



Nevada State Board of Pharmacy

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May 2, 2018

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 9:00 a.m. on Thursday, June 7, 2018, 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 Chapter 639 to add a new section thereto providing for the dispensing of drugs with prescription readers. Enacts provisions of Senate Bill 131 (79th Session 2017) requiring certain pharmacies to, upon request, provide a prescription reader or advice on obtaining a prescription reader.
(LCB File No. R131-17)

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

To comply with Senate Bill No. 131 of the 79th Legislative Session, a retail community pharmacy that dispenses drugs will be required to notify each person to whom a drug is dispensed that a prescription reader is available to the person.

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.

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

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 there will be no immediate or long-term economic effect on businesses or the public, or that any such effects will be negligible.

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

There will be no additional or special 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.

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

The regulation is not 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 Chapter 453 to add a new section thereto relating to practitioner access to the Prescription Monitoring Program (PMP) database established pursuant to NRS 453.162.

(LCB File No. R013-18)

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

To require practitioners to register with the Board to access the PMP database. To allow a practitioner to designate members of his or her staff to act as delegates for the purposes of accessing the PMP database. To provide for the suspension or termination of access to the PMP database if the Board or the Division has probable cause to believe that the PMP database has been intentionally accessed by a person or for a purpose not authorized by law.

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.

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

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 there will be no immediate or long-term economic effect on businesses or the public, or that any such effects will be negligible.

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

There will be no additional or special 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.

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

The regulation is not 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 at least fourteen days 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

Nevada State Board of Pharmacy
Las Vegas, Nevada

Mineral County Courthouse
Hawthorne, Nevada

Elko County Courthouse
Elko, Nevada

Washoe County Courthouse
Reno, Nevada

**REVISED PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R131-17

April 17, 2017

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

AUTHORITY: §1, NRS 639.070 and section 1 of Senate Bill No. 131, chapter 112, Statutes of Nevada 2017, at page 484 (NRS 639.28015).

A REGULATION relating to pharmacies; specifying the manner in which certain retail community retail pharmacies must provide notice of the availability of prescription readers; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Senate Bill No. 131 of the 79th Legislative Session requires a retail community pharmacy that dispenses drugs to notify each person to whom a drug is dispensed that a prescription reader is available to the person. (Section 1 of Senate Bill No. 131, Chapter 112, Statutes of Nevada 2017, at page 484, (NRS 639.28015)) This regulation specifies the manner in which such notice must be provided.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. To comply with the provisions of section 1 of Senate Bill No. 131, chapter 112, Statutes of Nevada 2017, at page 484, (NRS 639.28015), regarding notice about the availability of prescription readers, a retail community pharmacy shall provide:

(a) Written notice in the form of a sign that is posted in the pharmacy;

(b) Notice in writing that is given directly to the patient or caregiver of the patient to whom the drug is dispensed; or

(c) Verbal notice by direct conversation between the staff of the pharmacy and the patient or caregiver of the patient to whom the drug is dispensed.

2. Upon request of the patient or caregiver of the patient to whom a drug is dispensed, a retail community pharmacy shall provide to the patient or caregiver a prescription reader or directions or advice on the manner in which to obtain a prescription reader.

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R013-18

April 27, 2018

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

AUTHORITY: §§1, 2 and 5-9, NRS 453.221 and 639.070; §3, NRS 639.070 and section 58 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4434 (NRS 639.23916); §4, NRS 639.070 and 639.23507; §10, NRS 639.070 and 639.0727.

A REGULATION relating to controlled substances; requiring a practitioner to register with the State Board of Pharmacy to access the database that tracks each prescription for certain controlled substances; authorizing a practitioner or hospital to have a delegate access the database to obtain a patient utilization report; authorizing the Board to suspend or terminate before a hearing the Internet access of a practitioner or other person to the database in certain situations; providing the procedure used by the Board to suspend the registration of a practitioner or other person to dispense any controlled substance in certain circumstances; authorizing the Board to provide certain information from the database to a practitioner or other person whose Internet access is suspended or terminated; setting forth the notice and hearing requirements for a practitioner or other person to use if his or her Internet access to the database is suspended or terminated; setting forth certain requirements for the disclosure of information from the database; 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 in Nevada. (NRS 453.221) Existing law further authorizes the Board to adopt regulations that: (1) are necessary for the protection of the public relating to the practice of pharmacy; (2) authorize the Executive Secretary of the Board to issue certificates, licenses and permits required for the practice of pharmacy or for the dispensing of controlled substances; and (3) govern the dispensing of poisons, drugs, chemicals and medicines. (NRS 639.070) Existing law provides that the Board and the Investigation Division of the Department of Public Safety will develop a computerized

