DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

CONTROLLED SUBSTANCE ADVISORY COMMITTEE

Statutory Authority: 16 Delaware Code, Section 4731 (16 **Del.C.** §4731)

EMERGENCY

ORDER

Uniform Controlled Substances Act Regulations

In Re: EMERGENCY RULE
PLACING ILLICIT XYLAZINE
IN SCHEDULE III

WHEREAS, pursuant to 29 **Del.C.** §10004(e)(1) of the Freedom of Information Act, an emergency meeting of the Delaware Controlled Substance Advisory Committee ("Committee") was held on May 5, 2023 in Dover, Delaware concerning the non-opioid sedative xylazine; and

WHEREAS, the Committee considered the following exhibits: H.R. 1839, 118th Congress, "Combating Illicit Xylazine Act" (Ex. 1); Proposal from Ohio Board of Pharmacy to Place Xylazine in Schedule III (Ex. 2); Executive Order 2023-08D from Ohio Governor DeWine Adding Xylazine to Schedule III (Ex. 3); and Notice from Pennsylvania Department of Health Concerning Adding Xylazine to Schedule III (Ex. 4); and

WHEREAS, the Committee made certain findings of facts, including:

1. Although approved only for veterinary use, xylazine is a non-opioid with increasing presence as an adulterant, often in conjunction with opioids, in the illicit drug supply. Adulterants are often added to illicit drugs to (1) increase or decrease a drug's effects or (2) increase a drug's resale value. Both isolated and in conjunction with other drugs, xylazine is implicated as a cause or contributing cause of death in the United States. According to the United Stated Drug Enforcement Administration ("DEA"): (1) the emergence of xylazine across the United States appears to be following the same path as Fentanyl, starting in the Northeast and then spreading to the South and working its way into drug markets westward, and (2) the low cost of xylazine contributes, in part, to xylazine's increased presence in the nation's illegal drug supply.

2. Heroin and xylazine have some similar pharmacological effects including bradycardia, hypotension, central nervous system depression and respiratory depression. When used in conjunction with an opioid, such as heroin or fentanyl, xylazine may worsen respiratory depression in the event of a drug overdose. Because xylazine is not an opioid, naloxone is not known to be effective at reversing overdoses caused by xylazine and there is no known antidote or reversal agent for xylazine overdose in humans. Xylazine may be accompanied by skin ulcers with wounds that secrete pus, decaying tissue and bacterial infections which can lead to amputations at higher rates than other injectable drugs.

3. Other states have taken steps to schedule xylazine. The Governor of Ohio issued an Executive Order adopting an emergency regulation to place xylazine in Schedule III. The Pennsylvania Department of Health issued a Notice of Intent to temporarily place xylazine in Schedule III. In addition, there is a bill pending in the United States Congress, H.R. 1839, 118th Congress, 1st Session, "Combatting Illicit Xylazine Act", adding illicit xylazine to Schedule III in the Controlled Substance Act, 21 U.S.C. 802; and

WHEREAS, the Committee found that allowing xylazine to remain unscheduled in the State of Delaware presents an imminent peril to the public health, safety and welfare and recommended to the Secretary that xylazine be added to Schedule III of the Delaware Uniform Controlled Substances Act pursuant to an emergency regulation; and

WHEREAS, emergency regulations may be promulgated pursuant to the Administrative Procedures Act, so long as an agency determines there exists "an imminent peril to the public health, safety or welfare." 29 **Del.C.** §10119. Such regulation will only be effective for a maximum of 120 days, but may be renewed once for an additional period of 60 days. 29 **Del.C.** §10119(3); and

WHEREAS, subsection 10.3 of the Uniform Controlled Substance Act Regulations provides that if the Secretary, upon

the recommendation of the Committee, finds that an imminent peril to the public health, safety or welfare requires adoption of a regulation upon fewer than twenty (20) days' notice and states in writing the reasons for that finding, the Secretary may proceed without prior notice or hearing or upon any abbreviated notice and hearing the Secretary finds practicable, to adopt an emergency regulation; and

WHEREAS, the Secretary has been charged by the General Assembly with placing a substance in Schedule III if the Secretary finds that: "(1) The substance has a potential for abuse less than the substances listed in Schedules I and II; (2) The substance has currently accepted medical use in treatment in the United States; and (3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence." 16 **Del.C.** §4717; and

WHEREAS, the proposed federal "Combatting Illicit Xylazine Act" makes a distinction between the illicit use of xylazine in the human species, and the licit, legitimate use of xylazine in the context of veterinarian use; and

WHEREAS, while the illicit use of xylazine poses an imminent peril to the public health, safety or welfare, the licit use of xylazine is needed to ensure the availability of the substance for use in the non-human population; and

WHEREAS, the Secretary finds that adoption of a regulation placing illicit xylazine temporarily in Schedule III in Delaware must occur on an emergency basis in order to properly protect the public until such time as the legislature may adopt a statutory amendment to 16 **Del.C.** §4718; and

WHEREAS, the Secretary will accept, consider and respond to petitions by any interested person for the reconsideration or revision of this regulation by addressing the same to the attention of the Office of Controlled Substances, Cannon Building, 861 Silver Lake Blvd., Dover, DE 19904; and

WHEREAS, a copy of this Emergency Order will be submitted to the Registrar of Regulations for publication in the next Delaware *Register of Regulations*;

NOW, THEREFORE, IT IS ORDERED this 2nd day of June 2023:

1. The Uniform Controlled Substance Act Regulations are amended as follows:

10.3.2 Pursuant to 16 **Del.C.** §4717, the Secretary of State has the authority to place a substance in Schedule III where the Secretary finds that the substance has a potential for abuse less than the substances listed in Schedules I and II; has currently accepted medical use in treatment in the United States; and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence, and therefore:

10.3.2.1 The Secretary of State, as authorized by 16 **Del.C.** §4717, does hereby add by regulation illicit xylazine and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, in Schedule III of the Uniform Controlled Substances Act, 16 **Del.C.** Ch. 47.

