March 18, 2020

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Draft 2020-2025 Federal Health IT Strategic Plan
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: ACLA Comments on Proposed Strategic Plan regarding, "Draft 2020-2025 Federal Health IT Strategic Plan"

Dear Dr. DeSalvo:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the proposed rule regarding, "Draft 2020-2025 Federal Health IT Strategic Plan".

ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy.

ACLA member laboratories appreciate the opportunity to provide comments on this strategic plan. We hope these comments serve to continue to move interoperability forward.

If there are any questions regarding these comments, please do not hesitate to contact us by phone (202)-637-9466 or via email at jkegerize@acla.com.

Sincerely,

Joan Kegerize, MS, JD
Vice President, Reimbursement and Scientific Affairs

ATTACHMENT: ACLA COMMENTS

Agency: The Office of the National Coordinator for Health Information Technology Office of the Secretary (ONC), United States Department of Health and Human Services (DHHS)
Title: 2020-2025 Federal Health IT Strategic Plan (Draft for Public Comment)
ACLA Comments:

2020-2025 Federal Health IT Strategic Plan Text: (Page 7)

As of 2017, 80 percent of physician offices and 96 percent of acute care hospitals use ONC-certified health IT.

With the use of health IT rapidly advancing, it is essential for the federal government to continue to ensure health IT and electronic health information are accessible to patients and are used appropriately to improve healthcare decision making and health outcomes.

ACLA Comment:

While a large percentage of physician offices and acute care hospitals use ONC-certified health IT, we want to emphasize that using end to end laboratory exchange does not necessarily represent this same level of adoption.

How does ONC intend to define and measure if "electronic health information" is "used appropriately" to improve healthcare decisions.

Is ONC considering a transition plan for the future to enable the private sector to "self-regulate" health IT accessibility and usage? This might eventually transition ONC to an adjudication/arbiter role when "self-regulators" differ in their conformance claims.

We encourage ONC to provide guidance and/or FAQs regarding the release of EHI to a patient and its impact to HIPAA and PHI governance.

2020-2025 Federal Health IT Strategic Plan Text: (Page 9)

Even among Americans with health insurance, access to care can be a challenge due to lack of affordability. [xvii] The insured may face significant out-of-pocket spending from deductibles, co-pays, and unknowing use of out-of-network healthcare providers. Access can also be limited by a lack of available healthcare providers within an insurer's network. In addition, barriers to entry and impediments to competition in healthcare can exacerbate access problems by increasing prices associated with products and services [xviii]

ACLA Comment:

For laboratory results, it's important that the patient realizes that lab data is only a portion of their overall healthcare continuum. Therefore, we recommend the patient collaborates with their ordering/attending provider as their trusted healthcare provider for comprehensive care.

2020-2025 Federal Health IT Strategic Plan Text: (Page 12)

Reducing Regulatory and Administrative Burden

While interoperable health IT has the potential to improve patient care and outcomes, current system designs can be burdensome to healthcare providers and other users. Much of the burden on healthcare providers is a result of EHRs being originally designed to support reimbursement and financial processes. Activities such as clinical documentation and prior authorization take time that healthcare providers could otherwise spend seeing patients. Strategies to advance health IT should minimize burden by considering how best to incorporate technologies into existing workflows and reducing reporting requirements.

ACLA Comment:

We strongly support an approach that considers existing workflows first, and then incorporates technologies to support the workflows in order to provide optimal patient care. However, there must be a balance, because sometimes new health IT can improve workflows, but there must be a way to equitably balance the two to minimize burden.

While migration to these new technologies and standards has value, the impact of a full "rip and replace' functional interoperability could be extensive. Therefore, we suggest that ONC permit trading partners and their clients to move to a later release when they agree there is justification to do so, for example additional data/improved functionality is available. There should be a tangible benefit offsetting the cost (time, resources and money) to upgrade an interface. Changes to existing laboratory interfaces could become timely as re-certification would also require an additional CLIA certification cycle.

We realize this would require ONC to support certification of multiple versions of standards/implementation guides/etc. but hopefully this would not be an undue burden to ONC.

