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April 3, 2015

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Office of the National Coordination for Health Information Technology
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Dr. DeSalvo:

On behalf of the Blue Cross Blue Shield Association – a national federation of 37 independent, community-based and locally operated Blue Cross and Blue Shield companies (“Plans”) that collectively provide healthcare coverage for nearly 105 million members, one-in-three Americans – we are pleased to respond to your questions on *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* (DRAFT Version 1.0).

We commend the Office of the National Coordinator for Health Information Technology (ONC) for launching a multi-stakeholder process involving the public and private sectors to identify critical actions that all stakeholders should take to advance interoperability – especially as an interoperable health IT ecosystem is critical to improving the quality and value of health care. Blue Cross and Blue Shield Plans are keenly attuned to the benefits of interoperability. Our collective experiences include Arkansas Blue Cross and Blue Shield’s Advanced Health Information Network, as they pioneered one of the nation’s first successful and sustainable statewide health information exchanges more than ten years ago. Many Plans have built sophisticated infrastructures to support HIPAA administrative simplification and other statewide health information exchanges. Moreover, Blues Plans established the nation’s leading network of value-based payment (VBP) programs that promote the bi-directional exchange of health information to empower clinicians and engage consumers. We understand the value of interoperability and the challenges it presents. We look forward to carefully pacing our collective efforts to achieve this national vision.

As this is DRAFT Version 1.0, we appreciate that the Roadmap will undergo future iterations, and welcome this opportunity to suggest revisions that we believe will strengthen the Roadmap's next version. Therefore, we are pleased to offer the following key recommendations in response to your questions on the roadmap:

- *General: What, if any, gaps need to be addressed?* **Immediately address, in the 2015-2017 period, the full range and timing of health IT actions facing payers and providers, including HIPAA Administrative Simplification requirements.** If not, the Roadmap may do little to mitigate, and may inadvertently amplify, what has been called "implementation fatigue," the plethora of requirements, ranging from HIPAA Administrative Simplification to Insurance Marketplaces to new market demands that all pull on the same IT resources within an organization. **In addition, immediately bring the intersection (or convergence) of clinical and administrative electronic data into the scope of the roadmap.** Both these recommendations will help leverage existing information infrastructures, and avoid developing divergent, potentially conflicting information systems.
- *Priority Use Cases: what use cases from this list should inform technical and policy priorities?* **As a top priority, establish a use case that calls attention to the critical importance of payer and provider partnerships in moving, analyzing, and acting on clinical data and information on costs and patient-specific coverage to advance value-based payment.** In the short-term, it may make sense to narrow the focus of this use case to high-need patients with certain chronic conditions.
- *Governance: How can ONC best recognize and support the industry-led governance effort?* **Do not automatically apply all policy, operational, and technical standards to all private sector programs and initiatives.** Health IT stakeholders should consider which private sector initiatives, such as those payer-provider partnerships supporting locally-operated value-based payment programs (consistent with revised use case 31), should lie outside the scope of national governance principles or criteria.
- *Supportive Business, Cultural, Clinical and Regulatory: How can private health plans support providers through financial incentives, and should they align with federal policies?* **Moving from volume-based to value-based reimbursement requires not only changing financial incentives, but also empowering providers by giving them the individualized support they need to be successful under new payment and care delivery models.** The Roadmap should recognize payers' role in providing access to the data, tools, funding, and analytical expertise providers need to effectively and efficiently manage the patient population and deliver the most

appropriate care in the most appropriate setting. **In addition, while aligning principles may be important – and alignment is a two-way street, not only private payers aligning with federal approaches, but also federal payers aligning with private sector approaches** – payers need the flexibility to customize VBP to the needs of widely varying markets, purchasers, and consumers.

- *Privacy and Security Protections for Health information: Initiatives addressing cybersecurity security generally should guide the Roadmap.* Any approach to cybersecurity protection guidance for the healthcare industry and health information exchange systems should coordinate with the Department of Homeland Security's National Infrastructure Protection Program, consider any broad new solutions enacted by Congress, and accommodate private sector industry efforts and commitments to address cyber threats through ISAOs, like HITRUST, and the National Healthcare ISAC, the NH-ISAC.
- *Core Technical Standards and Functions:* Which data elements in the proposed common clinical data set list need to be further standardized? **The common clinical data set that will be the focus of the first governance rules should be tailored to support the initial high priority use cases.**

Our detailed comments on the Roadmap follow. We appreciate your consideration of our comments and recommendations. We look forward to working with ONC and the Department to ensure that electronic health information is available when and where it matters most to improve the quality and affordability of health care. If you have questions, please contact Joel Slackman at 202.626.8614.

