

Nevada State Board of Pharmacy

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April 27, 2016

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 1:30 p.m., on Wednesday, June 1, 2016, at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment of Nevada Administrative Code (NAC) 639.921 Sharing of information between two or more pharmacies.

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment would allow for the sharing of information concerning prescriptions between the computerized system of two or more pharmacies that are commonly owned or contractually related.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

<u>3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:</u>

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation on businesses or the public. The proposed amendment will benefit small businesses by allowing the sharing of information and services.

(b) Both immediate and long-term effects.

There will be no immediate or long-term economic effect on businesses or the public.

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

There will be no significant new costs incurred by the Board of Pharmacy for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

<u>6. If the regulation is required pursuant to federal law, a citation and description of the federal law.</u>

The Board of Pharmacy is not aware of this regulation being required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

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. Whether the proposed regulation establishes a new fee or increases an existing fee.

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

Amendment of Nevada Administrative Code (NAC) 639.955 Imposes fines for not transmitting information regarding the dispensing of controlled substances.

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment provides a penalty for the failure to transmit certain information concerning the dispensing of controlled substances.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

<u>3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:</u>

(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.

There will be no immediate or long-term economic effect on businesses or the public.

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

There will be no significant new costs incurred by the Board of Pharmacy for

enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

<u>6. If the regulation is required pursuant to federal law, a citation and description of the federal law.</u>

The Board of Pharmacy is not aware of this regulation being required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

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. Whether the proposed regulation establishes a new fee or increases an existing fee.

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

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada 89509, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board <u>at least fourteen days</u> before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise

statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy Reno, Nevada

Mineral County Courthouse Hawthorne, Nevada Nevada State Board of Pharmacy Las Vegas, Nevada

Elko County Courthouse Elko, Nevada

Washoe County Courthouse Reno, Nevada

PROPOSED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R035-16

April 7, 2016

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

AUTHORITY: §1, NRS 639.070 and 639.0745.

A REGULATION relating to pharmacy; authorizes the sharing of information concerning prescriptions between the computerized systems of licensed pharmacies that are not commonly owned under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing regulations authorize the sharing of information concerning prescriptions between the computerized systems of two or more licensed pharmacies that are commonly owned under certain circumstances. (NAC 639.921) This regulation authorizes the sharing of such information between the computerized systems of two or more licensed pharmacies that are not commonly owned if, in addition to satisfying other requirements, the pharmacies share the information pursuant to a written agreement which sets forth the services which each pharmacy is to provide.

Section 1. NAC 639.921 is hereby amended to read as follows:

639.921 1. Information concerning prescriptions may be shared between the computerized

systems of two or more pharmacies licensed by the Board if:

(a) The pharmacies are commonly owned [;] or, if not commonly owned, the pharmacies

share such information pursuant to a written agreement which sets forth the services which

each pharmacy is to provide; and

(b) The computerized systems for recording information concerning prescriptions share a common database that:

(1) Except as otherwise provided in subsection 3, contains all the information concerning a patient that is contained in each computerized system that has access to the common database;

(2) Except as otherwise provided in subsection 3, contains all the information concerning a prescription that is contained in each computerized system that has access to the common database;

(3) After a prescription has been filled, automatically decreases the number of refills remaining for the prescription, if any, regardless of which pharmacy filled the prescription;

(4) Automatically stores any modification or manipulation of information concerning a prescription made by a pharmacy with access to the common database so that the modification or manipulation is available to each pharmacy with access to the common database;

(5) Allows access only by a person who is authorized to obtain information from the common database;

(6) Requires any person who is authorized to modify or manipulate information concerning a prescription, before modifying or manipulating the information concerning the prescription, to identify himself or herself in the computerized system by:

(I) Using a biometric identification technique; or

(II) Entering into the computerized system another unique identifier which is approved by the Board and which is known only to and used only by that person;

(7) Makes and maintains an unchangeable record of each person who modifies or manipulates information concerning the prescription, that includes, without limitation:

(I) The name or initials of the person;

(II) An identifier that can be used to determine the pharmacy in which the person modified or manipulated the information concerning the prescription; and

(III) The type of activity concerning the prescription that the person performed, including, without limitation, modifying or manipulating the information concerning the prescription;

(8) Contains a scanned image of the original prescription if the original prescription is a written prescription; and

(9) Provides contact information for the first pharmacist who verifies the correctness of the information contained in the common database concerning the prescription.

