

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DHHS

Stacie Weeks, JD MPH Administrator

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

NOTICE OF ADOPTION OF REGULATION

The Division of Health Care Financing and Policy, on behalf of the Department of Health and Human Services, adopted regulations assigned LCB File No. R173-24, which pertains to chapter 439 of the Nevada Administrative Code (NAC) on October 31, 2024. A copy of the regulations as adopted is attached hereto.

LEGISLATIVE REVIEW OF ADOPTED REGULATIONS INFORMATIONAL STATEMENT AS REQUIRED BY NRS 233B.066

LCB FILE NO. R173-24

The following statement is submitted for adopted amendments to Nevada Administrative Code (NAC) Chapter 439:

1. A clear and concise explanation of the need for the adopted regulation.

Revisions to Nevada Administrative Code (NAC) Chapter 439 have been proposed in accordance with Assembly Bill 7 (AB 7) of the 2023 Legislative Session. This bill requires all providers of health care and medical facilities to implement an interoperable electronic health records system by January 1, 2030. AB 7 further 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 adopt regulations that prescribe 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. The regulations are necessary to fulfill statutory requirements set forth in AB 7.

2. Description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

Copies of the proposed regulations, notice of public workshop, and notice of intent to act upon regulations were posted at various locations. These notices were placed on file at the State Library and Archives, 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 were made available at all Division of Health Care Financing and Policy (DHCFP) locations and in all counties at the main public library, for inspection and copying by members of the public during business hours. These notices and the text of the proposed regulation were made available at 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. In addition, copies of these notices and the regulation were mailed to members of the public upon request.

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

http://www.leg.state.nv.us/

https://dhcfp.nv.gov/Public/AdminSupport/PublicNotices/

Division of Health Care Financing and Policy 1100 E. William Street, Suite 101 Carson City, Nevada 89701

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

Public comment was solicited through multiple avenues, including the Electronic Health Information Advisory Group (EHIAG) open public meetings, public workshop, public notices, postings on the DHCFP website, and distribution via email through Listserv. Additionally, a formal public hearing was held on October 31, 2024, to provide stakeholders with an opportunity to voice their opinions and concerns regarding the proposed regulation. Persons wishing to comment upon the proposed action of the regulation were advised of their right to appear at the scheduled public hearing and their right to address comments, data, views or arguments, and the opportunity to submit in writing to DHCFP on or before October 31, 2024.

Meetings of the EHIAG were held virtually on:

- March 7, 2024
- April 4, 2024
- May 2, 2024
- June 17, 2024

The EHIAG members were appointed by the DHHS Director to develop regulations in advisement to the Director in the adoption of regulations pursuant to Nevada Revised Statute (NRS) 439.589 [effective July 1, 2024]. The EHIAG conducted four open public meetings to develop proposed regulatory language, approved on June 17, 2024. All EHIAG meeting publications were posted here:

https://dhcfp.nv.gov/Public/AdminSupport/MeetingArchive/EHIAG/2024 EHIAG/.

A Public Workshop was noticed on August 19, 2024, and a revised agenda posted on September 3, 2024. The Public Workshop was held on September 4, 2024, virtually and in-person. This was a workshop to gather further

input, which was considered in assessing the impact of these regulations. Publication was posted here: https://dhcfp.nv.gov/Public/AdminSupport/MeetingArchive/Workshops/2022/Workshops 2022/.

A Notice of Intent to Act upon the Regulations was noticed on September 30, 2024, and an agenda posted on September 30, 2024. A public hearing was held on October 31, 2024, at DHCFP 4070 Silver Sage Drive, Main Conference Room in Carson City. Publication was posted here: <u>NAC Archives 2024 (nv.gov)</u>.

Recordings of the EHIAG meetings, Public Workshop and Notice of Intent to Act upon the Regulations is on file with the Division of Health Care Financing and Policy 1100 E. William Street, Carson City, Nevada 89703. To obtain access to the recordings, please email documentcontrol@dhcfp.nv.gov.