Sincerely,



Justine Handelman
Vice President, Legislative and Regulatory Policy

BCBSA DETAILED COMMENTS AND RECOMMENDATIONS ON CONNECTING HEALTH AND CARE FOR THE NATION: A SHARED NATIONWIDE INTEROPERABILITY ROADMAP (DRAFT VERSION 1.0)

Our comments and recommendations are grouped according to page 6's "Questions on the Roadmap."

1. General: What, if any, gaps need to be addressed?

Issue 1. The draft interoperability Roadmap focuses primarily on actions to enable interoperability among providers exchanging health information. Considering the importance of reciprocal clinical data exchange in health plans' efforts to support value-based payment programs, new interoperability specifications will place heavy demands on payers' IT resources: for example, plans will have to analyze, build or reprogram and test systems to complete bi-directional translation of clinical data elements conforming to any new standardized terminologies, and beyond code-to-code data interchange, plans must have a knowledge base in place to integrate all the terminologies and leverage the relationships among concepts.¹

However, a plethora of other IT requirements will be placing similarly heavy burdens, at the same time and on the same resources. Among them:

- The Affordable Care Act of 2010 (ACA) has generated enormous IT demands that are likely to continue beyond 2016 – e.g., insurance exchanges (the Marketplaces) product filing and approval

¹ Sheide, A., "Success doesn't just happen. It's planned." <https://www.hddaccess.com/hdd-access-community/blog/item/145-success-doesn-t-just-happen-it-s-planned-reflections-on-the-onc-interoperability-roadmap> (March 26, 2015).

(SERFF, HIOS), enrollment (issuer direct, FFM based), electronic data maintenance (pre-audit files, data baselining / reconciliation), and financial reconciliation (risk adjustment, risk corridors and reinsurance).

- As a result of legislative and regulatory initiatives that modified the original Health Information Portability and Accountability Act (HIPAA) administrative standards and broadened the scope of the Health IT infrastructure – primarily the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and the ACA – health plans must over the next several years implement multiple new standards and operating rules and identifier enhancements, develop new processes for testing and certifying compliance, and possibly prepare for new HIPAA requirements. In addition, within the next three to five years, it is likely that industry will have to initiate a major upgrade to the next generation (version) of the HIPAA administrative simplification transactions (e.g., version ASC X12N 007030). In the meantime, plans and providers are moving to the new ICD-10-CM/PCS code sets, a change of epic proportions affecting not only IT infrastructures but virtually every core business function. Finally, current statutory deadlines are either out of date or, perhaps, no longer rational in light of all the other demands and need serious review.
- Meeting new market demands, health plans are investing heavily in highly automated features and functionalities for their members to help them make informed purchasing and health care decisions. It is imperative that health plans engage consumers through a new generation of consumer-oriented tools for navigating new benefit designs, providing health coaching, and offering transparency on the cost and quality of healthcare services.

The Roadmap only tangentially touches on HIPAA, by indicating that the Office of the National Coordinator for Health Information Technology (ONC) will work with the new governance process, in 2018-2020, to address an expanded data set and uses of health information beyond treatment, including but not limited to payment and health care operations. We are concerned this is too long to wait.

Recommendation. The Roadmap should fill a major gap in the goals for 2015-2017 by explicitly addressing HIPAA administrative simplification, ACA-generated IT demands, and market-driven needs, to help stakeholders set priorities holistically.

Rationale. Filling this gap will help industry better navigate the competing requirements for interoperability, ACA implementation, HIPAA administrative simplification, consumer engagement, etc., to ameliorate the “implementation fatigue” that is affecting all major stakeholders. Moreover, addressing HIPAA now, rather than (possibly) parts of it several years hence, may uncover opportunities to leverage existing, well-developed infrastructures for exchanging administrative health data – and avoid the

confusion and potential conflicts that would arise from the emergence of divergent paths for various IT requirements.

Issue 2. The Roadmap identifies the intersection of clinical and administrative electronic health information – or, as the National Committee on Vital and Health Statistics (NCVHS) has discussed, the “convergence” between administrative and clinical standards – as a critical consideration, but considers it out of scope for the Roadmap at this particular time. The Roadmap notes that although use cases, standards, technologies and tools that leverage both administrative and clinical electronic health information will be an important topic to address in future iterations, these topics are out of scope for this Roadmap at this particular time and deserve separate, dedicated attention.

