DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
CONTROLLED SUBSTANCE ADVISORY COMMITTEE
Statutory Authority: 16 Delaware Code, Section 4731 (16 **Del.C.** §4731)

FINAL

ORDER

Uniform Controlled Substances Act Regulations

Pursuant to 29 **Del.C.** §10118, the Secretary of State issues this Order adopting proposed amendments to the Controlled Substance Advisory Committee's Rules. Following notice and a public hearing on May 25, 2011, the Secretary makes the following findings and conclusions:

SUMMARY OF THE EVIDENCE

1. The Committee posted public notice of the proposed amendments in the April 1, 2011 *Register of Regulations* and in the *Delaware News Journal* and *Delaware State News*. Committee Exhibits 1 & 2. The Committee attempted to address the audit requirements when a pharmacy relocates, broaden the categories classes of persons who may give and accept verbal prescriptions, permit electronic transmission of prescriptions, clarify the non-resident practitioner waiver, require identification to be presented at the time a controlled substance prescription is picked up only, bar the pick-up of certain controlled substance prescriptions at drive-through windows, and impose additional security requirements on newly constructed or renovated pharmacies with these proposed amendments.
2. The Committee received written comments from CVS, stating that CVS supports obtaining identification for controlled substances only at pickup. Committee Exhibit 3. The Committee received written comments from Rite Aid stating that Rite Aid supports requiring identification only on pickups for the existing required schedules. Committee Exhibit 4.
3. The Committee received written comments from the Cancer Action Network of the American Cancer Society urging the Committee to end the seven day prescription validity rule and the 100 unit dosage limitation. Committee Exhibit 5.
4. The Committee received additional written comments from the Cancer Action Network of the American Cancer Society entitled "Joint Position Statement: Pain Medication and Prescribing Restrictions" encouraging the Committee to work with the health care community and patient advocates to develop a balanced policy toward controlled substances. Committee Exhibit 6.
5. At the public hearing, the Committee received public comment from Jeanne Chiquoine, Government Relations Director for Delaware, Cancer Action Network of the American Cancer Society. Ms. Chiquoine testified that her organization makes it a priority to not have cancer patients have their lives overtaken by pain. Almost all cancer pain can be managed with pain medication. Studies show that patients have better health outcomes when their pain is properly managed. Neither the American Cancer Society ("ACS") nor the Cancer Action Network ("CAN") want additional barriers impeding pain policy and practitioners willingness to provide pain medication and pain management when treating patients with cancer. The Federal Controlled Substance Act does not limit the quantity of a Schedule II controlled substance and Delaware's current regulation limiting to 100 units and seven day prescription validity is more stringent than the federal rules and the ACS and CAN ask the Committee to reconsider these regulations. The federal regulations allow practitioners to issue multiple prescriptions of a schedule II controlled substance in a prescription series, allowing up to a 90 day supply in situations where the practitioner determines that a periodic review of treatment effectiveness is not required more frequently.
6. At the public hearing, the Committee received public comment from Geoffrey Christ on behalf of Walgreens Pharmacy. Mr. Christ informed the Committee that he is a professional member of the Board of Pharmacy. He commended the Committee for clearing up the identification requirement only at pick-up. Regarding the regulation that allows for controlled substances scripts to be dropped off at the drive-thru, but picked up inside, he is opposed to this because he believes it is a huge barrier to patient care. He believes the rule could be changed to address the fraud concerns and he suggests that the regulation require in-store pick-up only if the pharmacist can't clearly identify the person in the car. He has never had a problem with people passing fraudulent prescriptions in his drive-thru, and he doesn't know what the impetuous for this was. Overall, this will negatively affect patient care, especially for chronic pain patients. Mr. Christ commented on the drive-thru window is that it does not allow any discretion to the pharmacist. If, as the overnight pharmacist, he can collect a license and identify the person collecting the prescription, he should have the discretion to allow for filling the prescription at the window. The pharmacist should have some discretion. He works at a 24 hour store, and the only pharmacy open for 30 miles. This stigmatizes certain people based on the classification of their drug.

With regard to the new 5.1.1.4 requirement of floor to ceiling barriers, Mr. Christ feels this will have a huge economic

impact on stores already in existence and he thinks there has only been one burglary of a pharmacy in the past three years and the real problem is robbery and diversion, not after hours burglary. Also, this is extremely cost prohibitive. Also, the floor to ceiling barrier requirement is going to be immediately enforceable regardless of what is said off the record.

