



**18A**

# Proposed Regulation of the Nevada State Board of Pharmacy

Workshop January 17, 2019

Explanation – Language in *blue italics* is new; language in *red text* [*omitted material*] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: §1, NRS 639.070

## **A REGULATION relating to controlled substances; adding certain substances to the controlled substances listed in Schedule II; and providing other matters properly relating thereto.**

### **NAC 453.520 Schedule II. ([NRS 453.146](#), [453.2182](#), [639.070](#))**

1. Schedule II consists of the drugs listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis, is hereby enumerated in schedule II:

(a) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextroprhan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including:

- Codeine;
- Diprenorphine;
- Ethylmorphine;
- Etorphine hydrochloride;
- Granulated opium;
- Hydrocodone;
- Hydrocodone combination product (meaning any product that contains hydrocodone in combination with any other active ingredient);
- Hydromorphone;
- Metopon;
- Morphine;
- Opium extracts;
- Opium fluid;
- Powdered opium;
- Raw opium;
- Oxycodone;
- Oxymorphone;
- Thebaine; and
- Tincture of opium.

(b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) if they do not include the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Cocaine hydrochloride salt prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration.

(e) Benzoylcegonine or ecgonine.

(f) Concentrate of poppy straw (meaning the crude extract of poppy straw in either liquid, solid or powder form and containing the phenanthrene alkaloids of the opium poppy).

3. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (dextrophan and levopropoxyphene excepted), are hereby enumerated on schedule II:

Alfentanil;  
Alphaprodine;  
Anileridine;  
Bezitramide;  
Bulk dextropropoxyphene (in nondosage forms);  
Carfentanil;  
Dihydrocodeine;  
Diphenoxylate;  
Fentanyl;  
Isomethadone;  
Levo-alphaacetylmethadol (some trade or other names: levo-alpha-acetylmethadol;  
levomethadyl acetate; LAAM);  
Levomethorphan;  
Levorphanol;  
Metazocine;  
Methadone;  
Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;  
Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;  
Pethidine (meperidine);  
Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;  
Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;  
Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;  
Phenazocine;  
Piminodine;  
Racemethorphan;  
Racemorphan;  
Ramifentanil;  
Sufentanil; or  
Tapentadol.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system is hereby enumerated on schedule II:

- (a) Amphetamine, its salts, optical isomers and salts of optical isomers;
- (b) Phenmetrazine and its salts;

(c) Unless specifically excepted, any preparation which contains any quantity of methamphetamine, including its salts, isomers and salts of isomers, prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice, which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration;

- (d) Methylphenidate; or
- (e) Lisdexamfetamine.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule II:

Amobarbital;  
Glutethimide;  
Pentobarbital; or  
Secobarbital.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances is hereby enumerated on schedule II:

- (a) Immediate precursors to phencyclidine (PCP):

1-Phenylcyclohexylamine; or  
1-piperidinocyclohexanecarbonitrile (PCC).

- (b) Immediate precursors to amphetamine and methamphetamine:

Phenylacetone (some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone).

7. Any material, compound, mixture or preparation which contains any quantity of Nabilone (commonly referred to as: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzol[b,d]pyran-9-one) is hereby enumerated on schedule II.

***8. Dronabinol oral solution in a drug product approved by the Food and Drug Administration (some trade or other names: (6aR,10aR)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]-pyran-1-ol; (-)-delta-9-trans-tetrahydrocannabinol; Syndros) is hereby enumerated on schedule II.***

manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2013-N-0013 for “Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation—Small Entity Compliance Guide.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

#### FOR FURTHER INFORMATION CONTACT:

Carrol Burgundy, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2158.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 6, 2016 (81 FR 20091), we issued a final rule entitled “Sanitary Transportation of Human and Animal Food” (the final rule) that establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. The final rule, which is codified at 21 CFR part 1, subpart O, became effective June 6, 2016, and has compliance dates that started April 6, 2017.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 1, subpart O have been approved under OMB control number 0910-0773.