The public response can be summarized as individuals who testified at the public workshop or public hearing, and few written statements were provided at both the public workshop (9/4/24) and the public hearing (10/31/24) regarding this regulatory change. A copy of the minutes of the public workshop and/or hearing can be obtained accessing the links above. Copies of all written public comment received are located and available here: https://dhcfp.nv.gov/Boards/AdminSupport/EHIAdvisoryMain/.

3. The Number of Persons Who:

Public Workshop September 4, 2024:

a) Attended Workshop: 30b) Testified at Workshop: 4

c) Submitted Written Statements: 2-1 of which was presented during the public workshop

Public Hearing October 31, 2024:

a) Attended Hearing: 64b) Testified at Hearing: 5

c) Submitted Written Statements: 2 – 1 of which was presented during the public hearing

4. For each person identified in paragraphs (b) and (c) of number 3 above, the following information if provided to the agency conducting the hearing: (a) name; (b) telephone number; (c) business address; (d) business telephone number; (e) electronic mail address; and (f) name of entity or organization represented.

Public Workshop September 4, 2024:

Comments can be reviewed within the minutes located here: PW Minutes 09-04-24 (nv.gov)

Participants:

1. Name: Maya Holmes

Telephone number: 702-892-7342

Business address: 1901 S. Las Vegas Blvd, Suite 101, Las Vegas, NV 89104-1309

Business Telephone number: same

Electronic mail address: mholmes@culinaryhealthfund.org

Name of entity or organization represented: Culinary Health Fund

• Testified at Public Workshop and submitted a written statement on 9/4/24.

2. Name: Jim Flemming

Telephone number: 775-481-1585 Business address: not provided

Business Telephone number: not provided

Electronic mail address: jimflemingnyc@yahoo.com

Name of entity or organization represented: none, concerned citizen

Testified at Public Workshop and submitted a written statement on 9/13/24.

3. Name: Michael Gagnon

Telephone number: 802-355-2377 Business address: not provided

Business Telephone number: not provided

Electronic mail address: mgagnon@healthienevada.org
Name of entity or organization represented: HealtHIE Nevada

• Testified at Public Workshop.

4. Name: Jerry Reeves, MD

Telephone number: 702-743-1964 Business address: not provided

Business Telephone number: not provided

Electronic mail address: <u>Jreeves.healthinnovations@gmail.com</u>

Name of entity or organization represented: Health Innovations LLC

Testified at Public Workshop.

Public Hearing October 31, 2024:

Comments can be reviewed within the minutes located here: PH Minutes 10-31-24 (nv.gov)

Participants:

1. Name: Michael Gagnon

Telephone number: 802-355-2377 Business address: not provided

Business Telephone number: not provided

Electronic mail address: mgagnon@healthienevada.org
Name of entity or organization represented: HealtHIE Nevada

Testified at Public Workshop

2. Name: Robert Fliegler, MD

Telephone number: 775-315-8616

Business address: 206 North Curry Street, Carson City, NV 89703

Business Telephone number: same

Electronic mail address: robert@fliegler.com

Name of entity or organization represented: VIP Medical Access

• Testified at Public Hearing and submitted a written statement on 10/3/24.

3. Name: Assemblyman Ken Gray

Telephone number: 775-220-1935 Business address: not provided

Business Telephone number: not provided

Electronic mail address: ken.gray@asm.state.nv.us

Name of entity or organization represented: Nevada Assembly, District 39

• Testified at Public Hearing.

4. Name: Maya Holmes

Telephone number: 702-892-7342

Business address: 1901 S. Las Vegas Blvd, Suite 101, Las Vegas, NV 89104-1309

Business Telephone number: same

Electronic mail address: mholmes@culinaryhealthfund.org

Name of entity or organization represented: Culinary Health Fund

• Testified at Public Hearing and submitted a written statement on 9/4/24.

5. Name: Jim Willis

Telephone number: contact information not provided Business address: contact information not provided

Business Telephone number: contact information not provided Electronic mail address: contact information not provided

Name of entity or organization represented: CommonSpirit Health (formerly known as Dignity Health)

Testified at Public Hearing.

