



NEW YORK eHEALTH  
COLLABORATIVE

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Office of Quality and Patient Safety  
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Dear Anne:

On behalf of the New York eHealth Collaborative, Inc. (“NYeC”), we are pleased to submit these comments in support of the proposed amendments to Part 300 of the Regulations of the Department of Health (“DOH”) related to the Statewide Health Information Network for New York (the “SHIN-NY”). We do recommend several clarifications, as a result of questions and feedback we have received from stakeholders with whom we have discussed the proposed changes.

The proposed SHIN-NY regulatory changes will serve to reform and improve the services offered by the SHIN-NY, making it a more valuable resource to participants, the State and the public. These changes are **essential** to supporting health information exchange and overall interoperability and efficient service delivery in New York State.

## Background

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The current SHIN-NY regulations were established in 2016 to govern the SHIN-NY, which serves as the technical infrastructure and the supportive policies and agreements that make possible the electronic exchange of clinical information in New York State. The State of New York has invested in the SHIN-NY with the aim of improving the quality, coordination and efficiency of patient care, reducing medical errors, and carrying out public health and health oversight activities, while protecting patient privacy and ensuring data security.

Under this structure, data is exchanged through regional Qualified Entities (“QEs”) which are certified as being capable of providing connected health care organizations - or “participants” - with a standard set of core services, maintaining patient privacy protections, and actively participating as part of the SHIN-NY statewide “network of networks.”

The regulations prioritized the onboarding of health care organizations to the SHIN-NY via the QEs, with most general hospitals required to connect to the SHIN-NY by March 2017 and many other health care organizations, including certain ambulatory surgery centers, clinics, nursing

homes, and diagnostic and treatment centers required to connect by March 2018. The result has been the broad engagement of local health care organizations in data exchange in New York and the formation of an active statewide network and resource in the SHIN-NY.

While the current regulatory and policy structure of the SHIN-NY helped to establish widespread connectivity among health care organizations and QEs, reform is needed for New York to fully realize its goals for public health data services, and to keep pace with modern data exchange practices in the context of a shifting national landscape in health information exchange (“HIE”). Said succinctly:

- The capacity for the commercial marketplace to exchange health information has evolved, so the SHIN-NY regulations should change.
- The needs of the Department of Health for statewide health data exchange have grown, so the SHIN-NY regulations should change.

### **Benefits of DOH’s Regulatory Proposal**

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Given the substantial investment New York State has made in the SHIN-NY over several years, we believe that the regulatory amendments proposed by DOH will enable the SHIN-NY to further increase its capabilities and provide important enhancements to the SHIN-NY, making it a more valuable resource for New York and especially for statewide purposes.

The regulatory amendments will accomplish the following key objectives for New York State:

➤ ***Enable the SHIN-NY to better serve the State’s public health needs.***

The SHIN-NY regulations have not been updated since 2016. The proposed regulatory changes will allow NYS to modernize the SHIN-NY to support the state’s and SHIN-NY participants’ next generation of health information needs. For example, Governor Hochul, in her 2023 State of the State address, made it a priority for New York State to have a “nation-leading health monitoring and surveillance system to inform targeted and appropriate responses to public health crises and to drive broader health care insights.” The proposed regulatory changes will support the development of innovative approaches to ways in which the SHIN-NY can serve NYS DOH by collecting and analyzing public health data that will help inform appropriate responses to public health crises in line with the goals outlined by the Governor in her 2023 State of the State address.

➤ ***Enable the SHIN-NY to better serve Medicaid needs.***

The regulatory reforms will support the New York Health Equity Reform Section 1115 waiver amendment to the state’s Medicaid program, which the Office of Health Insurance Programs (OHIP) is administering. The program envisions coordination among Community Based Organizations (CBOs) and other healthcare organizations; the SHIN-NY should support this in a

single statewide manner with common rules. OHIP will need to data to monitor and evaluate the new health-related social needs services provided under the amendment. By fostering the development of a statewide data repository, the regulatory changes will help DOH ensure it has the information it needs to fulfill the potential of the 1115 waiver.

➤ ***Provide SHIN-NY participants increased flexibility to choose their SHIN-NY Qualified Entity (QE) partners.***

Currently, health care providers contract with one or more regional QEs which cover their service area(s) in order to contribute data to the SHIN-NY. Health systems have limited ability to choose their QE partner(s) due to the regional model – even if a different QE might provide the types of services better suited to that health system’s needs or more favorable contract terms,

The regulatory amendments require that certain health data is delivered to a statewide repository - whether via a QE or through direct participant contributions - instead of solely to the regional QEs. Having a common statewide source for critical data would provide opportunities for participants to select the QE(s) with which they participate based on the value-added services they provide. It will also support healthy competition among QEs and create an imperative to provide more value-added services.

