

# **Schedule 23 CON Forms Specific to All Projects Incorporating Health IT**

## **Contents:**

- **Instructions**
- **Background**
- **Schedule 23**
- **Vendor Contract Language for CON Applicants**

**Certificate of Need (CON)  
Interoperable Health IT Requirements**

**Instructions:** This self-description and certification should be utilized for ALL projects incorporating health IT as part of their application. Health IT refers broadly to electronic methods for storing and processing clinical and other data, and “interoperable” refers to the ability to exchange data in a standardized manner with other IT systems.

Applicants are asked to review and complete each of the sections below.

**Background**

Health IT plays a significant role in health care reform by ensuring that clinical information is in the hands of clinicians and New Yorkers so that it guides medical decisions and supports the delivery of coordinated, patient centered, high quality care. One of the principal health care reform initiatives New York has engaged in is the development and implementation of a health information infrastructure. New York’s plan includes the technological building blocks, clinical capacity, and mechanisms for governance and policy development, that are necessary to advance health IT in a consistent and meaningful way that supports improvements in health care quality, affordability and outcomes.

Through the Statewide Collaboration Process, facilitated by the New York eHealth Collaborative, a comprehensive set of information policies, standards, protocols and other technical approaches for the Statewide Health Information Network for NY (SHIN-NY) and Health IT Systems has been developed and released with the current version of the Statewide Policy Guidance. All CON health IT projects are required to comply with the Statewide Policy Guidance and are strongly encouraged to participate in the governance process.

For questions about the requirements or completion of the self-certification form, you may contact the Office of Quality and Patient Safety, Bureau of Health Information Exchange at (518) 474-4987.

In submitting a New York State Department of Health Certificate of Need (CON) application with a health IT component, you are asked to address a number of technical, organizational and clinical areas related to the New York’s health IT strategy dedicated to supporting improvements in health care quality, affordability and outcomes for all New Yorkers. In doing so, you will be aligning with the Department’s strategy in four arenas:

1. **Technical:** A technical architectural design and implementation plan for connecting institutional systems (inpatient and outpatient) to the Statewide Health Information Network for New York (SHIN-NY), ensuring such systems are interoperable and patients’ health information is available to all authorized clinicians when and where it is needed, regardless of where the patient receives care, to improve care coordination, management and quality. This includes plans for granting providers utilizing Health IT Systems access to clinical data gathered via institutional inpatient systems, consistent with the State’s architectural design, while ensuring seamless integration among providers using disparate Health IT Systems in inpatient and outpatient care settings.
2. **Organizational:** A governance plan including a description of participation with a Qualified Entity (QE) to ensure compliance with current health information policy, standards and technical approaches, collectively referred to as Statewide Policy Guidance.
3. **Clinical:** Two components: (i) A health IT adoption and support plan explaining how implementation services will be provided and sustained to support clinicians in achieving quality goals from Health IT Systems adoption and integration to the SHIN-NY. (ii) A quality measurement and reporting plan indicating how the system or facility will report and submit information on clinical quality measures and other measures in a form and manner specified by the NYSDOH or at the federal level by the Secretary of Health and Human Services (HHS).

**Schedule 23 – Interoperable Health IT Requirements**

Section One: Executive Summary – Please provide an executive level summary of your health IT project.

Section Two: Narrative Descriptions – Please describe how your health IT project will comply with each of the following requirements.

1. Please identify which Qualified Entities (QE) your organization has aligned with and your specific involvement in the governance process and structure. For more information about QEs in NYS, please refer to <http://www.nyehealth.org/shin-ny/qualified-entities/>

2. Inpatient and outpatient Health IT Systems must be interoperable with other provider systems to support improvements in patient care and be interoperable with public health systems to support quality and population health reporting utilizing the Statewide Health Information Network for New York (SHIN-NY). Inpatient and outpatient Health IT Systems must comply with Statewide Policy Guidance requirements promulgated by the New York’s Statewide Collaborative Process facilitated by the New York eHealth Collaborative (NYeC) and approved by the NYS DOH. Policy guidance can be found at: <https://www.health.ny.gov/technology/regulations/shin-ny/>

- a. Please describe your plan for complying with the current and subsequent requirements specifically related to interoperable Health IT Systems and the Statewide Health Information Network for New York (SHIN-NY).

