

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

LCB File No. R173-24

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EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§ 1, 2, 7 and 8, NRS 439.588 and 439.589; §§ 3-6, 9 and 10, NRS 439.589.

A REGULATION relating to health information; prescribing the conditions under which a health care provider is deemed to meet certain requirements relating to the maintenance, transmission and exchange of electronic health information; prescribing requirements governing an application for a waiver from those requirements; requiring an electronic health record system to meet certain requirements; prohibiting certain requirements from being construed or interpreted to require a person or entity to use a health information exchange; prescribing certain requirements governing health information exchanges; authorizing certain uses of a health information exchange with the consent of a patient or as required or authorized by law; providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Director of the Department of Health and Human Services, in consultation with health care providers, third parties and other interested persons and entities, to prescribe by regulation a framework for the electronic maintenance, transmittal and exchange of electronic health records, prescriptions and health-related information. Existing law requires that framework to establish standards for networks and technologies to be used to maintain, transmit and exchange health information, including standards that require: (1) the ability for patients to access and forward their electronic health records; and (2) the interoperability of such networks and technologies. With certain exceptions, existing law requires health care providers and certain other persons and entities to maintain, transmit and exchange health information in accordance with the regulations adopted by the Director relating to health information technology. (NRS 439.589)

Section 4 of this regulation provides that a health care provider is deemed to satisfy such requirements if the health care provider maintains an electronic health record system which meets the requirements of **section 5** of this regulation or connects with a health information exchange which meets the requirements set forth in existing law and regulations and **sections 2-6** of this regulation for the operation of a health information exchange. (NRS 439.581-439.597; NAC 439.572-439.596) **Section 5** prescribes certain requirements for the operation and

functionality of an electronic health record system. **Section 3** defines the term “electronic health record system.” **Section 2** indicates the applicability of that definition and an existing definition of the term “covered entity.” **Section 7** of this regulation deletes duplicative language from that existing definition.

Existing law authorizes a health care provider to apply to the Department for a waiver from the requirement to maintain, transmit and exchange health information in accordance with the regulations adopted by the Director relating to health information technology on the basis that the health care provider does not have the infrastructure necessary for compliance. (NRS 439.589) **Section 4** requires an application for such a waiver to meet certain requirements and provides the process for the Department to consider such an application.

Section 6 provides that the regulations adopted by the Director relating to health information technology, including **sections 2-6**, must not be construed or interpreted to require a person or entity to use a health information exchange.

Existing regulations require a health information exchange that operates in this State to: (1) comply with applicable requirements of federal and state law; (2) have certain operational capabilities; and (3) be accredited. (NAC 439.576) **Section 8** of this regulation additionally requires such a health information exchange to: (1) be a member of the Trusted Exchange Framework and Common Agreement, or its successor; and (2) meet certain operational requirements.

Existing regulations require a health information exchange to ensure that only covered entities who have entered into a business associate agreement and certain other persons who have a legitimate need to use the health information exchange are allowed to use the health information exchange. (NAC 439.584) Existing regulations generally prohibit a person from using, retrieving or disclosing more health information using a health information exchange than is necessary to accomplish the purpose of the use, retrieval or disclosure. (NAC 439.588) **Sections 9 and 10** of this regulation provide an exception to those restrictions on the use of a health information exchange if the patient or his or her legal representative consents to such use or the use is otherwise required or authorized by existing law.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 6, inclusive, of this regulation.

Sec. 2. *As used in NAC 439.572 to 439.596, inclusive, and sections 2 to 6, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in NAC 439.572 and section 3 of this regulation have the meanings ascribed to them in those sections.*

Sec. 3. *“Electronic health record system” means technology that:*

1. Has the ability to securely maintain, transmit and exchange electronic health information; and

2. Makes protected health information instantly and securely available to authorized users.

Sec. 4. 1. A health care provider shall be deemed to satisfy the requirements of subsection 4 of NRS 439.589 if the health care provider:

(a) Maintains an electronic health record system which meets the requirements of section 5 of this regulation; or

(b) Connects with a health information exchange which meets all applicable requirements of NRS 439.581 to 439.597, inclusive, and NAC 439.572 to 439.596, inclusive, and sections 2 to 6, inclusive, of this regulation.

2. An application for a waiver from the provisions of subsection 4 of NRS 439.589 must include a written statement signed by the health care provider which certifies that the health care provider meets the requirements set forth in subsection 6 of NRS 439.589 and any other documentation requested by the Department. The Department will consider each application individually and provide written notice of its determination to the applicant.

Sec. 5. To satisfy the requirements of NRS 439.589, an electronic health record system must:

1. Be certified by the Office of the National Coordinator for Health Information Technology of the United States Department of Health and Human Services.

2. Comply with all requirements governing the exchange, security and disclosure of electronic health records, health-related information and related data prescribed in the Health Information Technology for Economic and Clinical Health Act of 2009, 42 U.S.C. §§ 300jj et seq. and 17901 et seq., the Health Insurance Portability and Accountability Act of 1996,

Public Law 104-191, and any other applicable federal or state law and the regulations adopted pursuant thereto.

3. Securely exchange, integrate or cooperatively use electronic health information with other electronic health record systems in compliance with any applicable standards for the interoperability of health information prescribed by the Federal Government, including, without limitation, any applicable standards for the interoperability of Qualified Health Information Networks prescribed and designated by the Office of the National Coordinator for Health Information Technology of the United States Department of Health and Human Services.

4. Provide for the electronic transmission of prior authorizations for prescription medication.

5. Adhere to nationally recognized best practices for the secure maintenance, transmission and exchange of electronic health information.