## III. Electronic Access

Persons with access to the internet may obtain the SECG at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 16, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-25204 Filed 11-21-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-344]

#### Schedules of Controlled Substances: Placement of FDA-Approved Products of Oral Solutions Containing Dronabinol [(–)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in Schedule II

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Final rule.

**SUMMARY:** This final rule adopts without changes an interim final rule with request for comments published in the **Federal Register** on March 23, 2017. On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(–)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] oral solution. The Drug Enforcement Administration (DEA) maintains FDA-approved products of oral solutions containing dronabinol in schedule II of the Controlled Substances Act.

**DATES:** The effective date of this final rulemaking is November 22, 2017.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701

Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-8953.

#### SUPPLEMENTARY INFORMATION:

##### Background

On March 23, 2017, the DEA published an interim final rule to make FDA-approved products containing dronabinol in an oral solution a schedule II controlled substance. 82 FR 14815. The interim final rule provided an opportunity for interested persons to file written comments as well as a request for hearing or waiver of hearing, on or before April 24, 2017.

##### Comments Received

In response to the interim final rule, the DEA received 10 comments.

1. *Support for rulemaking:* Four commenters supported the interim final rule.

- *DEA Response:* The DEA appreciates the comments supporting the interim final rule.

2. *Opposition for rulemaking:* One commenter indicated that FDA-approved products of oral solutions containing dronabinol are in schedule II, but marijuana is in schedule I. Two commenters expressed concern that pharmaceutical companies are making a profit from approved drugs containing marijuana constituents. One commenter indicated that FDA should not approve drugs containing constituents of marijuana because, as the commenter alleged, of the lethality of those drugs.

- *DEA Response:* The DEA notes that FDA-approved products of oral solutions containing dronabinol have an approved medical use, whereas marijuana does not have an approved medical use and therefore remains in schedule I. Regarding the comments related to pharmaceutical companies and the approval of FDA drugs, these comments are outside the scope of this rulemaking because they do not relate to the factors determinative of control of a substance [21 U.S.C. 811(c)] or the criteria for placement of a substance in a particular schedule [21 U.S.C. 812(b)].

3. *Request for clarification:* One other commenter wanted clarification of the approval process, including effectiveness on a long-term basis. One commenter indicated hope that the regulation would clarify hiring practices for people testing positive for THC.

- *DEA Response:* The DEA notes that the comment regarding the approval process is written in vague terms; we interpret the comment to pertain to the FDA-approved drug product Syndros, rather than the regulatory process for the interim final rule, and respond accordingly. As such, the DEA notes that the FDA approved a New Drug

Application (NDA) for Syndros which is an oral product containing dronabinol and provided the DEA with a scheduling recommendation for Syndros. The scheduling recommendation by HHS and the FDA approval of the NDA initiated the DEA review and scheduling action. As stated in the interim final rule, after careful consideration of data from preclinical and clinical studies, the DEA concurred with the HHS recommendation that Syndros has abuse potential comparable to other schedule II substances and therefore supported—and continues to support in this final rule—placement of FDA-approved products containing dronabinol in an oral solution in Schedule II under the Controlled Substances Act (CSA). Regarding the commenter seeking clarification on hiring practices, this comment is outside the scope of this rulemaking because it does not relate to the factors determinative of control of a substance [21 U.S.C. 811(c)] or the criteria for placement of a substance in a particular schedule [21 U.S.C. 812(b)].

The DEA did not receive any requests for hearing or waiver. Based on the rationale set forth in the interim final rule, the DEA adopts the interim final rule, without change.

##### Requirements for Handling FDA-Approved Products Containing Dronabinol in an Oral Solution

As DEA stated in the interim final rule, it should be noted as a preliminary matter that any form of dronabinol other than in an FDA-approved drug product remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations. However, for those who handle dronabinol oral solution exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule II regulatory requirements that remain in effect as a result of this final rule.

