

**PROPOSED REGULATION OF THE DIRECTOR OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

LCB File No. R056-16

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 22, inclusive, of this regulation.

Sec. 2. As used in sections 2 to 22, inclusive, unless the context otherwise requires, the words and terms defined in sections 3 to 10, inclusive, of this regulation have the meanings ascribed to them in those sections.

Sec. 3. "Child" means a person who is less than 18 years of age.

Sec. 4. "Director" means the Director of the Department of Health and Human Services.

Sec. 5. "Electronic health record" has the meaning ascribed to it in NRS 439.582.

Sec. 6. "Health care provider" has the meaning ascribed to it in NRS 439.583.

Sec. 7. "Health information exchange" has the meaning ascribed to it in NRS 439.584.

Sec. 8. "HIPAA" refers to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy rules, Public Law 104-191, and implementing regulations set forth in 45 C.F.R. Parts 160, 162 and 164.

Sec. 9. "HITECH" refers to the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA) enacted on February 17, 2009, Public Law 111-5, and implementing regulations.

Sec. 10. "Person" has the meaning ascribed to it in NRS 439.585.

Sec. 11.

1. A Health Information Exchange operating in the state shall:

Comply with the specifications and protocols for exchanging electronic health records, health-related information and related data prescribed pursuant to the provisions of HITECH, HIPAA, and other applicable federal and state law;

Operate in a manner to improve the health of people in the State of Nevada and the efficiency and effectiveness of the delivery of health care services in Nevada through the collaborative use of health-related information;

Be commercially available to health care providers and other covered entities as defined in 45 C.F.R. § 160.103;

Facilitate the provision and sharing of information concerning health care for improved health care outcomes in this State;
Support population and public health initiatives and interactions;
Facilitate a cooperative health-related information sharing environment across the public and private sectors;
Be aligned with meaningful use criteria as defined by the federal government pursuant to the provisions of HITECH, HIPAA and other applicable federal and state law;
Ensure the privacy and security of health-related information in compliance with all relevant federal and state statutes and regulations.

Sec. 12.

The Director will encourage the use of health information exchange system by health providers, payers, and patients.

2. Except as otherwise provided in section 13 of this regulation, each health information exchange must be certified by the Director before providing services in this state.

3. The Director may certify a health information exchange if:

(a) The exchange adequately demonstrates to the Director its financial and operational sustainability in the manner specified by the Director and by providing the Director with all information requested by the Director;

(b) To maintain and protect the confidentiality of electronic health records and health-related information and to ensure the integrity of such information, each certified health information exchange shall use an enterprise master patient index and a master health care provider index before transmitting any electronic health records or health-related information;

(c) The Director determines that the exchange provides interoperable data, infrastructure and technology for the exchange of clinical data between and among health care providers and other persons involved in the provision of health care with quality and efficiency and allows for the secure transfer of clinical information;

(d) The Director determines that the exchange will be operational 24 hours a day, seven days a week, 99% of the time over the course of each month;

(e) The Director determines that the exchange will be interoperable on both an intrastate and interstate level so that the exchange is capable of transmitting information to other exchanges, health care providers and other persons involved in the provision of health care located in Nevada and in all other states and territories of the United States;

(f) The Director determines that the exchange has adequate privacy and security policies which comply with HIPAA and HITECH, as well as all other applicable federal and state laws;

(g) The Director approves the standards, submitted by the exchange, for routine electronic auditing of individual access to health-related information of patients; and

(h) The Director determines that the exchange complies with the specifications and protocols for exchanging electronic health records, health-related information and related data

prescribed pursuant to the provisions of HITECH and HIPAA, and other applicable federal and state law;

(i) The exchange submits the application for certification that includes items (a) to (h).

4. The Director may deny, suspend, or revoke a certification for failure to meet the requirements of Sec. 12, subsection 3, items (a) to (h). The Director shall provide written notice to the applicant via certified mail containing the legal authority, jurisdiction, and reasons for the denial.

5. Each health information exchange certified by the Director pursuant to this section must apply for recertification every 3 years.

Sec. 13.

1. A health information exchange shall not operate in this State without first obtaining certification. A health information exchange that is operational on the effective date of this regulation is automatically provisionally certified until it is certified by the Director pursuant to section 12 of this regulation. An automatic provisional certification obtained pursuant to this subsection expires 12 months after the effective date of this regulation.

2. A health information exchange which is provisionally certified pursuant to this section:

(a) May engage in the same activities as a health information exchange that is certified pursuant to section 12 of this regulation;

(b) Must comply with all relevant federal and state statutes and regulations governing health information exchanges;

3. When the Director denies, suspends or revokes a certification, a health information exchange may appeal the decision. The exchange may submit the appeal in writing to the Director. If the Director rejects the appeal, the exchange may elect to pursue a hearings process pursuant to the provisions of NRS 233B.121.

