ADOPTED REGULATION OF

THE DIRECTOR OF THE DEPARTMENT

OF HEALTH AND HUMAN SERVICES

LCB File No. R056-16

Effective _____, 2017

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

AUTHORITY: §1, NRS 439.587, 439.588, 439.589 and 439.590; §§2-5, NRS 439.587, 439.588 and 439.589; §§6 and 13, NRS 439.587 and 439.588; §§7-10 and 12, NRS 439.587 and 439.589; §11, NRS 439.587, 439.588 and 439.590.

A REGULATION relating to health information exchanges; prescribing requirements governing the retrieval, disclosure, maintenance and use of information using a health information exchange; establishing the manner in which a health information exchange applies to the Director of the Department of Health and Human Services for certification; authorizing a health information exchange whose certification has been denied, suspended or revoked to request an administrative hearing under certain circumstances; authorizing a person who becomes aware of violations of certain provisions of law governing health information exchanges to submit a complaint to the Director; requiring a health information exchange to take certain actions if the confidentiality of information disclosed, retrieved or maintained using the health information exchange is breached; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law defines the term "health information exchange" as a person who makes available an electronic means of connecting disparate electronic systems on which health-related information is shared. A health information exchange must: (1) be made commercially available to health care providers and certain other persons involved in the provision of health care; and (2) allow the secure transfer of health information concerning a patient to any health care provider who provides services to the patient. (NRS 439.584) **Section 3** of this regulation interprets the term "commercially available."

Existing law: (1) prohibits a health information exchange from operating in this State unless it is certified by the Director of the Department of Health and Human Services; and (2) requires the Director to prescribe regulations governing the certification and operation of a health information exchange. (NRS 439.587-439.589) **Section 4** of this regulation requires a health information exchange to: (1) comply with applicable requirements of federal and state law; (2) have certain operational capabilities; and (3) be accredited. **Section 5** of this regulation

prescribes requirements for an application for certification of a health information exchange and requires the certification to be renewed every 3 years. **Sections 7 and 9** of this regulation prescribe who may use a health information exchange. **Section 7** also requires a health information exchange to adopt certain policies and procedures to regulate access to and ensure the security of information retrieved, disclosed or maintained using the health information exchange. **Section 8** of this regulation requires a health information exchange to perform routine audits and annual risk assessments to ensure the safety of health information and compliance with federal law. **Section 9** prohibits a user of a health information exchange from: (1) using, retrieving or disclosing more health information than necessary from the health information exchange; or (2) using health information from a health information exchange for a prohibited purpose.

Existing law: (1) authorizes the Director to deny, suspend or revoke the certification of a health information exchange under certain circumstances; and (2) authorizes a health information exchange that wishes to contest the denial, suspension or revocation of its certification to appeal to the Director. (NRS 439.588) **Section 6** of this regulation authorizes a health information exchange to request an administrative hearing if such an appeal is denied and provides for the appointment of a hearing officer. **Section 6** also authorizes a health information exchange to be represented at such a hearing and imposes certain requirements concerning the presentation of evidence and the rendering of a decision.

Existing law requires the Director to prescribe by regulation, in consultation with the State Board of Pharmacy, standards for the electronic transmission of prior authorizations for prescription medication using a health information exchange. (NRS 439.587) **Section 7** authorizes a prescription to be created, maintained or transmitted using a health information exchange in accordance with certain provisions of state law and regulations governing the transmission and contents of a prescription.

Existing law requires the Director to prescribe regulations for making any necessary corrections to information or records retained or shared by a health information exchange. (NRS 439.589) **Section 8** requires a health information exchange to: (1) adopt a standard procedure for incorporating amendments to records made by authorized users of the health information exchange; and (2) notify an authorized user who has disclosed information using the health information exchange of any error in the information.

Existing law requires the Director to prescribe by regulation standards for the electronic transmittal of electronic health records, prescriptions, health-related information, electronic signatures and requirements for the electronic equivalents of written entries or written approvals. (NRS 439.587) **Section 9** requires the electronic transmittal of electronic health records, prescriptions, health-related information, electronic signatures and requirements for electronic equivalents of written entries or written approvals to comply with certain provisions of state and federal law.

Existing law requires the Director to prescribe by regulation: (1) standards for obtaining consent from a patient before retrieving the patient's health records from a health information exchange; and (2) the manner in which a patient may revoke such consent. (NRS 439.589) **Section 10** of this regulation provides that any health information concerning a patient who is

authorized under state law to opt out of electronic disclosure of health information that is disclosed, retrieved or maintained using a health information exchange belongs to the patient. **Section 10** also: (1) requires a person to obtain the informed written consent of a patient before retrieving the health information of the patient from a health information exchange; and (2) prescribes procedures for providing and revoking such consent.

