

DEPARTMENT OF HEALTH AND HUMAN SERVICES



Stacie Weeks, JD MPH Administrator

DIVISION OF HEALTH CARE FINANCING AND POLICY Helping people. It's who we are and what we do.

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NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption of Permanent Regulations of the Department of Health and Human Services (DHHS),

Division of Health Care Financing and Policy (DHCFP)

DHCFP will hold a public hearing to receive comments from all interested persons regarding the Adoption of regulations that pertain to chapter 439 of the Nevada Administrative Code (NAC).

Thursday, October 31, 2024, at 10:30 a.m.

Division of Health Care Financing and Policy Main Conference Room 4070 Silver Sage Drive Carson City, NV 89701

Teleconference/Microsoft Teams Option

Join the Meeting at https://tinyurl.com/NAC103124
Call in by Phone (audio only) at (775) 321-6111, Event Number 124 857 871#
Please MUTE your phone while listening to the meeting, except when making public comment

The following information is provided pursuant to the requirements of NRS 233B.0603:

DHCFP, on behalf of the Department, is providing the following statements pertaining to the public hearing on the proposed 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 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 required by Nevada Revised Statute (NRS) 439.589 [Effective July 1, 2024].

1. Need and Purpose of Proposed Regulation.

Revisions to Nevada Administrative Code (NAC) Chapter 439 have been proposed in accordance with Assembly Bill (AB) 7 of the 2023 (82nd) Legislative Session. The development of this bill emerged from the Patient Protection Commission in recognizing the lack of electronic accessibility patients may experience through visiting a variety of health care

providers. This bill requires all providers of health care, as defined per NRS 629.031 – unless otherwise exempted – to implement an interoperable electronic health records system by January 1, 2030. Furthermore, Section 2.7(1.) of the bill reads: on or before July 1, 2023, the Director of the Department shall convene an advisory group to advise the Director of the DHHS in the adoption of regulations pursuant to NRS 439.589, as amended by section 1.08 of this act.

In response, the Electronic Health Information Advisory Group (EHIAG) was first convened on March 7, 2024, for the specific purpose to advise the DHHS Director in the adoption of regulations pursuant to NRS 439.589 [effective July 1, 2024]. The EHIAG conducted four, open public meetings to develop proposed regulatory language, approved on June 17, 2024, in prescribing a framework for the electronic maintenance, transmittal and exchange of electronic health records, prescriptions, health-related information and electronic signatures and requirements for electronic equivalents of written entries or written approvals in accordance with federal law, as directed through NRS 439.589.

2. Access to Proposed Regulation Prepared by Legislative Counsel Bureau (LCB).

Access to text of the proposed regulations prepared by the Legislative Counsel Bureau pursuant to NRS 233B.063, may be obtained by visiting the website of the Nevada Legislature at https://www.leg.state.nv.us/, hovering over the term "Law Library," hovering over the term "Nevada Register." Clicking upon the term "Browse," and then clicking upon the term "Numerical Index" appearing under the Category "2024 Regulations." Access may then be obtained by simply scrolling down the list of LCB File Numbers to seek "R173-24" and then specifically clicking upon the designation "R173-24P."

For immediate access to the document, please click on the following link: http://www.leg.state.nv.us/Register/2024Register/R173-24P.pdf

3. Estimated Economic Effects on Businesses.

- a. Adverse: Initial onboarding and set-up costs for businesses to comply with the electronic maintenance, transmittal and exchange of electronic health records requirements.
- b. Beneficial: grant opportunity for eligible providers and medical facilities as appropriated through AB 7 to help offset initial costs in compliance with this requirement.
- c. Immediate: Onboarding and set-up costs for businesses to comply with this requirement.
- d. Long-Term: Recurring maintenance costs for businesses to comply with this requirement.

4. Estimated Economic Effects on the Public.

- a. Adverse: No adverse/negative public effects identified.
- b. Beneficial: Improved direct patient access to their health records and health information electronically.
- c. Immediate: Enhanced access to personal health care data electronically and ability to forward health records electronically to other health care providers and individuals of the patient's choosing.
- d. Long-Term: Improved electronic health information communication and interoperability.