7. The Committee proposed the following changes to the regulations: (see text below:)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

8. The public was given notice and an opportunity to provide the Committee with comments in writing and by testimony at the public hearing on the proposed amendments to the Committee's Rules as required by 29 **Del.C.** §10117.

9. With regard to Ms. Chiquoine's request that regulation 4.8.1 be changed to allow for written prescriptions to remain good beyond seven days, the Committee recognizes that the pharmacist always has the power to change what is written on the prescription after contacting the doctor and so this can be worked around, but it requires communication between the pharmacist and the doctor.

10. With regard to Ms. Chiquoine's request that regulation 4.8.1 be changed to allow for a greater than 100 unit maximum, the Committee recognizes that this limitation was established at the request of the medical society because doctors had a problem with patients not coming in to see them on a monthly basis, and because patients were hording their controlled substances and there were suicide concerns. Further, the Committee notes that neither the seven day requirement nor the 100 unit maximum apply to long term care residents. By adding the 31 day supply alternative, the Committee created a way for doctors of cancer patients to write for more than 100 units at a time.

11. With regard to the drive-thru controlled substance pick-up, the Committee understands that someone who is able to drive themselves without being unsafely under the influence of controlled substances should be able to come into the pharmacy to pick up their medication. Also, the pick-up person does not have to be the person for whom the script is written. The balance that must be struck is between the few people who may be chronic pain patients or returning from taking themselves to the emergency room for whom this will be an inconvenience against the law enforcement concern of limiting diversion through the use of stolen identification and/or prescription pads. The Committee hears the hardship this regulation will cause, but the overall concern is to public safety and this is a limited hardship, affecting only a few individuals while public safety affects a greater number. The law enforcement presentation indicates that drive thru windows are a growing source of fraudulent activity. Also, this restriction is limited to Schedule II controlled substances, it is not applicable to Schedule III. Schedule III scripts can still be picked up at the drive thru. In this way, the Committee attempted to strike a balance between the two concerns.

12. With regard to the floor to ceiling barrier, the Committee does not believe this will be too cost prohibitive as many pharmacies are already in compliance with this. Shelving and computer systems that then are topped with a security fence will comply with this requirement. There will be some costs associated with this requirement, especially with the older pharmacies. The office of controlled substances will work with pharmacies pre-build or pre-remodel to help them comply with this regulation and Mr. Dryden assured everyone that he will not be enforcing this regulation unless the pharmacy has a problem. A floor to ceiling physical barrier can also be around the entire facility, it does not have to be just around the pharmacy. The Secretary finds that this regulation should only apply to pharmacies remodeled or newly constructed after July 31, 2011 and the regulation is amended to reflect this.

13. In addition to the changes previously published, the Secretary finds that certain non-substantive changes are necessary, including clarification of the floor to ceiling regulation applying only to pharmacies remodeled or newly constructed after July 31, 2011. These changes are reflected in Exhibit A.

14. Having heard and considered the public comments on the proposed regulations, the Committee recommended that no additional changes should be made to the regulations as published. The Secretary accepts the regulation changes as proposed, with the non-substantive changes reflected in Exhibit A. These regulations will become effective ten days after their publication on December 1, 2011.

IT IS SO ORDERED this 3rd day of November, 2011.

Jeffrey Bullock, Secretary of State

Uniform Controlled Substances Act Regulations

~~(Adopted by the Secretary of Health and Social Services pursuant to 16 **Del.C.** §4731 effective February, 1973 amended July 8, 1974, May 27, October 30, 1975, September 27, 1976, February 1, 1983, July 1, 1985, January 28, 1987, March 5, 1992, and August 29, 1995.)~~

~~**Adoption of Federal Regulations**~~

~~To the extent consistent with 16 **Del.C.** Ch. 47, regulations promulgated by the Federal Government pursuant to the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, and in effect as of this date, are adopted as a part of these regulations. Readopted October 30, 1975.~~

~~**13 DE Reg. 281 (08/01/09)**~~

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 **[~~by their respective regulatory board~~]**.