- b. Please list the vendor(s) you will be utilizing and the specific product(s) you will be implementing.

3. Seamless integration between providers using disparate Health IT Systems in inpatient and outpatient care settings is critical for high quality cost effective patient care. Please describe your organization’s plans for exchanging health information between disparate inpatient and outpatient Health IT Systems utilizing the SHIN-NY.

4. Please describe your plans for integration of your organization's ancillary clinical systems (eg. radiology, PACs, laboratory, pharmacy, etc) into your Health IT Systems.

5. Integrated hospital pharmacy systems, electronic medication administration record/chart documentation and computerized physician order entry, patient bar coding and medication identification are all important components to medication safety. Clinical decision support and order sets that include best practice and clinical alerts can all be effective methods to leverage information systems to improve patient safety. Without strong physician participation in the design and implementation process, there is risk in implementation if not planned carefully.

If applicable, please describe your institution's plans for improving patient medication safety (e.g., computerized physician order entry, patient bar coding, automated dispensing, medication administration, etc), including your plans for physician participation in the design and implementation of these systems.

6. If electronic prescribing to outside pharmacies using your Health IT System is included as part of your implementation, please identify what sources of medication history will be provided to the providers.

a. Please identify what sources of medication history will be provided to the providers.

b. Please describe how provider connectivity for medication management will be provided.

c. Please describe how medication histories will be reconciled to give an accurate list of current medications as the patient moves between care settings.

7. Please describe your health IT adoption and support plan explaining how implementation services will be provided and sustained to support clinicians in achieving quality goals from Health IT System adoption and integration to the SHIN-NY.

# New York State Department of Health Certificate of Need Application

## Schedule 23

### Section Three: Technical and Clinical Requirements

Statewide Policy Guidance Requirements. Compliance with current and subsequent versions of the interoperability requirements as promulgated through the Statewide Collaboration Process is required for CON approval.

Requirement	Will Comply	Will Not Comply
1. Vendors are contractually obligated to comply with the Statewide Policy Guidance requirements as described here: <a href="https://www.health.ny.gov/technology/regulations/shin-ny/">https://www.health.ny.gov/technology/regulations/shin-ny/</a>	<input type="checkbox"/>	<input type="checkbox"/>

Inpatient and outpatient Health IT Systems must be interoperable to facilitate safe, efficient, high quality patient care. These systems must also be interoperable with public health systems to support quality and population health reporting through the Statewide Health Information Network for New York (SHIN-NY). Inpatient and outpatient Health IT Systems must be certified as described in the Federal Department of Health and Human Services(HHS) Standards and Certification Criteria, and must make, at a minimum, the “common clinical dataset” available. This information must be made available as a structured document, using the Consolidated Clinical Document Architecture described by Office of the National Coordinator for Health IT certification requirements in 45 CFR 170.205(a)(3).

Information on HHS health IT certification can be found here: <https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>

A description of the common clinical dataset can be found here:  
[https://www.healthit.gov/sites/default/files/commonclinicaldataset\\_ml\\_11-4-15.pdf](https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf)

Requirement	Will Comply	Will Not Comply
2. Vendors are contractually obligated to maintain certification for both inpatient and outpatient electronic health records as described above.	<input type="checkbox"/>	<input type="checkbox"/>
3. Ambulatory and inpatient Health IT Systems will make, at a minimum, the common clinical data set available to the SHIN-NY in the format specified.	<input type="checkbox"/>	<input type="checkbox"/>
4. Providers are able to access data available from the SHIN-NY via a qualified entity.	<input type="checkbox"/>	<input type="checkbox"/>

**New York State Department of Health  
Certificate of Need Application**

**Schedule 23**

Clinical Requirements: Clinical informatics services are required to facilitate quality and population health measurement and reporting through utilization of Health IT and the SHIN-NY. The New York State Department of Health in conjunction with the Statewide Collaborative Process may determine the methodology to assess and evaluate external entity or entities that are involved in the collection, aggregation and analysis of quality metric information derived from provider health information systems. Compliance with each of the following is required for CON approval. If you check “will not comply” please provide an explanation as to the reason and a plan when you will be in compliance (if applicable). Please indicate N/A if not applicable to your application.