Recommendation. The Roadmap should address use cases, standards, terminologies, and tools related to the intersection or convergence of clinical and administrative electronic health information immediately, in the goals for 2015-2017.

Rationale. Considering how health plans are today using administrative data to bridge gaps in the availability of interoperable, longitudinal electronic health records data, and how important administrative data are in the context of value-based payment (VBP) models, immediately including intersection/convergence as part of the larger discussions about interoperability will only help advance the all-important transition from volume-based to value-based payment and delivery models.

BCBS Plans have long believed that changing payment is necessary but not sufficient to achieve value-based health care: clinicians need the means to identify and implement best practices. Therefore, a key tenet of Plans’ VBP programs is partnering with clinicians by giving them the individualized support they need to be successful under new payment and care delivery models. This includes not only hands-on technical assistance and practice coaching on redesigning workflows and adopting best practices, and tools such as embedded nurse care managers, but also giving them data, actionable information on their practices, their peers, and their patients, and IT services and capabilities that enhance practices’ ability to coordinate care.

Plans’ administrative data have provided an essential bridge to clinically and economically meaningful information, for providers treating individual patients at the point of service, and for providers managing populations. For example, to encourage the integration and coordination of clinical care services, Plans are giving primary care physicians information about the costs of procedures and services being charged by specialists and hospitals in their referral areas. To improve population health, Plans are giving accountable care organizations (ACOs) information about care the ACOs’ attributed members are receiving outside the ACO. In a variation on interoperability use case #23, payers are already notifying

ACOs through current health IT system infrastructures when an attributed member is admitted to a non-ACO hospital.

Beyond bridging current gaps in clinical interoperability, we believe that administrative data will be vital in pushing the frontiers of VBP by focusing providers ever more effectively on the value proposition. As the Roadmap notes, the availability of holistic longitudinal information on each individual in a computable format will enable significant advancements in the quality of care through more rapid and efficient cycles of improvement, using clinical decision support (CDS) tools – and integrating administrative data dynamically with data in the EHR will amplify the power of CDS. In the context of VBP program, providers will make better decisions if they could easily see, for example, cost information only obtainable from health plans' claims systems, such as the costs for specific procedures charged by potential referral specialists, or variations in the total costs of care associated with different episodes of treatment across various specialists. With sophisticated informatics, cost information can be made increasingly granular to highlight differences related to variations in patient characteristic, illness burden, etc. And further value can be achieved by making it possible for EHRs to interact with other health plan tools and programs, such as care guidelines or pathways, and case management as the patient progresses.²

² If payers were able to use HL7 and CDA elements to support the capture of relevant clinical and administrative data to gain perspective on the total cost of care for a medical condition (e.g., the total information of a care cycle through transitions in care settings) opportunities will arise to identify benchmarks, practice improvements, and standardizations that lead to reduced costs and improvements in quality of care. “Using FHIR to Support a Peer Messaging Architecture for Continuity of Care,” <http://static1.squarespace.com/static/53c98477e4b0985ac7917c0d/t/54c14038e4b07d778fe84b62/1421951043193/3e+-+FHIR+HL7+Use+Case+-+January+2015.pdf> (March 26, 2015).

2. Priority Use Cases

Issue. The Roadmap lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. ONC believes the list is too lengthy and needs further prioritization so that public and private stakeholders can establish policies and identify standards for specific use cases in the 2015-2017 period.

The stress on use cases is consistent with recommendations made by the Brookings institution that the Roadmap be implemented in a manner that emphasizes interoperability driven by actual business cases, including cost and coverage data interoperability. Consistent with the Roadmap's emphasis on VBP programs, Brookings finds that the efforts underway to shift provider payment from pay-for-volume towards pay-for-value depend on a more adaptable and effective health IT infrastructure. Brookings emphasizes that achieving these innovations requires timely, accurate and actionable information, including usable information on costs and patient-specific coverage, which is not yet widely available. Providers (and patients) are struggling to make informed, shared decisions about testing and treatment in the absence of access to key cost and coverage information before and at the point of care.³

However, none of the 56 use cases comprehensively addresses Brookings's recommendation for a business case tailored to advancing pay-for-value. Use case #31 (Payers use integrated data from clinical and administrative sources to determine reimbursement in support of payment reform) moves in the right direction by mentioning integrated clinical and administrative data, but it is too narrow in being limited to payers and reimbursement. Similarly, use case #25 (Payer/purchaser requirements for payment, such as prior authorization, are clear to the provider at time of order and transacted

³ High Value Health IT: Policy Reforms for Better Care and Lower Costs (The Brookings Institution: March 2015).

electronically and timely to support efficient care delivery), and use cases 53 and 54 (Payers review clinical documentation for payment purposes and for approval of services) are important, but also too limited.