FDA-approved products containing dronabinol in an oral solution have been controlled as a schedule II controlled substance since March 23, 2017. With publication of this final rule, such products remain subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with,

and possession involving schedule II substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) FDA-approved products containing dronabinol in an oral solution, or who desires to handle such products, must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Quota.* Only registered manufacturers are permitted to manufacture FDA-approved products containing dronabinol in an oral solution in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Upon obtaining a schedule II registration to handle FDA-approved products containing dronabinol in an oral solution, any person who does not desire or is not able to maintain such registration must surrender all quantities of such products, or may transfer all quantities of such products to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

4. *Security.* FDA-approved products containing dronabinol in an oral solution are subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71-1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of FDA-approved products containing dronabinol in an oral solution must take an inventory of such products on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for FDA-approved products containing dronabinol in an oral solution, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Order Forms.* Every DEA registrant who distributes FDA-approved products containing dronabinol in an oral solution is required to comply with

order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing dronabinol in an oral solution may only be for the legitimate purposes authorized by the FDCA and CSA.

11. *Importation and Exportation.* All importation and exportation of FDA-approved products containing dronabinol in an oral solution must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving FDA-approved products containing dronabinol in an oral solution not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

## Regulatory Analyses

### *Administrative Procedure Act*

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. This action was taken March 23, 2017. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause.

*Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review*

In accordance with 21 U.S.C. 811(j), this scheduling action is subject to

formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

### *Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

### *Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

### *Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

### *Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding applicability of the Administrative Procedure Act, the DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. Consequently, the RFA does not apply.

### *Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined that this action would not result in any Federal mandate that may

result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### *Congressional Review Act*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

### **List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

### **PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

■ Accordingly, the interim final rule amending 21 CFR part 1308, published on March 23, 2017 (82 FR 14815), is adopted as a final rule without change.

Dated: November 6, 2017.

**Robert W. Patterson,**  
*Acting Administrator.*

[FR Doc. 2017–25275 Filed 11–21–17; 8:45 am]

**BILLING CODE 4410–09–P**

**18B**

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

Workshop January 17, 2019

LCB File No. R0XX-19

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

AUTHORITY: NRS 639.070 and 639.170.

A REGULATION relating to pharmacy; establishing the requirements for a licensed dispensing practitioner who is employed by a Federally Qualified Health Center (FQHC), as defined by Federal law, to obtain approval from the State Board of Pharmacy to dispense dangerous drugs from a FQHC-owned vehicle to patients who qualify for assistance from the FQHC; and providing other matters properly relating thereto.

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

1. *A dispensing practitioner who is employed by a Federally Qualified Health Center may apply to the Board to transport and dispense dangerous drugs to patients of the Federally Qualified Health Center from a Federally Qualified Health Center vehicle if:*
  - a. *The dispensing practitioner holds a dispensing practitioner registration issued by the Board pursuant to NAC 639.742 that is active and in good standing.*
  - b. *The dispensing practitioner applies, and the Board approves the application in writing.*
2. *Approval from the Board pursuant to this section:*
  - a. *Entitles the dispensing practitioner to dispense dangerous drugs from a Federally Qualified Health Center vehicle.*
  - b. *Must be renewed at the same time and in the same manner as the dispensing practitioner registration of the practitioner.*
  - c. *Is a revocable privilege, and no holder of such an approval acquires any vested right therein or thereunder.*

3. *A dispensing practitioner who the Board has approved to dispense dangerous drugs from a Federally Qualified Health Center vehicle may dispense dangerous drugs to patients of the Federally Qualified Health Center only.*

4. *A dispensing practitioner who the Board has approved to dispense dangerous drugs from a Federally Qualified Health Center vehicle pursuant to this section must:*

a. *Comply with all of the requirements of NAC 639.742 through NAC 639.745, unless otherwise specifically excepted herein.*

b. *Not dispense any controlled substance.*

c. *Not charge for any dangerous drug he or she dispenses.*

d. *Not leave any prescription medication in the Federally Qualified Health Center vehicle from which he or she dispenses when the dispensing practitioner is not present.*

**Section. 2.** NAC 639.010 is hereby amended to read as follows:

**NAC 639.010 Definitions.** (NRS 639.070) As used in this chapter, unless the context otherwise requires:

1. “Board” means the State Board of Pharmacy.