Existing law requires the Director to adopt regulations establishing the manner in which a person may file a complaint with the Director regarding a violation of certain provisions of law. (NRS 439.588, 439.590) **Section 11** of this regulation provides that any person who becomes aware of such a violation may submit a written, signed complaint in the form prescribed by the Director.

Existing law requires the Director to prescribe by regulation standards for notifying a patient if the confidentiality of information contained in an electronic health record is breached. (NRS 439.589) **Section 12** of this regulation requires a health information exchange to: (1) notify a patient in a manner that complies with federal law if the confidentiality of information concerning the patient that is disclosed, retrieved or maintained using the health information exchange is breached; and (2) take any appropriate measures to mitigate or remediate damage caused by the breach.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 12, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 12, inclusive, of this regulation, unless the context otherwise requires, "covered entity" has the meaning ascribed to it in 45 C.F.R. § 160.103.***

Sec. 3. ***As used in NRS 439.584, the Director will interpret the term "commercially available" to mean that information is available for a fee to any health care provider or other covered entity who is authorized to use a health information exchange pursuant to section 7 of this regulation, regardless of the relationship of the health care provider or other covered entity to other users of a health information exchange.***

Sec. 4. ***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. 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. 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. 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. Use an enterprise master patient index and a master provider index for the secure and efficient exchange of health information;

6. 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. Be operational for at least 99 percent of each month; and

8. Hold a nationally recognized accreditation for health information exchanges or meet comparable accreditation standards approved by the Director.

Sec. 5. *1. A health information exchange that operates or wishes to operate in this State shall apply to the Director for certification pursuant to NRS 439.588, or for the renewal of such certification, as applicable, in the form prescribed by the Director. The application must include, without limitation:*

(a) Proof that the applicant meets the requirements of section 4 of this regulation and is operationally and financially sustainable;

(b) The standards for routine auditing of access to health information of patients as required by section 8 of this regulation that the applicant intends to use; and

(c) Any other information requested by the Director.

2. The certification of a health information exchange must be renewed every 3 years.

Sec. 6. *1. If the Director denies a written appeal submitted pursuant to subsection 4 of NRS 439.588, the health information exchange may request an administrative hearing in the manner described in NRS 233B.121. The request must be made in writing and submitted to the Director within 30 days after the date of the notice of the decision of the Director to reject the written appeal. The failure of the health information exchange to request a hearing within this period operates as a waiver of the right of the health information exchange to request such a hearing.*

2. Except as otherwise provided in this subsection, the Director will schedule a hearing not later than 45 days after receiving a timely request for a hearing pursuant to subsection 1. The Director may deny a request for a hearing if he or she determines that, because the health information exchange is not in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, or the regulations adopted pursuant thereto, information concerning patients may not be secure.

3. If the Director schedules a hearing pursuant to subsection 2, he or she will appoint a hearing officer to conduct the hearing. If the health information exchange is a natural person, he or she may represent himself or herself at the hearing. A health information exchange may authorize any person, including, without limitation, an attorney, to represent the health information exchange at the hearing.

4. The hearing officer may request each party to submit, in advance of the hearing, copies of any evidence or exhibits that the party plans to present at the hearing. All testimony received at a hearing must be given under oath. The decision of the hearing officer must be based exclusively on the evidence and testimony presented at the hearing.

5. Within 30 days after the date of a hearing, the Director will provide the written decision of the hearing officer to the health information exchange by certified mail.

Sec. 7. *1. A health information exchange shall:*

(a) Ensure that only covered entities with which the health information exchange has entered into a business associate agreement as described in section 9 of this regulation 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 section 4 of this regulation.

(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, as amended by section 61 of Assembly Bill No.

474, chapter 605, Statutes of Nevada 2017, at page 4436, 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. 8. *A health information exchange shall:*

1. Routinely audit access to health information by users of the health information exchange to ensure that such access complies with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and make the records of such audits available to the Director upon request;

2. Annually conduct a risk assessment of measures taken by the health information exchange to safeguard the health information of patients and develop strategies for mitigating the risk of unauthorized access to such information;

3. Adopt a standard procedure for incorporating revocations of consent made pursuant to section 10 of this regulation and amendments to records made by authorized users of the health information exchange in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191; and

4. If the health information exchange becomes aware of an error in information disclosed using the health information exchange, notify the authorized user who disclosed the information of the error.

Sec. 9. *1. Except for a disclosure for the purpose of treating a patient or as otherwise required 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. 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.

