DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

Controlled Substance Advisory Committee

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

FINAL

ORDER

After due notice in the *Register of Regulations* and two Delaware newspapers, public hearings were held on March 11, 2008, and October 20, 2008 to receive comments regarding proposed amendments to the Controlled Substance Regulations including the creation of a Controlled Substance Advisory Committee ("the Committee"). James L. Collins, Director of the Division of Professional Regulation ("the Director"), served as the Secretary of State's designee for purposes of conducting the public hearings and making recommendations on the proposed regulations.

The purpose of the Committee is to advise the Secretary of State ("the Secretary") on controlled substance regulatory matters and to conduct hearings related to registrants. The proposed regulations were first published in the *Register of Regulations* on February 1, 2008 at 11 DE Reg 1082. The March 11th hearing was noticed in the *Register of Regulations* on March 1, 2008 at 11 DE Reg 1269. As a result of the public comment, and upon the recommendation of the Director, the Secretary determined to make both substantive and non-substantive revisions to the proposed regulations and republished the regulations in the *Register of Regulations* on September 1, 2008 at 12 DE Reg 301. A second public hearing was noticed for and conducted on October 20, 2008.

Summary of the Evidence and Information Submitted

The following individuals submitted correspondence and/or offered public comment at the March 11, 2008 hearing: Elizabeth Roe, Assistant Director, State Government Affairs, American Academy of Physician Assistants (AAPA), Darlene L. Jackson-Bowen, MPAS, BS, PA-C, University of Maryland, Eastern Shore Physician Assistant Department, Matthew M. Dows, MS, PA-C, Salisbury Immediate Care, Natalie Miller, PA Student, Drexel University, Chris Carrier, PA-C, ATC, Peninsula Orthopedic Associates, Mark Key, PA-C, President, Delaware Academy of Physicians Assistants (DAPA), Kemuel Carey, MHS, PA-C, ATC, Peninsula Orthopaedic Associates, Hal G. Brown, Deputy Director, Office of the Chief Medical Examiner, Craig Johnson, PA-C, Kevin N. Nicholson, R. Ph., J.D., Vice President, Pharmacy Regulatory Affairs, Eric Eaton, PA-C, Peninsula Orthopaedic Associates, Hooshang Shanehsaz, R.Ph, Dan Holst, R.Ph, Sandra Robinson, R.Ph, Vice-President of the Delaware Board of Pharmacy, Pat Carroll-Grant, Executive Director, Delaware Pharmacists Society (DPS), Gaurang Ghandi, DPS, Sam Wetherill, DPS, Maryanne Holzapfel, DPS, Bruce Divencenzo, Chief Agent for the Office of Narcotics and Dangerous Drugs (ONDD), Dr. Phillip Kim, and Dr. Michael Kremer, State Board of Dental Examiners. Fourteen (14) documents were marked as exhibits to the public hearing.

The following individuals submitted correspondence and/or offered public comment at the October 20, 2008 hearing: Thomas John Chambers, R.Ph, Geoffrey Christ, Esquire, R.Ph, President of the Delaware Board of Pharmacy, Jeanne Chiquone, American Cancer Society and the American Cancer Society Cancer Action Network, Sandra Robinson, R.Ph, Vice-President of the Delaware Board of Pharmacy, Karl Berky, R.Ph, Pat Carroll-Grant, Executive Director, Delaware Pharmacists Society (DPS), Adam Solola, R.ph, Board of Directors of DPS, Hooshang Shanehsaz, R.Ph, Phil Anderson, R.Ph, Tim Dillon, R.Ph, Theresa Gillis, M.D., Christiana Care Cancer Liaison Physician for the Commission on Caner of the American College of Surgeons, Nicholas Biasotto, D.O., President of the Delaware Medical Society. Ten (10) documents were marked as exhibits to the public hearing.

Findings of Fact With Respect to the Evidence and Information Submitted

1. As a result of comment received at the first public hearing on March 11th the Secretary made the following changes to the regulation before republishing on September 1, 2008. The regulations were republished with the following changes:

Regulations 1.2 and 1.3 - The composition of the Controlled Substance Advisory Committee (the

"Committee") established under Regulation 1.2 was increased to 9 members by adding 1 additional pharmacy member and 1 physician assistant member. The Secretary also clarified that the public member is exempted from the 5 year prescribing, dispensing or storing of controlled substances requirement. The language requiring the public member to be accessible to inquiry was deleted. The Committee member term length was decreased from 5 years to 3.

Regulation 1.7 - The quorum and voting provisions were amended to reflect the 2 additional Committee members, raising the quorum to 5 members.