10.3.2.1.1 Testing strips to determine the presence of xylazine or xylazine-related substances are exempt from subsection 10.3.2.1.

10.3.2.2 For the purpose of this subsection:

10.3.2.2.1 "Illicit" use of xylazine means any use in the human species or any use that is not licit use.

10.3.2.2.2 "Licit" use of xylazine means:

10.3.2.2.2.1 Any administration to nonhuman species a drug containing xylazine that has been approved by the Secretary of Health and Human Services under section 512 of the Federal Food, Drug, and Cosmetic Act (21 **U.S.C.** 360b); or that is permissible under section 512(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 **U.S.C.** 360b(a)(4)).

10.3.2.2.2.2 The manufacturing, importation, or use of xylazine as an active pharmaceutical ingredient for manufacturing an animal drug approved under section 512 of the Federal Food, Drug, and Cosmetic Act (21 **U.S.C.** 360b) or issued an investigation use exemption under subsection (j) of such section 512.

10.3.2.2.2.3 The manufacturing, importation, or use of a xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians.

10.3.2.2.2.4 Another use approved or permissible under the Federal Food, Drug, and Cosmetic Act (21 **U.S.C.** 301 et seq.).

2. In accordance with the requirements of 29 **Del.C.** §10119(3), this Order shall be effective 120 days from the date of execution.

IT IS SO ORDERED this 2nd day of June 2023.

DELAWARE DEPARTMENT OF STATE
SECRETARY OF STATE
Jeffrey W. Bullock

Uniform Controlled Substances Act Regulations

1.0 Controlled Substance Advisory Committee

1.1 The Controlled Substance Advisory Committee (hereafter designated as "the Committee") has a primary objective to promote, preserve and protect the public health, safety and welfare by regulating and monitoring controlled substance use and abuse through a program of registration, inspection, investigation and education. The Committee regulates by registering prescribers, dispensers, manufactures, distributors, clinics, researchers and other controlled substance registrants (i.e. – dog handler). Among its functions, the Committee issues and renews licenses; and makes recommendations to the Secretary of State of new or amended controlled substance regulations and disciplinary actions of registrants who violate the law. (16 **Del.C.** §4700 to the end)

1.2 The Committee shall consist of 9 members: one physician, one dentist, one podiatrist, one veterinarian, one nurse practitioner, two pharmacists, one physician assistant and one public member. The Secretary of State will be provided recommendations for appointments to the Committee from the associated licensing Boards. Members shall have engaged in the prescribing, dispensing or storing of controlled substances for at least 5 years except for the public member. All Committee members will be appointed by the Secretary of State or their designee.

1.3 A member of the Committee may not serve more than 3 full, consecutive 3-year terms, which is not diminished by serving an unexpired term. Upon serving 3 full, consecutive 3-year terms, a former member is eligible for reappointment to the Committee no earlier than 1 year after the expiration of the last term served on the Committee by the former member. A Committee member whose appointment has expired remains eligible to participate in Committee proceedings until replaced.

1.4 The Committee shall hold regularly scheduled meetings at least four times a calendar year and at other times the Committee considers necessary at the request of a majority of the members. A president and vice-president shall be elected by the members annually. Each officer shall serve for 1 year and shall not succeed himself or herself for more than 2 consecutive terms.

1.5 The conduct of all hearings and issuance of orders shall be in accordance with the procedures established pursuant to this section, Chapter 101 of Title 29, section 8735 of Title 29, and sections 4731 through 4736 of Title 16.

1.6 The Drug Control Administrator for the Division of Professional Regulation is responsible for the performance of the regular administrative functions of the Committee and other duties as the Committee may direct.

1.7 A majority of the members shall constitute a quorum for the purpose of transacting business and no action shall be taken without the affirmative vote of a majority of the quorum. No disciplinary action may be recommended to the Secretary without the affirmative vote of a majority of the members of the Committee.

1.8 Any member who fails to attend 3 consecutive meetings, or who fails to attend at least half of all regular business meetings during any calendar year, shall automatically upon such occurrence be deemed to have resigned from office and a replacement shall be appointed by the Secretary of State.

1.9 Minutes of all meetings shall be maintained by the Division of Professional Regulation. A record from which a verbatim transcript can be prepared shall be made of all hearings where evidence is presented. The expense of preparing any transcript shall be borne by the person requesting it.

22 DE Reg. 79 (07/01/18)

2.0 Definitions

"**Act**" means the Controlled Substance Act, 16 **Del.C.** Ch. 47.

"**Administer**" or "**administration**" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means. The administration of a drug directly to a patient by a practitioner is administration not an act of dispensing.

"**Controlled substance**" means any substance or drug defined, enumerated or included in this chapter and Title 21, Code of Federal Regulations.

"**Direct supervision**" means the supervising practitioner, pharmacist or licensee will be present and immediately available within the dispensing area.

"**Dispense**" or "**dispensing**" means the interpretation, evaluation, and implementation of a prescription drug or, including the preparation and delivery of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

"**Dispenser**" means a person authorized by this State to dispense or distribute to the ultimate user any controlled substance.