➤ ***Align SHIN-NY data policy to better meet the needs of users across QE regions.***

QEs have varying approaches to data collection, management, and disclosure policies and participants and users with an interest in multiple regions must navigate many technical and contractual variables.

The proposed regulation changes will require that SHIN-NY QEs and participants adopt a common participation agreement, which will reduce regional inconsistencies and offer a standard statewide framework for data access, use, and disclosure. The concept of a common participation agreement mirrors national norms and allows for a single high standard of data governance to apply throughout the state.

➤ ***Enable the state to modernize QE services.***

Current SHIN-NY regulations specify a set of minimum technical “core services” that all QEs must provide, which in some cases has proven to be outdated. Market competitors have emerged to provide alternatives to some of these “core services.” Electronic Health Record (“EHR”) vendor concentration, for instance, supports intra-EHR clinical data exchange without the need to engage with an external HIE. Similarly, the launch of the Trusted Exchange Framework and Common Agreement (“TEFCA”) may make some organizations less reliant on certain QE services. The “core services” requirements have become an impediment to any organization other than the existing QEs which might otherwise offer a service to SHIN-NY participants. The “core services” were not intended to become a barrier to new services.

The regulatory amendments modify the minimum technical “core services” requirements to better align with current data needs and allow DOH to make more flexible and timely updates through SHIN-NY policy guidance or contract modifications in the future, rather than requiring further regulatory changes. DOH will also gain the flexibility to purchase value-added services from QEs, further diversifying the role that QEs can play in the evolving HIE ecosystem.

➤ ***Establish a centralized patient consent framework to further enhance patient privacy and reduce burdens on patients and providers.***

Currently, each provider independently collects and manages patient consent for access to patient data in the SHIN-NY and data exchange. Patients must provide consent separately for each health care provider they see. These consent forms are currently uploaded to six separate QE registries.

The regulatory amendments require the use of a statewide consent form and development of a centralized statewide consent registry. This will reduce the need for repetitive re-consenting of patients, saving time and effort for providers and patients alike. It will also promote patient privacy: patients will be able to express their privacy preferences by filling out one form, rather than having to fill out many forms to indicate how they want their information to be used. Further, all existing state and federal patient privacy laws will continue to govern how SHIN-NY data is collected and used. Without this change, the SHIN-NY will have difficulty engaging with national networks, some of which have previously denied QE participation due to the incompatibility of consent approaches.

➤ ***Enhance stakeholder engagement and data governance.***

The regulatory amendments will enable a new statewide collaboration process to develop recommendations based on stakeholder engagement, including developing data sharing policies and technical interoperability standards. Increased centralization of data policies enables the establishment of a consistent, transparent governance process for data access, use, and disclosure.

The regulatory amendments also offer a new opportunity to engage stakeholders statewide in the common agreement development process.

### **Suggested Clarifications**

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1. We recommend clarifying that approval of the use and re-disclosure of data for any purposes not enumerated in the regulation will be through the statewide collaboration process, and that in particular the State will not obtain data from the statewide data infrastructure for health oversight purposes without following that process. While the regulations call for this statewide collaboration process, this clarification will remove doubt as to whether it will be followed.
2. We recommend adding a clarifying definition of *Public health surveillance and Medicaid purposes*. Supporting these purposes should be a core aim of the SHIN-NY, pursued with minimal friction, and the clarification will make clear that these purposes are different than oversight of healthcare organizations.
3. We recommend clarifying that healthcare facilities may seek a waiver from connectivity requirements if they are effectively making patient records available to a patient's other

healthcare providers, such as through participation in national health information exchange, and are causing patient data to be contributed to the statewide data infrastructure for public health surveillance and Medicaid purposes. We also recognize that certain statewide services in the SHIN-NY will need to be enhanced as a prerequisite to these waivers being granted, but the perception of this provision by other stakeholders causes concern that such provisions will not necessarily be in place. Clarifications about the waiver process might be best described in regulatory guidance.

Collectively, these reforms and enhancements would make the SHIN-NY a more valuable and efficient resource for participants and the state, resulting in higher quality data collection, exchange, and use that complements private and national HIE services and solutions.

Reform of the SHIN-NY via the proposed regulatory changes comes at a time of significant change in the national HIE landscape and the state's need to fulfill its public health duties, including detecting and responding to public health emergencies, and to implement the 1115 waiver. Its timely advancement has never been more important.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "David Horrocks".

David Horrocks  
Chief Executive Officer