NEW YORK eHEALTH COLLABORATIVE

Valerie Grey
Executive Director

May 28, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers - CMS-9115-P

Dear Ms. Verma:

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the recently proposed regulations aimed at expanding patient access and improving interoperability. 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 Centers for Medicare & Medicaid Services (CMS) leadership in advancing interoperability and patient access. While we believe there is a need for additional alignment, we want to acknowledge the effort to coordinate with other agencies such as the Office of the National Coordinator for Health Information Technology (ONC), specifically in their recent proposals related to implementation of the 21st Century Cures Act.

Examples that require further consideration relate to the reconciliation of policy variation across jurisdictions (i.e. consent requirements), the identification of technical standards, enforcement, and the overall interactions and/or distinctions with information blocking and the Trusted Exchange Framework and Common Agreement (TEFCA). We do acknowledge that all of these ambitious and large-scale endeavors must maintain a balance between specificity and flexibility as they evolve, so our comments are intended to strike that balance where sufficient information exists.

We are pleased to largely support the priorities of CMS and provide the following comments for consideration in finalizing this regulation. Attached you will find our full comments, but to summarize our big picture perspective, NYeC:

- Supports widespread adoption of patient event notifications but urges CMS to leverage existing alert systems. Hospitals who participate in robust Health Information Networks (HINs) like the SHIN-NY, or other similarly robust alert systems, should be deemed in compliance with this requirement. This approach would minimize burden and maximize existing efforts and investments;

- Supports payer participation in trusted exchange networks but urges CMS to clarify that existing mature HINs fall within the definition of trusted exchange network. Ensuring HINs like the SHIN-NY can help payers fulfill this requirement will allow payer choice and leverage past federal funding efforts;

- Supports the ability of payer-to-payer exchange to be facilitated via Health Information Exchanges (HIEs) like those that make up the SHIN-NY, or Application Programming Interfaces (APIs). We think it is essential CMS remain flexible in the approach payers may take to enable this exchange;

- Supports patient access through APIs and encourages CMS to work across offices within the Department of Health and Human Services (HHS) to help ensure reasonable safeguards and consumer awareness with regards to privacy and security implications;

- Supports CMS' continued efforts to advance interoperability across the continuum in future rulemaking. We believe engaging traditionally "left behind" sectors and including new data types to increase the value of interoperability across the continuum are essential next steps.

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

Conditions of Participation – Electronic Patient Event Notifications

- NYeC appreciates and is supportive of the CMS proposal to ensure widespread use of patient event notifications, but seeks the following amendments as explained in greater detail herein:
  - CMS should deem hospitals who generate and transmit feeds to mature HIEs like NY's QEs that participate in a robust HIN like the SHIN-NY to be compliant;
  - CMS should provide latitude in the proposed alert specifications and clarify hospitals are not required to confirm receipt; and
  - CMS should consider how varying consent laws could impact this requirement.

We agree that admit, discharge or transfer (ADT) notifications or alerts improve care coordination and result in better health outcomes. While supportive of CMS' intent, we believe changes to the proposal are necessary to ensure this requirement is implementable and does not add burden or create unintended consequences for providers who already participate in mature ADT systems that have reached a critical mass of the care continuum, particularly with hospital participation with Medicare and Medicaid at stake. We urge CMS to leverage the investment and success of existing ADT systems by deeming hospitals to be compliant with this ADT requirement if they generate and transmit feeds to mature HIEs Like NY's QEs that participate in robust HINs, like the SHIN-NY, which provide notification services to a critical components of the care continuum like primary care physicians and home care professionals.

Recognizing value of ADT alerts, the SHIN-NY QEs have been providing both inpatient and emergency room ADTs to participants for several years. In 2017, NYeC sponsored a study which showed that alerting providers through event notifications may be an effective tool for improving the quality and efficiency of care among high-risk populations, with estimates indicating that active hospitalization alert services were associated with a reduction in the likelihood of readmission for Medicare fee-for-service beneficiaries.[1] In one year, over 49 million alerts were delivered through SHIN-NY QEs. ADT alerts are a core service offered free of charge to participants, with all hospitals in the state generating and contributing feeds and alerts reaching providers across the continuum statewide. Even though state policy is based on an "opt-in" model, alerts can be transmitted to participants absent affirmative written consent if the participant provides treatment or care management to the patient, provided the alert does not contain sensitive health information such as that pertaining to substance use disorder, mental health or HIV status. Alerts are sent on a subscription basis, giving providers ability to customize the types of alerts they receive, which can limit data overload and ensures the notifications achieve their intended effect of improving patient care. We note that CMS does not require emergency room alerts as part of this proposal. In our experience, emergency department alerts are the most frequent alerts delivered, and they provide a significant value and opportunity to intervene.