Sec. 10. *1. Except for health information concerning a patient who is prohibited by NRS 439.538 from opting out of electronic disclosure of individually identifiable health information, health information concerning a patient, including, without limitation, a child under 18 years of age who has received health care services without the consent of a parent or guardian, that is retrieved, disclosed or maintained using a health information exchange belongs to the patient. A patient may control access to such information by providing or refusing to provide informed written consent in the manner prescribed by this section.*

2. Except as otherwise provided in subsection 7, a person shall, before retrieving the health information of a patient that belongs to the patient pursuant to subsection 1 from a health information exchange:

(a) Provide the patient with a statement of information about health information exchanges, including, without limitation, the manner in which health information is collected, retrieved and disclosed using the health information exchange; and

(b) Obtain informed written consent from the patient or the legal representative of the patient.

3. Informed written consent obtained pursuant to subsection 2 must be voluntary and must be given on a form signed by the patient or the legal representative of the patient that is written in plain language and contains sufficient information for the patient to make a fully informed decision, including, without limitation:

(a) Information concerning the manner in which health information is collected, retrieved and disclosed using the health information exchange;

(b) A statement of the provisions of subsections 5, 6 and 7; and

(c) A statement that the health information of the patient may be retrieved from the health information exchange if the patient provides consent by signing the form.

4. A person who requests informed written consent pursuant to this section shall maintain a record of the patient's consent or refusal to consent for at least 6 years after the date on which the consent or refusal is executed.

5. A person shall not use informed written consent for any purpose prohibited by law, including, without limitation, discrimination prohibited by federal or state law, or require informed written consent as a condition of receiving medical treatment.

6. Informed written consent provided pursuant to this section is valid until revoked. A patient may revoke his or her informed written consent at any time and for any reason by providing written notice of the revocation to a person who is authorized to retrieve or disclose health information using a health information exchange pursuant to section 7 of this regulation. A person who receives such a revocation shall communicate the revocation to the

health information exchange. A health information exchange shall accept and carry out any such revocation communicated to the health information exchange.

7. A health care provider may retrieve the health information of any patient from a health information exchange without obtaining informed written consent from the patient:

(a) During an emergency using the procedures adopted pursuant to 45 C.F.R. § 164.312(a)(2)(ii); or

(b) If the patient is prohibited by NRS 439.538 from opting out of having his or her individually identifiable health information disclosed electronically.

8. Any informed written consent provided by a patient for a person to retrieve the health information of the patient from a health information exchange that is executed before the effective date of this regulation and complies with all applicable state and federal laws, including, without limitation, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, is valid until such informed written consent is revoked in the manner prescribed by subsection 6.

9. Any notice, information, revocation or signature described in this section may be delivered or obtained electronically in conformance with the requirements of chapters 719 and 720 of NRS.

Sec. 11. *1. Any person who becomes aware of a violation of the provisions of NRS 439.588 or 439.590 may submit to the Director a written, signed complaint in the form prescribed by the Director. The Director will determine whether to take action concerning the complaint, which may include, without limitation, referring the complaint to the Office of the Attorney General or the appropriate district attorney for investigation.*

2. The Department will retain all complaints submitted pursuant to this section for at least 6 years, regardless of whether action is taken concerning the complaint.

Sec. 12. *If the confidentiality of information contained in an electronic record of a patient that is retrieved, disclosed or maintained using a health information exchange is breached, the health information exchange shall:*

1. Notify the patient of the breach in a manner that meets the 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

2. Take any appropriate action to mitigate or remediate any damage caused by the breach.

Sec. 13. 1. A health information exchange that is operating in this State on the effective date of this regulation shall be deemed to be certified pursuant to NRS 439.588:

(a) Until, on and after the date its application for certification is approved by the Director of the Department of Health and Human Services;

(b) Until the date its application is denied by the Director; or

(c) Until the expiration of 1 year after the effective date of this regulation,

➥ whichever occurs first.

2. Nothing contained in this section shall be deemed to restrict the authority of the Director of the Department of Health and Human Services to suspend or revoke the certification of a health insurance exchange pursuant to NRS 439.588.

3. As used in this section, "health information exchange" has the meaning ascribed to it in NRS 439.584.

BRIAN SANDOVAL
Governor

RICHARD WHITLEY, MS
Director

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INFORMATIONAL STATEMENT
FOR THE ADOPTION OF REGULATION

STATE OF NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES
LCB FILE NO. R-056-16

The Director of The Division of Health and Human Services adopted regulation assigned LCB File No. R-056-16 which pertains to Chapter 445A of the Nevada Administrative Code.

1. Explanation of need for and the purpose of the proposed regulation.
Under existing law, the Director of the Department of Health and Human Services is required to establish a statewide health information exchange system and a governing entity for the system. SB48, enacted in the 78th Legislative Session, eliminated the requirement that the Director establish a statewide health information exchange (HIE), and requires the Director to establish a regulation for health information exchanges. This proposed regulation prescribes the requirements for a statewide health information exchange.

