# PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R164-20I

The following document is the initial draft regulation proposed by the agency submitted on 10/22/2020

## Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – October 15, 2020

Explanation – Language in *blue italics* is new; language in *red text* [*omitted material*] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.100

A REGULATION relating to the locations where a pharmacist may practice pharmacy; and providing other matters properly relating thereto.

# Section. 1. NAC Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

- 1. A registered pharmacist who is:
- a) Employed by or under contract with a pharmacy other that an institutional pharmacy; or
  - b) Employed by the State of Nevada,
- $\rightarrow$  may perform the functions set forth in NRS 639.0124(2)-(4) and (7)-(9) at a site other than the site of the pharmacy subject to the requirements set forth in subsections 2 and 3.
- 2. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall:
- c) Identify and update the current address of the site of practice in conformance with NAC 639.225;
- d) Comply with all provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, the regulations adopted pursuant thereto, and all other federal and state laws and regulations concerning the privacy of information regarding health care;
- e) Be provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that would be available in the pharmacy, including, without limitation the information set forth in NAC 639.4916(1)(c);
- f) Ensure that all required records are made readily accessible to members of the Board and employees, agents and designees of the Board; and
- g) Comply with all applicable state and federal statutes, regulations and rules, including, without limitation:
  - (1) All recordkeeping requirements imposed upon the pharmacy; and
  - (2) All requirements for maintaining the confidentiality and security of patient data.
- 3. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall not:
  - a) Maintain an inventory of drugs at the site of practice;
  - b) Act as a managing pharmacist; or
  - c) Provide services pursuant to the provisions of:
    - (1) NAC 449.15347;
    - (2) NAC 449.6138;
    - (3) NAC 449.722;
    - (4) NAC 449.74531;
    - (5) NAC 449.9905 and 639.4996;

- (6) Subsection 2 of NAC 639.465; or
- (7) NAC 639.690.

#### Section. 2. NAC 639.403 is hereby amended to read as follows:

- 1. Except as otherwise provided in subsection 2, a A registered pharmacist who is not employed by or under contract with a pharmacy must may apply to the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy by submitting an application on a form prescribed by the Board. An application must be approved before a pharmacist may commence any practice pursuant to this section. The application must include, without limitation:
  - (a) The name of the pharmacist;
- (b) A description of the services that the pharmacist intends to provide at the site, which must be limited to one or more of the functions set forth in NRS 639.0124(2)-(4) and (7)-(9);
  - (c) The location at which the pharmacist will provide the services;
- (d) An identification of the types of patients or other persons to whom the pharmacist intends to provide the services;
- (e) An identification of the types of pharmacies or other entities to whom the pharmacist intends to provide the services;
- (f) A description of all resources, both paper and electronic, that will be available to the pharmacist in the course of providing the services;
  - (g) The days and hours during which the pharmacist intends to provide the services;
- (h) An explanation of the policy of the pharmacist for users of the services when the pharmacist is unavailable;
- (i) An explanation of the policy of the pharmacist regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records;
- (j) Whether the services provided will be affiliated with, an adjunct of or otherwise related to a licensed pharmacy The identity of the business under which the services will be performed, as registered with the domicile business registration agency; and
  - (k) A description of the business plan for the services provided.
- 2. A registered pharmacist may not submit an application pursuant to subsection 1 if he or she provides services:
- (a) Pursuant to the provisions of NAC 449.15347;
- (b) Pursuant to the provisions of NAC 449.6138;
- (c) Pursuant to the provisions of NAC 449.722;
- (d) Pursuant to the provisions of NAC 449.74531;
  - (e) Pursuant to the provisions of NAC 449,9905 and 639,4996;
- (f) Pursuant to the provisions of subsection 2 of NAC 639.465;
- (g) Pursuant to the provisions of NAC 639.690;
- (h) Voluntarily or without compensation, regardless of whether the services are provided individually or through an employer; or
- (i) Pursuant to a medication therapy management program approved pursuant to 42 C.F.R. § 423.153(d).
- 3. A registered pharmacist who administers immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive, is not required to submit an

application pursuant to this section for purposes of administering the immunizations at the authorized location.

