ADOPTED REGULATION

OF THE STATE BOARD OF PHARMACY

LCB File No. R007-17

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

AUTHORITY: §1, NRS 453.221 and 639.070.

A REGULATION relating to controlled substances; revising provisions relating to the partial filling of certain controlled substances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the registration and control of the dispensing of controlled substances within this State. (NRS 453.221) Existing regulations authorize a pharmacist to partially fill a prescription for a controlled substance listed in schedule II, III, IV or V. (NAC 453.460) This regulation revises the circumstances in which a pharmacist is authorized to partially fill a prescription for a controlled substance listed in schedule II. This regulation: (1) generally requires that the remaining portion of a prescription for a controlled substance listed in schedule II that has been partially filled may be filled, but must not be filled more than 30 days after the date on which the prescription was written; (2) provides that in an emergency situation, the remaining portion of such a prescription must be filled not later than 72 hours after the prescription was issued; and (3) requires a pharmacist to refuse to fill or partially fill any prescription for a controlled substance listed in schedule II more than 30 days after the date on which the prescription was written.

Section 1. NAC 453.460 is hereby amended to read as follows:

453.460 1. A pharmacist may partially fill a prescription for a controlled substance listed in schedule II:

(a) If the [~~pharmacist~~] *partial filling* is [~~unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The~~] *requested by a patient or the prescribing practitioner and the total quantity of the controlled*

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substance that is dispensed in all partial fillings does not exceed the total quantity of the controlled substance that is prescribed. Except as otherwise provided in this paragraph, the remaining portion of the prescription may be filled ~~[within]~~ *, but in any event must not be filled more than 30 days after the date on which the prescription was written. In an emergency situation as set forth in 21 U.S.C. § 829(a), the remaining portion of the prescription must be filled not later than* 72 hours after the ~~[first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing practitioner. No further quantity may be supplied beyond the 72-hour period without a new]~~ prescription ~~[.]~~ *was issued.*

(b) For a patient in a facility for long-term care or for a patient who has been diagnosed as having a terminal illness. The pharmacist shall record on the prescription that the patient is a "LTC patient" or "terminally ill." The date of the partial filling, the quantity of the medication that is dispensed, the remaining quantity which is authorized to be dispensed, and the signature or initials of the pharmacist must be recorded on the back of the prescription. The total quantity of the controlled substance that is dispensed in all partial fillings must not exceed the total quantity of the controlled substance that is prescribed. A prescription is valid for 60 days after the date of the prescription unless the prescription is terminated earlier by the discontinuance of medication.

2. A pharmacist may partially fill a prescription for a controlled substance listed in schedule III, IV or V. A partial filling *of a prescription* pursuant to this subsection does not constitute a ~~[full]~~ refill for the purposes of subsection 3 of NRS 453.256. A ~~[full refill of a]~~ prescription ~~[does not occur]~~ *that is partially filled pursuant to this subsection is not completely filled* until the total quantity dispensed in all partial fillings equals the total quantity prescribed.

3. Whenever a patient requests a partial filling, ~~[the]~~ *a* pharmacist shall:

(a) Create and maintain a record of each partial ~~[refill]~~ *filling* that reflects the total quantity dispensed for any particular prescription;

(b) Ensure that the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(c) Refuse to fill or partially fill any prescription *for a controlled substance listed in:*

(1) Schedule II more than 30 days after the date on which the prescription was written; and

(2) Schedule III, IV or V more than 6 months after the date on which the prescription was issued.

~~[3.]~~ *4.* As used in this section, "facility for long-term care" means a medical facility that provides 24-hour nursing services.

R007-17
NAC Chapter 453.460
Requirements to Partially Fill a Controlled
Substance Listed in Schedule II
January 30, 2018

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

This regulation revises the circumstances in which a pharmacist is authorized to partially fill a prescription for a controlled substance listed in schedule II. The regulation requires that the remaining portion of a partially filled schedule II prescription must be filled not later than 30 days after the date the prescription was written; the remaining portion of an emergency schedule II prescription must be filled not later than 72 hours after the prescription was issued; requires a pharmacist to refuse to fill or partially fill a schedule II prescription more than 30 days after the date the prescription was written.

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 Hearing 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 dispensing practitioners, 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:
Not Applicable

The names of the agencies that submitted statements:
Not Applicable

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 Hearing 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 dispensing practitioners, 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.

The Board adopted LCB File R007-17 with a non-substantive change at Section 1.1(a), page 2, line 7 to read as follows:

> ...remaining portion of the prescription [~~may~~] *may be filled, but in any event, must not* be filled [~~within~~] [~~not~~] *later than 30 days after...*

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 economic impact from this regulation on businesses or the public.

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, or any such effects will be negligible.

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 Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

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 regulations of the same activity in which the federal 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.

SMALL BUSINESS IMPACT STATEMENT AS REQUIRED BY NRS 233B.0608

LCB File No. R007-17

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.

The Board of Pharmacy (Board), through its executive staff and legal counsel, have carefully examined the proposed amendment and have determined that it is not likely to (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses."

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 Hearing 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 dispensing practitioners, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board also 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.

2. The manner in which the analysis was conducted.

Board Staff analyzed the regulation to determine whether it could perceive a direct and significant economic burden on pharmacies, which are the businesses most likely to be affected by the regulation. It also analyzed whether the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis, but received none.

3. The estimated economic effect of the proposed regulation on the small businesses which it is to regulate, including, without limitation:

(a) Both adverse and beneficial effects; and

The Board anticipates no significant adverse or beneficial economic impact from R007-17 on Nevada small businesses.

(b) Both direct and indirect effects.

The Board anticipates no direct or indirect effect on small businesses from R007-17.

4. 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 Board anticipates no significant adverse economic impact from R007-17 on Nevada businesses, so no alternative methods of regulation are deemed necessary.

5. The estimated cost to the agency for enforcement of the proposed regulation.

No additional cost to enforce.

6. If the proposed 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.

Not Applicable.

7. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

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

8. The reasons for the conclusion of the agency regarding the impact of a regulation on small businesses.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small businesses. It also found no evidence that the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis, and received none.

9. The methods used by the agency in determining the impact of the regulation on small business and the reasons for the agency's conclusions.

The Board, through its executive staff and legal counsel, carefully examined the regulation and determined that it is not likely to (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses."

In reaching that conclusion, the Board solicited comment on the regulation by (1) posting notice, with a link 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 Hearing 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.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small business. It also found no evidence that the proposed regulation would restrict the formation, operation or expansion of such small businesses. Absent any evidence, the Board concluded that no such impacts are likely to exist.

I hereby certify that to the best of my knowledge or belief a concerted effort was made to determine the impact of this proposed regulation on small businesses and that the information contained in the statement was prepared properly and is accurate.

Larry Pinson, Pharm.D.
Executive Secretary
Nevada State Board of Pharmacy