5. Methods Used to Determine the Impact on Small Businesses.

Pursuant to NRS 233B.0608(2)(a), DHCFP requested input from Nevada-licensed and regulated providers of health care. A survey questionnaire was sent electronically to all licensing boards and agencies associated with the list of "provider of health care" defined in NRS 629.031, asking for the licensing board or agency to deploy the survey to their licensees broadly, on May 20, 2024.

AB 7 appropriated funding to DHHS to award grants to providers of health care and medical facilities for the purposes of complying with the new requirements set forth by the bill. DHCFP received a total of 3,035 responses. The survey first gave an overview of the requirements of AB 7 and outlined the grant program for the appropriated funding.

Based on the quantitative and qualitative data received through the survey questionnaire, the several discussions and deliberations of the EHIAG surrounding the proposed regulations, and the availability of grant funding directed specifically toward a subset of small businesses to support implementing the requirements of AB 7, it would be fair to conclude the impact of the framework proposed through the draft regulations for health information maintenance, transmittal and exchange to be minimal to small businesses as defined by NRS 233B. The Division concludes that there is minimal adverse impact on small businesses in Nevada.

6. Estimated Costs to the Agency for Enforcement.

The estimated cost to the agency for enforcement of the proposed regulation includes administrative costs, and costs for ongoing monitoring and compliance activities which is expected to be managed within the current budget of the Department.

7. Overlap or Duplication with Other Regulations.

The proposed regulations do not overlap or duplicate any other Nevada state or federal regulations.

8. Whether the Proposed Regulations are Required by Federal Law.

The proposed regulations are not required by federal law. However, per the direction provided in AB 7, the proposed regulations are in alignment with federal best practices and in accordance with federal law. Specifically, the Trusted Exchange Framework and Common Agreement developed under section 3001(c)(9)(B) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(9)(B)), in the Federal Register, prescribed by the Office of the National Coordinator for Health Information Technology of the United States Department of Health and Human Services; the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 300jj et seq. and 17901 et seq., the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

9. Provisions More Stringent than Federal Regulation.

None known at the time of this posting. This is a state-driven regulation pursuant to NRS legislation.

10. New or Increased Fees.

The proposed regulations do not establish a new fee or increase an existing fee.

Persons wishing to comment upon the proposed action of DHCFP may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to:

Division of Health Care Financing and Policy Attn: Malinda Southard 1100 E William Street, Suite 101 Carson City, NV 89701

Written submissions must be received by DHCFP on or before **October 31, 2024**. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, DHCFP may proceed immediately to act upon any written submissions. A copy of this notice and the regulation to be Adopted will be on file at the State Library, Archives and Public Records, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be Adopted will be available at Division of Health Care Financing and Policy, 1100 E. William Street, Suite 101, Carson City, Nevada and online at https://dhcfp.nv.gov/ and https://dhcfp.nv.gov/ and copying by members of the public during business hours.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations, which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us/. Copies of this notice and the proposed regulation will also be mailed to members of the public at no charge upon request. Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Division of Health Care Financing and Policy 4070 Silver Sage Drive Carson City, NV 89701

Division of Health Care Financing and Policy 1010 Ruby Vista Drive, Suite 103 Elko, NV 89801

Division of Health Care Financing and Policy 1210 S. Valley View Blvd. Las Vegas, NV 89102

Division of Health Care Financing and Policy 745 W. Moana Lane, Suite 200 Reno, NV 89509

Nevada State Library and Archives 100 Stewart Street Carson City, NV 89701

> Grant Sawyer Building 555 E. Washington Avenue Las Vegas, NV 89101

Copies may also be obtained from any of the public libraries listed below:

Carson City Library 900 North Roop Street Carson City, NV 89702

Churchill County Library 553 South Main Street Fallon, NV 89406

Clark County District Library 833 Las Vegas Boulevard North Las Vegas, NV 89101

> Douglas County Library 1625 Library Lane Minden, NV 89423

Elko County Library

720 Court Street Elko, NV 89801

Esmeralda County Library Corner of Crook and 4th Street Goldfield, NV 89013

Eureka Branch Library 210 South Monroe Street Eureka, NV 89316

Henderson District Public Library 280 South Water Street Henderson, NV 89105

> Lander County Library 625 South Broad Street

Battle Mountain, NV 8982

Lincoln County Library 63 Maine Street Pioche, NV 89043

Lyon County Library 20 Nevin Way Yerington, NV 89447

Mineral County Library 110 1st Street Hawthorne, NV 89415 Pahrump Library District 701 East Street Pahrump, NV 89041

