NEW YORK eHEALTH COLLABORATIVE

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U.S. Department of Health and Human Services
330 C St, SW, Floor 7
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RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program - RIN 0955-AA01

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the recently proposed regulation implementing provisions of the 21st Century Cures Act (Cures) addressing information blocking, interoperability and advancing the certification program. 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 as a public/private partnership with the New York State Department of Health (DOH) on the development of policies and procedures that govern how electronic health information is shared via 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). Participants include hospitals, clinics, labs, radiology centers, ambulatory physicians, home care agencies, nursing homes, long-term care facilities, public health departments, health plans, behavioral health providers, DOH, and Federally-Qualified Health Centers (FQHCs). 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's mission is to improve health care through the exchange of health information whenever and wherever needed. As such, NYeC applauds the Office of the National Coordinator for Health Information Technology's (ONC's) leadership in advancing interoperability, reducing burden, increasing innovation and promoting patient access. We appreciate all ONC efforts in developing these complex rules, as well as all the guidance to help stakeholders digest these initiatives. While we largely support ONC's goals and general direction, we do have some concerns and suggestions we hope ONC will consider as it works to finalize this regulation. Attached you will find our full comments, but below is a big picture summary of our perspective.

- NYeC believes an additional exception for Health Information Networks (HINs) and Health Information Exchanges (HIEs) is necessary. As ONC is well aware, HIEs and HINs as business associates are limited in the permitted purposes for which they can disclose personal health information (PHI) based on the business associate agreements they have with their covered entity participants. An exception for such permitted purposes would align with ONC's recently released Trusted Exchange Framework and Common Agreement (TEFCA) v2 which proposes to limit permitted purposes to a subset of those permitted under Health Insurance Portability and Accountability Act (HIPAA).

- We also strongly encourage ONC to create a safe harbor or set of principles that if complied with, an actor can be presumed to not be information blocking. The complexity of the various exceptions will make compliance very difficult for a number of smaller actors, particularly some health care providers. As we work to engage more providers to adopt EHRs and join interoperability efforts, it will important to provide them a clear path to simply comply with information blocking provisions. For example, if a provider connects to a robust HIN, like the SHIN-NY, it could be presumed to not be information blocking. This would help increase participation in HIE and help ease compliance for providers.

- NYeC urges ONC to continue to work with stakeholders to provide additional clarity, and to extend the timeline for many of the proposed provisions. As we all move forward to implement these large-scale initiatives it is imperative we get it right. While we believe that the information blocking provisions and APIs without special effort in particular have the potential to accelerate interoperability across the country, they also raise significant questions related to privacy, security, legal interpretation, enforcement, HIPAA, and other issues. Due to the wide range and substantive nature of the questions being raised with respect to these proposed regulations, combined with the Centers for Medicare & Medicaid Services (CMS) proposed rule and the TEFCA, we advocate for further clarifications as well as numerous additional examples with the associated processes for interpretation, implementation, and enforcement. In our experience as a network of HIEs, stakeholders will need to quickly develop and/or modify arrangements with their partners, institute new processes, implement technology, and many other activities to meet these proposed requirements.

- Of the proposals most warranting additional time and clarification is the information blocking provisions. We believe the currently proposed effective date will leave many at risk of falling out of compliance, and more time should be provided to educate stakeholders and for the industry to update legal agreements as needed. We similarly request that ONC provide sample documentation requirements and model compliant policies for entities to comply with the complexities of information blocking.

- NYeC supports the updates to the certification program. We applaud ONC on the proposals to free up communications and remove "gag clauses" on EHR experience. We believe these provisions will increase usability and patient safety. While supportive of the changes to the United States Core Data for Interoperability Standard (USCDI) v.1, we seek

- amendment to the proposed timeline. We believe HIEs will need time after the changes to Certified EHR Technology (CEHRT) to be able to appropriately move this data.

- NYeC supports patient access through APIs and encourages ONC to ensure the roles of various entities with regards to identity proofing and authentication are clear, and to work across offices within the Department of Health and Human Services (HHS) to help ensure all parties are aware of the privacy and security requirements and implications.

- Patient matching is a fundamental challenge to nationwide interoperability. Given the need to accurately resolve patient identity among disparate providers and networks to achieve ONC's broader objectives, and the essential role matching plays in patient safety, we support a unified coordinated effort to develop a national strategy on patient matching.