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**[~~, who is an ex officio member of the Committee without a vote,~~]** 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.

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2.0 Requirements

2.1 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 substances are manufactured, distributed, dispensed, or kept for research or analysis. Out-of-State registrants who dispense or distribute controlled substances to patients or facilities in Delaware are required to obtain a registration.

2.2 Revocation and Suspension

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

2.2.2 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.

2.2.3 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 therefore, 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.

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3.0 Records and Inventory

3.1 Requirements

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

3.1.1.1 Name and address of patient

3.1.1.2 Date prescribed

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

3.1.2 Other records required by 21 **CFR** 1300 to 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.

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

3.1.3.1 Amount received or distributed.

3.1.3.2 Names, addresses and dates regarding these transactions.

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

3.1.4 When a pharmacy relocates to a new building, a complete audit of all controlled substances must be conducted before the move and within twenty-four hours after the move is complete. 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.

3.2 Accountability Audits

3.2.1 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.

3.2.2 Accountability audits of registered practitioners will be accomplished through a review of records to be kept by paragraph 3.1 of this section.

3.2.3 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.

3.3 Final inventory

3.3.1 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 will 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.

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

3.4 Retention of Records

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

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4.0 Prescriptions

4.1 Definitions. As used in this section:

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

4.1.2 The term "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.

4.1.3 The term "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.

4.1.4 The term "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.)

4.1.5 The terms "register" and "registered" refer to registration required by 16 **Del.C.** §4732.

4.2 Persons Entitled to Issue Prescriptions

4.2.1 A Prescription for a controlled substance may be issued only by a practitioner who is:

4.2.1.1 Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and

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

4.2.2 A verbal prescription for a controlled substance may only be communicated to a pharmacist ~~or~~, 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. ~~Prescriptions for controlled substances communicated by an employee or agent of the prescriber are not valid.~~ 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.

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

4.2.~~3~~4 **[~~Written pP~~]**rescriptions for controlled substances may be transmitted via facsimile or electronic transmission by a practitioner or by the practitioner's authorized agent to a pharmacy ~~only when the transmission complies with 21 **CFR** 1306.11, 1306.21 and 1306.31~~.

4.3 Purposes of Issue of Prescription

4.3.1 A prescription for a controlled substance to be effective 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.

4.3.2 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.

4.3.3 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.

4.4 Manner of Issuance of Prescriptions. All prescriptions for controlled substances shall be dated **[~~and signed~~]** 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.

4.5 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.

4.6 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.

4.7 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.

4.8 Expiration of Prescription.

4.8.1 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 ~~cannot be written nor dispensed for more than~~ may be dispensed up to 100 dosage units or a 31 day supply whatever is the greater ~~at one time~~. 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.

4.8.2 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.

4.9 Mail Order Prescription. Before dispensing prescriptions for Schedules II, III, IV, 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.

4.10 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. ~~Pharmacists may dispense controlled substances pursuant to a prescription written by a non-resident practitioner (who is not registered under 16 **Del.C.** Ch. 47) provided that:~~

4.10.1 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.

4.10.2 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.~~10.1~~11 The pharmacist must establish that the ~~non-resident~~ a practitioner is properly registered to prescribe controlled substances under Federal Law. ~~The pharmacist may keep a record which contains the name and address of the non-resident practitioner, his Federal registration number, and the name and address of the source of the registration data.~~

4.~~10.2~~11.1 The pharmacist and/or an employee under his/her direct supervision must verify the identification of the ~~bearer and~~ receiver of the controlled substance prescription by reference to valid photographic identification ~~and record the unique number associated with the valid photographic identification as part of the prescription record~~. For the purposes of this section, a valid photographic identification is limited to the following:

4.~~10.2.1~~11.1.1 A valid Delaware motor vehicle operator's license which contains a photograph of the person ~~presenting~~ receiving the prescription - record the license number listed on the license as part of the ~~prescription~~ patient record.

4.~~10.2.2~~11.1.2 A valid Delaware identification card which contains the photograph of the person ~~presenting~~ receiving the prescription - record the identification number listed on the card as part of the ~~prescription~~ patient record.

4.~~10.2.3~~11.1.3 A valid United States passport.

