

## Qualified Health Information Technology Entities

Effective date: 2/15/12

Pursuant to the authority vested in the Department of Health and the Commissioner of Health by sections 201 and 206 of the Public Health Law and sections 363-a and 365-a(2) of the Social Services Law, Section 504.9 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register.

Subdivision (h) of section 504.9 is added to read as follows:

(h)(1) A Qualified Health Information Technology Entity, as defined in paragraph (2) of this subdivision, seeking access to medical assistance information must enroll in the medical assistance program in accordance with this Part and must meet the appropriate additional requirements set forth in this section.

(2) Qualified Health Information Technology Entities, which may include but are not limited to regional health information organizations (RHIOs), are entities to whom recipient-specific medical assistance information is released, with the consent of the medical assistance recipient, for the purpose of sharing such information with one or more of its members that are providing medical care, services, or supplies to such recipient. The release of such information is intended to improve the quality of care delivered to medical assistance recipients, reduce the occurrence of medically adverse events, and reduce costs through better coordination of care.

(3) As a condition of enrollment and of receipt of medical assistance information pursuant to this subdivision, Qualified Health Information Technology Entities must develop and maintain policies and procedures:

(a) to ensure that informed consent is obtained from medical assistance recipients for the release of confidential information;

(b) to handle and safeguard confidential information in compliance with all applicable federal and state laws and regulations; and

(c) to ensure that their members comply with all applicable federal and state laws and regulations regarding confidential information.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Social Services Law section 363-a and Public Health Law section 201(1)(v) provide that the Department of Health is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program. In addition, Public Health Law section 206(18-a)(b) authorizes the Commissioner to promulgate regulations to implement provisions of the federal American Recovery and Reinvestment Act of 2009 relating to the use of electronic health record ("EHR") technology by Medicaid providers.

### **Legislative Objectives:**

Federal law at 42 U.S.C. section 1396b(t) establishes a program for incentive payments to Medicaid providers who demonstrate meaningful use of certified EHR technology through a means that is approved by the State, with the ultimate goal of promoting health care quality and health information exchange. In furtherance of this goal, Public Health Law section 206(18-a) creates a demonstration program to promote the development of EHR technologies and authorizes the Commissioner to promulgate regulations necessary to disburse the incentive payments provided for in 42 U.S.C. section 1396b(t). These incentive payments will be made to Medicaid providers who purchase, implement, and operate certified EHR technology. These providers will be the end users of data that is compiled and analyzed by Qualified Health Information Technology Entities.

### **Needs and Benefits:**

The proposed regulatory amendment would define the term "Qualified Health

Information Technology Entity” to mean an entity that, with the consent of a Medicaid recipient, is given recipient-specific information to share with Medicaid providers who are members of the entity and who are providing medical care, services, or supplies to the recipient. In addition, the regulation would require entities seeking to act as Qualified Health Information Technology Entities to enroll in the Medicaid program for such purpose, to enable the Department to regulate and control the terms under which Medicaid data is made available to such entities and to assure the confidentiality of individually identifiable confidential enrollee health information.

**Costs:**

There should be no additional costs associated with this regulatory amendment.

**Local Government Mandates:**

The proposed regulatory amendment does not impose any new mandates to local social services districts.

**Paperwork:**

The proposed regulatory amendment will result in a minimal amount of additional paperwork for medical providers, since the Qualified Entities will be required to submit the same documentation to the Medicaid program as other such enrolled providers.

**Duplication:**

This proposed regulatory amendment does not duplicate, overlap, or conflict with any other State or federal law or regulations.

**Alternatives:**

One alternative would be for Medicaid to take responsibility for distributing beneficiary specific information to thousands of individual providers, and establish interfaces with dozens of different electronic health records systems directly. Given that the Department has already

established a governance policy and technical infrastructure to manage those responsibilities through the existing RHIOs, this alternative is not practical. The other alternative would be to take no action, which in turn would limit access to data for Medicaid providers and potentially make it more difficult for them to qualify for the EHR incentive payment program. This alternative would result in reduced federal funds coming to New York State and slow down the process of physicians adopting and using EHRs.