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

New York eHealth Collaborative (NYeC)
Detailed Comments

Information Blocking

NYeC applauds ONC's hard work in defining parameters and appropriate exceptions for what should be considered information blocking. We understand Congress gave ONC a difficult task and we appreciate the diligence from ONC to strike an appropriate balance with this proposal. We offer several changes which we believe will improve the information blocking provisions and will elimination the potential for unintended consequences.

Definitions

NYeC encourages ONC to define Health IT developers as broadly as permissible. We support ONC interpreting Cures as liberally as possible in this regard. We believe the more developers subject to information blocking, the better Congress' intent will be achieved. Additionally, we share the concerns of many that limiting information blocking to developers that make one or more certified products at the time of the conduct provides a perverse incentive for developers to avoid voluntarily certification of their products going forward.

With regards to the definition of electronic health information (EHI), which is already significantly broad, we urge ONC to refrain from further expanding this definition in the final rule. The current definition is already broader than what is typically being exchanged today and may present implementation hurdles to a number of stakeholders. While supportive of the free flow of information, we would caution ONC from further expanding this in a manner that could further complicate this and potentially delay or frustrate the larger intent and objective of the information blocking provisions.

Additionally, we encourage ONC to provide regulatory clarity around its intention with regards to actors that currently fall under two definitions. This is particularly important in instances when the enforcement and penalties vary based on the type of actor engaging in the conduct. Should ONC address this by amending the definitions to ensure there is no overlap, we would believe entities such as SHIN-NY should continue to fall under the definition of a Health Information Network (HIN).

Exceptions

We urge ONC to consider an additional exception and to make adjustments to several of the exceptions currently proposed.

1. New exception and safe harbor

We urge ONC to adopt a new exception specific to robust HINs and HIEs. HINs and HIEs, as business associates, generally can only exchange data for the purposes authorized by the covered entities participating in their networks. Based on the restrictions placed on them by covered entity participants, most HINs and HIEs only allow data to be exchanged over their networks for a limited set of permitted purposes, typically a subset of the HIPAA treatment, payment and health care operations purposes. As ONC is well aware, the draft TEFCA v 2 recently released, similarly

limits permissible exchange purposes to a subset of HIPAA purposes, namely, treatment, quality assessment and improve, business planning and development, utilization review, public health, benefits determination and individual access services. Thus, providing an exception for robust, matureHINs and HIEs aligns with ONC's objectives and is necessary to harmonize these proposals.

Additionally, many HIEs limit the types of entities that can participate in their network to covered entities and government agencies. While some HIE networks like the SHIN-NY have and are looking to expand to more non-covered entity participants, they are not the typical participant. Furthermore, HIPAA guidance limits the purposes of disclosures to non-covered entities to treatment, which includes care coordination and care management, unless the patient authorizes the disclosure.[1] Including an specific exception would clarify that HINs and HIEs are not required to provide access, exchange or use of EHI in a manner not permitted under HIPAA.

This exception would also clarify that an HIN or HIE without ability to offer direct patient access is not information blocking. As ONC is aware, HINs and HIEs currently vary in their approaches to patient access, including providing data to the patient portals of their participants. Some may have patient portals themselves, some may be in the process of developing such access and others may refer patients to providers for access. This exception would make it clear that HINs and HIEs that provide data for the patient portals of participants and respond to queries for patient access are compliant with information blocking. Such approach would be consist with TEFCA v2, which includes patient access as an exchange purpose, but only requires a Qualified Health Information Network (QHIN) and participants (including HINs) to provide direct patient access when they have a direct relationship with the individual, meaning they offer services to the individual in connection with one or more of the Framework Agreements and the individual agree to such services, or if the applicable business associate agreement requires such.

This exception should also be crafted in a way to provide a safe harbor to HIN participants. Compliance with the information blocking provisions will require significant resources and increased cost to actors. As we work collectively to engage more providers and traditionally "left behind" sectors, some of which fall under the current definition of a health care provider for purpose of information blocking, to adopt EHRs and join interoperability efforts, it will important to provide them a clear path to simply comply with information blocking provisions. For example, if a provider connects to a robust HIN like the SHIN-NY, it could be presumed to not be information blocking. Setting forth clear, affirmative steps an actor can take to comply will help increase participation in HIE, ease compliance and decrease burden and costs.