Request for hearing; scheduling of hearing.

An HIE which seeks to appeal a decision by the Director concerning denial, suspension, or revocation of a certification must file a written request for a hearing with the Director within 30 days after the date of the notice of decision from the Director.

The Director will schedule a hearing within 45 days after it receives the request for a hearing. Denial of request for hearing.

The Director may deny a request for hearing if the request is not received by the Director within the time limit set forth in Sec. 14(3)(1).

The Director may deny a request for hearing if it is determined that continued operation of the HIE may jeopardize patient information due to lack of adherence to HIPAA regulations.

Testimony under oath. All testimony to be considered in a hearing must be taken under oath. Conducting a hearing.

A hearing must be conducted in person by a hearing officer appointed by the Director.

An HIE may represent itself and may authorize a person represent the HIE, including, without limitation, an attorney.

Upon request, each party to the hearing shall submit to the hearing officer before the hearing copies of any evidence or exhibit the party will present during the hearing.

Decision of hearing officer.

The decision of a hearing officer must be in writing and be based exclusively on evidence presented at the hearing.

Within 30 days of the date of the hearing, the Director will send the decision of the hearing officer by certified mail to the HIE or its representative.

Sec. 14.

1. Electronic health records must be created, maintained and transmitted in accordance with the requirements of all applicable federal and state laws including, without limitation, in the manner authorized by HIPAA, HITECH, and implementing regulations.

2. Prescriptions that are created, maintained or transmitted electronically must be created, maintained or transmitted in the manner set forth in NRS 639.2353 and in the manner set forth in the regulations adopted by the State Board of Pharmacy related to the electronic transmission of prescriptions.

Sec. 15.

1. Each certified health information exchange shall:

(a) Ensure that only workforce members, agents and contractors, as defined by HIPAA, and HIPAA covered entities with which the exchange has a business associate agreement and who have a legitimate and appropriate need to use the exchange, or release or obtain information through the exchange, are able to access the exchange.

(b) Establish authorization policies and procedures for verifying the identity of all persons accessing health-related information of patients through the exchange. The ability of authorized users to access health-related information of patients through an exchange must be based on a minimum set of role-based access standards that apply to all participants in the exchange. The authorization policy must include, without limitation:

(1) A process and registry for verifying the identity and credentials of each person seeking authorization to access or exchange health-related information;

(2) A set of systems and a process to enable specific access permissions approved for the person seeking access; and

(3) A process for providing a person seeking authorization to access or exchange health-related information with the information and a mechanism to obtain authorization to access or exchange health-related information upon approval.

(c) Adopt and comply with national policies that require a minimum level of authentication for verifying the identity of all persons accessing health-related information of patients through the exchange.

(d) Establish procedures to verify that access to patient health-related information is consistent with the purposes outlined in Section 11, 1 c-g.

2. The infrastructure for each certified health information exchange must meet the physical, administrative, and technical safeguards as set forth under HIPAA regulations.

3. Each certified health information exchange must conduct a risk assessment of its administrative safeguards and identify risks and develop mitigation strategies. The exchange

must record access to the data by each user and maintain an audit trail of data accessed for a period of 6 years. Data must be encrypted and data moving within the system must be controlled by user authentication procedures and system protections. Each exchange must use integrity controls to protect the data and to assure that it has not been altered or tampered with during storage or transmission. User access must be routinely audited for compliance to HIPAA regulations and logs made available to the Director upon request.

4. Each person participating in any certified health information exchange shall comply with the standards established pursuant to this section.

Sec. 16.

1. Each person using any certified health information exchange shall provide or request health-related information through the exchange only:

(a) To the extent necessary;

(b) For those purposes that are permitted by applicable federal and state laws; and

(c) As authorized by the patient through his or her informed consent provided pursuant to section 18 of this regulation.

2. Information may not be requested or provided for a discriminatory purpose.

3. Except for disclosures to a health care provider for treatment purposes and disclosures required by law, a person:

(a) Shall disclose through any certified health information exchange system only the minimum amount of health-related information as is necessary for the intended purpose of the disclosure;

(b) Shall request only the minimum amount of health-related information as is necessary for the intended purpose of the request; and

(c) Shall not use, disclose or request the entire medical record of a patient except where specifically justified as the amount that is reasonably necessary to accomplish the intended purpose of the use, disclosure or request.

4. To ensure the confidentiality of electronic health records and health-related information, HIPAA covered entities must obtain a business associate agreement from each certified health information exchange with which they share Protected Health Information as set forth in 45 C.F.R. Part 164.504(e).