Storey County Library 95 South R Street Virginia City, NV 89440

Washoe County Library 301 South Center Street Reno, NV 89505



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PUBLIC HEARING AGENDA NOTICE OF INTENT FOR THE ADOPTION OF REGULATIONS

NOTICE IS HEREBY GIVEN that the State of Nevada, Department of Health and Human Services (DHHS), Division of Health Care Financing and Policy (DHCFP) will hold a public hearing to consider amendments to Chapter 439 of Nevada Administrative Code (NAC), Administration of Public Health.

Date of Publication: September 30, 2024

Date and Time of Meeting: October 31, 2024, at 10:30 AM

Name of Organization: The State of Nevada, Department of Health and Human Services (DHHS), Division of

Health Care Financing and Policy (DHCFP)

Place of Meeting: In-Person at DHCFP

4070 Silver Sage Drive Main Conference Room Carson City, Nevada 89701

Or

Microsoft Teams

Space is limited at the physical location and subject to any applicable social distancing or mask wearing requirements as may be in effect at the time of the meeting for the county in which the physical meeting is held.

Please use the teleconference/Microsoft Teams options provided below. If accommodations are requested, please advise using the information at the end of this agenda.

Note: If at any time during the meeting an individual who has been named on the agenda or has an item specifically regarding them included on the agenda is unable to participate because of technical or other difficulties, please email Jenifer Graham at documentcontrol@dhcfp.nv.gov and note at what time the difficulty started so that matters pertaining specifically to their participation may be continued to a future agenda if needed or otherwise addressed.

Please be cautious and do not click on links in the chat area of the meeting unless you have verified they are safe. If you ever have questions about a link in a document purporting to be from Nevada Medicaid, please do not hesitate to contact documentcontrol@dhcfp.nv.gov for verification.

Webinar: https://tinyurl.com/NAC103124

Select "Join," enter your name and email and then select "Join."

The meeting should not require a password.

Audio Only: (775) 321-6111 **Event Number:** 124 857 871#

PLEASE DO NOT PUT THIS NUMBER ON HOLD (hang up and rejoin if you must take another call)

YOU MAY BE UNMUTED BY THE HOST WHEN SEEKING PUBLIC COMMENT, PLEASE HANG UP AND REJOIN IF YOU ARE HAVING SIDE CONVERSATIONS DURING THE MEETING OR THOSE MAY BE HEARD BY OTHERS AND RECORDED

This meeting may be recorded to facilitate note-taking or other uses. By participating you consent to recording of your participation in this meeting.

AGENDA

- 1. General Public Comments (No action may be taken upon a matter raised under public comment period unless the matter itself has been specifically included on an agenda as an action item. To provide public comment telephonically, you may join the meeting by dialing (775) 321-6111 and when prompted to provide the Meeting ID, enter 124 857 871#. You may then press *5 to raise your hand during the public comment periods to provide your comment. Comments will be limited to three minutes per person. Persons making comment will be asked to begin by stating their name for the record and to spell their last name. Those who wish to provide a written comment may submit their comment via mail to 1100 E. William Street, Suite 101, Carson City, Nevada 89701 or via email to documentcontrol@dhcfp.nv.gov).
- 2. **Review proposed regulations:** LCB File No. R173-24 NAC Chapter 439. The proposed regulations provide provisions for the following:
 - A framework for the electronic maintenance, transmittal and exchange of electronic health records, prescriptions, health-related information and electronic signatures and requirements for electronic equivalents of written entries or written approvals in accordance with federal law.
 - Standards that require the use of networks and technologies that allow patients to access electronic health records directly from the health care provider of the patient and forward such electronic health records electronically to other persons and entities; and
 - The interoperability of such networks and technologies in accordance with the applicable standards for the interoperability of Qualified Health Information Networks prescribed by the Office of the National Coordinator for Health Information Technology of the United States Department of Health and Human Services

The effective date of change is upon approval by the Nevada Legislative Commission.

- 3. Public Comment regarding subject matter.
- 4. **For possible action:** Adoption of Proposed Regulation. LCB File No. R173-24 NAC Chapter 439.
- 5. General Public Comments
- 6. Adjournment

See the NOTICE OF INTENT TO ACT UPON A REGULATION for more information.

