ADOPTED REGULATION

OF THE DEPARTMENT OF HEALTH

AND HUMAN SERVICES

LCB File No. R121-20

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

AUTHORITY: §§ 1-12, NRS 439B.685, as amended by section 16 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3728, and 439B.695, as amended by section 18 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3730; §§ 13-15, NRS 439B.685, as amended by section 16 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3728.

A REGULATION relating to prescription drugs; requiring the Director of the Department of Health and Human Services to appoint hearing officers; providing that the Department will provide notice to a pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative of the intent to impose an administrative penalty for failure to report certain information relating to the cost of prescription drugs; providing that such an administrative penalty stops accruing when such information is reported; prescribing procedures for appealing such an administrative penalty; providing that the Department will make available on an Internet website maintained by the Department certain forms that must be used by wholesalers to submit certain reports to the Department; authorizing a wholesaler that submits such a report to request that the Department keep certain information confidential as a trade secret under federal law; providing that the Department will not disclose the identity of a wholesaler in certain reports compiled by the Department concerning the prices of certain prescription drugs; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires a pharmacy, manufacturer of certain prescription drugs, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative to report certain information related to the cost of prescription drugs to the Department of Health and Human Services. (NRS 439B.635-439B.665, as amended by sections 11-14 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at pages 3724-3727; section 6 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723) Existing law authorizes the

Department to impose an administrative penalty against a pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative that fails to report the required information in a timely manner. (NRS 439B.695, as amended by section 18 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3730) **Sections 2-6** of this regulation define necessary terms. **Section 7** of this regulation requires the Director of the Department to appoint three permanent employees to serve as hearing officers in addition to their regular duties. **Section 8** of this regulation provides that the Department will provide written notice to a person or entity upon whom an administrative penalty is to be imposed. **Section 8** also provides that an administrative penalty stops accruing when the required information is submitted to the Department. **Section 9** of this regulation prescribes the procedure by which such an entity may request an appeal of an imposed administrative penalty. **Section 9** also: (1) provides for the assignment of a hearing officer to hear such an appeal; and (2) provides that the Department will not attempt to collect an administrative penalty while an appeal is pending. **Section 10** of this regulation prescribes the evidentiary rules that must be used during a hearing on an appeal. **Section 10** also provides that the Department will keep a record of such a hearing. If a party fails to appear at a hearing, **section 11** of this regulation authorizes the hearing officer to dispose of the matter based on the evidence before him or her. **Section 11** also provides that, if the appellant fails to appear at the hearing, the charges against the appellant are presumed to be true. **Section 11** additionally authorizes the hearing officer to grant a recess or continuance under certain circumstances. **Section 12** of this regulation: (1) requires the hearing officer to render an order at the conclusion of a hearing; and (2) provides that the decision of a hearing officer is final for purposes of judicial review.

Existing regulations provide that the Department will make available on the Internet the forms on which a manufacturer of certain prescription drugs, pharmacy benefit manager or pharmaceutical sales representative must submit the required report. (NAC 439.730) Existing regulations establish a process by which a manufacturer or pharmacy benefit manager may request to prevent the public disclosure of trade secrets contained in a report. (NAC 439.735) Existing law requires the Department to compile a report on the pricing of prescription drugs that is based on the information submitted by manufacturers, wholesalers and pharmacy benefit managers, and existing regulations provide that the identity of a drug, manufacturer or pharmacy benefit manager will not be disclosed in that report. (NRS 439B.650, as amended by section 14 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3727; NAC 439.740) Section 6 of Senate Bill No. 380 of the 2021 Legislative Session added requirements for wholesalers to submit information to the Department concerning sales of prescription drug shipped into this State. **(**Section 6 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723) **Sections 13-15** of this regulation accordingly make those regulatory provisions relating to forms, protection of trade secrets, and confidentiality of the identities of reporting entities applicable to wholesalers.

Section 1. Chapter 439B of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 12, inclusive, of this regulation.