Sec. 17.

1. Except as otherwise provided in subsection 2 of NRS 439.538, health care providers and other persons involved in the provision of health care shall obtain the written informed consent of a patient before retrieving the patient's health care records from any certified health information exchange including, without limitation, the written consent of a child who has received health care services without the consent of a parent or guardian. Written informed consent from each patient is only required once. Written informed consent obtained pursuant to this section is valid until it is revoked in writing by the patient and submitted to any participating entity.

2. Informed consent obtained pursuant to this section must be voluntary and made with full transparency, be written in plain language, contain material information and education consistent with patient expectations, to include:

(a) A statement that consent is revocable at any time, and instructions on how to revoke consent.

(b) A statement that consent to participation in the exchange is not used for discriminatory purposes or given as a condition for receiving medical treatment.

(c) A statement authorizing the patient's health information be shared via the exchange, as evidenced by the signature of the patient and date signed.

3. A health care provider or other person involved in the provision of health care who obtains written informed consent pursuant to this section must provide the patient with a notice which explains the benefits and answers questions about health information exchange, without limitation the role and manner in which the information is collected, disclosed, accessed and the manner in which the information may be obtained in an emergency.

4. Each health care provider or other person involved in the provision of health care obtaining written informed consent pursuant to this section must document and maintain documentation of each patient's decision whether to allow his or her health care records to be retrieved electronically and whether to participate in a certified health information exchange.

5. Consent declarations made to any certified health information exchange shall apply to all certified health information exchanges in the state.

6. A health care provider or other person involved in the provision of health care must not withhold care from a person on the basis of that person's choice not to allow his or her health care records to be retrieved electronically from any certified health information exchange.

7. A patient may revoke his or her written informed consent at any time and for any reason by providing notice in writing of his or her revocation to any participant in any certified Health Information Exchange. The exchange shall accept and implement all requests for revocation.

8. Nothing in this section prohibits a health care provider or other person that is involved in the provision of health care from following the procedures established pursuant to 45 C.F.R. § 164.312(a)(2)(ii) for obtaining necessary electronic protected health information during an emergency.

9. Informed consent, educational materials, revocations, and other written notices may be delivered and obtained electronically, pursuant to the NRS 719 and 720.

10. Any written informed consent obtained prior to the effective date of this regulation and in compliance with HIPAA and other state and federal laws is considered valid.

Sec. 18.

A certified health information exchange shall adopt a reasonable method of incorporating revocations and amendments to records by its business associates as necessary to accurately reflect corrections in the health information exchange which have been made in accordance with the HIPAA privacy rule including, without limitation, the correction principle set forth in 45 CFR. § 164.526.

Sec. 19.

- 1. Any person who becomes aware of a violation of NRS 439.590 may file a complaint specifying the relevant facts with the Director, in the manner specified by the Director.*
- 2. A complaint must be made in writing on a form prescribed by the Director and be signed and verified, in the manner specified by the Director, by the person making it.*
- 3. The Director will determine which complaints to refer to the Office of the Attorney General for investigation, enforcement or referral to the appropriate district attorney.*
- 4. The Department of Health and Human Services will retain all complaints filed pursuant to this section for at least 6 years, including, without limitation, any complaints not acted upon.*

Sec. 20.

Except for information concerning a person who is a recipient of Medicaid or insurance pursuant to the Children's Health Insurance Program:

- 1. Electronic health records, health-related information and related data in a certified health information exchange belongs to the person who is the subject of the information, including a child who has received health care services without the consent of a parent or guardian, and except as excluded from access by HIPAA regulations; and*
- 2. The person who is the subject of an electronic health record, health-related information or related data in a certified health information exchange has the right to control the dissemination of such information through the informed consent process pursuant to Section 17.*

Sec. 21.

Any person using an electronic signature and electronic equivalents of written entities or written approval in the electronic movement, storage, analysis or exchange of electronic health records, health-related information and related data must do so in accordance with the provisions of chapter 719 and 720 of NRS and the Federal Electronic Signatures in Global and National Commerce Act, 15 U.S.C. § 7001 et seq.

Sec. 22.

- 1. A certified health information exchange, shall adopt a reasonable method to ensure patient notification, in the manner set forth in sections 13402 and 13407 of HITECH, if the exchange, provider, payer or person becomes aware that the confidentiality of information contained in an electronic health record of the patient is breached.*
- 2. Each certified health information exchange that becomes aware that the confidentiality of information contained in an electronic health record of a patient is breached by the exchange shall mitigate and take appropriate remedial action to remedy, to the extent practicable, any harmful effect that is known to the exchange to have resulted from the breach.*