The specifications cited in the proposed rule are generally consistent with how the SHIN-NY operates alerts, with some exceptions, which suggest modification in terms of allowable latitude

[1] https://academic.oup.com/jamia/article/24/e1/e150/2907910

without undermining the intent. QE alerts are currently sent immediately before or after the triggering event. They include patient demographics and diagnosis with some variation based on the alert event. For example, a diagnosis may be less likely for emergency room admit alerts, or the diagnosis could be labeled as a preliminary or as a working diagnosis. The QEs all have an approach that determines if the alerts were received. While not all hospitals are currently sending at the HL7 2.5.1 standard, the QEs are capable of presenting this data in the proper format for the provider. Additionally, QEs are capable of transmitting alerts received from out-of-state hospitals. Thus, we urge that CMS consider hospitals who are providing alert feeds, that include basic demographic information and diagnosis where possible, to the SHIN-NY QEs, or similar mature and robust networks be given deemed status for purposes of this requirement. CMS could establish participation thresholds for such networks to ensure widespread hospital participation as well as broad use by community providers. Under this approach CMS should also clarify that hospitals are not required to demonstrate a reasonable certainty of receipt. Rather hospitals should only be responsible for the activities within their control, the generation of the ADT message and transmission to the notification system. This approach leverages the current capabilities of mature notification systems, minimizes burden and ensures hospitals are not responsible for components outside of their control such as alerts that are not sent because there is no subscribing provider.

Lastly, in developing the final rule we encourage CMS to consider varying consent requirements that may apply to alerts, particularly with regards to psychiatric hospitals. States have varying consent requirements pertaining to individuals treated in mental health facilities. In New York, for example, information held by licensed mental health facilities typically cannot be disclosed without written consent for treatment and care coordination, although such disclosure is permitted if the recipient of the data is another mental health facility, a managed care organization, or a health home.[2] Accordingly, QEs can only send alerts from mental health facilities in New York without affirmative consent to payers, health homes or other entities authorized by the state Office of Mental Health. With patient consent, clinical information can be released from mental health facilities to persons and entities who have a demonstrable need and the disclosure will not reasonably be expected to be detrimental to the patient or another.[3] This law permits hospital emergency rooms to exchange information concerning patients with mental health facilities only upon prior approval of the Commissioner of the Office of Mental Health and such exchange must be consistent with standards developed by the Commissioner, and any limitation on the release of such information must be imposed on the party receiving the information.[4] As proposed, the rule does not appear to contemplate state laws such as this and it is unclear what CMS' intent is with regards to consent laws that may limit or prohibit the sending of certain hospital alerts.

[2] N.Y. Mental Hygiene Law § 33.13(d).
[3] N.Y. Mental Hygiene Law § 33.13(b)(7).
[4] N.Y. Mental Hygiene Law § 33.13(d).

Trusted Exchange Network Participation

- NYeC is very supportive of the proposal to require certain payers participate in a trust exchange network, but urges CMS to clarify that mature HINs, like the SHIN-NY, fall within the current definition of a trusted exchange network.

As an entity charged with advancing HIE in New York, we have and continue to advocate for payer participation in the SHIN-NY, as we believe it is a vital step to interoperability, particularly for care coordination and quality measurement. Currently, a number of health plans that provide both commercial and public offerings are SHIN-NY participants.

It is our understanding CMS intends to leverage existing networks for this requirement, which NYeC is very appreciative of this intent. However, we believe clarification is necessary within the regulation text to ensure public HINs like the SHIN-NY can be utilized by payers to fulfill this proposed requirement. Namely, the requirements that trusted exchange networks must be able to exchange personal health information (PHI) "in compliance with all applicable state and federal laws across jurisdictions," and that a trusted exchange network "support secure messaging or electronic querying by and between patients, providers and payers."

As CMS is aware, HIEs currently vary in their approaches to patient access, including providing data to the patient portals of their participants. Some HIEs may have patient portals themselves, some may be in the process of developing such access and others may refer patients to providers for access. We urge CMS to clarify that networks of HIEs, like the SHIN-NY, which support exchange between payers and providers today, and where some but not all QEs provide direct patient access, satisfies the definition of a trusted exchange network. Understanding that patient access is a CMS priority, many HIEs and networks will likely add this direct patient access in the future, but absent this flexibility in the rule there will be a lack of options and choice for payers who need to comply with this requirement, particularly under the ambitious timeframe proposed. Encompassing state-based interoperability initiatives many of which are supported through Medicaid HITECH funds, like the SHIN-NY, in this definition allows CMS to leverage existing investments and ensure payers are provided choice in fulfilling this proposed requirement.