"**Practitioner**" means physician, dentist, veterinarian, podiatrist, nurse practitioner, physician assistant or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to prescribe, dispense or store a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner.

"**Pharmacist**" means any pharmacist licensed by the State of Delaware to dispense controlled substances and shall include any other person (e.g. pharmacist intern) authorized by the State of Delaware to prescribe, dispense or store controlled substances under the supervision of a pharmacist licensed by this State.

"**Pharmacist in charge**" or "**PIC**" means a pharmacist registered with the State Board of Pharmacy and who is responsible for the prescription department of the registrant.

"**Prescription**" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g. an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

"**Register**" and "**registered**" means registration required by 16 **Del.C.** §4732.

25 DE Reg. 873 (03/01/22)

3.0 Requirements

3.1 Registration shall be on a biennial basis upon forms supplied by the Division of Professional Regulation or Secretary of State for that purpose. A separate registration is required at each principal place of business or professional practice where controlled substances are manufactured, distributed, dispensed, or kept for research analysis. Out-of-State registrants who dispense or distribute controlled substances to patients or facilities in Delaware are required to obtain a registration.

3.1.1 All practitioners registered under Title 16, Chapter 47 as of July 1, 2013, must attest to completion of a one hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances on or before June 30, 2015 in order to qualify for continued registration.

3.1.2 All practitioners who obtain new registration under Title 16, Chapter 47 after July 1, 2013 must attest to completion of a one hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances within the first year of obtaining registration in order to qualify for continued registration.

3.1.3 All practitioners must attest to completion of two hours of continuing education biennially in the areas of controlled substance prescribing practices, treatment of chronic pain, or other topics related to the prescribing of controlled substances.

3.1.4 The Secretary shall periodically review the requirements of paragraphs 3.1.1, 3.1.2, and 3.1.3 to determine adequacy.

3.2 Administrative inspections of controlled premises may be conducted in accordance with the provisions under 16 **Del.C.** §4782(b).

3.3 Revocation and Suspension

3.3.1 Revocation of registration by the Federal Government will result in automatic revocation of the State registration.

3.3.2 Proceedings for denying, suspending or revoking a registration shall be held before the Committee. The Committee will forward their recommendation in writing to the Secretary of State for the Secretary's review and decision. Persons complained against may appear personally or by counsel, and may produce any competent evidence in answer to the alleged violation.

3.3.3 Whenever a registration is denied, suspended, or revoked by the Secretary of State, the Secretary of State or the Secretary's designee will reduce in writing the findings and rulings, and the reasons therefor, and forward them to the persons applying for registration or complained against within 15 days of receiving the written recommendation of the Committee. This provision shall in no way stay any such denial, suspension, or revocation. The Secretary of State's decision is final and conclusive. A person aggrieved may file an appeal as provided in 16 **Del.C.** §4786.

25 DE Reg. 873 (03/01/22)

4.0 Prescriptions

4.1 Persons Entitled to Issue Prescriptions

4.1.1 A prescription for a controlled substance may be issued only by a practitioner who is:

4.1.1.1 Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practiced the licensed profession; and

4.1.1.2 Either registered or exempt from registration pursuant to 16 **Del.C.** §4732.

4.1.2 A verbal prescription for a controlled substance may only be communicated to a pharmacist, a pharmacy intern or a pharmacy student participating in an approved College of Pharmacy coordinated practical experience program under the direct supervision of a licensed pharmacist by the prescriber. Verbal prescriptions for schedule III-V controlled substances in a hospice or long term care facility may be communicated by an authorized agent of the prescriber.

4.1.3 All verbal prescriptions for controlled substances must be verified and authorized by the prescriber.

4.1.4 Prescriptions for controlled substances may be transmitted via facsimile or electronic transmission by a practitioner or by the practitioner's authorized agent to a pharmacy.

4.2 Purposes of Issue of Prescription

4.2.1 A prescription for a controlled substance must be issued for a legitimate medical purpose by practitioner acting in the usual course of their professional practice. The responsibility for proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of §4738 of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances.

4.2.2 A prescription may not be issued in order for a practitioner to obtain controlled substances for supplying the practitioner for the purpose of general dispensing to patients.

4.2.3 A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a person engaged in substance abuse or misuse, as defined in subsections 9.3.11 and 9.3.12, for the purpose of continuing such person's dependence upon such drugs, unless otherwise authorized by law.

4.3 Manner of Issuance of Prescriptions. All prescriptions for controlled substances shall be dated on the day when issued and shall bear the full name and address of the patient, and the name, address, telephone number and registration number of the practitioner. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g. J.H. Smith or John H. Smith). When an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner but the prescribing practitioner is responsible where the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations. Each written prescription shall have the name of the practitioner stamped, typed, or hand-printed on it, as well as the signature of the practitioner.

4.4 Persons Entitled to fill Prescriptions. A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or by a registered institutional practitioner.

4.5 Dispensing Narcotic Drugs for Maintenance Purposes. No person shall administer or dispense narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing the person's dependence except in compliance with and as authorized by Federal law and regulation.

4.6 Emergency Dispensing of Schedule II Substances. In an emergency situation a pharmacist may dispense controlled substances listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that the procedures comply with Federal law and regulation.

4.7 Expiration and Partial Filling of Controlled Substance Prescriptions

4.7.1 Expiration

4.7.1.1 Prescriptions for controlled substances in Schedules II and III will become void unless dispensed within seven (7) days of the original date of the prescription or unless the original prescriber authorizes the prescription past the seven (7) day period.