program to track each prescription for a controlled substance listed in schedule II, III, IV or V that is filled by a pharmacy or dispensed by a practitioner. (NRS 453.162)

Existing law requires a practitioner or other person who dispenses any controlled substance to obtain biennially a registration that is issued by the Board. (NRS 453.226) Existing regulations require that a practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board for a certificate of registration to dispense controlled substances or dangerous drugs. (NAC 639.742) Existing law provides that a person must present proof that he or she is authorized to access the database of the computerized program that tracks each prescription for a controlled substance before the Board issues or renews a registration to dispense any controlled substance. (NRS 453.226) **Section 2** requires a practitioner or other person who is required to register with the Board to dispense controlled substances or to dispense controlled substances or dangerous drugs to register with the Board to access the database of the computerized program. **Section 10** of this regulation provides that a practitioner must present proof that he or she is registered pursuant to **section 2** of this regulation to access the database of the computerized program before the Board will issue a certificate of registration to dispense controlled substances or dangerous drugs. **Section 2** sets forth that: (1) the Board will deem such registration as proof that the practitioner is authorized to access the database of the computerized program; and (2) access to the database of the computerized program is a revocable privilege.

Existing law requires a practitioner other than a veterinarian to obtain from the database of the computerized program a patient utilization report before issuing an initial prescription for a controlled substance and at least once every 90 days thereafter for the duration of the course of treatment. Existing law requires the Board to adopt regulations that allow a hospital to designate members of the hospital staff to act as delegates for the purposes of accessing the database of the computerized program and obtaining patient utilization reports from the computerized program on behalf of a physician while he or she is providing service in a hospital emergency department. (NRS 639.23507) Existing law authorizes the Board to adopt any regulations necessary to enforce the provisions requiring a practitioner to obtain a patient utilization form from the database of the computerized program. (Section 58 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4434 (NRS 639.23916)) **Sections 3 and 4** of this regulation authorize a practitioner and a hospital, respectively, to designate certain persons as delegates for the purpose of accessing the database of the computerized program to obtain: (1) the information needed by a practitioner for the practitioner to create a patient utilization report; or (2) a patient utilization report on behalf of a physician providing service in a hospital emergency department. **Sections 3 and 4** require such a delegate to complete certain courses of training before he or she may access the database of the computerized program. **Sections 3 and 4** hold the practitioner or hospital, respectively, liable for any action of the delegate relating to accessing the database of the computerized program.

Existing law authorizes the Board or the Division to suspend or terminate access to the database of the computerized program if a law enforcement agency or employee violates certain provisions. (NRS 453.165) **Section 5** of this regulation authorizes the Board or the Division to

suspend or terminate, before a hearing, the Internet access of a practitioner or other person to the database of the computerized program if the practitioner or other person violates certain provisions. **Section 7** of this regulation authorizes a practitioner or other person whose Internet access to the database of the computerized program is suspended or terminated pursuant to **section 5** to request from the Board information from the database of the computerized program concerning a patient of the practitioner or other person. **Section 7** provides that the Board will provide the requested information if: (1) the person whose information is being requested is a patient of the practitioner or other person; (2) the person whose information is being requested is not deceased; and (3) the request for information complies with existing law. **Section 8** of this regulation sets forth the notice and hearing requirements that must occur if: (1) a practitioner's or other person's Internet access to the database of the computerized program is suspended or terminated pursuant to **section 5**; or (2) a law enforcement agency's or employee's Internet access to the database of the computerized program is suspended or terminated pursuant to existing law.