Recommendation 1. The first priority should be a use case that supports the exchange of clinical and administrative data between providers and payers to support value-based payment reform. We recommend revising use case 31 as follows:

- “Payers and providers use integrated data from clinical and administrative sources, taking advantage of current as well as new bi-directional interfaces, to determine reimbursement and to enable seamless reporting, feedback, and decision support from payers to clinical providers in support of payment reform.”
- In the near-term, consider narrowing this use case to focus on high-need patients with certain chronic conditions that are prevalent across a wide range of publically and privately covered populations (e.g., diabetes).

Rationale. In order to effectuate value based care/payment reform, the healthcare industry needs to be able to exchange both administrative and clinical information. Accordingly, efforts to move forward with administrative and clinical data exchange must be harmonized. This is a key priority not only for payers, but for the healthcare industry, in general.

Recommendation 2. Three uses cases relate to admissions, discharges, and transfers – all critical actions related to the top priority use case above – and we recommend combining these into a second-priority use case:

- Hospitals automatically send an electronic notification of admission or ER visit to the patient’s health plan, the patient’s primary care provider, and (in the context of a VBP program) any other provider entity to whom that patient is attributed; upon patient’s discharge, hospitals automatically send electronic notification and care summary to the same recipients.

Rationale. Providers and payers need this information to improve coordination of care, streamline claims adjudication, and expedite payment.

Recommendation 3. A number of use cases share a common theme in seeking to engage patients more fully in their care, whether rendered “conventionally” (i.e. in person healthcare encounters) or through telehealth and remote monitoring. We recommend combining these (use cases 14, 17, 20, 52) into a third-priority use case:

- Patients routinely engage in the full range of potential health care encounters – from in person visits to telehealth and remote monitoring – by receiving and responding to alerts and reminders for preventive screenings, care, and medication regimens, and using their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records (including mental health risk assessments) and use it or make it available to payers and providers to support decision-making.

As a start, this use case could be focused on at-risk patients.

Rationale. Achieving value-based health care ultimately depends not only on changing payment incentives through VBP program and empowering providers with the individualized support they need to be successful under new payment and care delivery models (especially information), but also engaging patients so they understand the quality and costs of services, and information on how to keep healthy and manage chronic conditions. Neither changing payments nor empowering clinicians will achieve its full potential if patients are not engaged in helping to manage their own health and care – and this use case implicitly requires action by both providers and payers to promote patients' engagement.

3. Governance

Issue. 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. Although not explicitly stated, it appears that the governance process would apply to all private sector initiatives involving health data exchange:

1. ONC notes that in 2012 it released a request for information (RFI) on a proposed regulatory approach to governance, titled *Nationwide Health Information Network: Conditions for Trusted Exchange*. The industry response to the RFI indicated a general desire for ONC to refrain from formal governance activity and to allow nascent and emerging governance efforts in industry to take shape. As health information exchange was in its infancy, but growing at a fast pace, commenters were concerned that regulatory action would stifle innovation and improvements in health information exchange. In response to the industry's comments, ONC decided not to move forward with regulation around governance.
2. Since then, a number of organizations have been created or enhanced to define policies, practices and standards to enable interoperability between entities in their trust communities and hold participants accountable to these guidelines. However, ONC notes that technical and governance policies that are adopted by each are often incompatible, as are their respective business practices

and policies for establishing trust. The result is a complex web of electronic health information sharing arrangements that create some degree of interoperability within specific geographic, organizational and vendor boundaries, but fail to produce seamless nationwide interoperability to support a learning health system.

3. The challenge, according to ONC, is finding a way for health information to flow between these networks with varying policies and architectures, as there is no single process or mechanism to bring them all together in a coordinated manner or in a manner that can reconcile differences. Therefore, it is important that there be a set of "rules of the road," and a multi-stakeholder process to address operational issues to support the rules of the road.
4. Although there would not necessarily be a mandate to comply with the governance framework, ONC would call on "private sector stakeholders across the ecosystem" to come together, and it would identify a mechanism for demonstrating and identifying compliance with the rules, as well as addressing non-compliance.