4.7.1.2 Schedule II prescriptions for terminally ill or LTCF patients, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

4.7.2 Partial Filling of Controlled Substance Prescriptions

4.7.2.1 Schedule II prescriptions may be dispensed up to 100 dosage units or a 31 day supply, whatever is the greater, and may be filled in partial quantities. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed and must be filled not later than 30 days after the date on which the prescription is written. In accordance with 21 CFR Section 1306.13(b), prescriptions for controlled substances in Schedule II for patients either having a medically documented terminal illness or patients in Long Term Care Facilities (LTCF), may be filled in partial quantities, to include individual dosage units, and must be filled not later than 60 days after the date on which the prescription is written.

4.7.2.2 Schedules III, IV and V prescriptions may be filled in partial quantities provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed and must be filled not later than 6 months after the date on which the prescription is written.

4.8 Mail Order Prescription. Before dispensing prescriptions for Schedules II, III, IV and V controlled substances by mail, the registrant or the pharmacist-in-charge must assure that the prescription is valid and written by a prescriber properly registered with the Federal Government. Such verification may be made either in writing or orally.

4.9 Pursuant to authority granted by 16 **Del.C.** §4732 the Secretary of State finds that waiver of the registration requirements contained in that section as to non-resident practitioners is consistent with the public health and safety subject to the conditions contained in this regulation.

4.9.1 The pharmacist must establish that the name of the non-resident practitioner does not appear on the list kept by the Office of Controlled Substances of those non-resident practitioners to whom the waiver granted by this regulation does not apply.

4.9.2 The waiver of the registration requirement provided by the registration shall not apply to non-resident practitioners determined by the Office of Controlled Substances to have acted in a manner inconsistent with the Public Health and Safety. The Office of Controlled Substances shall maintain a list of those non-resident practitioners found by them to have so acted. Pharmacists shall not honor the prescriptions of non-resident practitioners whose names appear on that list unless such non-resident practitioners have registered pursuant to the provisions of 16 **Del.C.** §4732.

4.10 The pharmacist must establish that a practitioner is properly registered to prescribe controlled substances under Federal Law.

4.10.1 The pharmacist or an employee under the pharmacist's direct supervision must verify the identification of the receiver of the controlled substance prescription by reference to valid photographic identification. For the purposes of this section, a valid photographic identification is limited to the following:

4.10.1.1 A valid Delaware motor vehicle operator's license which contains a photograph of the person receiving the prescription - record the license number listed on the license as part of the patient record.

4.10.1.2 A valid Delaware identification card which contains the photograph of the person receiving the prescription - record the identification number listed on the card as part of the patient record.

4.10.1.3 A valid United States passport.

4.10.1.4 A valid passport or motor vehicle operator's license or state identification card of another state, territory or possession of the United States or a foreign country only if it:

4.10.1.4.1 Contains a photograph of the person receiving the prescription.

4.10.1.4.2 Is encased in tamper-resistant plastic or is otherwise tamper-resistant.

4.10.1.4.3 Identifies the date of birth of the person receiving the prescription and has an identification number assigned to the document which can be recorded as part of the patient record.

4.10.2 Identification for mail order dispensed controlled substances must comply with all federal standards.

4.10.3 No filled prescription for any Schedule II controlled substance may be received at any drive through window unless the pharmacy is authorized to do so by the Office of Controlled Substances. Written prescriptions for Schedule II controlled substances may be initially presented at a drive through if the pharmacy has not obtained authorization, but the filled prescription must be picked up inside the pharmacy. Authorization to permit the receipt of filled Scheduled II controlled substances prescriptions at a drive through window may be granted only if the pharmacy can demonstrate all of the following:

4.10.3.1 A security camera system that captures clear images of the driver's face and the license plate of the vehicle receiving any filled prescription; and

4.10.3.2 A written policy indicating that when picking up a Schedule II controlled substance at a drive through window, the driver must be recorded as the person picking up the prescription; and

4.10.3.3 A written policy requiring staff to review the identification of the driver, capture an image of the identification of the driver, and store that image in the pharmacy's records for at least three years for every filled Schedule II prescription picked up at the drive through window.

4.11 Except when dispensed directly by a practitioner other than a pharmacy to an ultimate user, no Schedule V cough preparation containing codeine, dilaudid or any other narcotic cough preparation may be dispensed without the written or oral prescription of a practitioner.

20 DE Reg. 564 (01/01/17)
25 DE Reg. 873 (03/01/22)

5.0 Labeling

5.1 All dispensed prescriptions including samples shall be labeled in compliance with 24 **Del.C.** §2522.

5.2 A pharmacist shall affix to every container in which a drug is dispensed a label containing the following information:

5.2.1 Prescription number;

5.2.2 The date the prescription is dispensed;

5.2.3 Patient's full name;

5.2.4 Brand or established name and strength of the drug to the extent that it can be measured;

5.2.5 Practitioner's directions as found on the prescription;

5.2.6 Practitioner's name;

5.2.7 Name and address of the dispensing pharmacy or practitioner.

5.3 Practitioners who sell drugs directly to patients shall label all such drugs in accordance with subsection 5.2 of this regulation with the exception of a prescription number.

5.4 Practitioners who dispense drugs directly to patients without sale shall label all drugs or provide a document including the following information:

5.4.1 The patient's full name;

5.4.2 The date the drugs were dispensed to the patient;

5.4.3 The practitioner's name;

5.4.4 The practitioner's directions.

25 DE Reg. 873 (03/01/22)

6.0 Records and Inventory

6.1 Requirements

6.1.1 All practitioners and pharmacies registered and authorized to prescribe or dispense controlled substances shall maintain records that adhere to all State and federal laws.