#### Section. 3. NAC 639.406 is hereby amended to read as follows:

- 1. Upon submission of an application pursuant to NAC 639.403, the Board will schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
  - (a) The information contained in the application;
  - (b) The education, experience and expertise of the applicant;
  - (c) The disciplinary history of the applicant, if any; and
  - (d) Whether the applicant has sufficient malpractice or other liability insurance.
  - 2. At the hearing, the Board may request that the applicant modify his or her application.
- 3. If the Board approves an application, the Board will provide the applicant with documentation indicating the approval and setting forth the terms and conditions under which the applicant may provide the services approved by the Board, which shall be subject to the requirements set forth in subsections 5 and 6.
- 4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.
- 5. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall:
- a) Identify and update the current address of the site of practice in conformance with NAC 639.225;
- b) Comply with all provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, the regulations adopted pursuant thereto, and all other federal and state laws and regulations concerning the privacy of information regarding health care;
- c) Ensure that all required records are made readily accessible to members of the Board and employees, agents and designees of the Board; and
- d) Comply with all applicable state and federal statutes, regulations and rules, including, without limitation:
  - (1) All recordkeeping requirements imposed upon the pharmacy; and
  - (2) All requirements for maintaining the confidentiality and security of patient data.
- 6. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall not:
  - a) Maintain an inventory of drugs at the site of practice;
  - b) Act as a managing pharmacist; or
  - c) Provide services pursuant to the provisions of:
    - (1) NAC 449.15347;
    - (2) NAC 449.6138;
    - (3) NAC 449.722;
    - (4) NAC 449.74531;
    - (5) NAC 449.9905 and 639.4996;
    - (6) Subsection 2 of NAC 639.465; or

#### Section. 4. NAC 639.412 is hereby repealed:

- 1. Except as otherwise provided in subsection 2, a licensed pharmacy may apply to the Board to use the services of one or more registered pharmacists, including, without limitation, pharmacists employed by or under contract with the pharmacy, to engage in the practice of pharmacy at a site other than the site of the licensed pharmacy by submitting an application on a form prescribed by the Board. The application must include, without limitation:
- (a) The name of the pharmacy;
- (b) A description of the services that the pharmacy intends to provide at the site;
- (c) The location at which the pharmacy will provide the services;
- (d) An identification of the types of patients or other persons or entities to whom the pharmacy intends to provide the services;
- (e) A description of all resources, both paper and electronic, that will be available to the pharmacy in the course of providing the services;
- (f) The days and hours during which the pharmacy intends to provide the services;
- (g) An explanation of the policy of the pharmacy for users of the service when a pharmacist is unavailable;
- (h) An explanation of the policy of the pharmacy regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records; and
- (i) A description of the business plan for the services provided.
- 2. A pharmacy may not submit an application pursuant to subsection 1 to use the services of a registered pharmacist who is prohibited from submitting an application pursuant to subsection 2 of <u>NAC 639.403</u>.

#### Section. 5. NAC 639.415 is hereby repealed:

- 1. Upon submission of an application pursuant to NAC 639.412, the Board will schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
- (a) The information contained in the application;
- (b) The disciplinary history of the applicant, if any; and
- (c) Whether the applicant has sufficient malpractice or other liability insurance.
- 2. At the hearing, the Board may request that the applicant modify the application.
- 3. If the Board approves an application, the Board will provide the pharmacy whose application is approved with documentation indicating the approval and setting forth the terms and conditions under which the pharmacists employed by or under contract with the pharmacy may offer the services approved by the Board.

4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.

#### Section. 6. NAC 639.418 is hereby repealed:

The Board may revoke, suspend or place restrictions on the approval granted to a licensed pharmacy to use the services of one or more registered pharmacists to engage in the practice of pharmacy at a site other than the site of the licensed pharmacy pursuant to <u>NAC</u> 639.415 based upon proof that:

- 1. The pharmacy has violated the terms and conditions under which the pharmacy was approved by the Board to provide the services; or
- 2. During the course of providing the services approved by the Board, the pharmacy has committed one or more acts that are grounds for disciplinary action pursuant to this chapter or chapter 639 of NRS.

### Section. 7. NAC 639.4915 is hereby amended to read as follows:

A pharmacy located within a hospital or correctional institution that is required to have a full-time managing pharmacist pursuant to <u>NAC 639.465</u> shall provide chart order processing services to the hospital or correctional institution *at all times*. *The pharmacy shall provide the chart order processing services by:* 

- 1. Operating at all times; or
- 2. Employing a pharmacist who is on duty at all times that the pharmacy is operating and either:
- (a) Employing a pharmacist who is available at all times that the pharmacy is not operating; or
- (b) Contracting with an off-site pharmaceutical service provider that is available at all times that the pharmacy is not operating.