Regulation 4.1.2 - The term "individual practitioner" in the definitional section was changed to "practitioner" and the word "individual" was stricken from each reference to individual practitioner throughout the regulations. Nurse practitioners and physician assistants were added to the definition of practitioner.

Regulation 4.4 - The word "manually" was reinserted into the language dealing with the manner of issuance of prescriptions.

Regulation 5.1.1.1.3 - The words "or Drug Control Administrator" were removed as unnecessary since the Secretary has the power to make designations. Clarifications were also made throughout the regulations that the word "Secretary" means the "Secretary of State."

2. A number of individuals commented on the requirements of Regulation 4.10 and 4.12 at both public hearings. The regulations provide that "The pharmacist and/or employee under his/ her direct supervision must verify the identification of the bearer and receiver of the controlled substance prescription by reference to a valid photographic identification and record the unique number associated with the valid photographic record as part of the prescription record…" The objection to the requirement of having to verify identification on the drop-off of the prescription is that it is burdensome on the pharmacist and the patient. However, the Secretary is not persuaded that the minimal burden of verifying identification outweighs the need to take measures to prevent prescription fraud, diversion and abuse of controlled substances. As a result, the Secretary finds that the adoption of the regulation as proposed without modification is consistent with public safety and welfare. The Secretary also finds that the issue should be referred to the newly formed Committee to revisit.

3. A number of the public comments were directed to sections of the regulations that are not being proposed for substantive modification at this time. Those comments included recommended changes to the prescriptions and prescription pads, amendments to regulation 3.0 regarding records and inventory, 4.1.4 defining the term "prescription", amendments to 4.2.2 regarding verbal prescriptions, amendments to 4.3.1 to define "usual course of professional treatment", amendments to 4.8.1 to with regard to prescriptions for schedule II and III controlled substances becoming void unless dispensed within seven days, and 5.1.1.4 with regard to security of storage of controlled substances.

The Secretary appreciates thought that was given by those individuals who provided comment to improving many areas of the regulations. However, the primary purpose of the regulations as currently proposed is to establish the Committee and to reference the transfer of the controlled substance regulation authority to the Secretary of State. As a result, the Secretary finds that requests for additional amendments should be referred to the newly formed Committee to address since they are new proposals for changes to additional sections of the regulations.

4. Public comment was reiterated at the October 20th hearing that the composition of the Committee should be further increased. The Secretary finds that the composition as proposed provides balanced representation for pharmacists and practitioners. Any additional changes to the composition may be recommended for future rule changes after the Committee is established if the Committee finds that there is a need.

5. One commenter was concerned that the Committee would be taking disciplinary action against physicians that is properly under the jurisdiction of the Board of Medical Practice. The Committee's only disciplinary role will to be to make findings to the Secretary regarding denying, suspending or revoking a controlled substance registration. Discipline related to practice issues is still vested with the appropriate licensing body having jurisdiction over the practitioner. The Secretary finds that the regulations do not require any clarification as to the Committee's function.

6. The Secretary is persuaded, however, that Regulation 1.7 would be improved by clarifying that for proceedings involving the denial, suspension or revocation of a controlled substance registration at least 1 member quorum must be from the same profession as the practitioner whose registration is the subject of the proceeding. The Secretary finds that the change is for clarification and consistency and is not substantive.

The Law

The Secretary's rulemaking authority is provided by 16 Del. C. §4731.

Decision and Effective Date

The Secretary hereby adopts the proposed amendments to the controlled substance regulations to be effective 10 days following publication of this order in the *Register of Regulations.*

Text and Citation

The text of the regulation including the revisions made to Regulation 1.7 as a result of the public hearing is attached hereto as Exhibit A.

SO ORDERED this 16th day of July, 2009.
SECRETARY OF STATE
Jeffrey W. Bullock

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.)

~~1.0~~ 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.

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.

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. ~~Such proceedings shall be tape recorded.~~

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 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.

3.0 Records and Inventory

3.1 Requirements

3.1.1 Practitioners authorized to prescribe or dispense controlled substances 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. ~~at least 8 by 11 inches in dimension~~. 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.

3.2 Accountability Audits

3.2.1 ~~Pharmacies~~ 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 ~~Medical, dental and veterinary~~ Accountability audits of ~~medical, dental and veterinary~~ registered practitioners will be accomplished through a review of records to be kept by paragraph ~~3.2.1~~ 3.1 of this section.

3.2.3 ~~Manufacturers and distributors~~ 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 ~~Narcotics and Dangerous Drugs~~ 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 ~~Medical, dental and veterinary. Medical, dental and veterinary~~ **Registered** practitioners who cease legal existence or discontinue business or professional practice shall notify the Office of ~~Narcotics and Dangerous Drugs~~ 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.