We believe an HIN/HIE exception effective contemporaneous with the other information blocking provisions is aligned ONC's intentions as evidence by the recently released TEFCA v2 and necessary given the many factors relative to TEFCA that will remain unfinalized upon the effective date of information blocking.

2. Recovering costs reasonably incurred

We believe ONC should clarify that reasonable margins or profits are permitted under this exception. While the preamble discusses permissible profits, the regulatory text refers to recovery of costs incurred. Understanding that ONC is rightfully looking to prohibit unreasonable costs that

[1] https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html

act as barriers to information sharing, we do not believe it is the intention of ONC to prohibit reasonable margins for non-profits such as the SHIN-NY QEs working to provide a public good to their community. We request that in finalizing this exception, ONC clearly permit recovery of reasonable margins above actual costs for the exchange of EHI.

Additionally, NYeC believes this provision as currently written could have the unintended effect of prohibiting the fee structure of many public HIEs. More specifically, many HIEs choose to charge fees to only a subset of their participants. For example, some HIEs may charge hospitals but provide services for free to ambulatory providers. However, as currently proposed the requirement that costs be "reasonably allocated among all customers" could undercut this ability. The ability to offer free services to smaller providers, particularly as HIEs work to engage providers across the care continuum, is an important flexibility to have.

3. Maintaining and improving health IT performance

NYeC also encourages ONC to consider amendments to the exception for maintaining the improving health IT performance. While agreeing with ONC's intent to ensure bad actors do not use extended downtime or other technological issues as a basis to not share information, we believe this interest must be balanced with that of good actors who may fall slightly out of compliance with terms agreed to in a service-level agreement (SLA). Typically, the failure to comply with a SLA is addressed through contract. Whereas under this exception as currently proposed, an actor could be accused of information blocking if the downtime extends at all beyond what agreed to, even if such extension is de minimis. While ONC discusses in preamble the ability of actors to obtain informal or even verbal agreement to this downtime, such requirement could burdensome to implement and there could instances in which a party will not agree to any additional downtime outside of an SLA. We believe that ONC's intent could be better served by requiring the practice be a reasonable and good-faith activity that last no longer than necessary.

4. Responding to requests that are infeasible

In addition, we request ONC clarify that the proposed requirement to identify a reasonable alternative means of accessing, exchanging, or using EHI is only necessary where any such alternative exists. Under this exception, as currently drafted, in all instances an actor must work with the requestor to identify and provide a reasonable alternative means for providing the EHI. NYeC understands the concerns many raise regarding the potential for this exception to be used as a basis to not share by many, and ONC's intention in balancing that concern with the obligation to timely respond and to provide a reasonable alternative. However, we could foresee instances in which no reasonable alternative exists, and the request is in effect impossible to comply with. Thus, we encourage ONC to provide flexibility in finalizing this exception for instances where no reasonable alternative means for providing the access or exchange of the EHI exists.

5. Promoting the privacy of electronic health information

With regard to the proposed exception for promoting privacy of EHI, NYeC appreciates the inclusion of provisions which aim to ensure privacy practices do not become an excuse for the lack of sharing, particularly the requirement that actors must do all things reasonably necessary within their control to provide an individual with a meaningful opportunity provide consent or authorization. We encourage ONC to maintain this balanced approach in the finalized rule.

Enforcement
NYeC encourages ONC, as it works to finalize the complaint process for information blocking, to clarify and delineate the respective roles of ONC and the Office of Inspector General (OIG). As you know, in addition to Cures requiring ONC to develop a process for the public to submit comments of information blocking, Cures also allows the OIG to investigate any claim that information blocking has occurred. While the proposed regulation says ONC may coordinate review or defer to OIG, we believe ONC should be explicit to ensure an actor is not subject to separate review from both entities. For example, if a complaint of information blocking was submitted to both ONC and OIG, and ONC finds it does not amount to information blocking, OIG should not continue investigating.

We also encourage ONC to work with OIG as it eventually enforces and implements penalties, to ensure the maximum $1 million dollar per violation penalty is reserved for the most egregious bad actors. Congress explicitly provided for the consideration of factors in setting penalties, such as nature and extent of the information blocking, the harm caused, and the parties affected. Given the various actors impacted by the information blocking provisions - ranging from small providers, non-profit HINs and HIEs, to for-profit developers, there are likely a range of activities, with varying levels of severity and intent beyond the requisite knowledge standard that triggers information blocking. For guidance, ONC and OIG could look to the HIPAA violation structure, which delineates penalties based on the culpability of the actor which would likewise be appropriate for information blocking where fairness dictates and certain actors who may inadvertently engage in information blocking should not be held to the same penalties as those who act willfully and intentionally.