6.1.2 Practitioners authorized to prescribe or dispense controlled substances shall maintain a record with the following information:

6.1.2.1 Name and address of patient;

6.1.2.2 Date prescribed;

6.1.2.3 Name, strength, refills authorized and amount of medication.

6.1.3 Other records required by 21 CFR 1300 to the end of 1316. The information for prescribed controlled substances may be kept either in a log or on patient records provided such records or logs are made available for inspection. The information for dispensed controlled substances must be maintained in a separate log. Entries must include the date dispensed, name and address of the patient, name and strength of medication, and amount dispensed.

6.1.4 Other persons registered to manufacture, distribute, or dispense controlled substances shall maintain a record with the following information:

6.1.4.1 Amount received or distributed;

6.1.4.2 Names, addresses and dates regarding these transactions;

6.1.4.3 Other records required by 21 CFR 1300 to the end of 1316.

6.1.5 When a pharmacy relocates to a new building, or there is a change in Pharmacist-in-Charge, a complete audit of all controlled substances must be conducted before the move and within twenty-four hours after the move is complete or the PIC change occurs. If the relocation occurs in the same building, no inventory count shall be required, so long as a pharmacist physically moves the controlled substance inventory.

6.1.6 Transfers of controlled substances are only permitted if both parties are registered. Transfers of schedule II controlled substances must be transferred via DEA 222 forms. Schedule III through V transfers may be done so via invoice. Controlled substances obtained under one registration must be transferred according to this procedure when this registrant wants to transfer possession of said controlled substances to another registrant.

6.2 Accountability Audits

6.2.1 Accountability audits in pharmacies will be accomplished through a review of invoices, prescription files, other records required by 21 **CFR** 1300 to the end of 1316.

6.2.2 Accountability audits of registered practitioners will be accomplished through a review of records to be kept by paragraph 6.1 of this section.

6.2.3 Accountability audits of registered manufacturers and distributors (including wholesalers) will be accomplished through a review of invoices received and distributed and other records required by 21 CFR 1300 to the end of 1316.

6.3 Final Inventory

6.3.1 Pharmacies. Whenever the pharmacist in charge of a pharmacy in the State of Delaware leaves that pharmacist's position, a complete inventory of all medication covered by 16 **Del.C.** Ch. 47 be taken by the present and prospective pharmacist-in-charge. A copy of such inventory will be sent to the Office of Controlled Substances and another copy retained on the premises.

6.3.2 Registered practitioners who cease legal existence or discontinue business or professional practice shall notify the Office of Controlled Substances within 30 days of such fact, and shall provide the Office with an inventory of controlled substances on hand.

6.4 Retention of Records

6.4.1 All records required by this Regulation must be retained for a period of at least two (2) years.

25 DE Reg. 873 (03/01/22)

7.0 Security, Disposal and Loss or Theft

7.1 Security

7.1.1 Practitioners who store more than 400 total dosage units of all controlled substances and pharmacies who store schedule II controlled substances must store these controlled substances in a burglar resistant type safe unless another storage area is approved by the Office of Controlled Substances. Other storage may include but not be limited to automated dispensing systems approved by the Office. If the safe weighs less than 750 pounds, it must be bolted, cemented, or secured to the wall or floor in such a way that it cannot be readily removed. Safes and other approved systems containing controlled substances must be kept locked at all times. Unless otherwise authorized by the Office of Controlled Substances, they may be opened only by the registered practitioner or by a licensed pharmacist or other approved licensed personnel. Only pharmacies may disperse schedule III, IV and V throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

7.1.2 Unless otherwise authorized by the Office of Controlled Substances, all controlled substance storage area or areas shall be provided with electronic intrusion detection equipment to all sections of the said area or areas where controlled substances are stored, so as to detect four-step movement. Four-step movement is the movement of a Four-step person walking not more than four consecutive steps at a rate of one step per second. Such Four-step movement shall constitute a "trial", and a sufficient number of detection units shall be installed so that, upon test, an alarm will be initiated in at least three out of every four consecutive "trials" made moving progressively through the protective area. Electronic intrusion detection equipment shall be installed using equipment that must be U.L. approved and listed. The said system must be capable of transmitting a local alarm to an outside audible device that shall comply with U.L. Standards.

7.1.3 The immediate area in a pharmacy remodeled or newly constructed after July 31, 2011 containing dispersed, controlled drugs must be secured in a manner approved by the Office of Controlled Substances which will prevent entry by unauthorized persons. Such a manner includes, but is not limited to, the implementation of a floor to ceiling physical barrier limiting access to the pharmacy area, motion detectors, strategically placed surveillance cameras and back-up alarm systems.

7.1.4 Access to controlled substances by non-registered personnel is only permitted under the direct supervision of the pharmacist or registered practitioner or other approved licensed personnel.

7.1.5 Practitioners who store no more than 400 total dosage units of controlled substances are not required to comply with the safe or alarm requirements of the Regulation. However, their controlled substances must be stored in securely locked, substantially constructed cabinets and only available to licensed personnel.

7.1.6 The Secretary of State may require additional security requirements if the Secretary deems it necessary as a result of the possibility of diversion of controlled substances.

7.2 Disposal:

7.2.1 Any registrant in possession of any controlled substances and desiring or required to dispose of such substance or substances shall do so according to established federal and State guidelines or may contact the Office of Controlled Substances for proper instructions regarding disposal.