Existing law authorizes the Board to suspend any registration before a hearing if the Board finds that there is an imminent danger to the public health or safety which warrants such action. (NRS 453.241) **Section 6** of this regulation authorizes the Board or Executive Secretary of the Board, if a practitioner's or other person's Internet access is suspended or terminated pursuant to **section 5**, to also suspend the practitioner's or other person's registration to dispense controlled substances or certificate of registration to dispense controlled substances or dangerous drugs if the Board finds that there is an imminent danger to the public health or safety that warrants such action.

Existing law requires the information obtained from the database of the computerized program to be disclosed upon the request of a person about whom the information requested concerns or upon the request of that person's attorney. (NRS 453.164) **Section 9** of this regulation: (1) requires the person or his or her attorney to submit such a request by using a notarized authorization form that the Board will provide on its Internet website; and (2) provides that the Board will, upon receiving such a notarized authorization form, disclose the information only to the person about whom the information requested concerns or to that person's attorney.

Section 1. Chapter 453 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 9, inclusive, of this regulation.

Sec. 2. 1. *A practitioner or other person who is required to register with the Board pursuant to subsection 1 of NRS 453.226 to dispense controlled substances or NAC 639.742 to*

dispense controlled substances or dangerous drugs must also register with the Board pursuant to this section to access the database of the program established pursuant to NRS 453.162.

2. To register pursuant to this section to access the database, the practitioner or other person must apply to the Board on an application provided by the Board. For purposes of subsection 1 of NRS 453.226, the Board will deem such registration as proof that the practitioner or other person is authorized to access the database.

3. Access to the database is a revocable privilege, and no holder of such access to the database of the program acquires any vested right therein or thereunder.

Sec. 3. 1. Except as otherwise provided in section 4 of this regulation, a practitioner other than a veterinarian may designate not more than two members of his or her staff to act as delegates for the purpose of accessing the database of the computerized program established pursuant to NRS 453.162 to obtain the information needed by a practitioner for the practitioner to obtain a patient utilization report pursuant to NRS 639.23507.

2. A delegate designated pursuant to subsection 1 must complete the course of training required pursuant to subsection 5 of NRS 453.164 before the delegate is provided with Internet access to the database.

3. The practitioner shall be liable for any action of the delegate relating to accessing the database.

Sec. 4. 1. A hospital may designate members of the staff of the hospital to act as delegates for the purpose of accessing the database of the computerized program established pursuant to NRS 453.162 to obtain a patient utilization report pursuant to NRS 639.23507 on behalf of a physician providing service in a hospital emergency department.

2. A delegate designated pursuant to subsection 1 must complete the course of training required pursuant to subsection 5 of NRS 453.164 before the delegate is provided with Internet access to the database.

3. The hospital shall be liable for any action of the delegate relating to accessing the database.

Sec. 5. 1. The Board or the Division may suspend or terminate, before a hearing, the Internet access of a practitioner or other person to the database of the program established pursuant to NRS 453.162 if the practitioner or other person violates any provision of NRS 453.162 to 453.165, inclusive, NRS 639.23507 or sections 52 to 58, inclusive, of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4430 (NRS 639.2391 to 639.23916, inclusive).

2. As used in this section, "practitioner" does not include a hospital or other institution which is licensed, registered or otherwise authorized in this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research.

Sec. 6. 1. If the Internet access of a practitioner or other person to the database of the program established pursuant to NRS 453.162 is suspended or terminated pursuant to section 5 of this regulation, the Board or Executive Secretary of the Board on behalf of the Board may, pursuant to NRS 453.241, also suspend, before a hearing, a registration of the practitioner or other person to dispense controlled substances issued pursuant to NRS 453.226 or a certificate of registration to dispense controlled substances or dangerous drugs issued

pursuant to NAC 639.742 if the Board finds that there is an imminent danger to the public health or safety that warrants such action.

2. The suspension of a registration pursuant to subsection 1 must continue in effect until the conclusion of the proceedings set forth in NRS 639.241 to 639.2576, inclusive, unless sooner withdrawn by the Board or dissolved by a court of competent jurisdiction.