Just as we were concerned about the mechanism ("a voluntary validation framework") proposed in the 2012 RFI, we remain concerned that the compliance mechanism envisioned in the Roadmap could become a de facto mandatory requirement because other public and private organizations could specify it as a condition in awarding contract, procumbent, or participating in other government programs (e.g., Insurance Marketplaces).

Recommendation. Do not develop a one-size-fits all *national* [emphasis added] governance framework. Instead, clarify that through the governance framework, ONC and industry stakeholders will specify in detail which private stakeholders in which part of the ecosystem should follow which policy, or operational, or technical rules of the road.

Rationale. The Roadmap notes that the health IT ecosystem is composed of multiple systems that are interconnected, including EHRs, laboratory systems, patient portals, medical devices, and many other systems. Therefore, without the recommended clarification, there is a considerable risk that all private sector stakeholders across the ecosystem engaged in exchanging clinical or administrative health information will be compelled to comply with all of the framework's principles for policy, operations, and standards. For example, health plans and providers are continuing to develop new and more sophisticated value-based payment and delivery models that are moving beyond the medical homes and ACOs of 2012 (such as statewide organized systems of care, or global payment models), many of which have infrastructures, policies, and operations for exchanging information that are tailored to their particular markets. Rigid, nationwide criteria could have a chilling effect on these fast-evolving models, hence the need for stakeholders to take a more granular approach to building a governance framework.

Further, if, as we recommend above, the Roadmap immediately includes use cases involving the intersection or convergence of clinical and administrative data, any governance mechanism will invariably touch on health plans' and providers' traditional TPO operations. Unless Congress were to revamp the entire health IT regulatory scheme, it is important to protect traditional and existing business operations from the otherwise significant and unnecessary compliance overhead above and beyond HIPAA.

4. Supportive Business, Cultural, Clinical and Regulatory

Issue 1. The Roadmap notes that in parallel with public sector efforts over the years, commercial payers have developed and deployed a wide range of value-based payment programs within their provider networks that offer new opportunities to focus attention on and generate demand for interoperability. For example, the Roadmap suggests that payers make interoperability a condition of participation in VBP programs, or partner with health information exchange organizations and require participation by providers seeking to join these programs.

As noted in our comments above, focusing on generating the demand for interoperability is an unduly narrow view of the role of plans. Plans have as great a need for interoperability as providers. Plans, for example, need consistent, standardized data extracts from providers' EHRs to meet quality reporting requirements, to monitor providers' performance, and to give providers feedback on their performance relative to various benchmarks (e.g., practice pattern variation analyses for clinicians in a multi-physician practice).

Be that as it may, we agree that providers' use of EHRs and their participation in health information exchange are important. But, as Plans put more and more effort into measuring outcomes, the value of knowing that a provider is using an EHR is becoming increasingly marginal. And giving providers incentive to participate in health information exchanges (HIEs) is a challenge if (1) no financially sustainable HIE exists (which is why a number of Plans, such as Anthem BCCA and BSCA, and Highmark BCBS, are filling the gap by building HIEs in their states); (2) physician practices are not independent, but owned by hospitals or health systems that affect how physicians respond to incentives; or (3) providers see this as a financial burden to extract and send data from their EHRs because of issues with vendors.

Recommendation 1. The Roadmap should clarify that incentives should first and foremost reward outcomes. To the extent providers achieve better outcomes through superior use of data – data from their EHRs, or data provided by payers, and patient-generated data – payers' incentives should not necessarily distinguish between the type of tool or type of data that the provider is using.

Rationale. Incentive systems that reward or penalize providers based on varying structural and process metrics are confusing for providers, administratively burdensome to operate, and ultimately not consistent with the Roadmap's core goal of protecting and improving the health of all Americans. Moreover, Plans are increasingly developing products and benefit design to incentivize consumers to choose high-quality and efficient providers. However, IT-enabled capabilities are only part of the equation, there has to be broader evidence that the IT-enabled provider is delivering better outcomes and value.

Recommendation 2. The Roadmap should address barriers to interoperability that are beyond the ken of private health plans' incentives, in particular (1) the effects of provider consolidation on competition and willingness to exchange health information; and (2) costs of extracting and sending data.