2. If a pharmacy is the initial pharmacy to receive a written prescription, a pharmacist shall ensure that:

(a) The written prescription is numbered consecutively in accordance with NAC 639.914;
and

(b) The image of the prescription is scanned into the computerized system of the pharmacy.

3. If a pharmacy other than the pharmacy that initially received a prescription enters information concerning a prescription into a computerized system for recording information concerning prescriptions, the information must not be accessible from the common database for the purpose of filling or dispensing a prescription until a pharmacist verifies the correctness of the information entered into the computerized system. After verifying that information, the pharmacist shall enter a notation in the computerized system that includes the pharmacist's name, contact information and the date on which he or she verified the information.

4. A pharmacy that fills a prescription using the information from the common database, other than the pharmacy that initially received the prescription, shall:

(a) Process the prescription in the same manner as a prescription that is initially received by the pharmacy;

(b) Except as otherwise provided in paragraph (c), dispense the prescription in the same manner as a prescription that is initially received by the pharmacy; and

(c) Place on the label of the container in which the prescription will be dispensed:

(1) The number assigned to the prescription by the pharmacy that initially received the prescription; and

(2) An additional number or other identifier that ensures that the number placed on the label pursuant to subparagraph (1) is not confused with a prescription number of the pharmacy that is filling the prescription.

5. The filling of a prescription pursuant to the provisions of subsection 4 shall not be considered a transfer of the prescription.

PROPOSED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R036-16

April 7, 2016

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

AUTHORITY: §1, NRS 453.1545, as amended by Senate Bill No. 459, chapter 26, Statutes of Nevada 2015 at page 114, and NRS 639.070.

A REGULATION relating to pharmacy; providing a penalty for the failure to transmit to the State Board of Pharmacy certain information concerning the dispensing of certain controlled substances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing regulations set forth certain fines which the State Board of Pharmacy may impose against a pharmacist or pharmacy for certain violations of statute or regulation. (NAC 639.955) This regulation establishes a fine of \$100 per day for the failure to transmit to the Board certain information concerning the dispensing of certain controlled substances.

Section 1. NAC 639.955 is hereby amended to read as follows:

639.955 1. Except as otherwise provided in this section, the Board may impose a fine

against a pharmacist or pharmacy pursuant to paragraph (f) of subsection 1 of NRS 639.255

according to the following schedule:

(a) For failing to counsel a patient	\$7	'5	0
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(b) For failing to maintain documentation of counseling given to a

patient......750

(c) For an error in a prescription that resulted in a negative outcome to
the patient or discomfort to the patient, but did not require intervention or
treatment by a medical facility or a physician 500
(d) For an error in a prescription that resulted in a significant negative
outcome to the patient or required intervention or treatment by a medical
facility or a physician1,000
(e) For an error in a prescription that resulted in or contributed to a
patient's death 5,000
(f) Working as a pharmacist or employing a pharmacist to work in a
pharmacy without a certificate of registration
(g) Working as a pharmaceutical technician or employing a
pharmaceutical technician to work in a pharmacy without a certificate of
registration100 per day
(h) For failing to make or maintain a biennial inventory of controlled
substances 1,000
(i) For failing to transmit the information required pursuant to NAC
639.926 100 per day
2. The Board may impose a fine for a violation listed in subsection 1 that is less than or
greater than the amount set forth in that subsection for that violation after giving consideration to

the conduct for which the fine is being imposed, and the unique circumstances of each case.

any aggravating and mitigating factors that relate to the violator's role in and responsibility for

3. If a pharmacy or pharmacist commits a violation listed in subsection 1 more than once during any 36-month period, the Board may impose a fine for any subsequent violation in an amount that is greater than the amount set forth in subsection 1 for that violation.

4. If a pharmacy under common ownership with one or more pharmacies commits a violation listed in subsection 1, and any pharmacy under that common ownership thereafter commits the same violation within any 36-month period, the Board may impose a fine for those subsequent violations in an amount that is greater than the amount set forth in subsection 1 for that violation.

5. The Board may, as it deems appropriate, impose a fine for a violation not listed in subsection 1 that is commensurate with the severity of the violation.

6. No fine imposed by the Board will exceed \$10,000.

7. If, within an accusation, a member of the Board's staff groups similar violations into one cause of action, that grouping is for administrative convenience only and does not affect the authority of the Board to take disciplinary action for each separate violation.

8. This section will be construed and applied so as to preserve the discretion of the Board to take any disciplinary action authorized by NRS 639.255.