6. Name: Jerry Reeves, MD

Telephone number: 702-743-1964

Business address: 18 Vintage Court, Las Vegas, NV 89113

Business Telephone number: same

Electronic mail address: <u>Jreeves.healthinnovations@gmail.com</u>

Name of entity or organization represented: Health Innovations LLC

• Submitted a written statement only.

Four written statements were received by October 31, 2024, along with five formal comments collected during the public hearing, which reiterated one of the submitted written statements, and another reiterated one submitted written statement from the 9/4/24 public workshop. Each of these responses were formally reviewed and considered. At this time, the proposed regulations meet the standards required by NRS 439.589. The Division believes the current regulation structure satisfies the necessary requirements.

Below is a summary of the seven statements provided and the Department's response:

James Fleming, concerned citizen, jimflemingnyc@yahoo.com - Testified at Public Workshop.

Mr. Fleming provided comment and stated that the proposed regulations required the State to contract with an HIE and therefore may be in violation of the Federal Trade Commission rules against competition; he further stated concerns that the provisions of AB 7 included exemptions for providers of health coverage for federal employees or providers of coverage subject to the Employee Retirement Income Social Security Act of 1974.

DHCFP on behalf of DHHS found that the presented proposed regulations do not require the State to contract with an HIE; and the exemptions noted are listed in AB 7, not a new requirement contained in the proposed regulations. Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Mr. Fleming's comment.

Michael Gagnon, Executive Director, HealtHIE Nevada, mgagnon@healthienevada.org - Testified at Public Workshop and Public Hearing.

HealtHIE Nevada provided comment to request that the proposed regulations under Section 4.1(a) be revised back to the original draft regulatory language provided by the EHIAG, stipulating maintenance of an electronic health record system which must have components or services for exchanging data installed.

After careful consideration, DHCFP on behalf of DHHS found that the language presented in the public hearing had undergone thorough assessment by Legislative Counsel Bureau staff who removed several redundancies included in the initial draft regulations presented at the public workshop, this being one of them. No changes were made or necessary in response to HealtHIE Nevada's requests.

Dr. Robert Fliegler, VIP Medical Access, <u>robert@fliegler.com</u> – Testified at Public Hearing and submitted written statement.

Dr. Fliegler requested exemption of his small (under 200 patients total) practice from the statutory requirements proposed today. He cites reasoning as such that his practice does not bill insurance, nor accept Medicare or Medicaid; and clarified that all health record information his patients request is readily available through current online platforms, outside the EHR or HIE connections.

After careful consideration, DHCFP on behalf of DHHS found these considerations to be insightful and supported by state law. Therefore, DHCFP has committed to outlining flexibilities further in future guidance as required in its development of the waiver process for exempting providers from the bill requirements as authorized under AB 7, Section 1.08, subsection 6. DHCFP will hold a public workshop on the provider waiver development process prior to calendar year 2024 end. Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Dr. Fliegler's comment.

Assemblyman Ken Gray, Nevada Assembly District 39, ken.gray@asm.state.nv.us - Testified at Public Hearing.

Assemblyman Gray supported Dr. Fliegler's comments and added stated concerns to him personally from young doctors who stated they would not be able to afford implementing an EHR or HIE as required by law. Assemblyman Gray encouraged a wide-reaching exemption waiver to help maintain and attract providers to our state.

DHCFP on behalf of DHHS is currently managing the grant program, as appropriated through AB 7, Section 2.5, whereby funding is available for the purpose of awarding grants to providers of health care and medical facilities for the purposes of complying with the requirements of subsection 4 of NRS 439.589, as amended by section 1.08 of this act. To receive such a grant, a provider of health care or a medical facility must have a staff of less than 50 persons or work for an entity that has a staff of less than 50 persons, as applicable. This grant program will be available through June 30, 2025, with the goal of mitigating any initial financial burden to smaller providers and medical facilities. Additionally, DHCFP on behalf of DHHS is taking these comments into consideration as it develops the exemption or waiver process for providers that is authorized through AB 7, Section 1.08, subsection 6. Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Assemblyman Gray's comment.

Maya Holmes, Health Policy Director, Culinary Health Fund, mholmes@culinaryhealthfund.org – Testified at Public Workshop, Public Hearing, and submitted written statement.

