ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R003-15

Effective December 21, 2015

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

AUTHORITY: §§1-10, NRS 639.070 and 639.100.

A REGULATION relating to pharmacy; requiring, under certain circumstances, an outsourcing facility to obtain a license from the State Board of Pharmacy as a manufacturer; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

The federal Compounding Quality Act establishes a new category of "outsourcing facilities" and provides for the voluntary registration with the Secretary of Health and Human Services of facilities which conduct large-scale compounding of sterile drugs. (21 U.S.C. § 353b) The federal law defines "outsourcing facility" as a facility at one geographic location or address that: (1) is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with all of the requirements of 21 U.S.C. § 353b. (21 U.S.C. § 353b(d)(4)(A)) Traditional compounding pharmacies are governed under separate provisions of federal law. (21 U.S.C. § 353a)

Existing law requires a manufacturer, including a manufacturer who engages in furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State, to obtain a license from the State Board of Pharmacy. (NRS 639.100, 639.233) **Section 6** of this regulation requires an outsourcing facility, as defined in **section 4** of this regulation, to obtain a license from the Board as a manufacturer if the outsourcing facility is engaged in the compounding of sterile drugs either in this State or for shipment into this State. **Section 7** of this regulation provides, consistent with federal law, that an outsourcing facility is not required to be a licensed pharmacy unless the outsourcing facility dispenses dangerous drugs or controlled substances for identified individual patients pursuant to a prescription.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 7, inclusive, of this regulation.

Sec. 2. *As used in sections 2 to 7, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3, 4 and 5 of this regulation have the meanings ascribed to them in those sections.*

Sec. 3. *"Compounding" includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug.*

Sec. 4. *"Outsourcing facility" means a facility at one geographic location or address that:*

1. Is engaged in the compounding of sterile drugs; and

2. Has registered with the Secretary of Health and Human Services as an outsourcing facility pursuant to 21 U.S.C. § 353b.

Sec. 5. *"Sterile drug" means a drug that is:*

1. Intended for parenteral administration;

2. An ophthalmic or oral inhalation drug in aqueous format; or

3. Required to be sterile pursuant to the provisions of federal law or the provisions of NAC 639.661 to 639.690, inclusive.

Sec. 6. *An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:*

1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;

2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and

3. Comply with all the requirements of 21 U.S.C. § 353b.

Sec. 7. ***1. Except as otherwise provided in subsection 2, an outsourcing facility is not required to be licensed as a pharmacy.***

2. An outsourcing facility may dispense dangerous drugs or controlled substances for identified individual patients pursuant to a prescription only if the outsourcing facility is licensed by the Board as a pharmacy in accordance with NRS 639.230 or 639.2328, as applicable.

Sec. 8. NAC 639.609 is hereby amended to read as follows:

639.609 As used in NAC 639.609 to 639.619, inclusive, unless the context otherwise requires, the term "manufacturer" has the meaning ascribed to it in NRS 639.009. ***The term includes an outsourcing facility as defined in section 4 of this regulation.***

Sec. 9. NAC 639.610 is hereby amended to read as follows:

639.610 The premises occupied by any person holding a manufacturer's ~~[permit]~~ ***license*** or the premises to be occupied by any applicant for such a ~~[permit]~~ ***license*** must meet the following minimum standards:

1. The premises must be well lighted and well ventilated and must be maintained in a clean and orderly manner.

2. Adequate lavatory and toilet facilities and dressing areas must be provided, and washbasins to be used in connection with those facilities must be supplied with hot and cold running water. All such facilities must be maintained in a clean and orderly condition and in good repair.

3. The building must be constructed in such a manner as to provide maximum security and must be equipped with an adequate alarm system.

Sec. 10. NAC 639.615 is hereby amended to read as follows:

639.615 1. Any person to whom a manufacturer's ~~[permit]~~ ***license*** has been issued shall provide and maintain the following equipment if it is needed in the operation of the business, and shall comply with the following requirements as they apply to the operation of the business:

(a) If drugs requiring refrigeration are stocked, the holder of the ~~[permit]~~ ***license*** shall provide refrigerators for proper storage.

(b) The area in which drugs are stocked must be arranged so that dangerous drugs, chemicals, poisons, controlled substances and devices are not accessible to unauthorized persons.

(c) Drugs which are damaged, deteriorated, misbranded, adulterated or outdated must be stored in an area separate from the area containing the drugs, chemicals, poisons, controlled substances or devices which are to be sold or distributed for resale.

(d) The holder of a ~~[permit]~~ ***license*** shall maintain such records as may be necessary to provide accountability for the disposition of dangerous drugs, controlled substances, chemicals and devices.

(e) Equipment must be provided and maintained as may be considered necessary and consistent with the licensed operation, and maintained in proper working order at all times.

2. All persons who in the course of their employment with a manufacturer handle any drugs, chemicals or devices shall keep themselves and their apparel in a clean and sanitary condition.

R003-15
NAC Chapter 639.609, NAC 639.610, NAC 639.615; 639.New Language
Outsourcing Facilities

October 28, 2015

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION

The amendment will require an outsourcing facility to obtain a license as a manufacturer if the outsourcing facility is engaged in the compounding of sterile drugs. The proposed amendment will update the regulation to be consistent with federal Drug Quality and Security Act (DQSA).

2. A 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.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board further provided time for public comment at the workshop(s) concerning the proposed amendment.

3. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was: 11
The number of persons who testified at the hearing was: -0-
The number of agency submitted statements was: -0-
The name of persons who testified at the hearing: N/A

4. 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.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. Further, the Board provided time for public comment at the workshop(s) concerning the proposed amendment.

Parties interested in obtaining a copy of the summary of the proposed amendment, or that wish to view the text of the proposed amendment, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

5. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The Board received no comments from industry or the public requesting any changes.

6. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

There should be no adverse or beneficial economic effect of this regulation on the business or the public. The amendment creates a sub-category of license for businesses that have historically been licensed as pharmacies.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that this regulation will have no immediate or long-term economic effects on business or the public.

7. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the board for enforcement of this regulation.

8. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH 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.

The Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Title II of DQSA, The Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. One of those steps is to create a new sub-category of licensure – Outsourcing Facility – for certain types of pharmacies that have historically been licensed as pharmacies. Nevada and other states are creating this sub-category of licensure so that these businesses can be licensed at the state level. Otherwise, the FDA will create a program to license such facilities at the federal level.

9. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar federal regulations of the same activity in which the state regulation is more stringent.

10. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.