**Federal Standards:**

The proposed regulatory amendment does not exceed any minimum federal standards.

**Compliance Schedule:**

The proposed regulatory amendment will become effective upon publication of a Notice of Adoption in the New York State Register.

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**REGULATORY FLEXIBILITY ANALYSIS**  
**FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

A Regulatory Flexibility Analysis is not required because the proposed rule will not have a substantial adverse impact on small businesses or local governments.

## **RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis is not required because the proposed rule will not have any adverse impact on rural areas.

## **JOB IMPACT STATEMENT**

A Job Impact Statement is not required because the proposed rule will not have any adverse impact on jobs and employment opportunities.

## Assessment of Public Comment

The only comments received by the Department on the proposed regulation were submitted by an entity that anticipates applying to be recognized as a Qualified Health Information Technology Entity once the proposed rule is finalized. These comments and the Department of Health's responses are summarized below.

### **Comment:**

The commenter states that the Medicaid enrollment process is designed for health care providers, not health information technology organizations such as Qualified Entities. As a result, this commenter is concerned that the enrollment process may impose unnecessary administrative burdens on Qualified Entities, which will divert limited resources away from their core mission without addressing the legitimate needs of the Medicaid program. In lieu of enrollment, the commenter recommends that the Medicaid program enter into specially tailored agreements with Qualified Entities that focus on the unique role played by these organizations.

### **Response:**

The proposed regulations require Regional Health Information Organizations (RHIOs) or Qualified Entities (QEs) to enroll in the Medicaid program as service bureau providers. As such, RHIOs or QEs can obtain access to Medicaid data and other benefits of Medicaid enrollment in order to disseminate Medicaid data to their participating provider organizations as appropriate. While DOH does not look upon this process as burdensome, we will work with the Medicaid program and the QEs to develop a process that is both efficient and effective and ensure that there is a level playing field as to rules and procedures.

**Comment:**

This commenter requests a change in wording from “members” to “participants” in paragraph (h)(2) of the proposed regulation, which refers to QEs sharing information with their members. The commenter states that the term “members” suggests a level of ownership or control in the organization

**Response:**

While the word “participants” may be more consistent with the terminology used in the New York eHealth Collaborative’s Privacy and Security Policies, the intent of the language is the same. No change to the regulation was made in response to this comment.

**Comment:**

This commenter questions the use of the phrase “informed consent” in paragraph (h)(3)(a) of the proposed regulation, stating that this term is usually used in connection with medical treatment, and not in New York’s confidentiality laws. The commenter recommends the term “consent” or “authorization” instead.

**Response:**

Informed consent connotes an understanding by the medical assistance recipient of what they are consenting to. The New York eHealth Collaborative’s Privacy and Security Policies use the term “affirmative consent” for the same reason. The Department considers the terms “informed consent” and “affirmative consent” to be equivalent in this context. No change to the regulation was made in response to this comment.

**Comment:**

This commenter questions the definition of the term Qualified Entity in paragraph (h)(2) of the proposed regulation and states that the language used could be interpreted as requiring QEs to be

listed in the consent form signed by the medical assistance recipient.

**Response:**

The Department believes the language of the proposed regulation clearly conveys its intent, that disclosures of recipient-specific information to QEs must be made with the consent of the medical assistance recipient. Therefore, no change was made to the regulation in response to this comment.

**Comment:**

The commenter recommends a change in the language of paragraph (h)(3)(c) of the proposed regulation, to obligate QEs to “require” their members to comply with all applicable confidentiality laws and regulations, rather than to “ensure” that they comply. The commenter is concerned that a QE will be held responsible, and possibly sanctioned, for improper conduct committed by one of its members that is beyond its control.

**Response:**

The proposed language change does not change the intent of the regulation, and therefore no change to the regulation was made in response to this comment.