7.3 Loss or Theft

7.3.1 Registrants shall notify the Office of Controlled Substances of any theft or significant loss of any controlled substances, or of any prescription blanks, upon the discovery of such loss or theft.

7.3.2 Registrants shall complete the Federal forms regarding loss or theft of controlled substances. A copy must be filed with the Office of Controlled Substances.

25 DE Reg. 873 (03/01/22)

8.0 Practitioner Dispensing of Controlled Substances

8.1 No prescriber who is not the owner of a pharmacy or who is not in the employ of such owner, may dispense more than a 72-hour supply of schedule II through V controlled substances except for the following, who still must comply with other sections of this Regulation including but not limited to subsection 4.7 of this regulation:

8.1.1 A practitioner who confines their activities to dispensing complimentary packages of controlled substances to the practitioner's own patients in the regular course of their practice without payment of a fee or remuneration of any kind, whether direct or indirect.

8.2 Any registered practitioner who dispenses controlled substances for sale must adhere to all State and federal laws including but not limited to the following:

8.2.1 Must notify the Office of Controlled Substances prior to dispensing any controlled substance that they will be dispensing controlled substances for sale.

8.2.1.1 A practitioner who confines their activities to dispensing complimentary packages of controlled substances to the practitioner's own patients in the regular course of their practice without payment of a fee or remuneration of any kind, whether direct or indirect, and who dispenses the drug themselves is not required to notify the Office of Controlled Substances.

8.2.2 Before dispensing any controlled substance the patient must be advised that the prescription may be filled in the practitioner's office or any pharmacy.

8.2.3 Prior to dispensing the practitioner must conduct a medication reconciliation review and offer to counsel the patient.

8.2.4 Prior to dispensing the practitioner must inspect the prescription product to verify its accuracy in all respects and personally place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

8.2.5 If the patient chooses to purchase the controlled substance from the practitioner, the practitioner shall have the patient sign the prescription and return it to the practitioner as a hard copy record of the sale. If the practitioner chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically and maintain a record for at least two years.

8.2.6 Inventories and records of all controlled substances listed in schedule II shall be maintained separately from all other records of the registrant.

8.2.7 Inventories and records of controlled substances listed in schedules III through V may be maintained separately from schedule II controlled substances records but shall not be maintained with non-controlled substances records of the registrant.

8.2.8 All records of schedule II through V controlled substances shall be maintained at the office site or an off-site retrievable within 72 hours of a request of the Office of Controlled Substances.

8.2.9 Practitioners shall perform an inventory of controlled substances at least every two years.

8.2.10 Compounding of a controlled substance by a practitioner is permitted as long as the United States Pharmacopoeia (USP) 795 and 797 standards and guidelines are followed.

8.2.11 Technicians may assist practitioners in the filling processes but only under direct supervision of the practitioner.

8.2.12 Practitioners must comply with all previous sections of this Regulation.

8.3 Administrative inspections of controlled premises may be conducted in accordance with the provisions under 16 **Del.C.** §4782.

25 DE Reg. 873 (03/01/22)

9.0 Safe Prescribing of Opioid Analgesics

9.1 Preamble: This Section provides requirements for the prescribing of opioid analgesics in order to address potential prescription drug overdose, abuse, and diversion and encourage the proper and ethical treatment of pain. Pursuant to the requirements of this Section, the practitioner can meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care.

9.2 License and DEA registration required: To prescribe opioid analgesics in Delaware, the practitioner must be licensed in this state and registered with the U.S. Drug Enforcement Administration and must comply with all applicable federal and state regulations. Out-of-state practitioners, who are prescribing controlled substances to patients in Delaware, must hold active licensure and registration in their home states. Practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances.

9.3 Definitions: The following words and terms, when used in Section 9.0 of this regulation, have the following meaning unless the context clearly indicates otherwise:

"**Acute Care**" means the treatment of Acute Pain, as defined in subsection 9.3 of this regulation.

"**Acute Pain**" means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time limited. For the purpose of this regulation, Acute Pain is less than three months in duration.

"**Acute pain episode**" means a discrete period of pain that usually follows some sort of injury to the body and generally dissipates when the injury heals.

"**Addiction**" means a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

"**Chronic Care**" means the treatment of Chronic Pain, as defined in subsection 9.3 of this regulation.

"**Chronic Pain**" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years. For the purpose of this regulation, Chronic Pain means continuous or nearly continuous pain more than three months in duration.

"**Opioid Analgesic**" means a drug that is used to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (synthetic drugs). Examples include: morphine, codeine, fentanyl, meperidine, and methadone. For purposes of this regulation, it does not include, unless specifically designated as controlled under 16 **Del.C.** §4711, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"**PMP**" means the Delaware Prescription Monitoring Program.

"**Practitioner**" means a physician, dentist, podiatrist, nurse practitioner, physician assistant or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to prescribe a controlled substance in the course of professional practice but does not include veterinarians.

"**Risk Assessment**" means utilizing a tool appropriate for the patient, such as but not limited to, the Screener and Opioid Assessment for Patients with Pain ("SOAPP"), Opioid Risk Tool ("ORT"), or Screening, Brief Intervention and Referral to Treatment ("SBIRT"), which are designed for predicting the likelihood that a patient will abuse or misuse a prescribed controlled substance based on past behavior, genetic predispositions, social or environmental factors, or other risks.

"**Substance Abuse**" means using a controlled substance without a legitimate medical need, for the purpose of altering one's emotional experience.