Sec. 2. *As used in NAC 439.730, 439.735 and 439.740 and sections 2 to 12, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 6, inclusive, of this regulation have the meanings ascribed to them in those sections.*

Sec. 3. *"Manufacturer" has the meaning ascribed to it in NRS 439B.605, as amended by section 9.3 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723.*

Sec. 4. *"Pharmacy" has the meaning ascribed to it in NRS 439B.610.*

Sec. 5. *"Pharmacy benefit manager" has the meaning ascribed to it in NRS 439B.615.*

Sec. 6. *"Wholesaler" has the meaning ascribed to it in section 4 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723.*

Sec. 7. *1. The Director shall appoint three permanent employees of the Department to serve as hearing officers.*

2. An employee appointed as a hearing officer pursuant to this section shall perform the duties of a hearing officer in addition to the regular duties of the employee.

Sec. 8. *1. If the Department intends to impose an administrative penalty pursuant to NRS 439B.695, as amended by section 18 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3730, the Department will notify in writing the pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative upon whom the administrative penalty is to be imposed at least 15 business days before the effective date of the administrative penalty. The notice must include, without limitation:*

(a) A citation to the statutory and regulatory authority for the penalty;

(b) A description of the facts on which the penalty is based;

(c) A description of the circumstances considered by the Department in imposing the penalty;

(d) Instructions for responding to the notice and a statement of the available appeal procedures, including, without limitation, a statement of the right to a hearing, the period during which a hearing must be requested and the consequences of waiving a hearing; and

(e) The effective date of the penalty.

2. The Department will provide notice pursuant to this section to the last known physical address and last known electronic mail address of the pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative upon whom the administrative penalty is to be imposed.

3. An administrative penalty imposed pursuant to NRS 439B.695, as amended by section 18 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3730, stops accruing on the day on which the required information is submitted to the Department.

Sec. 9. *1. To appeal an administrative penalty imposed pursuant to NRS 439B.695, as amended by section 18 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3730, a pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative, as applicable, must submit a request for an appeal to the Director not later than 15 business days after the date on which the notice was provided pursuant to section 8 of this regulation. If the pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative fails to request a hearing within that time, the pharmacy, manufacturer, wholesaler, pharmacy benefit manager, nonprofit organization or pharmaceutical sales*

representative, as applicable, shall be deemed to have waived the appeal and the penalty becomes effective on the date specified in the notice.

2. The Director shall use a rotation of the hearing officers appointed pursuant to section 7 of this regulation when selecting a hearing officer to hear an appeal. Upon receiving a request for an appeal pursuant to subsection 1, the Director shall select the next hearing officer in the rotation who does not have a conflict of interest and is not otherwise disqualified to hear the appeal.

3. The Department will not attempt to collect a penalty while an appeal is pending.

Sec. 10. *1. Except as otherwise provided in this subsection, a hearing on an appeal requested pursuant to section 9 of this regulation must be open to the public. Upon the motion of a party, the hearing officer, in his or her discretion, may exclude from the hearing room any witness in the matter not at the time under examination except a party to the proceeding or his or her counsel.*

2. The hearing officer shall determine the evidence upon the charges and specifications as set forth by the Department in the notice provided pursuant to section 8 of this regulation.

3. The technical rules of evidence do not apply. All testimony and exhibits offered must be relevant and bear upon the matter in contention. The hearing officer may exclude any testimony or exhibit that he or she determines does not meet this criterion. The hearing officer shall also consider the objection of either side to the introduction of evidence, whether oral testimony or exhibit. When ruling on the objection, the hearing officer shall primarily consider the competence and relevance of the evidence at issue.

4. The hearing officer shall base his or her decision on the weight of the evidence presented at the hearing. Findings of fact, conclusions of law and decisions must be based on substantial evidence.

5. At the beginning of his or her testimony, each witness who has not previously testified in the hearing shall state his or her name and business, employment or position.

6. Any letter, paper or object offered in evidence must be properly authenticated and, if received, must be marked by the hearing reporter with a distinguishing number or letter, such as "Department's Exhibit 1" or "Appellant's Exhibit A."

7. Testimony may be presented in statement or question and answer form.

8. With the approval of the hearing officer, the parties may stipulate as to any fact at issue, either by a written stipulation introduced in evidence as an exhibit or by oral statements shown upon the record. Any such stipulation is binding upon all parties so stipulating and may be regarded by the hearing officer as evidence at the hearing.

9. The Department or an appellant may subpoena a witness to testify at a hearing. Such a witness must receive the fees and mileage allowed by law to a witness in a civil case.

10. The Department will keep a record of the proceedings, but the record need not be transcribed unless the decision is appealed or a transcript is requested by an interested party. Any party who requests a transcript shall pay the cost of transcription.