Culinary Health Fund raised concerns that the proposed regulations for AB 7 indicate that compliance for covered parties is based on either maintaining an electronic health record system that meets specified interoperability standards **OR** maintaining a connection with a health information exchange. They disagree that a connection to a health information exchange (HIE) should not be an alternative to an interoperable electronic health record system, and this inclusion conflicts with the provisions of Section 1.08 in AB 7, which require the Department to establish standards that allow patients to directly access electronic health records from their providers and electronically forward those records; access through an HIE is not direct access from a provider. Culinary Health Fund stated AB 7 did not have a provision stating providers can use an HIE connection to be compliant so such a connection should not be an alternative to having an interoperable electronic health system in the regulations. It will prevent patient access, and the proposed regulations exceed the intent and scope of the law.

After careful consideration and review with DHCFP Deputy Attorney Generals, DHCFP on behalf of DHHS confirms that as prescribed by AB 7, Section 1.08(1)(a)(1) both EHR and HIE solutions, as defined under the

proposed regulations, meet the statutory requirement for direct patient access and the forwarding of patient health information, electronically. Furthermore, the proposed regulations are in alignment with federal guidelines and national standards as outlined in the <u>Trusted Exchange Framework and Common Agreement</u> (TEFCA), which establishes a universal floor for interoperability across the country. The proposed regulations require that HIEs become a member of TEFCA, 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, as 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 TEFCA membership requires that the HIE allows for patients to have direct access to their records, electronically, consistent with the requirement of AB7, Section 1.08(1)(a)(1). EHRs under the proposed regulations must also be certified as having sufficient interoperability in accordance with the applicable standards for Qualified Health Information Networks (QHINs) as prescribed by the ONC Health IT.

Because the HIE must be a member of TEFCA and the EHR must be certified by ONC Health IT, both platforms as defined under the proposed regulation meet the requirements of state law. Both HIE and EHR platforms must be aligned with federal interoperability standards and provide direct access to patient records for patients for all providers of health care to meet the requirements of the regulations adopted pursuant to NRS 439.589, as amended by Section 1.08 of AB7. Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Culinary Health Fund's comment.

Jim Willis, CommonSpirit Health, <no contact information provided> - Testified at Public Hearing.

Mr. Willis mentioned potential challenges with managing consent in certain provider groups across the state. Based on AB 7, all national standard networks are considered HIEs due to their ability to connect disparate systems. The proposed regulations require that HIEs operating in Nevada become certified and manage informed consent. CommonSpirit Health notes there are no national networks currently certified, which will therefore likely present major challenges with managing consent.

DHCFP on behalf of DHHS has reviewed the proposed regulations and confirms the regulation requires that providers utilizing an HIE must ensure that such HIE is meets the requirements of the regulation, which includes being a member of TEFCA, or its successor. If such an HIE is found to be out of compliance with the requirements, corrective action(s) may be imposed on the provider or medical facility by the accordingly regulatory agency. Once the proposed regulation is approved and finalized, the Department will be notifying any HIEs certified to operate in the state regarding the next steps with respect to ensuring compliance with the regulation, including but not limited to appropriate notice to HIE-contracted providers to ensure transparency for providers regarding whether the HIE platform is compliant with this regulation. Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Mr. Willis' comment.

Dr. Jerry Reeves, Health Innovations LLC, <u>Jreeves.healthinnovations@gmail.com</u> – Testified at Public Workshop and submitted written statement.

Dr. Reeves is in opposition to statements made by Culinary Health Fund and argues that adopting Culinary Health Fund's requests would result in essentially no health data exchange between sites of care because a very small minority of patients in Nevada would initiate an exchange of health information between their health service providers.

Because the proposed regulation addresses all mandatory requirements of AB 7 in its current form, no changes were made based on Dr. Reeves' comment.

5. 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.