"**Substance Misuse**" means using a controlled substance in a way that is not prescribed.

"**Treatment Agreement**" means a written agreement, signed by the practitioner and the patient (or the patient's proxy), which shall become part of the patient's medical record. The Treatment Agreement may include, at the practitioner's discretion:

- The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
- Reasons for which medication therapy may be re-evaluated, tapered or discontinued, including but not limited to, violation of the Treatment Agreement or lack of effectiveness;

- The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;
- The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;
- Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan, a referral to a pain specialist, or referral to an addiction treatment program; and
- The requirement that fluid drug screens be performed at random intervals at the practitioner's discretion, but not less than every six months.

9.4 Practitioner-patient relationship: A practitioner may not prescribe opioid analgesics unless a practitioner-patient relationship has been established, or the practitioner is seeing the patient in lieu of the patient's prescribing practitioner on a limited basis and on the practitioner's request or behalf.

9.5 First time, outpatient prescription for Acute Pain; maximum seven-day supply.

9.5.1 When issuing a prescription for an opioid analgesic to an adult patient for outpatient use for the first time, for an Acute Pain Episode, a practitioner may not issue a prescription for more than a seven-day supply.

9.5.2 A practitioner may not issue a prescription for an opioid analgesic to a minor for more than a seven-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opioid use and the reasons why the prescription is necessary.

9.5.3 Notwithstanding subsections 9.5.1 and 9.5.2, if, in the professional medical judgment of a practitioner, more than a seven-day supply of an opiate is required to treat the adult or minor patient's acute medical condition, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition. The condition triggering the prescription of an opiate for more than a seven-day supply shall be documented in the patient's medical record, the practitioner shall query the PMP to obtain a prescription history, and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition and comply with subsections 9.6.4 and 9.6.5.

9.6 Subsequent prescriptions. Subject to the exemptions set forth in subsection 9.7, after the first time prescription, or after the patient has been issued outpatient prescriptions totaling up to a seven day supply, prior to issuing a subsequent prescription for an opioid analgesic for Acute Pain, the practitioner must perform an appropriate evaluation of the patient's medical history and condition, including the following:

9.6.1 Query the PMP to obtain a prescription history for the first subsequent prescription that goes beyond the initial 7-day period and, for any subsequent prescriptions after that, the PMP shall be queried at the discretion of the practitioner unless otherwise required;

9.6.2 Administer a fluid drug screen, at the discretion of the practitioner;

9.6.3 Conduct a physical examination which must include a documented discussion between the practitioner and patient to: Elicit relevant history, explain the risks and benefits of opioid analgesics and possible alternatives to the use of opioid analgesics, identify other treatments tried or considered, and determine whether opioid analgesics are contra-indicated;

9.6.4 Obtain an Informed Consent form, signed by the patient (or the patient's proxy), that must include information regarding the drug's potential for addiction, abuse, and misuse; and the risks associated with the drug of life-threatening respiratory depression; overdose as a result of accidental exposure potentially fatal, especially in children; neonatal opioid withdrawal symptoms; and potentially fatal overdose when interacting with alcohol; and other potentially fatal drug/drug interactions, such as benzodiazepines; and

9.6.5 Schedule and undertake periodic follow-up visits and evaluations of the patient to monitor and assess progress toward goals in the treatment plan and modify the treatment plan, as necessary. The practitioner must determine whether to continue the treatment of pain with an opioid analgesic, whether there is an available alternative, whether to refer the patient for a pain management or substance abuse consultation.

9.7 Exemptions to subsection 9.6:

9.7.1 If a patient has been discharged from an in-patient facility or out-patient surgical center, and, in the professional medical judgment of the practitioner, more than a seven-day supply of an opiate is required to treat the patient's acute medical condition, the practitioner may issue a second prescription for not more than a seven-day supply without satisfying the requirements of subsection 9.6.

9.7.2 If a practitioner satisfies the requirements of subsection 9.6 at the time of the first time prescription, the practitioner may issue a subsequent prescription for not more than a seven-day supply without repeating the requirements of subsection 9.6.

9.8 Chronic Pain patients. In addition to the requirements of subsection 9.6, the practitioner must adhere to the following additional requirements for Chronic Pain patients:

9.8.1 Query the PMP at least every six months, more frequently if clinically indicated, or whenever the patient is also being prescribed a benzodiazepine;

9.8.2 Query the PMP whenever the patient is assessed to potentially be at risk for substance abuse or misuse or demonstrates such things as loss of prescriptions, requests for early refills or similar behavior;

9.8.3 Administer fluid drug screens at least once every six months;

9.8.4 Obtain a signed Treatment Agreement, pursuant to subsection 9.3.13;

9.8.5 Conduct a Risk Assessment as defined in subsection 9.3.10;

9.8.6 Document in the patient's medical record alternative treatment options that have been tried by the patient, including non-pharmacological treatments, and their adequacy with respect to providing sufficient management of pain;

9.8.7 Make efforts to address psychiatric and medical comorbidities concurrently, rather than sequentially, when concurrent treatment is clinically feasible; and

9.8.8 At the practitioner's discretion, seek a case review and consult with, or otherwise refer the patient to, a state-licensed physician who holds a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology or an addiction certification from the American Board of Addiction Medicine or an addiction specialist if any of the following occur:

9.8.8.1 Adulterated drug tests;

9.8.8.2 Diversion of prescribed medications; or

9.8.8.3 The patient has obtained controlled substances elsewhere without disclosure to the physician, as evidenced by PMP data.

