

April 3, 2020

Donald W. Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St, SW, Floor 7
Washington, DC 20201

RE: Draft 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker:

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the recently released Draft 2020-2025 Federal Health IT Strategic Plan (the Plan). NYeC is a 501(c)(3) and New York's State Designated Entity (SDE) charged with the governance, coordination, and administration of the Statewide Health Information Network for New York (SHIN-NY). In this capacity, NYeC works in a public/private partnership with the New York State Department of Health (NYS DOH) on the development of policies and procedures that govern health information exchange through the SHIN-NY. The SHIN-NY is a "network of networks" consisting of Qualified Entities (QEs) also known as Regional Health Information Organizations (RHIOs) and a statewide connector that facilitates secure sharing of clinical data from participating providers' electronic health records (EHRs). The SHIN-NY connects all hospitals in the state, is used by over 100,000 healthcare professionals, and serves millions of people who live in or receive care in New York.

NYeC continues to advance its mission of improving healthcare through the exchange of health information whenever and wherever needed by expanding participation beyond the hospitals, clinics, labs, radiology centers, ambulatory physicians, home care agencies, nursing homes, long-term care facilities, public health departments, health plans, behavioral health providers, Federally-Qualified Health Centers, and community based organizations (CBOs) served today. NYeC also strives to improve the quality and capabilities of health information exchange through our qualified entity (QE) certification and performance-based contracts.

The next five years will be a transformative period for the industry. We continue to support the underlying intent and potential of recent Office of the National Coordinator for Health IT (ONC) initiatives, including the 21st Century Cures Act (Cures Act) Final Rule and the Trusted Exchange Framework and Common Agreement (TEFCA). NYeC applauds ONC's continued leadership, transparency, and forward-thinking vision, and is appreciative of the work of ONC and other federal partners. There is much to support in ONC's draft Plan for the future of federal health IT. Specifically, advancing person-centered care and patient access, focusing on value, strengthening community health care infrastructure, integration of social determinants of health (SDOH) data, improving provider workflows, and advancing and harmonizing data elements and standards. While largely supportive of the

direction and elements included in the draft Plan, there are a few areas that demand further emphasis and attention. Described in greater detail in the attached, we believe the following should have additional focus in the Plan in order to achieve many of ONC's laudable, large-scale initiatives:

- **Advancing interoperability across the care continuum.** It is vital that the healthcare interoperability ecosystem include those sectors that were left out of the meaningful use programs and investments. Sectors like long-term care, behavioral health, pharmacies, and others need funding, technical assistance, and other supports to truly participate in the value-based care world. Furthermore, CBOs are key to moving the needle, and they also need supports even if they do not utilize fully functioning EHRs.
- **Privacy and security requirements for disclosure to third-party applications.** While we understand ONC does not have authority over non-HIPAA entities, we need stronger guidance and requirements in this space for the good of the country. We implore ONC to help lead these efforts as they are imperative to the public trust and ensuring patients have what they need to truly engage in their healthcare.
- **Patient safety and enforcement of certification requirements.** Many health IT vendors still struggle to maintain pace with current standards. While ONC's strategy to encourage consumer reviews for health IT products may assist in mitigating this challenge, ONC must also hold vendors accountable. As ONC focuses on advancing and harmonizing standards through certification, it will be essential that certification requirements are effectively monitored and enforced.
- **Information blocking compliance.** We support ONC's Final Cures Act Rule and applaud their work to prohibit bad actors who intentionally engage in practices of information blocking. It is critical that ONC fully leverage the six month phase-in period by releasing timely and meaningful guidance in light of the significant changes the new rules represent.
- **Nationwide consensus on consent.** While the draft Plan places a strong emphasis on patient empowerment and streamlining processes to reduce barriers to sharing health information, it does not adequately address strategies for streamlining patient consent in a manner that ensures the right health information is flowing when and where it is needed. NYeC believes current proposals have failed to sufficiently address the topic and much more work needs to be done to ensure alignment.
- **Prescription Drug Monitoring Program (PDMP) workflow integration.** NYeC applauds the ongoing efforts to leverage health IT to combat the opioid epidemic. While not a focal point of this Plan, there is a reference to using advances in health IT to help prevent the overprescribing of controlled substances. We feel ONC could further expand this goal with greater integration and streamlined interoperability of Prescription Drug Monitoring Programs (PDMPs).