Sec. 11. *1. If a party fails to appear at a hearing scheduled by the hearing officer after receiving a request pursuant to section 9 of this regulation and no continuance has been granted:*

(a) The hearing officer may hear the evidence and proceed to consider the matter and dispose of it on the basis of the evidence before the hearing officer; and

(b) The charges specified in the proposed finding are presumed to be true.

2. Upon determining that good cause exists for a recess, the hearing officer may recess a hearing until a future date agreeable to the hearing officer and the parties.

3. The hearing officer may, before or during a hearing, upon a proper showing, grant a continuance for the submission of additional proof or another reasonable purpose.

Sec. 12. *1. The hearing officer shall render an order or decision with separately stated findings of fact and conclusions of law after the completion of a hearing on an appeal pursuant to section 10 of this regulation. A hearing is complete after the taking of evidence, the filing of briefs or the presentation of such oral or written arguments as may have been allowed by the hearing officer.*

2. The decision of a hearing officer made pursuant to the procedures set forth in sections 2 to 12, inclusive, of this regulation is a final decision in a contested case. Any person aggrieved by such a decision is entitled to judicial review of the decision pursuant to NRS 233B.130.

Sec. 13. NAC 439.730 is hereby amended to read as follows:

439.730 The Department will make available on an Internet website maintained by the Department the forms on which:

1. A manufacturer is required to submit the reports required by NRS 439B.635 *, as amended by section 11 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page*

3724, and 439B.640 ~~[.]~~ ***, as amended by section 12 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3725.***

2. ***A wholesaler is required to submit the report required by section 6 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723.***

3. A pharmacy benefit manager is required to submit the report required by NRS 439B.645 ~~[.]~~ ***, as amended by section 13 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3726.***

~~[3.]~~ ***4.*** A person included on a list of pharmaceutical sales representatives provided by a manufacturer to the Department pursuant to subsection 1 of NRS 439B.660, is required to submit the report required by subsection 4 of that section.

Sec. 14. NAC 439.735 is hereby amended to read as follows:

439.735 1. In complying with NRS 439B.635, ***as amended by section 11 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3724,*** 439B.640 ***, as amended by section 12 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3725,*** or 439B.645, ***as amended by section 13 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3726, or section 6 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723,*** if a manufacturer ***, wholesaler*** or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the manufacturer ***, wholesaler*** or pharmacy benefit manager may submit to the Department a request to keep the information confidential.

2. A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:

(a) The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records pursuant to NRS 239.010, the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.

(b) The second part of the request for confidentiality must include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. Upon a request for public records pursuant to NRS 239.010, the Department will disclose the explanation set forth in the request for confidentiality.

3. If the Department receives a request for public records pursuant to NRS 239.010 seeking disclosure of any information for which a manufacturer ***, wholesaler*** or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:

(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer ***, wholesaler*** or pharmacy benefit manager with:

(1) Written notice of the request for public records and the procedures set forth in this section; and

(2) A copy of the request for public records and the date on which the Department received the request.

(b) Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term "trade secrets" in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended.

4. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of NRS 239.0107 that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer ***, wholesaler*** or pharmacy benefit manager with:

(1) Written notice that the Department denied the request for public records; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of NRS 239.0107 that the Department intends to disclose the information, except that:

(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and

(2) If the manufacturer ***, wholesaler*** or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer ***, wholesaler*** or pharmacy benefit manager with:

(1) Written notice that the Department intends to disclose the information; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer ***, wholesaler*** or pharmacy benefit manager:

(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.

(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:

(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.

(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

Sec. 15. NAC 439.740 is hereby amended to read as follows:

439.740 In the report compiled by the Department pursuant to NRS 439B.650, ***as amended by section 14 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3727,*** the Department will include:

1. Only aggregated data that does not disclose the identity of any drug, manufacturer ***, wholesaler*** or pharmacy benefit manager; and

2. In addition to the information required by NRS 439B.650, ***as amended by section 14 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3727,*** a description of trends concerning the prices of prescription drugs that appear on the most current lists compiled by the

Department pursuant to NRS 439B.630, ***as amended by section 10 of Senate Bill No. 380, chapter 547, Statutes of Nevada 2021, at page 3723,*** and an explanation of how those prices and trends may affect:

(a) The prevalence and severity of diabetes in this State; and

(b) The system of health care in this State.