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

WHEREAS, the Secretary of the Department of State ("the Secretary") "may promulgate rules . . . relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State." 16 **Del.C.** §4731(a); and

WHEREAS, the Secretary may adopt emergency regulations if the Secretary finds that there exists an imminent peril to the public health, safety or welfare. 29 **Del.C.** §10119; Regulation 9.3 of the Uniform Controlled Substance Act Regulations; and

WHEREAS, available data and information pertaining to extended-release hydrocodone lacking abuse-deterrent formulation demonstrates that this medication poses imminent peril to the public, health safety and welfare in that it is approximately five times more potent than opioids currently being prescribed to treat pain. Further, the medication lacks an abuse-deterrent formulation, meaning that it can be chewed, crushed or dissolved, thereby causing rapid release and absorption of a potentially fatal dose of hydrocodone; and

WHEREAS, the Delaware Controlled Substance Advisory Committee has recommended the enactment of an emergency regulation placing limitations and requirements on the prescription of extended-release hydrocodone lacking abuse-deterrent formulation; and

WHEREAS, the Secretary finds that adoption of the recommended regulation must occur on an emergency basis in order to properly protect the public; and

WHEREAS, the Secretary will accept, consider and respond to petitions by any interested person for the reconsideration of adoption of this regulation by addressing the same to the attention of Mr. Dave Dryden, Cannon Building, 861 Silver Lake Blvd., Dover, DE 19904; and

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

NOW, THEREFORE, IT IS ORDERED this 18th day of June, 2014:

1. The Uniform Controlled Substance Act Regulations are amended as set forth in Exhibit A, attached hereto.
2. In accordance with the provisions of 29 **Del.C.** §10119(3), this Order shall be effective for 120 days from the date of execution.

SO ORDERED this 18th day of June, 2014.

Jeffrey W. Bullock, Secretary of State

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. The public member will be appointed by the Secretary of State or their designee.

1.3 Each Committee member shall serve a term of three years and may succeed themselves for one additional term. A Committee member whose appointment has expired remains eligible to participate in Committee proceedings unless 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.

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 members shall constitute a quorum, and no action shall be taken without the affirmative vote of at least 5 members. For proceedings involving the denial, suspension or revocation of a controlled substance registration at least 1 member of the quorum must be from the same profession as the practitioner whose registration is the subject of the proceeding. 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.

1.8 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.

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.

"**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**" refer to registration required by 16 **Del.C.** §4732.

3.0 Requirements

3.1 Registration shall be on a biennial basis upon forms supplied by the Division of Professional Regulation and/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 his/her review and decision. Persons complained against may appear personally or by counsel, and may produce any competent evidence in their behalf 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 his/her designee will reduce in writing his/her 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.

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 he/she is licensed to practiced his/her 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 narcotic drug dependent person for the purpose of continuing his 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 he 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 his 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 of Prescription

4.7.1 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. Such prescriptions may be dispensed up to 100 dosage units or a 31 day supply whatever is the greater. As an exception to dosage limitations set forth in this subparagraph, and in accordance with 21 CFR Section 1306.1(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. 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.

4.7.2 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.

4.8 Mail Order Prescription. Before dispensing prescriptions for Schedules II, III, IV and V controlled substances by mail, the registrant and/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 and/or an employee under his/her 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.

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 Regulation 5.2 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.

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 his 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.

For the purpose of this regulation, the "pharmacist-in-charge" is a pharmacist registered with the State Board of Pharmacy and who is responsible for the prescription department of the registrant.

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.

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 he/she 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.

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 Regulation 4.7:

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.

9.0 Procedures for Adoption of Regulations

9.1 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.

9.1.1 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. 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.

9.2 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.

9.3 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 his/her reasons for that finding, the Secretary of State may proceed without prior notice or hearing or upon any abbreviated notice and hearing he/she 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.

9.4 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.

10.0 Severability

10.1 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.

10.2 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:

10.2.1 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.

11.0 Prescription of Extended-Release Hydrocodone Lacking Abuse-Deterrent Formulation

11.1 Purpose: This rule provides requirements for the prescription of extended-release hydrocodone lacking abuse-deterrent formulation in order to address potential prescription drug overdose, abuse and diversion.

11.2 Definitions

"**Abuse-deterrent formulations**" or "**ADF**" means one of the following: physical /chemical barriers (i.e., physical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that can resist

extraction of the opioid using common solvents like water); aversion (i.e., substances that can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used); a formulation such that the drug is lacking in opioid activity until transformed in the gastrointestinal tract (known as a Prodrug); or a combination of the above methods).

"**Controlled Substance Treatment Agreement**" means a document that is agreed upon by both the practitioner and the patient acknowledging the rights, responsibilities and risks of being on a controlled substance and the treatment being received.

"**Hydrocodone**" means a semi-synthetic opioid derived from codeine.

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

"**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.

"**Risk Assessment**" means utilizing a tool, such as the Screener and Opioid Assessment for Patients with Pain ("SOAPP"), which is 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.

11.3 Requirements

11.3.1 Prior to prescribing an extended-release hydrocodone that is manufactured without an ADF, the practitioner shall:

11.3.1.1 Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record;

11.3.1.2 Prior to writing a prescription for a hydrocodone that is manufactured without an ADF, evaluate and document relative risks and benefits for the individual patient of the use of such a hydrocodone. The evaluation shall include, but not be limited to, a Risk Assessment as defined in Section 11.2;

11.3.1.3 Document in the medical record that the prescription of a hydrocodone without an ADF is required for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or would otherwise be inadequate to provide sufficient management of pain;

11.3.1.4 Receive a signed Informed Consent form from the patient, or if the patient is not competent to provide informed consent, from the patient's legal representative, that shall 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;

11.3.1.5 Receive a signed Controlled Substance Treatment Agreement from the patient that shall include requirements such as urine screening (no less frequently than every 120 days), pill counts, safe storage and disposal, and other appropriate conditions as determined by the practitioner to reasonably and timely inform the practitioner if the patient is misusing the prescribed substance;

11.3.1.6 Query the Delaware Prescription Monitoring Program ("PMP") and review other controlled substances prescribed to the patient prior to the first prescription. For any patient prescribed 40 mg or greater per day, the practitioner shall query the PMP no less frequently than once every 120 days for as long as the patient possesses a valid prescription for that amount;

11.3.1.7 Determine a maximum daily dose or a "not to exceed value" for the prescription to be transmitted to the pharmacy;

11.3.1.8 Write a prescription that must be filled within seven (7) days and that does not exceed 30 days in duration.

11.3.2 The practitioner shall schedule and undertake periodic follow-up visits and evaluations of the patient.

11.3.3 The practitioner shall schedule follow-up visits with the patient and at each such visit shall evaluate, determine and document:

11.3.3.1 Whether to continue the treatment of pain with a hydrocodone not manufactured with an ADF or whether there is an available alternative;

11.3.3.2 Whether to refer the patient for a pain management or substance abuse consultation;

11.3.3.3 A plan for the discontinuance of prescribed hydrocodone if the patient has failed to adhere to the Controlled Substance Treatment Agreement.

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)
18 DE Reg. 92 (08/01/14) (Emer.)