Thank you for the opportunity to provide comments. If you would like to discuss these issues further, please contact my assistant, Hope Redden at hredden@nyehealth.org or (518) 299-2321.

Sincerely,



Valerie Grey
Executive Director

NYeC Detailed Comments

Advancing interoperability across the care continuum

As part of the first goal, the draft Plan calls for the strengthening of communities' health IT infrastructure through the exchange of data across health and human services settings, as well as through the integration of SDOH data in the EHR. NYeC has long advocated for efforts to engage providers across the care continuum, particularly the "left behind" sectors (i.e. long-term and post-acute care, behavioral health, and pharmacies) that were not eligible for meaningful use. We have encouraged use of CMS incentives, regulatory relief, state matching programs, and technical assistance programs to engage these sectors in interoperability efforts and have recently submitted comments to New York State's Medicaid Redesign Team II encouraging the continued expansion of HIT to these sectors. Through both our Policy Committee and Community Based Organization (CBO) Advisory Group, we are developing policies aimed at increasing participation among non-HIPAA entity CBOs in our network with the ultimate goal of exchanging standardized SDOH data to help improve value-based care.

While appreciative of the call to support provider adoption and use of health IT, we believe a concerted effort in engaging these sectors is essential to interoperability. This will become increasingly important as value-based care initiatives continue to grow. The draft Plan references investments in health IT and resources to support adoption, as well as requirements to use health IT in order to participate in federal programs. While we believe use of this lever will drive health IT use, ONC should work with its federal partners to ensure appropriate incentives precede any such requirement.

Many post-acute (PAC) and home and community-based service providers (HCBS) avoid adoption of EHRs due to lack of resources, staff, and education or assistance on how to meaningfully use these products. Optional state matching programs could provide an incentive for states to invest in technical assistance and other activities that advance interoperability among these sectors. Such investments could build off previous efforts like the Regional Extension Centers (RECs) or state efforts like the New York State funded behavioral health information technology (BHIT) grant. With the support of a BHIT grant, NYeC was able to assist over 100 organizations implement their EHR systems by providing technical assistance. Further investments in such efforts would yield even greater adoption.

We also support CMS activities to improve interoperability by allowing providers to access Medicare claims data through Blue Button 2.0 and the Data at the Point of Care Pilot. We urge HHS and CMS to expand participation in such pilots beyond providers and their EHR vendors and allow for HIEs to integrate this data into their systems, which in turn will serve numerous providers across the care continuum. ONC working with CMS could also incentivize providers to collect and exchange standardized data elements that could enhance the value of interoperability across the care continuum and expand upon data classes included in the U.S. Core Data for Interoperability (USCDI).

Furthermore, NYeC supports objectives in the Plan to leverage health IT to promote a variety of public health use cases that help officials identify and respond to public health threats. A current SHIN-NY pilot project is testing flu surveillance work for NYS DOH. Due to their vast networks and ability to securely exchange and integrate health information from a variety of sources, health information exchanges and networks are uniquely positioned to improve the efficiency and quality of public health reporting, facilitate public health investigation, improve emergency response, and enable public health to communicate

information to the clinical community. These services are critical to managing disasters and containing dangerous outbreaks.

Lastly, we also strongly support leveraging health IT to accelerate research. The SHIN-NY has a history of research to demonstrate the value of health information exchange to the quadruple aim. We believe these efforts will continue to spur innovation. The research can support a learning health system that benefits the full continuum of care, as well as assist in the prioritization of use cases.

