietary systems, but failure to allow its appropriate development and testing prior to adoption could cause future unintended consequences. We further recommend evaluating all standards and specifications based on their position in the spectrum of maturity and use, rating them as proposed, emerging, pilot, and broadly deployed.

We do *not* believe regulated standardization is necessary for everything. Specifically, we do not believe that the Roadmap's starter list of patient-matching variables is necessary or that it needs to be standardized via regulation. Establishing core data elements needed for patient matching is best left to the marketplace. In fact, private companies that specialize in patient matching as well as other exchange solution vendors are already meeting this business need. Instead, ONC would be better served by creating or facilitating the creation of resources that can be used by

other stakeholders attempting to match patients for data exchange, research and reporting purposes and requiring patient matching solution providers to report on their accuracy level or error ratios.

In general, we believe that ONC should drive certification and standardization for interoperability based on the same basic model as EHR certification under the HITECH Act – i.e., the Health IT system vendor should be required to be certified, and providers must attest to the use of certified, interoperable Health IT systems.

Ultimately, imposing regulations – even noble ones – can come at a cost to all involved – payers, providers, vendors, and patients. If the costs are excessive, the regulation will create marketplace uncertainty and increase the financial burden on participants. We believe ONC should move very thoughtfully and deliberatively forward in this process and avoid adding burdens that do not clearly produce an assured benefit.

III. Reduce the SSN data footprint and mandate stronger encryption policies:

The health care system uses Social Security numbers (SSNs) to identify people when it comes to receiving and paying for care. While assurance of identity is critical to achieving interoperability, the handling, processing and storing of SSNs (used as unique attributes for authentication and verification) throughout the health care ecosystem today results in a large attack surface that has attracted the attention of sophisticated threat actors. Continued dependence on the handling of SSNs is not sustainable and will undermine important efforts to improve Health IT interoperability. We encourage the ONC to continue to work with the private sector to develop enhanced and secure identity and patient matching solutions without relying on SSNs.

With the prevalence of portable technologies, from laptops to external devices, theft of these sources of patient data has risen substantially. Further, hackers are becoming more sophisticated in their attacks on Health IT systems. We encourage ONC to require stronger encryption policies to protect all data, not just during exchange but also at rest on end-point devices. Aetna works diligently every day to monitor threats, modify systems and procedures with leading security measures to thwart attacks, and help protect data. The coordinated governance process outlined in the Roadmap will help to identify best practices in cyber security, including data encryption, continual security upgrades, and reducing the data footprint—i.e., limiting the personal health information shared during exchange to only data that is necessary. The objective of a learning health care system also applies to security. With that in mind, ONC should facilitate ongoing information sharing about potential threats and appropriate actions to prevent them.

IV. Reduce redundancies and misalignments associated with state-driven interoperability visions:

ONC's intent to secure state-level support and promotion of nationwide interoperability is commendable. However, we see no valid reason to recommend, as the Roadmap appears to do, that each state has its own interoperability roadmap. While each state may have its own challenges and policies that could impede nationwide interoperability, asking each state to create its own interoperability roadmap does not guarantee alignment across states to achieve nationwide interoperability. For evidence of this, we need look no further than to initial implementation of the HITECH Act, which empowered states to define their own MU

requirements for Medicaid incentives and to establish independent health information exchanges. In the end, such uncoordinated state activity was ultimately shown to be ineffective, and in many cases, it actually lowered the performance threshold established for participants. Worse yet, for providers and payers that operate across state lines, such variability in data exchange policies threatens to create patient safety problems, increase administrative costs, and ultimately inhibit the stated overall goal of effective information exchange.

V. ***Assure a critical role for private payers in advancing interoperability:***

Like the authors of the Roadmap, we agree that private payers – working in concert with Medicare, Medicaid, and employers – have an important role to play in advancing interoperability. In our view, a critical component in driving interoperability is to foster development of an appealing business case for providers through value-based payment and health systems.

We work with providers at every level of expertise, engaging them in patient-centered medical homes, bundled payments, accountable care organizations, and co-branded, value-based health plans. In our experience, both providers and payers are best served when providers are rewarded across payers for the same or similar goals. Thus, we hope that ONC, to the extent feasible, will work with the private payer community to facilitate, to the extent feasible, the application of harmonized interoperability standards across multiple payers.

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