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 "~~individual~~ 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 dispense 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~~n individual~~ 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 pharmacy intern by the prescriber. Prescriptions for controlled substances communicated by an employee or agent of the prescriber are not valid.

4.2.3 Written prescriptions for controlled substances may be transmitted via facsimile 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 a~~n individual~~ practitioner acting in the usual course of ~~his~~ 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~~n individual~~ practitioner to obtain controlled substances for supplying the ~~individual~~ 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 ~~individual~~ 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 ~~if~~ unless the original prescriber authorizes the prescription past the seven (7) day period. Such prescriptions cannot be written nor dispensed for more than 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 ~~physicians or dentists~~ 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 ~~physician or dentist~~ practitioner (who is not registered under 16 **Del.C.** Ch. 47) provided that:

4.10.1 The pharmacist must establish that the non-resident ~~physician or dentist~~ 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 ~~physician or dentist~~ practitioner, his Federal registration number, and the name and address of the source of the registration data.

4.10.2 ~~The pharmacist must verify the identification of the bearer of the prescription by reference to a driver's license or some other identification which contains the bearer's photograph, and must keep a record of such person.~~ 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 A valid Delaware motor vehicle operator's license which contains a photograph of the person presenting the prescription - record the license number listed on the license as part of the prescription record.

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

4.10.2.3 A valid United States passport.

4.10.2.4 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:

4.10.2.4.1 Contains a photograph of the person presenting the prescription:

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

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

4.10.3 The pharmacist must establish that the name of the non-resident ~~physician or dentist~~ practitioner does not appear on the list kept by the Office of ~~Narcotics and Dangerous Drugs of the Division of Public Health~~ Controlled Substances of those non-resident ~~physicians and dentists~~ 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 ~~physicians and dentists~~ practitioners determined by the ~~Narcotics and Dangerous Drugs of the Division of Public Health~~ Office of Controlled Substances to have acted in a manner inconsistent with the Public Health and Safety. ~~and Safety, and the Office of Narcotics and Dangerous Drugs~~ The Office of Controlled Substances shall maintain a list of those non-resident ~~physicians and dentists~~ practitioners found by them to

have so acted. Pharmacists shall not honor the prescriptions of non-resident ~~physicians and dentists~~ practitioners whose names appear on that list unless such non-resident ~~physicians and dentists~~ practitioners have registered pursuant to the provisions of 16 **Del.C.** §4732.

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. ~~effective date January 1, 1974.~~

4.12 ~~The pharmacist or an employee under his/her supervision must verify the identity of the person receiving a dispensed controlled substance at the time it is transferred to that person. A driver's license or a similar document containing a photograph and the name and address of the person is an acceptable document. The name and address of the person should be recorded on either the prescription or patient's profile. The pharmacist or employee is not required to follow this procedure for each transaction if the identify of the person is clearly established by visual recognition. In those cases, the information shall be recorded at least once.~~ 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.

5.0 Security and Disposal

5.1 Security

5.1.1 Schedule II Substances Storage

5.1.1.1 Pharmacies and ~~medical, dental and veterinary~~ practitioners must store Schedule II controlled substances in a burglar resistant type safe ~~or GSA Class 5 grade steel cabinet or their equivalent~~. 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 ~~either~~ he/she deems it necessary as a result of ~~excessive~~ 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~~, cabinets or drawers~~ 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 containing dispersed, controlled drugs must be secured in a manner approved by the Office of Controlled Substances ~~Narcotics and Dangerous Drugs~~ which will prevent entry by unauthorized persons. 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~~, cabinets or drawers~~ 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 ~~Narcotics and Dangerous Drugs of the Division of Public Health~~ 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 ~~Narcotics and Dangerous Drugs~~ 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 ~~Narcotics and Dangerous Drugs of the Division of Public Health~~ 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.

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.

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 ~~Narcotics and Dangerous Drugs~~ 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. ~~He may appoint subordinates~~ The Secretary of State shall designate the Committee to preside over ~~such~~ hearings. The ~~Secretary~~ 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, ~~he~~ 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. ~~with the Secretary of State. Regulations will become effective upon such filing.~~ In addition, copies of these regulations will be available for public inspection at the Office of ~~Narcotics and Dangerous Drugs of the Division of Public Health Jesse S. Cooper Building, Dover, Delaware, 19901.~~ Controlled Substances**.**

7.0 Severability

7.1 If any provision of these regulations is held invalid the invalidity does not effect 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.