Furthermore, it is unclear what CMS' intent is with regard to the trusted exchange network's ability to exchange "in compliance with all applicable state and federal laws across jurisdictions." More specifically, it is unclear whether CMS intends this to mean a trusted network exchange must comply with the laws of any jurisdiction it may happen to exchange with, or whether CMS intends this to be an affirmative obligation to exchange outside of jurisdictional or state lines. As CMS is likely aware, there is great variation in consent laws across states. This patchwork of legal requirements remains a barrier to interstate interoperability. Unfortunately, the ONC's recently released TEFCA draft 2 fails to address or provide guidance on navigating this myriad of laws as well. Thus, we urge CMS to clarify in the final rule that this obligation to comply with other state jurisdictions only applies to multi-jurisdictional networks or networks who voluntarily share across jurisdictions.

Lastly, CMS should clarify what is intended for "participation" in such network. In our experience most health plans that see the value in HIE participate to obtain data, and this level of participation is extremely valuable from a care coordination and value-based care prospective. We feel that requiring this level of participation is appropriate at this time. Payers could still voluntarily engage

in the bi-directional exchange and CMS should consider bi-directional exchange as a longer-term objective.

Payer-to-Payer Exchange

- NYeC supports CMS' proposal to require payer-to-payer exchange and urges CMS to retain the flexibility for this exchange to be done through HIE.

We support the requirement for payer-to-payer exchange as it will enable patient choice and mobility. We appreciate the flexibility CMS currently provides in allowing this exchange to be achieved through API or HIE. We urge that such flexibility be maintained in the final rule. Given the CMS proposal that the same payers subject to this proposal must also join a trusted exchange network, we believe payers should have the choice and ability to facilitate this exchange through either means. Allowing this exchange to be facilitated by HIE could also lead to more payers providing data to HIEs they may not otherwise. We would also suggest CMS consider aligning the timeline of this requirement with the U.S. Core Data for Interoperability (USDCI) implementation timeline in the ONC rule.

Patient Access through open API

- NYeC has been a supporter of CMS' push for open APIs to provide patients electronic access to their health information, as CMS continues this push we support further HHS efforts to ensure reasonable safeguards and consumer awareness exists regarding the security and privacy implications associated with this access.

We believe patient access through open APIs is the right path to push forward and applaud CMS' leadership. We support CMS leveraging the API standards as set forth by ONC. Additionally, we support the inclusion of the claims and clinical data, as well as provider directories as set forth by CMS. While we agree with CMS that empowering patients through consumer-directed exchange is integral to engaging patients in their care and advancing health care transformation, we also share the concerns of others that consumers may not be fully aware of the implications of such exchange.

Most consumers have a general sense that their personal health information (PHI) is afforded certain protections, but are not aware that when authorizing access to a third-party application not associated with their provider or payer, their PHI is no longer protected by the privacy and security protections under the Health Insurance Portability and Accountability Act (HIPAA). We support the provisions CMS proposes to require payers subject to this requirement post educational materials such as those made available by the HHS and we encourage HHS to further explore efforts to more broadly ensure consumers are meaningfully informed prior to authorizing a third-party application's access and use of their PHI. Similarly, we urge CMS to maintain the proposed provisions that allow for denial or discontinuation of access by third-party applications when it is reasonably determined the application would pose an unacceptable security risk to the PHI maintained by the payers, including state Medicaid.

National Plan Provider Enumeration System (NPPES)

- NYeC supports CMS efforts to update the NPPES directory and to encourage providers to input their digital contact information.

The inability to locate digital contact information is often a barrier to direct messaging. We agree with CMS that better enabling providers to find each other digitally will help reduce continued reliance on faxes. Once included, this information should also be updated by providers in accordance with the 30-day timeframe currently permitted under regulation for updates to required data elements.

Information Blocking Attestations

- We encourage CMS to work with ONC to clarify the intent regarding the consequence when a provider properly attests that they will not engage in information blocking, but the Office of the Inspector General (OIG) has determined the provider has engaged in information blocking.

It is our understanding that under the CMS rule eligible clinicians would fail the Promoting Interoperability Performance Category and hospitals would fail the Medicare Promoting Interoperability Program and face negative payment adjustments if they were to negatively attest to information blocking. However, it is unclear whether a provider who affirmatively attests that they will not engage in information blocking, but nonetheless has been found to engage in information blocking by the OIG, would be subject to these same disincentives.