2. Explanation of how public comment was solicited, a summary of public response, and an explanation of how other interested persons may obtain a copy of this summary.
A Public Workshop was held on June 9, 2016 at 10:00 am. Notice of the meeting was posted on the DHHS and DHCFP websites, the DHCFP Carson City Central Office and the Las Vegas office. It was also posted at the following public libraries: Nevada State Library; Carson City Library; Churchill County Library; Las Vegas Library; Douglas County Library; Elko County Library; Esmeralda County Library; Lincoln County Library; Lyon County Library; Mineral County Library; Tonopah Public Library; Pershing County Library; Goldfield Public Library; Eureka Branch Library; Lander County Library; Storey County Library; Washoe County Library; and White Pine County Library. In addition, 501 stakeholders were emailed from the Health Information Technology (HIT) stakeholders

email list which was developed by the Nevada HIE Board and the Division of Health Care Finance and Policy Provider Association List. Also, multiple stakeholder meetings were held to solicit stakeholder feedback.

The Public Workshop, held at the State of Nevada Division of Health Care Financing and Policy, 1100 East William Street, 2nd floor conference room, Carson City, Nevada 89701, focused on letters and emails received from Stakeholders. The comments dealt with making sure the Health Information Exchange (HIE) is very effective in the state and that stakeholders support the regulation. The comments also addressed that the HIE not only be operational 99% of the time, but is accessible by providers that often. Comments also focused on making sure the regulation was consistent with the Board of Pharmacy regulation governing electronic prescriptions. Additionally, comments regarding the Health Information Exchange (HIE) recognizes that if there has been a breach, they will make sure that the covered entity is aware and can notify the patient. A copy of the Workshop Minutes can be obtained at http://dhhs.nv.gov/Programs/HIT/.

The number of persons attending this workshop was 16. Those that provided oral or written comment at this workshop are:

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A Public Hearing to adopt the regulation was held on April 13, 2017 at 10:00 am. Distribution of the notice for that Public Hearing was the same as the Public Workshop above.

Public comment was supportive of the adoption of the regulation.

The number of persons attending the Public Hearing was 12. Those that provided oral or written comment at this Public Hearing are:

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3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Comments were solicited from stakeholders through multiple emails to all 501 stakeholders and through the June 9, 2016 Public Workshop held at the State of Nevada Division of Health Care Financing and Policy, 1100 East William Street, 2nd floor conference room, Carson City, Nevada 89701. Furthermore, multiple stakeholder meetings were held to solicit stakeholder feedback. A summary of comments can be obtained at **http://dhhs.nv.gov/Programs/HIT/**.

4. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation of how other interested persons may obtain a copy of the summary. In addition to the above outreach, a Small Business Impact Statement, also available at the above web address, was sent to 501 stakeholders. Two comments received were supportive of a regulatory framework to assist Health Information Exchange participants to determine if there is a low risk of participation, and to increase participation. It was also noted that clarification of the consent process may foster additional HIE adoption. A summary of comments can be obtained at **http://dhhs.nv.gov/Programs/HIT/**.

5. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change.
The permanent regulation was adopted at the State of Nevada, Department of Health and Human Service hearing to adopt regulation on April 13, 2017. The regulation was adopted with an Errata – LCB File No. R056-16 which changed the language in Sec. 10. 1. from "is the property of" to "belongs to" and Sec. 10. 2. from "is the property of" to "belongs to."

6. The estimated economic effect of the adopted regulation on the businesses that it is to regulate and on the public. These must be stated separately, and each case must include: (a) Both adverse and beneficial effects; and (b) Both immediate and long-term effects.
a. The proposed revisions are expected to have an immediate or long-term beneficial economic effect upon the regulated community. The benefits are associated with improved medical care via immediate access to medical histories, which cannot be estimated at this time. No adverse economic effects are anticipated.

7. The estimated cost to the agency for enforcement of the adopted regulation.
There is no additional cost to the agency for enforcement of this regulation.

8. A description of any regulations of other state or government agencies that the proposed regulation overlaps or duplicates, and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, the name of the regulating federal agency.
There are no other state or government agency regulations that the proposed regulation duplicates. However, the regulation does cite NRS where it pertains to the HIE definitions, Federal HITECH Act and HIPAA privacy laws.

9. If the regulation includes provisions that are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.
This regulation does not include any provisions that are more stringent than any federal regulation that regulates the same activity.

10. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.
This regulation does not provide or involve a new fee, and hence since no fee is involved. There is not a total amount expected to be collected or used.