<u>NOTE</u>: To use the long link to the meeting in the event there are issues with the URL shortener, please use the following complete link:

https://teams.microsoft.com/l/meetup-

join/19%3ameeting_MThjYjA0YTUtOTc5Ny00OWY2LWJmYTQtYTFmNjQyNmM0YWQ5%40thread.v2/0?context=%7b%2 2Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%22b6bff5c9-c16b-4ba0-91a0-36c3222b14c4%22%7d

Nevada Medicaid is unaware of any financial impact to other entities or local government due to this public hearing, other than as stated above.

<u>PLEASE NOTE:</u> Items may be taken out of order, may be combined for consideration, and may be removed from the agenda or delayed for discussion at any time. All public comment will be limited to three minutes.

This notice and agenda have been posted online at http://dhcfp.nv.gov and http://notice.nv.gov, as well as Carson City, Las Vegas, Elko, and Reno central offices for DHCFP. E-mail notice has been made to such individuals as have requested notice of meetings (to request notifications please contact documentcontrol@dhcfp.nv.gov, or at 1100 E. William Street, Suite 101, Carson City, Nevada 89701.

DHCFP, 4070 Silver Sage Drive, Carson City, Nevada 89701 DHCFP, 1010 Ruby Vista Drive, Suite 103, Elko, Nevada 89801 DHCFP, 1210 S. Valley View, Suite 104, Las Vegas, Nevada 89102 DHCFP, 745 W. Moana Lane, Suite 200, Reno, Nevada 89509

If you require a physical copy of supporting material for the public meeting, please contact documentcontrol@dhcfp.nv.gov, or at 1100 E. William Street, Suite 101, Carson City, Nevada 89701. Supporting material will also be posted online as referenced above.

Note: We are pleased to make reasonable accommodations for members of the public with a disability and wish to participate. If accommodated arrangements are necessary, notify DHCFP as soon as possible in advance of the meeting, by e-mail at documentcontrol@dhcfp.nv.gov in writing, at 1100 E. William Street, Suite 101, Carson City, Nevada 89701.

PROPOSED REGULATION OF THE

DIRECTOR OF THE DEPARTMENT OF

HEALTH AND HUMAN SERVICES

LCB File No. R173-24

August 28, 2024

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 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 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 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** of this regulation defines the term "electronic health record system." **Section 2** of this regulation 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 of this regulation provides that the regulations adopted by the Director relating to health information technology must not be construed or interpreted to require a person or entity in this State to use a health information exchange.

Existing regulations require a health information exchange 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 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

8.1

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES



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Small Business Impact Statement

Proposed Amendments to NAC 439

EFFECTIVE DATE OF REGULATION:
Upon filing with the Nevada Secretary of State

The Division of Health Care Financing and Policy (DHCFP) has determined that the proposed regulation should have minimal adverse effect upon a small business or the formation, operation, or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes (NRS) 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608(3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business as stated below.

Background

The Nevada Division of Health Care Financing and Policy (DHCFP) has drafted revisions to Nevada Administrative Code (NAC) Chapter 439 in accordance with Assembly Bill 7 (AB 7) of the 2023 legislative session. The development of this bill emerged from the Patient Protection Commission in recognizing the lack of electronic accessibility patients may experience through visiting a variety of health care providers. This bill requires all providers of health care (as defined per Nevada Revised Statute (NRS) 629.031 – unless otherwise exempted – to implement an interoperable electronic health records system by January 1, 2030. Furthermore, Section 2.7(1.) of the bill reads: on or before July 1, 2023, the Director of the Department shall convene an advisory group to advise the Director of the Department of Health and Human Services (DHHS) in the adoption of regulations pursuant to NRS 439.589, as amended by section 1.08 of this act.