Advancing Interoperability RFI

- NYeC supports the Center for Medicare and Medicaid Innovation (CMMI) efforts to advance interoperability and agrees CMS should encourage models that:
  - Incorporate emerging standards and new data types;
  - Encourage adoption of certified EHR technology (CEHRT) by behavioral health providers; and
  - Encourage participation in trusted exchanges and reinforce state interoperability efforts.

We concur with CMS that new models incorporating emerging standards and leveraging non-traditional data in the design such as data from schools, data regarding housing and food insecurity would help engage other less traditional provider types. NYeC believes such models could assist state efforts to connect community-based organizations to other entities in the health care ecosystem, and increase the value of information exchange for these groups. We feel advancing efforts focused on inclusion of new data types beyond clinical data will improve care coordination and value-based care. We also support CMMI models including requirements for patient access via API and participation in trusted exchange networks, with the caveat discussed above - that HINs like the SHIN-NY fall within the definition of a trusted exchange network. In addition, we would urge CMMI to implement the authority granted under the SUPPORT for Community and Patient Act which authorized the testing of incentive payments to behavioral health providers to adopt CEHRT. NYeC continues to believe we should advance efforts to engage "left behind" sectors to truly advance interoperability.

We also continue to support the establishment of other activities that can count towards meeting the requirements of specific Promoting Interoperability Program measures. In developing new

options, CMS should explore how to expand and reinforce existing state interoperability efforts. CMS should allow each State Medicaid Agency, if they desire, to select a state-based mechanism that counts towards meeting the HIE measures (i.e. participation in a state designated HIE or HIN). CMS could then deem participation in that mechanism as one way for providers in the state to demonstrate compliance with the HIE measures. CMS could leverage existing mechanisms, for example State Medicaid HIT Plans (SMHP), as the means by which a state would request CMS approval of their selected state-based mechanism. This policy approach will reduce provider burden by further aligning state and national interoperability requirements and will reinforce state-based interoperability initiatives supported through public funds.

Increasing Interoperability Across the Care Continuum RFI

- NYeC appreciates CMS exploring options to increase interoperability across the care continuum and makes the following suggestions:
  - CMS should offer financial incentives and regulatory relief to increase adoption of CEHRT and participation in HIEs;
  - CMS should incentivize providers to collect and exchange data elements to enhance value of interoperability across the care continuum;
  - CMS should offer state matching programs to enable states to support technical assistance programs;
  - CMS should expand interoperability measurements and work with ONC to include additional data elements in the USCDI going forward; and
  - CMS should work with ONC to ensure there is a safe harbor or reasonable steps entities can take avoid information blocking implications

We must collectively work to engage "left behind" sectors to advance interoperability. As noted above, we support CMMI testing incentive payments to encourage non meaningful use providers to adopt CEHRT. While we feel incentives are necessary, many post-acute (PAC) and home and community-based service providers (HCBS) avoid adoption of EHRs due to lack of IT staff and education or assistance on how to meaningfully use these products. The availability of funding, through optional state matching programs could allow for states to invest in advancing interoperability among these sectors and could be used for both incentives and technical assistance. Such investments could build off previous efforts like the Regional Extension Centers (RECs) which provided on-the-ground technical assistance as well as state efforts like the New York State funded behavioral health information technology (BHIT) grant. With the support of a $10 million BHIT grant, NYeC was able to assist 114 organization across 52 counties by providing technical assistance to implement their EHR systems. Further investments in such efforts would yield greater adoption.

In addition to financial incentives, we believe CMS' ability to provide regulatory relief to providers would also encourage participation in interoperability efforts. We also support CMS activities to expand the scope of interoperability measurements beyond settings that were eligible for previous EHR incentive programs to include measures that assess interoperability among PAC, HCBS, behavioral health and other provider settings. Further, we support CMS offering incentives for providers to collect and exchange standardized data elements that could enhance the value of interoperability across the care continuum. CMS should work with ONC and the USCDI Task

Force to analyze inclusion of other data elements starting with the PAC data elements CMS set forth as part of its work under the IMPACT Act.

Lastly, we believe CMS should work with ONC to ensure alignment on efforts to engage these sectors in interoperability. As currently proposed, skilled nursing facilities, nursing facilities, home health entities, other long-term care facilities as well as certain community mental health centers would fall under the definition of a health care provider for purposes of information blocking. Given information blocking only applies to electronic health information, it could impact an organizations decision to move from a paper-based system to an electronic one given the potential complexity of compliance with information blocking. However, if ONC were to designate affirmative actions an entity could take to be presumed in compliance, such as participation in a HIN, this potential impact could be minimized.