Requirement	Will Comply	Will Not Comply
1. Health IT Systems must be capable of extracting de-identified health information in accordance with measures specifications, as determined by the Statewide Collaboration Process.	<input type="checkbox"/>	<input type="checkbox"/>
2. Health IT Systems must be capable of extracting health information including physician identifiers (utilizing the SHIN-NY) in a standardized electronic format for performance measurement as determined by the statewide collaboration process	<input type="checkbox"/>	<input type="checkbox"/>
3. Health IT Systems must be capable of electronic transmission of extracted de-identified and identified health information for performance measurement including physician identifiers (utilizing the SHIN-NY) in a standardized electronic format to an external entity or entities that are involved in the collection, aggregation and analysis of quality metric information from health information systems as determined by the Statewide Collaboration Process	<input type="checkbox"/>	<input type="checkbox"/>
4. Health IT systems are required to either display imported performance assessment results [imported through the SHIN-NY when appropriate] or have an embedded link to a quality measure data aggregation and reporting service, which presents performance comparison data and other appropriate information to participating providers to allow opportunities for clinical process improvement	<input type="checkbox"/>	<input type="checkbox"/>
5. Health IT Systems must ensure that data imported from an external source/interface will retain data integrity when imported into a providers' electronic medical record as determined by the Statewide Collaboration Process	<input type="checkbox"/>	<input type="checkbox"/>

Section Four: Applicant Certification

I certify that the above described information is a true and accurate reflection of the health IT project requested as part of this submission. I further certify to the project's current and ongoing compliance with the Statewide Policy Guidance Requirements as developed by the Statewide Collaboration Process.

**NOTE:** The self certification form should be completed for all projects involving the implementation of clinical information systems, EMRs, CPOE, radiology systems, lab ordering systems or other health information systems impacting patient care. If your project does not fall into any of these areas and you believe that this certification form is NOT Applicable to your project, please check the box below and sign and date the form.

I have reviewed the information contained in the self certification form and believe it is NOT Applicable to the project submitted for CON approval. Please include a brief description (one or two sentences) as to why the requirements are not applicable in the box below.	<input type="checkbox"/>
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\_\_\_\_\_  
CEO / COO / CFO / CIO Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Applicant (Printed Name)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Organization

**New York State Department of Health  
Certificate of Need Application**

**Schedule 23**

Section Four: Qualified Entity Certification

I certify that I have collaborated with the applicant submitting this application and am supportive of their understanding of Statewide Policy Guidance Requirements. The applicant has agreed to become an active collaborating member of this QE and participate in the relevant associated processes. I am collaborating with this applicant to help ensure interoperability of their systems containing personal health information and will work with them to facilitate the sharing of this information.

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QE Representative Signature

Date

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(Printed Name)

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Title

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QE



**Vendor Contract Language for CON Applicants**

**1. Statewide Collaborative Process requirements and ongoing requirement:**

*(Vendor) and (Project) will work together to configure the Program Property in a manner that conforms in all material respects with the Statewide Policy Guidance prior to (Project's) First Live Use of the Program Property. (Vendor) and its staff regularly monitor the activities of, and often participate in, various healthcare information technology groups, commissions and national standards-setting bodies. (Vendor) and (Project) will continue to deploy resources seeking to keep abreast of such standards, including standards adopted through the Statewide Collaboration Process and incorporated into the Statewide Policy Guidance. Moreover, if (Project) or other New York customers notify (Vendor) of an SPG Requirement, (Vendor) will meet with (Project) and other affected customers to consider possible modifications to the Program Property and other options for addressing the issue. Upon execution of a mutually agreeable Change Order, (Vendor) will develop at (Vendor) Standard Rates any modifications addressing such Statewide Policy Guidance Requirement. If more than one (Vendor) customers will benefit from the modifications to address the SPG Requirement, (Vendor) agrees to use good faith efforts to spread the cost of the Change Order equally among those electing to receive the benefit of the change. An "SPG Requirement" is a requirement of the Statewide Policy Guidance developed and adopted through the Statewide Collaboration Process that relates directly to the functionality of the Program Property as it is described in the Documentation Manuals and is necessary for (Project) to comply with the Statewide Policy Guidance to exchange health information with a Regional Health Information Organization (RHIO) for participation in the Statewide Health Information Network for New York (SHIN-NY). (Project) understands that achieving compliance with the Statewide Policy Guidance may require (Project) to pay fees or costs for third party products or services.*