In direct response, the Electronic Health Information Advisory Group (EHIAG) was first convened on March 7, 2024 for the specific purpose to advise the DHHS Director in the adoption of regulations pursuant to NRS 439.589 [effective July 1, 2024]. The EHIAG conducted four meetings to develop proposed regulatory language, approved on June 17, 2024. The main points of discussion held by the EHIAG throughout the draft regulations development process were:

Desire for Flexible Options for Providers of Health Care to Meet AB7 Requirements

The term "healthcare provider" applies to an extraordinarily diverse assortment of professionals, providing services in an innumerable variety of care settings, between and within each profession. Healthcare provider as defined in NRS 629.031 refers to physicians, podiatrists, dentists, licensed clinical social workers, perfusionists, audiologists, doctors of Oriental medicine, chiropractors, music therapists, medical lab technicians, dietitians, athletic trainers and more. From physicians practicing in state-of-the-art hospitals, to those making house-calls in rural areas; from occupational therapists doing in-home speech therapy on children, to athletic trainers working-out professional football players at

multi-million dollar practice facilities, etc. The diversity is profound, and the practical challenges, interests and desires of both providers and their patients with respect to electronic health records, privacy and data security, could not be more varied.

Thus, after due consideration, the EHIAG members determined not to require too strict a regulation by category for specific solutions that will be appropriate in every professional circumstance, when doing so risks promulgating a regulation that either goes beyond the authority under AB 7 or will be of undue burden for some providers of health care to comply with. Accordingly, the EHIAG declined to require any, one-size-fits-all solution, but rather, decided it more appropriate to allow for two options for compliance, as long as both of those options met all requirements for interoperability, security, and patient access outlined in AB 7.

Direct Patient Access and Forwarding Electronically of their Health Information

As prescribed by AB 7, Section 1.08, subsection 1(a.)(1.)(I.), the EHIAG confirmed that both electronic health record (EHR) and health information exchange (HIE) solutions offered under the current drafted regulation language, do indeed meet this statutory requirement for direct patient access and forwarding electronically of their health information. The proposed regulations were developed through a comprehensive and collaborative stakeholder process through the EHIAG, with legal guidance from the Attorney General's Office, to ensure the proposed regulation language meets the intent of the Nevada Legislature, without imposing requirements on providers and patients that go beyond the instructions of AB 7.

Alignment with Federal Best Practices Regarding Interoperability

Throughout the deliberations process in developing the draft regulations before the public today, the EHIAG held as a priority that the regulations must be in alignment with federal guidelines as outlined in the Trusted Exchange Framework and Common Agreement (TEFCA), which establishes a universal floor for interoperability across the country and provides individuals and organizations with easier, more efficient, secure access to more health information. Therefore, the EHIAG did not come lightly to the proposal that if an HIE were to be a viable solution for health care providers to meet the requirements outlined in AB 7, it had to meet federal interoperability standards and direct patient access requirements.

Because the draft regulation language developed by the EHIAG requires the HIE to be a member of TEFCA, as developed under section 3001(c)(9)(B) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(9)(B)), in the Federal Register, prescribed by the Office of the National Coordinator for Health Information Technology of the United States Department of Health and Human Services (ONC Health IT), the EHIAG confirmed the HIE as defined in the draft regulation language adhered to the requirements of AB 7, Section 1.08, subsections 1(a.)(1.)(I-II.), for direct patient access and forwarding of records electronically, as well as interoperability in accordance with the applicable standards for the interoperability of Qualified Health Information Networks (QHINs) prescribed by the ONC Health IT.

Furthermore, the EHR as defined in the EHIAG-approved draft regulation language, must be certified by the ONC Health IT, thereby maintaining interoperability and allowing patients to access EHRs directly from the health care provider of the patient and forward such electronic health records electronically to other persons and entities.

Because the HIE must be a member of TEFCA, and the EHR must be ONC Health IT certified, the EHIAG arrived at the affirmation that both proposed solutions align with federal interoperability standards, and both are viable interoperability and direct patient access options for all providers of health care to meet the requirements of the regulations adopted pursuant to NRS 439.589 [effective July 1, 2024].

Upon receipt of the EHIAG-approved draft regulations, DHHS included one addition of draft regulation language to clearly state "No provider of health care is required to use a health information exchange." This upholds the recommendations of the EHIAG, in allowing for *two options* for provider of health care compliance, while maintaining alignment with all requirements as set forth in the bill.

Statement of Method

1) A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608(2)(a), the Division of Health Care Financing and Policy has requested input from Nevadalicensed and regulated providers of health care. A survey questionnaire was sent electronically to all licensing boards and agencies associated with the list of "provider of health care" defined in NRS 629.031, asking for the licensing board or agency to deploy the survey to their licensees broadly, on May 20, 2024.