Privacy and security requirements for disclosures to third-party applications

The draft Plan, as well as other ONC and the CMS efforts, make it clear that patient access to electronic health information, facilitated through third-party applications, is a priority of this administration. NYeC supports these efforts to empower patients and agrees with ONC's stance that an individual should be able to easily access, exchange, and use their health information across platforms. As we have seen from recent enforcement actions by the Office of Civil Rights (OCR), currently the ability for consumers to access their data can be cumbersome, in some cases nearly impossible, and not in the spirit of the Health Insurance Portability and Accountability Act (HIPAA) right of access provisions. However, in the era of open application programming interfaces (APIs) there is valid concern among many healthcare stakeholders that sharing healthcare data through third-party applications not regulated by HIPAA could result in negative, unintended consequences for consumers who may be unaware of how their data is being used. These concerns should not block ONC's efforts to improve consumer access, exchange, and use but are cause for more thorough consideration, clear standards, and robust consumer education.

Under the fourth goal, ONC discusses strategies to integrate privacy and security protections into the design and use of health IT, including the use of multifactor authentication and encryption embedded in APIs. This goal also references increasing patient understanding and control over their data. While appreciative of these strategies, we feel that ONC and other offices within the Department of Health and Human Services (HHS) should further protect patient interests by placing some responsibility on non-HIPAA entities to dutifully inform consumers of the privacy and security protections surrounding their data.

NYeC acknowledges that HHS may not have the authority to regulate non-HIPAA entities. However, while Congress debates advancing protections in this area, HHS could use existing authorities to provide some guardrails as well as advance consumer education on privacy and security policies. For example, the Office for Civil Rights (OCR) has released some guidance in the form of FAQs clarifying the HIPAA right of access in relation to health apps and APIs.¹ We also appreciate provisions in both the CMS and ONC Final Rules that seek to advance consumer education and promise to provide materials and resources that stakeholders may use to educate consumers on the risks of sharing data with third party apps. HHS should continue to use similar levers to ensure patients are aware when their protected health information is leaving its protected status. Additionally, ONC could use its role as a coordinator to convene key federal regulators, industry leaders, and congressional representatives to raise awareness, draft guidelines, and advocate for updates to privacy and security rules that take into consideration the changing landscape of health IT.

Patient safety and enforcement of certification

NYeC applauds sections of the Plan targeted at following health IT safety and use-centered design principals, as well as the adoption and advancement of nationally endorsed standards through certification. NYeC believes safety and enforcement of certification standards will remain paramount in the years ahead, warranting further prominence in this strategy. Advancement and adherence to standards helps to drive

¹ <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access-right-health-apps-apis/index.html> and <https://www.hhs.gov/hipaa/for-professionals/faq/2039/what-is-the-liability-of-a-covered-entity-in-responding/index.html>

competition and will improve trust among users and patients.

Increasing user and market confidence in the safety and safe use of health IT was an objective of the 2015-2020 Federal Health IT Strategic Plan, because “for the nation to collectively move to an expansive electronic health information environment, individuals, healthcare providers, and organizations need confidence that health IT solutions are secure, safe, and useful.” As part of this objective, ONC strategies included: supporting the identification, monitoring, and reporting of complete, precise, and accurate challenges and hazards the health IT design and use; increasing data on the safe use of health IT and integrating such evidence into certification; and implementing a balanced, transparent, and risk-based approach to health IT oversight. We believe this objective remains essential, and as ONC works to implement the EHR reporting program, there is an opportunity to develop a process for properly addressing usability and other safety issues in health IT.

The second goal speaks to implementing data governance and provenance mechanisms in order to promote safety, security, and accountability throughout the health IT ecosystem. This goal also calls for “expanding use of health IT for promoting safer clinical practices by automating patient safety and rapid reporting features into health IT infrastructure.” However, to gain full trust of users, it is essential to perform a more comprehensive look at patient safety and usability that elicits the question of who is liable for certain data. We advise ONC to use caution to ensure such capabilities actually improve patient safety and do not add to provider burden.