Sec. 7. 1. A practitioner or other person whose Internet access to the database of the program established pursuant to NRS 453.162 is suspended or terminated pursuant to section 5 of this regulation may submit to the Board a request that the Board provide information which is obtained from the database of the program concerning a patient of the practitioner or other person if:

(a) Such information is necessary for the practitioner or other person to comply with the provisions of this chapter, chapter 639 of NAC or chapter 453 or 639 of NRS; and

(b) The practitioner or other person is registered to dispense controlled substances pursuant to NRS 453.226 or to dispense controlled substances or dangerous drugs pursuant to NAC 639.742.

2. The practitioner or other person must submit to the Board the request for information described in subsection 1 by use of an electronic mail address that the Board will provide on its Internet website.

3. Upon receiving a request for information pursuant to subsections 1 and 2, the Board will provide the requested information to the practitioner or other person if the Board determines that:

(a) The person whose information is being requested is a patient of the practitioner or other person;

(b) The person whose information is being requested is not deceased; and

(c) The request for information complies with this chapter, chapter 639 of NAC and chapters 453 and 639 of NRS.

Sec. 8. 1. If Internet access to the database of the program established pursuant to NRS 453.162 is suspended or terminated pursuant to section 5 of this regulation or NRS 453.165, the Board will provide written notice to the law enforcement agency or employee, person or practitioner whose Internet access to the database of the program is suspended or terminated:

(a) If practicable, before the suspension or termination occurs; or

(b) If notice cannot be provided before the suspension or termination occurs, as soon as practicable after the suspension or termination occurs.

2. In the event of a suspension or termination of Internet access to the database of the program pursuant to section 5 of this regulation or NRS 453.165, the Board will conduct a hearing at the next regularly scheduled meeting of the Board, but in any event, the hearing must be instituted and determined within 45 days after the date of the suspension or termination unless a continuance is requested by the law enforcement agency or employee, person or practitioner or the law enforcement agency or employee, person or practitioner otherwise prevents the holding or conclusion of the hearing.

3. The determination of the Board is final, except that the propriety of such action is subject to review by a court of competent jurisdiction.

Sec. 9. 1. *If a person wishes to obtain information concerning the person from the database of the program established pursuant to NRS 453.162, the person or his or her attorney must submit to the Board a request for information pursuant to paragraph (a) of subsection 8 of NRS 453.164 using a notarized authorization form which is provided on the Internet website of the Board.*

2. *Upon receiving the notarized authorization form, the Board will disclose the information obtained from the database only to the person about whom the information requested concerns or his or her attorney.*

Sec. 10. NAC 639.742 is hereby amended to read as follows:

639.742 1. A practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. *A practitioner must present proof that he or she is registered pursuant to section 2 of this regulation to access the database of the program established pursuant to NRS 453.162 before the Board may issue a certificate of registration to dispense controlled substances or dangerous drugs.* A practitioner must submit a separate application for each site of practice, including, without limitation, a telepharmacy, remote site or satellite consultation site, from which the practitioner wishes to dispense controlled substances or dangerous drugs. A certificate of registration to dispense controlled substances or dangerous drugs is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

2. If a facility from which the practitioner intends to dispense dangerous drugs or controlled substances is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.

3. Except as otherwise provided in NRS 639.23277 and NAC 639.395, the dispensing practitioner and, if applicable, the owner or owners of the facility, shall ensure that:

- (a) All drugs are ordered by the dispensing practitioner;
- (b) All drugs are received and accounted for by the dispensing practitioner;
- (c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;
- (d) All drugs are dispensed in accordance with NAC 639.745;
- (e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility;
- (f) All drugs are dispensed only to the patient personally at the facility;
- (g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;
- (h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and
- (i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.

4. With regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

- (a) Enter the room or cabinet in which drugs are stored;
- (b) Remove drugs from stock;
- (c) Count, pour or reconstitute drugs;
- (d) Place drugs into containers;
- (e) Produce and affix appropriate labels to containers that contain or will contain drugs;
- (f) Fill containers for later use in dispensing drugs; or
- (g) Package or repackage drugs.

5. A dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:

- (a) He or she were a pharmacist;
- (b) His or her practice site was a pharmacy; and
- (c) Any dispensing technician involved in the compounding was a pharmaceutical technician.