2. “Controlled substances” has the meaning ascribed to it in NRS 0.031.

3. “Dangerous drug” has the meaning ascribed to it in NRS 454.201.

4. “Direct supervision” means the direction given by a supervising pharmacist who is:

(a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and

(b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.

5. *“Dispensing Practitioner” means a practitioner, as defined in NRS 639.0125, who is also registered by the Board pursuant to NAC 639.742 to dispense dangerous drugs and/or controlled substances for human consumption.*

6. *“Dispensing Veterinary Practitioner” means a practitioner, as defined in NRS 639.0125, who is also registered by the Board pursuant to NAC 639.7423 to dispense dangerous drugs and/or controlled substances not for human consumption.*

7.5 *“Executive Secretary” means the Executive Secretary employed by the Board pursuant to NRS 639.040.*

8. *“Federally Qualified Health Center” means a federally-qualified health center as defined in 42 U.S.C. § 1396d(1)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community.*

9.6. *“Federally Qualified Health Center vehicle” means a vehicle that is owned by a Federally Qualified Health Center that is configured for the purpose of dispensing dangerous drugs to the Federally Qualified Health Center’s patients and which has been inspected and approved by the Board for the purpose.*

10. *“Pharmaceutical technician” means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.*

11.7. *“Pharmaceutical technician in training” means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (e) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.*

12.8. *“Practitioner” has the meaning ascribed to it in NRS 639.0125.*

13.9. *“Prescription drug” means a drug or medicine as defined in NRS 639.007 which:*

(a) *May be dispensed only upon a prescription order that is issued by a practitioner;*

*and*

(b) *Is labeled with the symbol “Rx only” pursuant to federal law or regulation.*

14.10. *“Public or nonprofit agency” means a health center as defined in 42 U.S.C. § 254b(a) which:*

(a) Provides health care primarily to medically underserved persons in a community;

(b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and

(c) Is not a medical facility as defined in NRS 449.0151.

~~15.11.~~ “Surgical center for ambulatory patients” has the meaning ascribed to it in NRS 449.019.

**Section. 3.** NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist .....	Actual cost of the examination
For the investigation or registration of an applicant as a registered pharmacist .....	\$180
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity .....	180
For the investigation or issuance of an original license to conduct a retail pharmacy .....	500
For the biennial renewal of a license to conduct a retail pharmacy .....	500
For the investigation or issuance of an original license to conduct an institutional pharmacy .....	500
For the biennial renewal of a license to conduct an institutional pharmacy .....	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution .....	500
For the biennial renewal of a license to conduct a pharmacy in a correctional institution .....	500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist .....	50
For the biennial renewal of registration as a registered pharmacist .....	180
For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse) .....	100
For the initial registration of a pharmaceutical technician or pharmaceutical technician in training .....	40
For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training .....	40
For the investigation or registration of an intern pharmacist .....	40
For the biennial renewal of registration as an intern pharmacist .....	40
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances .....	80
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances .....	80
For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances .....	80
For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances .....	80

For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler .....	500
For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler .....	500
For the investigation or issuance of an original license to a manufacturer or wholesaler .....	500
For the biennial renewal of a license for a manufacturer or wholesaler .....	500
For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon .....	50
For authorization of a <i>dispensing</i> practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both .....	300
For the biennial renewal of authorization of a <i>dispensing</i> practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both .....	300
For authorization of a [ <del>licensed veterinarian</del> ] <i>dispensing veterinary practitioner</i> to dispense controlled substances or dangerous drugs, or both .....	150
For the biennial renewal of authorization of a [ <del>licensed veterinarian</del> ] <i>dispensing veterinary practitioner</i> to dispense controlled substances or dangerous drugs, or both .....	150

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection [4] 6 of NRS 639.170, is 50 percent of the

renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as

that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151, is not required to pay the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.

6. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151, is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.