2020-2025 Federal Health IT Strategic Plan Text: (Page 13)
Objective 1a: Improve individual access to health information
Strategies
...
Promote greater portability of health information through APIs and other interoperable healthIT that permits individuals to readily send and receive their data across various platforms.

ACLA Comment:

We strongly endorse standardized API formats to enhance connectivity. Please change 'APIs' to "HL7 FHIR APIs" to clarify you intend to cite a standard for APIs as you have for other information exchanges. Otherwise, we could have a proliferation of proprietary, custom APIs which will not promote interoperability and would be burdensome and costly to implement.

Additionally, "HL7 FHIR APIs" in a search engine returns appropriate references to FHIR developed by the HL7 Standards Development Organization (SDO), but a search of "FHIR APIs" returns multiple ads from multiple sources (depending on the browser) which will help implementers find appropriate resource information.

As new use cases are identified, we encourage using the existing processes to submit via HL7.

2020-2025 Federal Health IT Strategic Plan Text: (Page 13)
Objective 1a: Improve individual access to health information
Strategies
...
Build the evidence base on the use of health information, including on the types of information that will benefit individuals most and the best ways to present information to patients and caregivers.

ACLA Comment:

How will this strategy be achieved, e.g. how will you include input from patients and caregivers? We would also ask ONC to consider whether patient generated data falls in line with this strategy as well as what determines the 'trusted' source of information, such as devices vs. manual entry.

2020-2025 Federal Health IT Strategic Plan Text: (Page 14)
Objective 1a: Improve individual access to health information
Strategies
...

Provide resources on how to access and use health information so that patients and caregivers understand how to use their data safely, securely, and effectively.

ACLA Comment:

We encourage this strategy. ONC's education offering: The Guide to Getting & Using Your Health Records is a great example, perhaps this could be expanded. Could the private sector (e.g. Google, Microsoft, and Firefox web browsers) assist in this effort by enhancing internet search capability so it's easier for patients and caregivers to find appropriate education resources on ONC and other federal agencies sites.

Additionally, we encourage federal agencies to collaborate vs. developing different/duplicative resources. Ideally, one federal site could be the "source of truth" for a particular topic with other federal sites hyperlinked to the "source of truth".

We encourage ONC to provide guidance and/or FAQs regarding the release of EHI to a patient and its impact to HIPAA and PHI governance.

2020-2025 Federal Health IT Strategic Plan Text: (Page 14)
Objective 1c: Integrate health and human services information

…

Strategies

…

Capture and integrate social determinants of health data into EHRs to assist in care processes, such as clinical decision support and referrals, integration of medical and social care, and address health disparities in a manner that is ethical and consistent with routine patient care.

ACLA Comment:

The 2015 Edition already includes criteria for SDOH data (§170.315 (a)(15) Social, psychological, and behavioral data) with EHR ability to record, change, and access. This data can already be sent in multiple HL7 standards, leveraging the "Observation" information:

- V2 - OBX - Observation/Result Segment
- CCDA - Social History Section Structure (this may require an update to the Social Hx section)
- FHIR – ObservationDefinition Resource

We agree that this information should be shared across health care entities and recommend a stronger regulatory stance on usage, responsibility and liability. We suggest factoring in regulations for requiring and sharing this information for the betterment of the patient's health.

Rather than mandate a particular HL7 standard, we suggest you require EHRs to attest to one of the 3 HL7 options (V2, CCDA, or FHIR) and permit trading partners to negotiate which observation standard they will jointly implement. This can reduce burden by leveraging existing interface technology, and provide maximum flexibility.