Effective date
NYeC strongly urges ONC to extend the effective date of the information blocking provisions in order to ensure a smoother implementation and to provide reasonable time for actor compliance. The provisions proposed by ONC present a drastic shift in the health information industry, shifting the presumption from sharing if permissible, to sharing unless prohibited or protected by an exception. As ONC notes repeatedly in the preamble, contract provisions that currently restrict sharing of EHI will be void and unenforceable. Many actors will need to re-negotiate terms for a great number of contracts. By making these provisions effectively immediately, ONC fails to provide actors time to make the necessary adjustments to ensure compliance and to ensure they can demonstrate compliance if investigated. There would be a general lack of awareness and confusion among the industry.

To draw a familiar comparison, HIPAA was enacted in 1996. Final regulations on the Privacy Rule were published in 2000, and amended in 2002, with compliance beginning in 2003. Similarly, the final regulations on the Security Rule were published in 2003 with compliance beginning in 2005. Given the impact and complexity of these rules, the Office of Civil Rights allowed for time for individuals to come into compliance. Even with that time, we continue to have confusion in the industry over what is and isn't permissible under HIPAA. Undoubtedly there will be similar issues with implementation of this rule. Given the nature, complexity and breath of this regulation, we implore that ONC provide ample time for actors to prepare, and also continue its work to educate the industry so all actors are aware of the final requirements.

Updates to Certification Criteria

USCDI

NYeC applauds all ONC's work to date on the USDCI and supports replacing the Common Clinical Data Set (CCDS). This change will increase the baseline of data that must be exchanged and will also create a glide path for the addition of future data elements as technology and standards evolve.

We also support the current data elements being proposed for inclusion in USCDI v.1 and encourage ONC to maintain them. Specifically, we believe clinical notes will be of great value to clinicians, and similarly, the inclusion of provenance data will enhance data quality and reliability. Additionally, NYeC believes the additional demographic elements of address and phone number, particularly mobile phone number, provided in a standardized format, will make great strides in improving patient matching. We encourage ONC to continue to exploring data elements for inclusion in USCDI that will further improve patient matching efforts in the future.
While supportive of these efforts, NYeC encourages ONC to adjust the implementation timeline for this provision. After certified developers upgrade their products, HIEs will need to work with vendors to upgrade systems in order to exchange this information. Accordingly, we request ONC structure the implementation timeline to allow for at a minimum of 6 months after developers upgrade existing products for exchange to be enabled.

EHI Export

NYeC strongly supports the EHI export criterion included in the proposed certification requirements. This provision provides long awaited flexibility and mobility to providers who want to switch to a different health IT system. Additionally, this provision, as well as the provision for payer-to-payer exchange will empower patients giving them the ability to switch providers and payers without fear of losing all EHI. We applaud ONC for advancing this provision to empower providers and patients, and ask that ONC to maintain the broad requirement that EHI export include all EHI produced and electronically managed by the health IT developer. NYeC believes patients and providers are entitled to the complete record maintained by the health IT.

Data Segmentation

NYeC supports ONC's proposal to update the data segmentation for privacy standard to enable privacy tagging at the document-level, section-level and individual data-element level. NYeC is hopeful that this more granular approach to privacy tagging that will make it easier to share data subject to 42 CFR Part 2, minor consent laws or other more stringent privacy standards. We are also appreciative of the potential in FHIR based consent management and the Substance Abuse and Mental Health Services Administration's Consent2share open source application for consent management and data segmentation.

Electronic Prescribing

NYeC agrees with adoption of a standard that can support exchange of Prescription Drug Monitoring Program (PDMP) data to enable integration into the EHR workflow. We appreciate

the ongoing federal efforts to help improve interoperability between health IT and PDMPs. New York was an early PDMP leader through adoption 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 presently queried by providers at a rate of over 18 million queries annually. These queries are not typically performed through the EHR, but through a state-secured portal supported by the state's Bureau of Narcotics Enforcement (BNE). While I-STOP has been instrumental in curbing illegal prescribing, doctor shopping and misuse of prescription opioids, providers continue to struggle with the additional burden and lack of integration into the workflow. We are hopeful standards that can ease integration into the workflow will lessen burden and also help achieve greater compliance with the legal requirement in New York to consult the PDMP. However, we do note that the NCPDP standards require a paid membership to obtain the technical specifications, which can limit widespread adoption. To truly standardize implementation nationwide, access to this standard should not be proprietary.