9.9 Practitioners treating the following patients are exempted from the requirements of this Regulation:

9.9.1 Hospice care patients;

9.9.2 Active cancer treatment patients;

9.9.3 Patients experiencing cancer-related pain;

9.9.4 Terminally ill/palliative care patients; and

9.9.5 Hospital patients, during the hospital stay, including any prescription issued at the time of discharge, so long as that discharge prescription is for a quantity of a 7-day supply or less.

20 DE Reg. 564 (01/01/17)
20 DE Reg. 826 (04/01/17)
25 DE Reg. 873 (03/01/22)

10.0 Procedures for Adoption of Regulations

10.1 Notice. Prior to the adoption, amendment or repeal of any of these controlled substances regulations, the Secretary of State/Committee will give at least twenty (20) days notice of the intended action.

10.1.1 The notice will include a statement of either the terms of substance of the intended action or a description of the subjects and issues involved, or the time when, and the place where to present their views thereon.

10.1.2 The notice will be mailed to persons who have made timely request of the Office of Controlled Substances for advance notice of such rule-making proceedings and shall be published in two newspapers of general circulation in this State.

10.2 Hearing. The Secretary of State shall designate the Committee to preside over hearings. The Committee will afford all interested persons a reasonable opportunity to submit data, views or arguments, orally or in writing.

10.3 Emergency Regulations. If the Secretary of State, upon the recommendation of the Committee, finds that an imminent peril to the public health, safety or welfare requires adoption of a regulation upon fewer then twenty (20) days notice and states in writing the reasons for that finding, the Secretary of State may proceed without prior notice or hearing or upon any abbreviated notice and hearing the Secretary finds practicable, to adopt an emergency regulation. Such rules will be effective for a period not longer than 120 days, but the adoption of an identical rule under the procedures discussed above is not precluded.

10.3.1 Pursuant to 16 **Del.C.** §4713 the Secretary of State finds that the synthetic opioid, 3, 4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700) and it isomers, esters, ethers, salts and salts of isomers, esters and ethers, has high potential for abuse; has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and therefore:

10.3.1.1 The Secretary of State, as authorized by 16 **Del.C.** §4713, does hereby add by rule 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700) and it isomers, esters, ethers, salts and salts of isomers, esters and ethers, in Schedule I of the Uniform Controlled Substances Act, 16 **Del.C.** Ch. 47.

10.3.2 Pursuant to 16 **Del.C.** §4717, the Secretary of State has the authority to place a substance in Schedule III where the Secretary finds that the substance has a potential for abuse less than the substances listed in Schedules I and II; has currently accepted medical use in treatment in the United States; and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence, and therefore:

10.3.2.1 The Secretary of State, as authorized by 16 **Del.C.** §4717, does hereby add by regulation illicit xylazine and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, in Schedule III of the Uniform Controlled Substances Act, 16 **Del.C.** Ch. 47.

10.3.2.1.1 Testing strips to determine the presence of xylazine or xylazine-related substances are exempt from subsection 10.3.2.1.

10.3.2.2 For the purpose of this subsection:

10.3.2.2.1 "**Illicit**" use of xylazine means any use in the human species or any use that is not licit use.

10.3.2.2.2 "**Licit**" use of xylazine means:

10.3.2.2.2.1 Any administration to nonhuman species a drug containing xylazine that has been approved by the Secretary of Health and Human Services under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b); or that is permissible under section 512(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(4)).

10.3.2.2.2.2 The manufacturing, importation, or use of xylazine as an active pharmaceutical ingredient for manufacturing an animal drug approved under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) or issued an investigation use exemption under subsection (j) of such section 512.

10.3.2.2.2.3 The manufacturing, importation, or use of a xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians.

10.3.2.2.2.4 Another use approved or permissible under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

10.4 Finding and Availability. The Secretary of State will maintain on file any adoption, amendment or repeal of these regulations. In addition, copies of these regulations will be available for public inspection at the Office of Controlled Substances.

20 DE Reg. 564 (01/01/17)
20 DE Reg. 826 (04/01/17)
25 DE Reg. 873 (03/01/22)

11.0 Severability

11.1 If any provision of these regulations is held invalid the invalidity does not affect other provisions of the regulations which can be given effect without the invalid provisions or application, and to this end the provisions of the regulation are severable.

11.2 Pursuant to 16 **Del.C.** §4718(f) and 16 **Del.C.** §4720(c) the Secretary of State finds that the compounds, mixtures or preparations listed in 21 **CFR** 1301.21, 21 CFR 1308.24 contain one or more active medical ingredients not having a stimulant or depressant effect on the central nervous system and that the admixtures included therein are in combinations, quantities, proportions, or concentrations that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system, and therefore:

11.2.1 The Secretary of State, as authorized by 16 **Del.C.** §4718(f) and 16 **Del.C.** §4720(c), does hereby except by rule the substances listed in 21 CFR 130.21, CFR 1308.24 and 21 CFR 1308.32 from Schedules III and IV of the Uniform Controlled Substances Act, 16 **Del.C.** Ch. 47.

13 DE Reg. 281 (08/01/09)
15 DE Reg. 891 (12/01/11)
16 DE Reg. 1198 (05/01/13)
17 DE Reg. 992 (04/01/14)
20 DE Reg. 564 (01/01/17)
20 DE Reg. 826 (04/01/17)
22 DE Reg. 79 (07/01/18)
25 DE Reg. 873 (03/01/22)
27 DE Reg. 7 (07/01/23) (Emer.)