As ONC focuses on advancing and harmonizing standards through certification, it will be essential that certification requirements are effectively monitored and enforced. While ONC’s strategy to encourage consumer reviews for health IT products may assist in achieving this goal, ONC must also hold vendors accountable. We far too often hear from our stakeholders that they struggle to get standardized information from certain EHR vendors, and that these vendors are not keeping pace with current standards. We expect this troubling trend to continue unless national standards are promoted and EHR vendors are held accountable through certification. As a health information exchange, the lack of enforcement presents several hurdles to ensuring that the correct information is flowing as it should be. As ONC rightfully advances nationwide interoperability efforts, we encourage the agency to ensure stakeholders are properly adhering to certification requirements.

Information blocking compliance

We congratulate ONC on the release of the Cures Act Final Rule and applaud them on their work integrating and responding to public comments. We appreciate that ONC addressed comments to provide more time between publication of the Final Rule and compliance with information blocking. Throughout this six-month phase in period, we urge ONC to continue transparent efforts to educate the industry on information blocking through instructive presentations, sub-regulatory guidance, frequently asked questions, and sample use case scenarios. This strategy of phasing enforcement by beginning with education and then ramping up toward rigorous enforcement in the future is more appropriate and feasible for the industry.

Nationwide consensus on consent

In order for true nationwide interoperability to occur, it is essential that ONC and HHS promote the alignment of varying consent policies across the country. While the draft Plan places a strong emphasis on patient empowerment and streamlining processes to reduce barriers to sharing health information, it does not adequately address strategies for streamlining patient consent in a manner that ensures the right health information is flowing when and where it is needed.

NYeC believes current proposals have failed to sufficiently address the topic. For example, TEFCA Draft 2 allows individuals to opt-out of information sharing through the Common Agreement (known as Meaningful Choice). This provision requires that all QHINs, Participants, and Participant Members post instructions on their public website explaining how an individual can exercise their Meaningful Choice. Under this proposal, an entity that has to obtain affirmative consent for Part 2 or other sensitive health data would likely also have to satisfy the requirements of Meaningful Choice if this information is to be shared via the Common Agreement. Furthermore, exercising such Meaningful Choice only applies to data sharing via the Common Agreement. An individual that wants to limit the use and disclosure of their PHI across the broader ecosystem would still need to make that request to their Covered Entity via the HIPAA Privacy Rule at 42 CFR §164-522. This does little to address differing standards and ultimately results in consumer confusion due to an added administrative layer.

Sharing information across sectors also raises consent issues as certain sectors are subject to different privacy and consent laws. While we understand some of these requirements are beyond ONC's control, we encourage ONC to work with other offices within HHS to align consent requirements to the greatest extent possible. We hope ONC, at a minimum, can provide guidance on the interplay and best practices for participants to adhere to all requirements while minimizing burden and patient confusion.

Prescription Drug Monitoring Program (PDMP) workflow integration

NYeC applauds the ongoing efforts to leverage health IT to combat the opioid epidemic. While not a focal point of this Plan, there is a reference to using advances in health IT to help prevent the overprescribing of controlled substances. We feel ONC could further expand this goal with greater integration and streamlined interoperability of Prescription Drug Monitoring Programs (PDMPs). New York was an early PDMP leader through the passage of a 2012 law requiring electronic prescribing and mandating the query of the Internet System for Tracking Over-Prescribing (I-STOP) prior to prescribing a Schedule II, III, or IV controlled substance. I-STOP is queried by providers at a rate of over 18 million queries annually. With the exception of a New York State pilot that NYeC facilitated, these queries are not typically performed through EHRs but rather through a state-secured portal supported by the state's Bureau of Narcotics Enforcement (BNE). I-STOP currently connects to PDMPs in 25 states and Washington, D.C. However, these connections require separate and distinct queries which can present a burden in the workflow. We agree that greater integration into the EHR workflow will lessen provider burden and increase the effectiveness of PDMPs, and that common standards for integration and seamless nationwide connections could further this impact. Guidance from ONC could assist states in overcoming some of the privacy and security concerns that may be raised by enabling greater workflow integration.

In summary, NYeC appreciates the opportunity to provide comments and input on the draft Plan, and we look forward to continued collaboration with ONC in advancing nationwide interoperability and improving patient access to their health information.