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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 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 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).

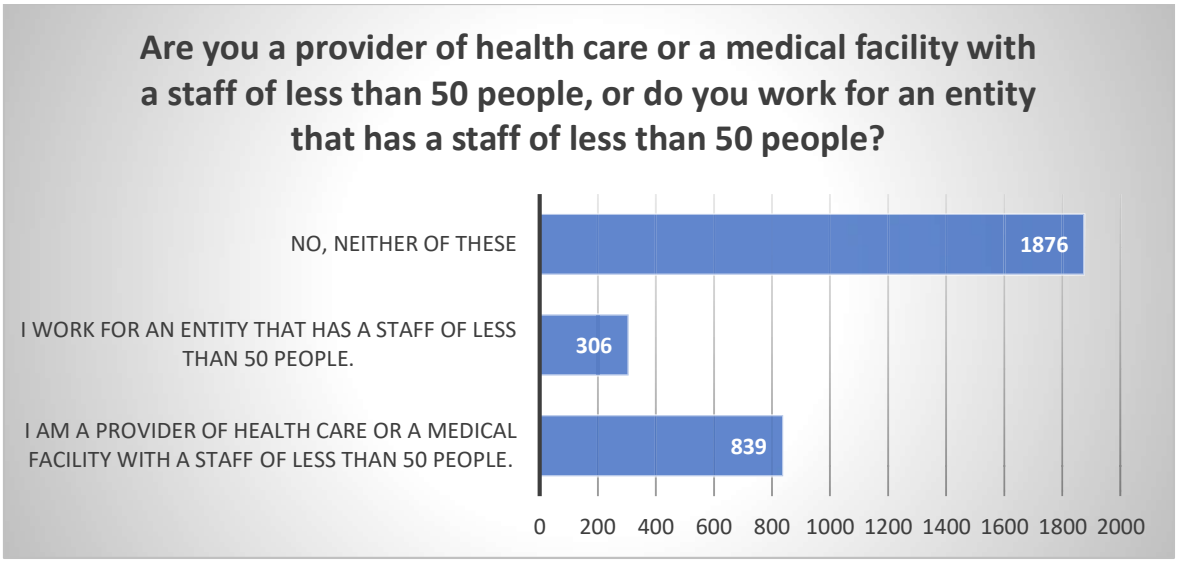

Fig 2. Respondents that meet the requirements of the bill to receive a grant

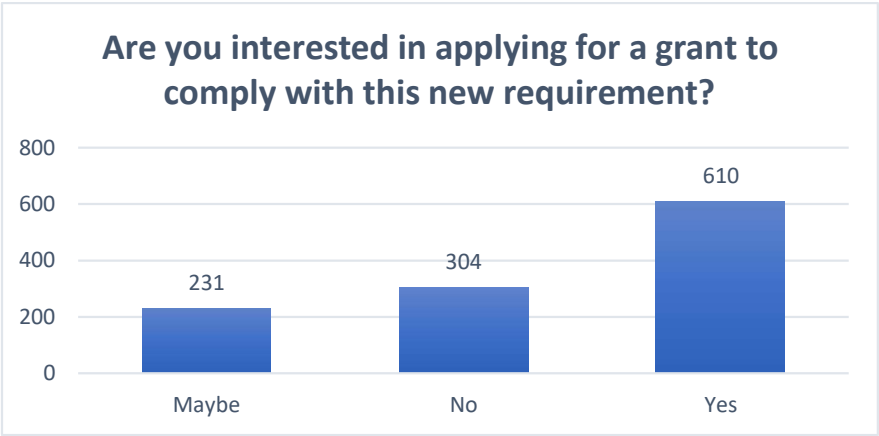

Fig 3. Eligible Businesses' interest in applying for a grant to comply with the new requirement

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).

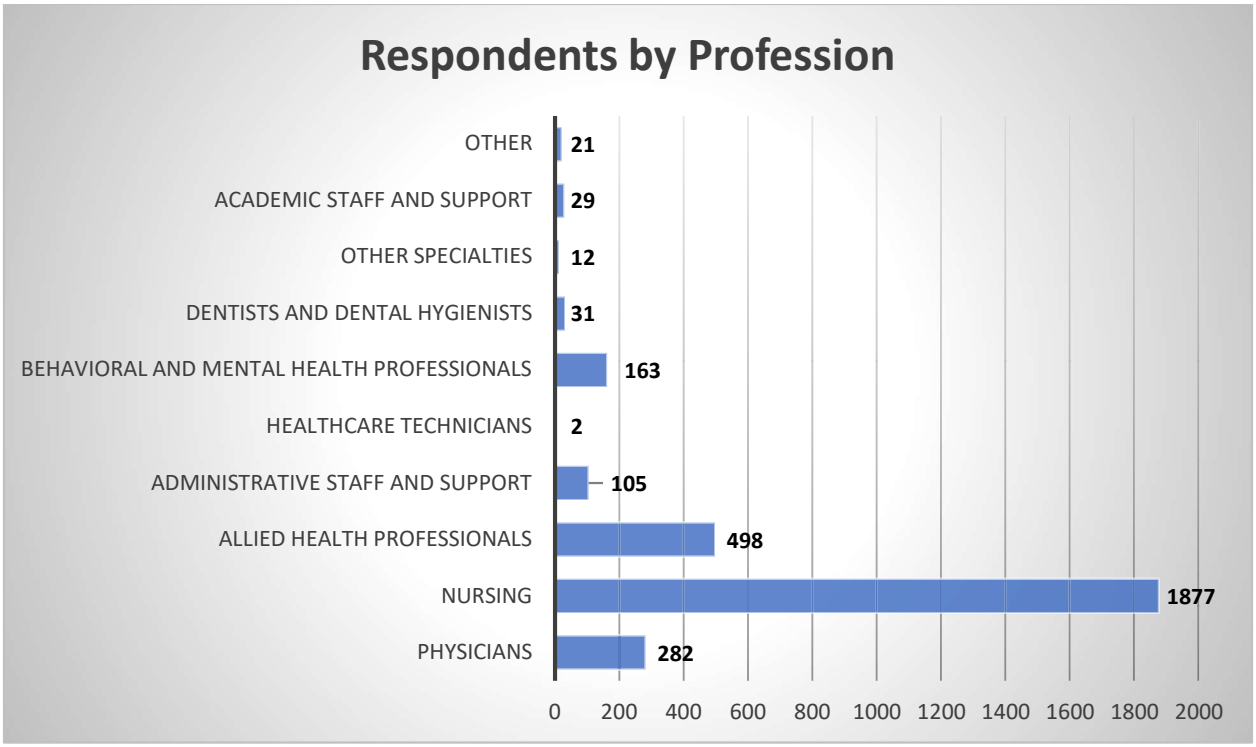

Fig 4. Clustered Column Chart: Respondents by Profession

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.
  - EHR/EMR systems imposed by the bill do not sufficiently enhance healthcare delivery.
  - patient data privacy and confidentiality.
  - EHR/EMR will cause providers/business/entities to leave or go out of business due to the bill.
- Questions regarding:
  - grant eligibility.
  - appropriate use of grant funds.
  - who is exempt from the EHR/EMR bill.
  - 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 ex-officio 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.

Signature:  Date: 8/15/2024

Stacie Weeks, JD, MPH
Administrator