2020-2025 Federal Health IT Strategic Plan Text: (Page 15)
Goal 2: Enhance the Delivery and Experience of Care
Objective 2a: Ensure safe and high-quality care through the use of health IT
Healthcare providers can develop care plans and deliver high quality, safe, person-centered care when health systems and programs deploy tools that collect, store, and use health data that addresses the unique needs of each individual patient. Achieving this objective will require the application of technologies such as machine learning, improved patient matching, patient safety solutions, and mechanisms for data governance and provenance. It will also require providing care daily and in the event of a public health emergency or disaster
Strategies
…

• **Continue efforts to establish identity solutions** that improve patient matching across data systems.
ACLA Comment:
We agree that improving patient matching impacts many areas of the patient healthcare continuum including patient safety, billing, analytics/trending, and quality reporting. Over the past 2 decades, there is an increasing challenge for patient matching especially as new discussions around gender identity continue to evolve. We recommend the agency encourage the removal of the legislation preventing funding for a national patient id. We also suggest patient education on the benefits of a universal patient identifier.

2020-2025 Federal Health IT Strategic Plan Text: (Page 16) **Objective 2c: Reduce regulatory and administrative burden on providers** **…** **Strategies** **…** **Harmonize provider data collection and reporting requirements across** federal agencies.
ACLA Comment:
We commend ONC and other Federal Agencies for recognizing the importance of collaboration across agencies. Additionally, we recommend folding in additional agencies such as State, Territorial, Regional, Local agencies and tribes as stated throughout this document.

2020-2025 Federal Health IT Strategic Plan Text: (Pages 16-17) **Objective 2d: Enable efficient management of resources and a workforce confidently using health IT** As a result of previous federal efforts, EHRs and other health IT tools are now widely used across the U.S. However, health IT requires a significant amount of resources to adopt and maintain, which on a day-to-day basis places strain on healthcare providers and other healthcare staff, especially in under-resourced locations. To help reduce health IT expenditures, federal agencies, researchers, payers, and healthcare provider organizations should use innovative approaches to automate care processes through health IT so healthcare providers can spend more time on patient care. **Strategies** • **Streamline processes** to reduce the effort required by healthcare providers and health systems to generate, input, and share health information. • **Implement education and training programs** to educate and build a strong, cross-functional health IT workforce that can support IT across healthcare settings, especially in rural areas. • **Continue to invest in the federal health IT workforce** by allocating more resources to train, recruit, and retain workers and to support adequate job opportunities.
ACLA Comment:
We suggest that agencies collaborate with specialty organizations in respective domains to take advantage of their expertise in developing education programs. If possible, work with healthcare providers, SDOs, EHR vendors, etc. to develop internship (or at minimum visitation) programs permitting federal employees to experience the healthcare and development environments first hand.

2020-2025 Federal Health IT Strategic Plan Text: (Page 17) **Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation**

Technology and analytic advancements like ML and forecasting have the potential to transform patient care and improve health. These tools will become essential in the future to support the individualized care of patients and communities. An integrated ecosystem that collects data from multiple sources is critical for these tools to unlock the power of data. Policies that promote use of secure, standards-based APIs can provide access to and use of data in EHRs can empower individuals, healthcare providers, payers, researchers and technology companies to work together on individual and population health research and management.

Objective 3a: Advance individual- and population-level transfer of health data
Access, exchange, and use of data using secure, standardized-based APIs is key to building an integrated ecosystem that can support research, clinical decision making, population health management, and individual access to quality and cost information.

Strategies
- **Improve harmonization of data elements and standards** by creating a common vocabulary set to improve the consistency, integrity, and quality of data and to enable data to be effectively shared between systems using APIs.

ACLA Comment:

We strongly endorse standardized API formats to enhance connectivity. Please change 'APIs' to "HL7 FHIR APIs" to clarify you intend to cite a standard for APIs as you have for other information exchanges. Otherwise, we will have a proliferation of proprietary, custom APIs which does not promote interoperability, and would be costly and burdensome to implement.

Additionally, "HL7 FHIR APIs" in a search engine returns appropriate references to FHIR developed by the HL7 Standards Development Organization (SDO), but a search of "FHIR APIs" returns multiple ads from multiple sources (depending on the browser), which will help implementers find appropriate resource information.

As new use cases are identified, we encourage using the existing processes to submit via HL7.