AB 7 appropriated funding to the Department of Health and Human Services to award grants to providers of health care and medical facilities for the purposes of complying with the new requirements set forth by the bill. DHCFP has received a total of 3,035 responses. The survey first gave an overview of the requirements of AB 7 and outlined the grant program for the appropriated funding. Questions on the survey were:

- 1. Are you interested in applying for a grant to comply with this new requirement (proof of invoice/purchase will be required)?
- 2. Are you a provider of health care or medical facility with a staff of less than 50 people, or work for an entity that has a staff of less than 50 people?
- 3. Are you a part of a for profit business, employing less than 150 full-time or part-time employees?
- 4. When additional information is available regarding this new requirement or the grant opportunity, would you like to be included on our email distribution list?
- 5. Please provide your name.
- 6. Please provide your provider or entity/business name.
- 7. Please provide your profession.
- 8. Please provide your email address.
- 9. Do you have any questions or feedback about this program or requirements for compliance?

Summary of Response

Small Businesses:

A total of 1,072 (35.5%) respondents affirmed to meet the definition of a "small business" (fig.1). A small business is defined as a "business for profit which employs fewer than 150 full-time or part-time employees."



Fig 1. Businesses that meet the definition of a small business

Eligible Businesses:

To receive a grant, a provider of healthcare or medical facility must have a staff of less than 50 people or work for an entity that has a staff of less than 50 people (see AB 7, Section 2.5(1.)). Of that group of respondents who affirmed they met the requirements to receive a grant (fig. 2), 610 (53.2%) answered "Yes" and 231 (20.2%) answered "Maybe" when asked if they were interested in applying for a grant to come into compliance with the new requirements (fig. 3).

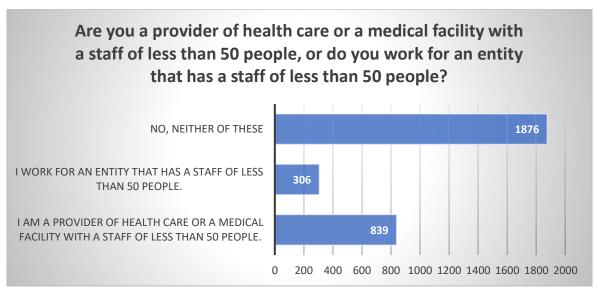


Fig 2. Respondents that meet the requirements of the bill to receive a grant



Fig 3. Eligible Businesses' interest in applying for a grant to comply with the new requirement

Respondents by Profession:

There was a total of 3,021 responses to the survey; of those responses, there were 737 unique responses asking for the respondent's profession. To extract useful information, the professions were grouped into categories: Physicians, Nurses, Allied Health Professionals, Administrative Staff and Support, Healthcare Technicians, Behavioral and Mental Health Professionals, Dentists and Dental Hygienists, Other Specialties, Academic Support and Staff, and Other. Specialties who fall under "Other Specialties" are Audiologists, Clinical Research Diabetes Specialists, and Professional Patient Advocates. Respondents who fall under "Other" are those not identified with any one of the previously aforementioned categories (fig. 4).

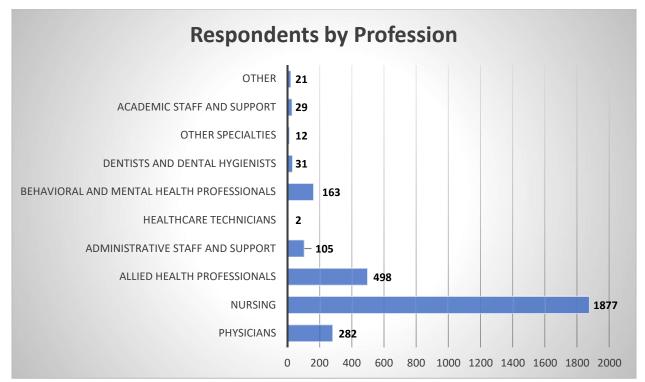


Fig 4. Clustered Column Chart: Respondents by Profession

Survey Comments - Common Themes:

Upon review of the free text comments provided through the survey, a few common themes emerged which included:

- Concerns regarding:
 - the financial strain associated with implementing and maintaining electronic health records/electronic medical records (EHR/EMR) systems imposed by AB 7.
 - AB 7 represents government overreach into healthcare.
 - o EHR/EMR systems imposed by the bill do not sufficiently enhance healthcare delivery.
 - o patient data privacy and confidentiality.
 - o EHR/EMR will cause providers/business/entities to leave or go out of business due to the bill.
- Questions regarding:
 - o grant eligibility.
 - o appropriate use of grant funds.
 - o who is exempt from the EHR/EMR bill.
 - o if existing EHR/EMR systems will comply with the new bill.
- Expressions of confusion and seeking clarity on AB 7 and how it will affect specific, individual practices.
- Requests for additional information.
- 2) Describe the manner in which the analysis was conducted. The Division of Health Care Financing and Policy prepared and distributed electronically a survey questionnaire to all licensing boards and regulatory agencies (22) for the types of providers of health care as listed in NRS 629.031 (33), requesting broad distribution amongst their licensees. The Division distributed the survey electronically on May 20, 2024. The Electronic Health Information Advisory Group has considered the impact on Nevada-licensed health care providers and facilities through discussion and development of the proposed regulations during four open public meetings. Results from the survey questionnaire were entered into a spreadsheet for review and analysis. A public workshop will be held September 4, 2024, to allow

further input by the public regarding the proposed regulations and how they will impact Nevada health care providers and facilities.

- 3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects. On the survey questionnaire, 1,072 out of the 3,035 respondents affirmed to meet the definition of a "small business" as defined by NRS 233B.0382. Of the 1,072 small business respondents, 841 (or 78%) answered they are, or might be, interested in applying for a grant to comply with the new requirement of AB 7, with the framework outlined in the draft regulation. Many appeared to be concerned with the financial strain associated with implementing and maintaining an electronic health records system imposed by the bill.
- 4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods. The Department of Health and Human Services, Division of Health Care Financing and Policy implemented the Electronic Health Information Advisory Group (EHIAG) to develop and advise the Department in the adoption of regulations as directed through AB 7. Through four open public meetings, this group of 20 appointed voting members, and 9 exofficio members discussed, deliberated, and debated several iterations of draft regulation language, eventually arriving at approval during the June 17, 2024 meeting. As noted previously in the *Background* section of this report, the primary goals which kept resurfacing during discussions held by the EHIAG throughout the shaping of the new regulations were:
 - Desire for flexible options for providers of health care to meet AB 7 requirements;
 - Direct patient access and forwarding electronically of their health information; and
 - Alignment with federal best practices regarding interoperability.
- 5) The estimated cost to the agency for enforcement of the proposed regulation. There is no direct cost to the agency for enforcement of the proposed regulations.
- 6) If the proposed regulation provides a new fee or increases an existing fee, the total annual amount DHCFP expects to collect and the manner in which the money will be used. There is no new fee or increase to an existing fee proposed in the draft regulations.
- 7) An explanation of why any duplicative or more stringent provisions than federal, state, or local standards regulating the same activity are necessary. The framework proposed through these draft regulations surrounding health information maintenance, transmittal and exchange are neither duplicative nor more stringent. Rather, they are aligned with federal best practices in the area of health information access and interoperability as outlined in the Trusted Exchange Framework and Common Agreement (TEFCA), which establishes a universal floor for interoperability across the country and provides individuals and organizations with easier, more efficient, secure access to more health information and direct patient access options.
- 8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses. Based on the quantitative and qualitative data received through the survey questionnaire, the several discussions and deliberations of the EHIAG surrounding the proposed regulations, and the availability of grant funding directed specifically toward a subset of small businesses to support implementing the requirements of AB 7, it would be fair to conclude the impact of the framework proposed through the draft regulations for health information maintenance, transmittal and exchange to be minimal. Many factors were considered in making this determination. Some factors include the number of respondents, specific concerns raised by the respondents, the

likelihood of misunderstanding the regulations intent, and connection to the mandated requirement set forth in AB 7.

Certification by Responsible Party

I, Stacie Weeks, Administrator of the Division of Health Care Financing and Policy certify to the best of my knowledge or belief that a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Date: 8/15/2024

Signature:

Stacie Weeks, JD, MPH

Administrator