

**PROPOSED REGULATION OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

LCB File No. R121-20

November 23, 2020

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

AUTHORITY: §§1-11, NRS 439B.685 and 439B.695.

A REGULATION relating to prescription drugs; requiring the Director of the Department of Health and Human Services to provide notice to a pharmacy, manufacturer, 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; prescribing procedures for appealing such an administrative penalty; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law requires a pharmacy, manufacturer of certain prescription drugs, 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) Existing law authorizes the Department to impose an administrative penalty against a pharmacy, manufacturer, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative that fails to report the required information in a timely manner. (NRS 439B.695) **Sections 2-5** of this regulation define necessary terms. **Section 6** 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 7** of this regulation requires the Department to provide written notice to a person or entity upon whom an administrative penalty is to be imposed. **Section 8** of this regulation prescribes procedures by which such an entity may request an appeal. **Section 8** also provides for the assignment of a hearing officer to hear such an appeal. **Section 9** of this regulation prescribes the evidentiary rules that must be used during a hearing on an appeal. **Section 9** also requires the Department to keep a record of such a hearing. If a party fails to appear at a hearing, **section 10** of this regulation authorizes the hearing officer to dispose of the matter based on the evidence before him or her. **Section 10** also provides that, if the appellant fails to appear at the hearing, the charges against the appellant are presumed to be true. **Section 10** additionally authorizes the hearing officer to grant a recess or continuance under certain circumstances. **Section 11** 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.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 11, inclusive, of this regulation.

Sec. 2. *As used in NAC 439.730, 439.735 and 439.740 and sections 2 to 11, 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. *“Manufacturer” has the meaning ascribed to it in NRS 639.009.*

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 683A.174.*

Sec. 6. 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. 7. 1. *If the Department intends to impose an administrative penalty pursuant to NRS 439B.695, the Department will notify in writing the pharmacy, manufacturer, 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, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative upon whom the administrative penalty is to be imposed.

Sec. 8. 1. To appeal an administrative penalty imposed pursuant to NRS 439B.695, a pharmacy, manufacturer, 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 of the notice provided pursuant to section 7 of this regulation. If the pharmacy, manufacturer, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative fails to request a hearing within that time, the pharmacy, manufacturer, 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 6 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.

Sec. 9. 1. Except as otherwise provided in this subsection, a hearing on an appeal requested pursuant to section 8 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 7 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 not to 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 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. 10. 1. *If a party fails to appear at a hearing scheduled by the hearing officer after receiving a request pursuant to section 8 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 submission of additional proof or other reasonable purpose.

Sec. 11. 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 9 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 11, 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.