APIs without Special Effort

NYeC has been a supporter of ONC's push for open APIs. We agree that APIs without special effort are essential to interoperability and patient empowerment. We strongly support ONC's proposed requirements that APIs be standardized, transparent and procompetitive. We would encourage ONC to adopt FHIR R4 as the standard. As the first normative version, supporting enhanced capabilities, with backward compatibility, we believe efforts are best focused on advancing this version as opposed to dividing industry focus on multiple standards.

While we agree the goals APIs without special effort, with understand the concerns of many regarding security and authentication around these connections and would support efforts to ensure the reliability of third-party applications. We encourage ONC to clearly define the roles of respective parties with regards to identity proofing and authentication. We also support ONC working with other offices within HHS to continue efforts to more broadly ensure consumers are aware of the consequences of sharing their EHI with third-party applications. Consumers should be meaningfully informed on how their data will be used and also understand that once their data is shared with a third-party application not associated with their provider or payer, it loses the protections afforded by HIPAA.

Conditions of Maintenance

NYeC is very supportive of ONC's proposal to prohibit or restrict communications regarding usability, interoperability, security, user experience and developer business practices. Removal "gag clauses" and allowing providers to share screenshots more freely will advance patient safety and improve functionality. These changes to business practices are essential as reports continue to surface regarding EHR usability issues that result in patient harm. The practices of hiding behind contract terms in light of these patient safety concerns is reprehensible. We applaud ONC for prohibiting these actions and urge adoption in the final rule.

Requests for Information

Registries

NYeC is supportive of efforts to improve interoperability and bidirectional exchange between EHRs and registries given the benefits it could have for providers, quality reporting, quality improvement and public health. While this RFI focuses on leveraging APIs and FHIR standards, we would urge that ONC, in any future rulemaking on this, leave open the ability for HIEs to be leveraged for bidirectional exchange with registries as well.

Health IT and Opioid Use Disorder and Prevention

NYeC is extremely appreciative all the efforts HHS has taken to help curb the devastation of the opioid epidemic. We support all of the ongoing efforts to leverage Health IT in fighting this epidemic, including the efforts to integrate PDMPs into the workflow, as discussed above. NYeC is currently facilitating a regional pilot program to enable PDMP integration, while also exploring options for scalable statewide integration into the workflow. We believe there could be a number of advantages to incorporating PDMPs with robust HIEs like the SHIN-NY. While supportive of integration from a provider burden and compliance standpoint, we also acknowledge that states need to balance access to PDMP data with also maintaining a high level of security. We believe a shared strategy or guidance from HHS on PDMP integration could help states overcome policy considerations such as this.

Patient Matching

NYeC appreciates ONC's continued focus on the importance of patient matching. While there is much positive work in this area focusing on biometrics, standardization of demographic data, patient empowered solution, including ONC's work on the Patient Demographic Data Quality Framework and the USCDI. However, we concur with sentiments of the recently released United State Government Accountability Office (GAO) report as well as the recent report from Pew Charitable Trusts on *Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records,* that we need a unified national strategy to address patient matching. Additionally, as ONC is aware, the recently proposed TEFCA v2 states that HINs should agree upon and consistently share a core set of demographic data each time EHI is requested and participants should ensure these core demographics are consistently captured. TEFCA v2 also raises a number of questions and requests information on the appropriate approach to patient identity resolution, how much risk is acceptable, whether a centralized or federated approach is better, and what demographic elements should be utilized. We feel an ONC and CMS led effort with other public and private partners, could work to answer these questions through discussing best practices and lessons learned to develop a consensus approach. Once developed, implementing this approach will also harmonize disparate approaches among different entities. Given the fundamental importance of patient matching in patient safety and the efforts of ONC and CMS to increase interoperability across state lines, a national approach is appropriate and would work to focus the industry on a unified approach. NYeC and the QEs welcome participation in such collaborative effort.