Rationale. In general, the impact of health plans' incentives on physicians depends in large part on whether the physicians' practice is independent or owned by a hospital or health system. The effects of these differences, and strategies for mitigating any differences, need the attention of stakeholders across the health IT ecosystem. In addition, as recent news reports have highlighted, there may be cost barriers to data extraction from EHRs that merit government attention.⁴

Issue 2. The Roadmap refers to the Centers for Medicare and Medicaid Services' (CMS) intention to support a public-private partnership to increase alignment of key value based payment model attributes among payers and purchasers to facilitate adoption of payment reform goals. This partnership will provide a venue to collaborate across sectors and disseminate best practices and policies that could

⁴ *Politico* (February 23, 2015) has reported instances where vendors of the health care software want thousands of dollars to unlock the data so they can be shared. . . "I believe this to be the biggest threat to the investment the nation has made in health IT," said David Kendrick [of the Tulsa OK HIE, MyHealth Access].

facilitate broader exchange of common clinical information to support care coordination across the care continuum.

BCBSA and a number of Blue Plans recently participated in HHS's launch of the Health Care Payment Learning and Action Network, the public-private partnership mentioned in the Roadmap, and we are excited by the initiative and committed to participate actively in the Network.

Consistent with the aims of the Network, the Roadmap calls for private payers, in 2015-2017, to implement provisions supporting interoperability within value-based payment arrangements covering commercial populations; for public and private payers, in 2018-2020, to align on common performance measures for interoperability and exchange for incorporation into value-based models; and, in 2021-2024, for public and private payers to be unified around a common approach to administering VBP models.

Recommendation 1. We support the move to aligning measures across public and private VBPs but would recommend clarifying that common performance measures have a strong evidence base, and be endorsed by a national consensus organization like the National Quality Forum (NQF). Further, we recommend creating a core set of high-priority mandatory measures with a menu of others on which VBP programs could draw. The primary focus should be on outcomes. Finally, we recommend not conflating standardization of measures with standardization of the total set of measures used in a VBP (e.g., a measure that may be appropriate for a Medicare ACO population may not be appropriate for a commercial ACO population, and vice versa).

Rationale. Our recommendations for alignment would facilitate quicker development of sustainable quality practices, thereby allowing an organization to subsequently shift its focus, in a sequential manner, to new measures and then allocate the resources and attention necessary for a subsequent success. Taking a core/menu approach would be administratively more feasible and less of an impediment to participation by payers and providers.

Recommendation 2. We recommend amending the actions for private payers in 2015-2017 to focus on being unified with public payers around common *principles* for administering value-based payment programs – for core issues such as beneficiary attribution, financial models, benchmarking, quality and performance, and risk adjustment – and avoiding one-size fits all approaches.

Rationale. A rigorous discussion among public and private payers that leads to common principles will provide a pathway for determining which core issues may eventually need common approaches, and how granular to go in defining the commonalities among those approaches.

5. Privacy and Security Protections

Issue 1. The Roadmap, by leveraging the Office of Civil Rights' (OCR) responsibility to administer and assess compliance with the HIPAA Security Regulations, would place ONC in the forefront of developing a short-term (2015-2017) solution strategy to ensure cybersecurity in healthcare. This includes plans to issue an updated HIPAA Security Risk Assessment, publish a crosswalk between the National Institute for Standards and Technology (NIST) Critical Infrastructure Cybersecurity Framework and the HIPAA Security Rule, and propose a uniform enforcement approach for healthcare cybersecurity.

BCBSA agrees that security of the health information exchange networks is pivotal to the success of interoperability and a basic necessity for trust. We commend the Roadmap for framing and highlighting the cybersecurity threats and risks confronting the healthcare industry and the need to do more to prepare for a cyber-security attack on health information exchange systems.

However, the cybersecurity threat is multifaceted, comprises increasingly sophisticated threat sources, and is not confined to healthcare. The current environment of heightened concern has generated Federal, state, and private sector initiatives to address the threats, including:

- Action by the Administration to enhance the scope of threat sharing and the capability to fight cyber-crime.⁵

⁵ See Executive Order 13691—Promoting Private Sector Cybersecurity Information Sharing Memorandum, February 15, 2015 and Executive Order 13694 – Blocking the Property of Certain Persons Engaging in Significant Malicious Cyber-Enable Activities, April 1, 2015.

- A 2015 Administration Legislative Proposal to improve cybersecurity information sharing, establish a single standard for data breach notification, and enhance key cybersecurity law enforcement tools.
- Legislation in multiple Congressional committees to support threat sharing between the government and affected entities and enhance breach notification to harmed individuals.