As part of DHCFP's due diligence on behalf of DHHS, a small business impact survey was distributed on 5/20/24 electronically to all licensing boards and agencies associated with the list of "provider of health care" defined in NRS 629.031 (27 contacts for such boards/agencies in total), asking for the licensing board or agency to deploy the survey to their licensees broadly. The survey garnered a total of 3,035 responses. The purpose was to gauge interest and assess needs from providers of health care and medical facilities to determine how to best distribute the grant funds appropriated through AB 7 as well as to solicit general questions or feedback about the grant program or requirements for compliance with the provisions of AB 7.

Businesses and entities were also invited to provide public comments during a workshop held on 9/4/24 and a public hearing on 10/31/24. Among the six responses we received, three came from a small business. One small business respondent provided feedback that the requirements imposed through AB 7, without the consideration of a waiver exemption, would impose a significant hardship on business operations. The other two did not comment on how the proposed regulations might impact their business operations, but did provide comment requesting to stipulate maintenance of an EHR system must have components or services for exchanging data installed – addressed through the LCB review criteria; as well as comment opposing the statements made by the Culinary Health Fund. The remaining three responses were from entities with more than 151 employees, which do not meet the criteria for small businesses, or did not represent any business. One respondent encouraged a wide-reaching exemption waiver and supported young doctors' stated concerns surrounding affordability of AB 7 requirements. Another raised concerns that an HIE is provided as an alternative to an interoperable electronic health record system, an issue mitigated through the proposed regulations requiring such an HIE to be a member of TEFCA, therefore aligning with federal interoperability standards and thus a viable interoperability and direct patient access solution. The final concern was surrounding management of consent.

The Department values all feedback provided. The availability of grant funding directed specifically toward a subset of small businesses to support implementing the requirements of AB 7 provides for moderate mitigation of negative financial impact on small businesses in Nevada.

6. 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 regulation was adopted with thoughtful consideration on the public feedback received from all commenters. The feedback provided by the public was considered, but the proposed regulation already included measures to mitigate concerns, such as requirements for an HIE to be a member of TEFCA, and an EHR to be ONC Health IT certified to confirm direct patient access requirements imposed by AB 7. The proposed regulations do not require or mandate the use of HIE by any provider or medical facility, and do not require or mandate the Department to contract with an HIE. Instead, the regulation maintains that the platform used by the provider or Department is a choice as long as the platform meets the requirements of regulation and state law (e.g., HIE is a TEFCA member and the EHR certified by ONC Health IT.)

If an HIE or EHR does not meet all interoperability, federal alignment, and direct patient access requirements prescribed by AB 7 and through the proposed regulation, contracting with such an HIE or EHR would not be considered sufficient for compliance purposes with respect to the mandate that providers utilize such a platform. The necessity of moving forward with the regulation in its current form was clear to ensure timely implementation in accurate alignment with timelines defined in AB 7.

7. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

Estimated Economic Effects on Businesses:

- a. Adverse: Initial costs for businesses not already compliant, to come into compliance with 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.
- b. Beneficial: Improved interoperability of health-related data access and exchange can lead to better health care decision-making across a variety of health care provider types and further lead to potential better health outcomes.
- c. Immediate: Potential costs and compliance required with setting up EHR system or HIE processes, if not already compliant.
- d. Long-Term: Potential for cost savings and improved health care strategies and patient health outcomes due to better health data interoperability with direct patient access and forwarding of patient records across a variety of health care provider types and medical facilities.

Estimated Economic Effects on the Public:

- a. Adverse: No adverse/negative public effects identified.
- b. Beneficial: Enhanced continuity of care, improved health care outcomes, and potential health care cost savings.
- c. Immediate: Improved, direct patient access to electronic health records across the full spectrum of patient's health care providers.
- d. Long-Term: Overall improvement in continuity of care.
- 8. The estimated cost to the agency for enforcement of the adopted regulation.

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

9. 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.

10. If the regulation includes provisions that are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

This is not required by Federal Law. This is a state-driven regulation stemming from the NRS legislation, which supports Assembly Bill 7, passed during the 82nd (2023) Session of the Nevada Legislature and signed into law on June 10, 2023.

Therefore, there are no stringent rules known at the time of this posting.

11. 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.

The regulation does not establish a new fee or increase an existing fee.