Sec. 6. *The provisions of NAC 439.572 to 439.596, inclusive, and sections 2 to 6, inclusive, of this regulation must not be construed or interpreted to require any person or entity to use a health information exchange.*

Sec. 7. NAC 439.572 is hereby amended to read as follows:

439.572 ~~As used in NAC 439.572 to 439.596, inclusive, unless the context otherwise requires, “covered~~ **“Covered** entity” has the meaning ascribed to it in 45 C.F.R. § 160.103.

Sec. 8. NAC 439.576 is hereby amended to read as follows:

439.576 A health information exchange that operates in this State must:

1. Comply with all applicable requirements of the Health Information Technology for Economic and Clinical Health Act of 2009, 42 U.S.C. §§ 300jj et seq. and 17901 et seq., the

Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and any other applicable federal or state law and the regulations adopted pursuant thereto, including, without limitation, requirements relating to the specifications and protocols for exchanging and maintaining electronic health records, health-related information and related data and the protection of the privacy and security of health information;

2. *Be a member of the Trusted Exchange Framework and Common Agreement, or its successor, developed or supported pursuant to 42 U.S.C. § 300jj-11(c)(9)(B);*

3. Facilitate the sharing of health information across the public and private sectors to increase efficiency and improve outcomes of health care in this State;

~~{3.}~~ 4. Support public health and population health initiatives and collaboration between organizations and governmental entities working in the fields of public health and population health;

~~{4.}~~ 5. Provide services to users of the health information exchange to assist the users in meeting the meaningful use requirements pursuant to the criteria prescribed in the Health Information Technology for Economic and Clinical Health Act of 2009, 42 U.S.C. §§ 300jj et seq. and 17901 et seq. and any other applicable federal statute or regulation;

~~{5.}~~ 6. Use an enterprise master patient index and a master provider index for the secure and efficient exchange of health information;

~~{6.}~~ 7. Provide interoperable infrastructure and technology for the efficient and secure exchange of information, including, without limitation, clinical data, between health information exchanges, health care providers and other persons involved in the provision of health care;

~~{7.}~~ 8. Be operational for at least 99 percent of each month; ~~and~~
~~—8.~~

9. Hold a nationally recognized accreditation for health information exchanges or meet comparable accreditation standards approved by the Director **H**;

10. Operate a secure exchange network in which health care providers and other authorized users are able to share information from different electronic health record systems; and

11. Provide for query and response communications and notifications for the delivery and receipt of exchanged materials.

Sec. 9. NAC 439.584 is hereby amended to read as follows:

439.584 1. A health information exchange shall:

(a) Ensure that *, except as consented to by a patient or his or her legal representative pursuant to NAC 439.592 or as otherwise required or authorized by law*, only covered entities with which the health information exchange has entered into a business associate agreement as described in NAC 439.588 and members of the workforces, contractors and agents of such covered entities who have a legitimate need to use the health information exchange are allowed to use the health information exchange.

(b) Establish policies and procedures to verify the identity of all persons who wish to retrieve or disclose the health information of patients using the health information exchange. The policies and procedures must include, without limitation:

(1) A process for verifying the identity and credentials of each person seeking authorization to retrieve or disclose health information and a registry of authorized users.

(2) Standards and procedures for determining whether a person is authorized to retrieve or disclose health information using the health information exchange. These standards and

procedures must be based on the role of the user and must apply to each user of the health information exchange.

(3) Systems and procedures for determining whether an authorized user is allowed to retrieve the health information of a patient and providing a person with health information that the person is authorized to retrieve.

(c) Adopt and comply with a policy that has been established by a nationally recognized organization or approved by the Director for authenticating the identity of all persons retrieving or disclosing health information using the health information exchange.

(d) Establish procedures to verify that access to health information on the health information exchange is consistent with the requirements of NAC 439.576.

(e) Create a record each time health information is retrieved using the health information exchange and maintain such records for at least 6 years after the date on which the record is created.

(f) Ensure that all data is encrypted and use integrity controls to ensure that data is not altered or tampered with during storage or transmission.

2. Any person who retrieves or discloses health information using a health information exchange shall comply with the policies and procedures adopted by the health information exchange pursuant to subsection 1.

3. A prescription may be created, maintained or transmitted using a health information exchange in accordance with NRS 639.2353 and any applicable regulations adopted by the State Board of Pharmacy.

4. As used in this section, “workforce” has the meaning ascribed to it in 45 C.F.R. § 160.103.

Sec. 10. NAC 439.588 is hereby amended to read as follows:

439.588 1. Except ~~for a disclosure for the purpose of treating~~ *as consented to by* a patient *or his or her legal representative pursuant to NAC 439.592* or as otherwise required *or authorized* by law, a person shall not use, retrieve or disclose more health information using a health information exchange than is necessary to accomplish the purpose of the use, retrieval or disclosure.

2. A person shall not use, retrieve or disclose health information using a health information exchange for a purpose prohibited by law, including, without limitation, discrimination prohibited by federal or state law.

3. ~~+~~ *Except as consented to by a patient or his or her legal representative pursuant to NAC 439.592 or as otherwise required or authorized by law, a* person shall not retrieve health information from a health information exchange unless the person has entered into a business associate agreement that is consistent with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

4. Electronic transmittal of electronic health records, prescriptions and health-related information, electronic signatures, electronic equivalents of written entries and written approvals must comply with the provisions of chapters 719 and 720 of NRS and the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. §§ 7001 et seq.