In the current environment of heightened concern, new initiatives and advice regarding “best practices” shifts and changes almost daily. The potential and ultimate impact of these various initiatives and advisory activities in terms of new or altered cybersecurity technical or policy requirements for healthcare industry entities is not predictable. Therefore, with regard to cybersecurity policy development under the Roadmap for the purpose of enhancing interoperability in health information exchange, we believe a cautious and collaborative approach is warranted.

Recommendation. For cybersecurity, ONC should:

- Move forward with the indicated activities in 2015-2017 to work with OCR on educational and outreach programs, and with NIST and OCR to finalize and publish the crosswalk between the NIST Critical Infrastructure Cybersecurity Framework and the HIPAA Security Rule.
- Expand its activities to support, promote and enhance cybersecurity sharing activities to include information sharing and analysis organizations, like the Health Information Trust Alliance

(HITRUST)⁶ as well as support for the existing National Health Information Sharing and Analysis Center (NH-ISAC).⁷

- Consider the current environment of heightened activity and concern across all sectors of government and private-sector businesses and proceed cautiously in working with appropriate stakeholders to determine a consistent, integrated approach to cybersecurity standards and enforcement for healthcare.⁸

Rationale. The healthcare industry stakeholders involved in establishing and implementing an interoperable health information exchange capability could benefit from the educational and promotional activities of the ONC, in collaboration with OCR and NIST, to clarify the interaction of the HIPAA Security Rule with the NIST Critical Infrastructure Cybersecurity Framework as it applies to the interaction of covered entities and business associates with those non-covered entities operating under the NIST framework as well as other security frameworks deemed appropriate to the various identified risks. But the next contemplated step of establishing a uniform cybersecurity enforcement approach for healthcare should not be attempted either with only the narrow focus on promoting interoperability or in a vacuum that ignores the developing and potentially cross-industry federal and private sector approaches to

⁶ <https://hitrustalliance.net/about-us/>

⁷ <http://www.nhisac.org/>

⁸ In 2010 the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) published the [Healthcare and Public Health Sector-Specific Plan as an Annex to the National Infrastructure Protection Plan. The Sector-Specific Plan](#) details how the National Infrastructure Protection Plan risk management framework is implemented for the healthcare and Public Health sector. As the designated Sector-Specific Agency, DHHS is expected to develop a sector-specific plan through a coordinated effort involving all its public and private sector partners.

managing the current and imminent cybersecurity threats to the national information technology infrastructure. The Roadmap concern is timely but the proffered solution has been overtaken by events that argue for a caution in setting Roadmap goals. Further, healthcare is a critical infrastructure in the Department of Homeland Security (DHS) Infrastructure Protection Program. As the designated Sector-Specific Agency, the Department of Health and Human Services (HHS) must consider all facets in charting a path to the appropriate integration of the healthcare sector with the DHS National Infrastructure Protection Plan.

Issue 2. The Roadmap would have ONC work with OCR and industry organizations to develop encryption standards, provide guidance for their implementation, and give consideration to rulemaking and additional guidance on the use of encryption.

Recommendation. The Roadmap should focus away from encryption to establishing and identifying the appropriate entity to conduct an ongoing process of evaluating the available and developing cybersecurity tools and best practices for factors related to their use in an interoperable health information exchange environment, including:

- Flexibility to support the identified Roadmap use case goals, including clinical decision support and value based payment interoperability incentives.
- Amenability to scalable application across various business sizes and capabilities.
- Compatibility with or certification of compliance with existing and future required security standards.

Rationale: Encryption is a single tool in securing data: no one tool or practice can serve as a panacea for achieving cybersecurity. We believe any approach to cybersecurity should start first with an entity-specific risk assessment, and the resulting cybersecurity plan should be flexible, scalable, practical, consistent – and, ultimately, appropriate for the business application and business goals of the implementing entity. Industry would benefit from a Roadmap that, rather than focusing on a single security tool, leads to identifying the security tools and practices that would best support the accomplishment of an interoperable health information network.

Issue 3. The Roadmap directs the accomplishment of many IT-based activities in the 2015-2017 time frame, including a uniform cybersecurity enforcement approach, guidance for implementing encryption of data at rest and in transit, the identification and adoption of best practices for authentication and identity proofing, including leveraging mobile technologies and smart phones for this purpose. In addition, the

Roadmap would enable and promote the development and use of radical, ground-changing data segmentation and persistent permission technology to empower “basic” and “granular” choice.