4.~~10.2.4~~11.1.4 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.~~10.2.~~11.1.4.1 Contains a photograph of the person ~~presenting~~ receiving the prescription:

4.~~10.2.~~11.1.4.2 Is encased in tamper-resistant plastic or is otherwise tamper-resistant.

4.~~10.2.~~11.1.4.3 Identifies the date of birth of the person ~~presenting~~ receiving the prescription and has an identification number assigned to the document which can be recorded as part of the ~~prescription~~ patient record.

4.11.2 **[~~I.D.s~~ Identification]** for mail order dispensed controlled substances must comply with all federal standards.

~~4.10.3 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.~~

~~4.10.3.1 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.~~

4.11.3 No filled prescription for any Schedule II controlled substance may be received at any drive through window. Written prescriptions for Schedule II controlled substances may be initially presented at a drive through, but the filled prescription must be picked up inside the pharmacy.

4.1~~1~~2 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.

~~4.12 The pharmacist and/or an employee under his/her supervision must also verify the identity of the person receiving a dispensed controlled substance at the time it is transferred to that person. The manner in which valid photographic identification is verified and recorded shall be the same as provided in 4.10.2.~~

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5.0 Security and Disposal

5.1 Security

5.1.1 Schedule II Substances Storage

5.1.1.1 Pharmacies and practitioners must store Schedule II controlled substances in a burglar resistant type safe. 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. Other types of substantially construed, securely locked cabinets or drawers are acceptable provided that the room, storage area or areas shall be provided with electronic intrusion detection equipment to all sections of the said area or areas where Schedule II controlled substances are stored, so as to detect four-step movement (as defined in Section 12.8 of U.L. Standards 681).

5.1.1.1.1 The aforementioned 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. Standard 4.64.

5.1.1.1.2 A local alarm connection shall not be permitted if the controlled substance premise is located more than 400 feet from a public roadway. If said controlled substances premise is more than 400 feet from public roadway or found to be within a location where such an alarm would not be effective, then the alarm system on said controlled substances premises shall transmit an alarm signal to a certified station or directly into a law enforcement agency that has 24-hour monitoring capabilities.

5.1.1.1.3 The Secretary of State may require additional security requirements if he/she deems it necessary as a result of diversion of controlled substances.

5.1.1.1.4 Definitions: Four-step movement - 12.8 - The system shall respond to 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.

5.1.1.2 Safes containing Schedule II controlled substances must be kept locked at all times. They may be opened only by the practitioner or by the pharmacist-in charge or other designees, who must be licensed medical professionals.

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

5.1.1.4 Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. Pharmacies may disperse such substances in 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. 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 matter 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. In addition, ~~T~~the keys to such area shall at all times be carried by a pharmacist. The doors shall be locked whenever the area is not directly under the supervision of a pharmacist or a responsible person designated by the pharmacist.

5.1.2 Pharmacies.

5.1.2.1 Schedule II controlled substances kept in areas other than prescription areas in pharmacies must be placed in safes of the type described above. These must be kept locked at all times and may be opened only by the pharmacist-in-charge or his designee, who must also be a registered pharmacist.

5.1.2.2 Schedule III through V controlled substances kept in areas other than prescription areas in pharmacies must be kept in adequately locked enclosures. They may be opened only by the pharmacist-in-charge, or his designees, who must be licensed pharmacists.

5.1.3 Report of Loss or Theft. 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. In addition, registrants shall complete the Federal forms regarding such loss or theft, one copy of which must be filed with the Office of Controlled Substances.

5.1.4 Hypodermic syringes and needles must be secured in an area only accessible to personnel authorized under 16 **Del.C.** Ch. 47 to dispense such items.

5.2 Disposal

5.2.1 Controlled Substances. Any registrant in possession of any controlled substances and desiring or required to dispose of such substance or substances shall contact the Office of Controlled Substances for proper instructions regarding disposal.

5.2.2 Hypodermic Syringe or Needle. Hypodermic syringes or needles shall be destroyed before disposal in such a manner as will render it impossible to adapt them for the use of narcotic drugs by subcutaneous injections.

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6.0 Procedures for Adoption of Regulations

6.1 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.

6.1.1 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, the place where 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.

6.2 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.

6.3 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.

6.4 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**.**

13 DE Reg. 281 (08/01/09)

7.0 Severability

7.1 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.

7.2 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:

7.2.1 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) (Final)