2020-2025 Federal Health IT Strategic Plan Text: (Page 17)

Objective 3a: Advance individual- and population-level transfer of health data
Access, exchange, and use of data using secure, standardized-based APIs is key to building an integrated ecosystem that can support research, clinical decision making, population health management, and individual access to quality and cost information.

Strategies
Improve harmonization of data elements and standards by creating a common vocabulary set to improve the consistency, integrity, and quality of data and to enable data to be effectively shared between systems using APIs

ACLA Comment:

Recommend changing this from 'creating' to '…leveraging existing common vocabulary sets when possible or creating new when necessary to improve the consistency, integrity, and quality of the data and to enable data to be effectively shared between systems using APIs.'

2020-2025 Federal Health IT Strategic Plan Text: (Page 19)
Objective 4b: Establish transparent expectations for data sharing
..

Strategies   ...   **Promote data liquidity** by working with developers, healthcare providers, payers, and state and federal entities to eliminate unnecessarily restrictive data sharing practices and to use endorsed standards, implementation specifications, and certification criteria.
ACLA Comment: We recommend ONC provide a list of which standards are endorsed.   Does this refer to artifacts (standards, implementation specifications, vocabulary etc.) that have been cited by a Federal Agency in a Final Rule? Or does 'endorsed' also include other artifacts such as those cited in ONC's Interoperability and Standards Advisory (ISA)? Or does 'endorsed' also include sharing data across these agencies for various requirements and regulations; such as 'Opt In' and the 'Opt Out' state level laws.

2020-2025 Federal Health IT Strategic Plan Text: (Pages 19-20)   **Objective 4c: Enhance technology and communications infrastructure**   The U.S. health IT and communications infrastructures are highly variable. While access to smartphones and broadband is increasing overall, gaps remain for some populations and regions. A disparity in health IT access and capabilities separates rural and other typically unserved or underserved areas from areas with substantially greater connectivity and service options. Smaller practices and rural healthcare providers are unable to adopt the same advanced health IT capabilities used by larger health systems due to constrained resources. To mitigate these disparities, stakeholders should continue to work together to develop innovative solutions to improve the health IT and communications infrastructure.   **Strategies**   ...   **Deploy cloud-based services** that comply with federal standards to modernize and streamline the way health information is stored and exchanged across the federal government.
ACLA Comment: Please explicitly define which "federal standards" for you which you are referring. Is this strategy solely applicable to federal agencies? If it is applicable to the private sector, are there other appropriate public sector standards developed Voluntary Consensus Standards that might be appropriate for federal adoption?[1]   We recommend that modernizing and streamlining of health information storage and exchange not be limited to the federal government but also include public and private sectors.

2020-2025 Federal Health IT Strategic Plan Text: (Page 20)   **Objective 4d: Promote secure health information that protects patient privacy**   **…**   **Strategies**   **…**   • **Implement privacy and security mechanisms as appropriate to the sensitivity of the data** to help protect individuals' health data, including multi-factor authentication and encryption embedded in APIs and other technologies.
ACLA Comment: Please change 'APIs' to "HL7 FHIR APIs" to clarify you intend to cite a standard for APIs as you have for other information exchanges. Otherwise, we will have a proliferation of proprietary, custom APIs which does not promote interoperability, and would be costly and burdensome to implement.

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[1] Per OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

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2020-2025 Federal Health IT Strategic Plan Text: (Page 22)

Appendix B. Measuring and Communicating Progress

…
- Individual access to their health information on their smartphone so they can shop for and have greater control over their healthcare;
- New business models made possible through the use of APIs that benefit individuals and providers; and

ACLA Comment:

Please change 'APIs' to "HL7 FHIR APIs" to clarify you intend to cite a standard for APIs as you have for other information exchanges. Otherwise, we will have a proliferation of proprietary, custom APIs which does not promote interoperability, and would be costly and burdensome to implement.

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2020-2025 Federal Health IT Strategic Plan Text: (Page 23)

Appendix C. Federal Contributors

ACLA Comment:

Shouldn't the National Institute of Standards and Technology (NIST) be participating in these collaboration efforts?