Recommendation. The Roadmap should spread its cyber-proposals throughout the 6-10 year timeframe to account for the competing information technology implementation requirements (as noted in comments above related to gaps in the Roadmap). We recommend letting current Administration initiatives and Congressional legislation work out and establish the nationwide response to cyber threats before attempting to develop a select a specific path for HIE and EHR data sharing.

Rationale. To ensure success it is imperative that the Roadmap assist in providing adequate timing for IT system enhancement, software changes and compliance process development across the competing demands for all entities’ IT resources.

Issue 4. The Roadmap pursues the enablement of consumer exercise of “basic” and “granular” choice to data sharing, access, and use through an alignment of laws, regulations, and organizational policies that will support and foster the development of capable, automated information technology tools and systems to restrict data access and use. We are concerned about achieving the right balance of policy and legal consensus around data accessibility and use, and not undermining the accessibility and use of information necessary to accomplish interoperability and value based care. There is also the risk that instead of policy driving technology, technological capability will drive and impact policy.

Recommendation. Develop policies for excluding the application of “basic” and “granular” choice enabling technologies to HIPAA permitted information exchanges for treatment, payment, and health care operation (TPO) purposes.

Rationale. The Roadmap pursuit of radical, ground changing data segmentation and persistent permission technology to empower “basic” and “granular” choice calls for a warning about undermining accessibility to necessary information to accomplish value-based care and the promotion of interoperability in support of value based care should relevant data become routinely “hidden” from providers and payers.

The automation of this access and use-restricting technology potentially threatens the decision making and care delivery process of covered entities currently exercised under the HIPAA TPO exception. We see the pursuit of this technology as potentially destabilizing in several areas:

- Data reliability is destabilized in the absence of a clear consensus standard guiding the need to employ basic and granular choice and the appropriate circumstances for it: for example, a “minimum necessary” standard for the exercise of basic and granular choice.

- EHR utility is undermined, as is the incentive for interoperability, when data are hidden without clear rules around the shortcomings of reliance on the EHR to produce reports and clinical decision support.
- To the extent that the elements in the common clinical data set are not exempt from exclusion through the exercise of basic and granular choice, the capability to establish meaningful value based care incentives for interoperability is compromised.

6. Core Technical Standards and Functions

Issue 1. The Roadmap would start any use case around a common clinical data set, and has proposed a list of 19 elements. ONC asks which data elements in the proposed common clinical data set list need to be further standardized, and in what way?

Recommendation 1. We strongly support starting with a common clinical data set, but recommend that the specific elements be revisited once the priority use cases are selected. For example, should the clinical data set include all unique device identifiers (UDIs) for implantable devices, or only certain high-risk implantable devices associated with certain procedures? (This begs the question of how long it may take for providers to generate UDIs as many current EHRs do not or are not able to capture and store UDIs, and clinicians will need time to examine and refine workflow issues with respect to inputting data into the EHR in a complex clinical environment.) Moreover, given the importance of converging clinical and administrative data, we recommend giving top priority to standardizing terminologies to ensure that data (structured and unstructured) extracted from EHRs – or from care plans or nurse-documented data – match with administrative data.

Rationale. As the Roadmap makes clear, standardized terminologies or vocabularies are a fundamental building block of interoperability. Normalizing clinical and claims-based data into standard terminologies is critical in supporting the success of VBP programs, consistent with the top priority use case we have recommended. The experience of many Plans seeking extracts from providers' EHRs is that terminology barriers (and less tangible variations in how physicians interpret data that lead to further inconsistencies) are pervasive, and mapping between multiple local terminologies and standards for clinical data, and then mapping to administrative data, is costly and time-consuming.

Recommendation 2. Considering the increasing importance given to addressing disparities in health and health care, we believe that Race and Ethnicity warrant considerable attention early on in the Roadmap.

Rationale. Depending on the use case, the race and ethnicity categories specified by OMB's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (as revised October 30, 1997) may not be sufficient. Research has shown, for example, there are significant differences in the physical and behavioral health of Cuban-Americans, Mexican-Americans, and Puerto Rican-Americans, and finding that may be of particular importance for a use case implemented in a state such as Florida.

Issue 2. The Roadmap proposes focusing in the near term on improving patient matching processes, and measuring the accuracy of those processes so that system can identify where improvements must be made. We strongly support these goals for standards and best practices.

Recommendation. Proceed as proposed, but add a data element to the starting point for standardization: driver's license number.

Rationale. Driver's license number is a form of a unique identifier that has been found substantially to improve matching accuracy.