#### Section. 8. NAC 639.4916 is hereby amended to read as follows:

- 1. A *registered* pharmacist who is employed by *or under contract with a pharmacy an off-site pharmaceutical service provider* to provide remote chart order processing services to a hospital or correctional institution pursuant to <u>NAC 639.4915</u> must:
  - (a) Be licensed to practice in Nevada;
- (b) Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the pharmacist must comply, including, without limitation, the provision of pharmaceutical services, security and confidentiality of patient records; and
- (b) (c) Except as otherwise provided in subsection 3, bBe provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a pharmacist employed by the pharmacy located within the hospital or correctional institution, including, without limitation:
  - (1) The height, weight and age of the patient and any allergies that the patient may have;
  - (2) The medical records regarding any medications prescribed to the patient;

- (3) The results of any relevant laboratory tests, to the extent that those results are available in the computerized system of the hospital or correctional institution;
- (4) The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
- (5) Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
- (6) A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
- (7) Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the pharmacist to provide pharmaceutical services; and
- (d) Demonstrate to the off-site pharmaceutical service provider that the pharmacist is competent and knowledgeable in the use of the computerized system of the hospital or correctional institution and in providing pharmaceutical services in a hospital or correctional institution.
- 2. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall:
- a) Identify and update the current address of the site of practice in conformance with NAC 639.225;
- b) Comply with all provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, the regulations adopted pursuant thereto, and all other federal and state laws and regulations concerning the privacy of information regarding health care;
- c) Ensure that all required records are made readily accessible to members of the Board and employees, agents and designees of the Board; and
- d) Comply with all applicable state and federal statutes, regulations and rules, including, without limitation:
  - (1) All recordkeeping requirements imposed upon the pharmacy; and
  - (2) All requirements for maintaining the confidentiality and security of patient data.
- 3. A registered pharmacist engaged in the practice of pharmacy pursuant to this section shall not:
  - a) Maintain an inventory of drugs at the site of practice;
  - b) Act as a managing pharmacist; or
  - c) Provide services pursuant to the provisions of:
    - (1) NAC 449.15347;
    - (2) NAC 449.6138;
    - (3) NAC 449.722;
    - (4) NAC 449.74531;
    - (5) NAC 449.9905 and 639.4996;
    - (6) Subsection 2 of NAC 639.465; or
    - (7) NAC 639.690.
- 4. Before a *registered* pharmacist who is employed by an off-site pharmaceutical service provider provides remote chart order processing services to a hospital or correctional institution pursuant to this section, the pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The pharmacist must, before approving a chart order to be filled, evaluate:

- (a) The overutilization or underutilization of a medication;
- (b) Therapeutic duplication;
- (c) The appropriateness of the prescribed dosage and route of administration;
- (d) The appropriateness of the directions for use of the medication;
- (e) The appropriateness of the duration of the treatment with the prescribed medication;
- (f) Any contraindications of the medication and a particular disease, ailment or allergy of the patient;
- (g) Any contraindications or interactions between multiple medications prescribed for the patient; and
  - (h) The potential abuse or misuse of a medication.
- **35**. In an emergency, a *registered* pharmacist *engaged in the practice of pharmacy pursuant to this section* may render remote chart order processing services without being provided with all of the information required by paragraph (c) of subsection 1 if the pharmacist believes, in his or her professional judgment, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
- 46. A registered pharmacist who is employed by an off-site pharmaceutical service provider engaged in the practice of pharmacy pursuant to this section may refuse to approve the filling of a chart order if, in the judgment of the pharmacist, the chart order is not safe or reasonable for the patient. A pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
- 57. Each time that a *registered* pharmacist who is employed by an off-site pharmaceutical service provider provides remote chart order processing services pursuant to this section, the pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:
  - (a) The name or other identifier of the pharmacist:
- (b) The date and time that the pharmacist provided the services and, if applicable, approved the filling of a chart order; and
  - (c) The specific services provided by the pharmacist.
- 68. The managing pharmacist of a pharmacy that has a contract with or is owned by the same entity as an off-site pharmaceutical service provider may limit the remote chart order activities pursuant to this section processing services. provided by a pharmacist employed by the off-site pharmaceutical service provider.

#### Section. 9. NAC 639.4917 is hereby repealed:

Each off-site pharmaceutical service provider shall establish and follow policies and procedures for:

- 1. Protecting the confidentiality and integrity of patient information;
- 2. Assuring that pharmacists employed by the off-site pharmaceutical service provider comply with the provisions of NAC 639.4916;
- 3. Complying with all applicable state and federal statutes, regulations and rules, including, without limitation, maintaining records;
- 4. Ensuring that its records are made readily accessible to members of the Board and employees, agents and designees of the Board;
- 5. Conducting an ongoing program for the improvement of the provision of pharmaceutical services that is designed to objectively and systematically monitor and evaluate the quality and

appropriateness of patient care, improve patient care and resolve problems identified by the program;

- 6. Performing an annual review of the program conducted pursuant to subsection 5;
- 7. Assuring that the pharmacists employed by the off-site pharmaceutical service provider are able to communicate with identified employees of the hospital or correctional institution as necessary to provide pharmaceutical services, including, without limitation, communicating with pharmacists employed by the hospital or correctional institution; and
- 8. The provision of pharmaceutical services at times when the off-site pharmaceutical service provider temporarily or permanently cannot provide such services.