

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

PROPOSED

PUBLIC NOTICE

Uniform Controlled Substances Act Regulations

Pursuant to 16 Del.C. §4731, the Delaware Secretary of State ("Secretary") proposes revisions to the Uniform Controlled Substance Act ("UCSA") rules and regulations.

On July 1, 2015, proposed revisions to the rules and regulations were published in the Delaware *Register of Regulations*, Vol. 19, Issue 1. Specifically, Section 9.0 was added to provide requirements for the prescribing of opiates in order to address potential prescription drug overdose, abuse and diversion. A public hearing was held on July 29, 2015 before the Controlled Substance Advisory Committee ("Committee"). The Committee deliberated on the evidence presented at its meeting on September 23, 2015 and recommended certain revisions to the Secretary. The Secretary considered both the evidence presented and the Committee's recommendations.

Based on that review, the Secretary struck the version of Section 9.0 published in the *Register of Regulations* on July 1, 2015 and proposed a revised Section 9.0, which was published in the Delaware *Register of Regulations* on May 1, 2016, Volume 19, Issue 11. The Secretary solicited written comments from the public regarding the proposed rules and regulations allowing the period of time for such submissions to remain open for the 30 days mandated by 29 Del.C. § 10118(a).

Based on those written comments, the Secretary has made further revisions to the rules and regulations, which are attached hereto as Exhibit A.

Any person who wishes to present written suggestions, testimony, briefs or other written materials concerning the proposed rules and regulations should submit such comments no later than Monday, August 1, 2016 to:

Christine Mast, Administrative Specialist III
Office of Controlled Substances
Delaware Division of Professional Regulation
Cannon Building, Suite 203
861 Silver Lake Blvd.
Dover, Delaware 19904
Email: christine.mast@state.de.us
Fax: (302) 739-2711.

Summary of the Evidence

The following written comments were submitted in response to the proposed rules and regulations published on May 1, 2016:

Exhibit 1: May 12, 2016 email from David Allen

Mr. Allen objected to limiting a first prescription to 7 pills. He also objected to twice a year drug screens and argued that these restrictions would place a hardship on people who need pain medication for a better quality of life.

Exhibit 2: May 12, 2016 email from Mary Reppy, PhD, President & CEO Abacalab, Inc.

Ms. Reppy expressed concern regarding the regulations' possible impact on chronic pain patients. Insurance companies may not pay for two drug screen each year. It can be difficult for pain patients to switch to other types of medication due to patient response and tolerance. These drugs, such as NSIADs, also have side effects. With respect to alternative treatments, such as physical therapy, lack of insurance coverage can pose problems.

Exhibit 3: May 12, 2016 email from Kerry McElwee

Ms. McElwee noted that the problem of insurance refusing to pay for long term alternative treatments is not addressed in the regulations.

Exhibit 4: May 12, 2015 email from Lisa Vandercook

Ms. Vandercook expressed her opposition to any more restrictions on what doctors can legally prescribe. Non-addict

patients shouldn't have to jump through hoops to get medication.

Exhibit 5: May 12, 2016 email from Kim Allen

Ms. Allen expressed her view that the regulations represent government getting in between doctor and patient. Requiring office visits to get a 7 day prescription would require patients to visit doctors weekly.

Exhibit 6: May 12, 2016 email from Clara Zahradnick

Ms. Zahradnick stated that the 7-day limit is much too short and will present a burden to the patient and the doctor. There are better ways to deal with opioid addiction than one size fits all methods.

Exhibit 7: May 18, 2016 email from Donna Monroe, M.S.

Ms. Monroe stated that she disagrees with the guidelines for opioid prescribing with respect to the 7-day limit, which would require frequent doctor and pharmacy trips.

Exhibit 8: May 24, 2016 email from Timothy Langan, M.D., Medical Director, Vitas Healthcare - Delaware.

As the medical director for a hospice in Delaware who prescribes Schedule II medications for end of life pain management, Dr. Langan asked for an exception to the regulations for patients under hospice care. These patients don't fit into acute or chronic pain syndromes. The PMP query requirements would be arduous and interfere with patient care.

Exhibit 9: May 24, 2016 and May 26, 2016 emails from Sally Matthews

Ms. Matthews questioned whether any research had been done concerning the impact of the regulations on the elderly with chronic pain. She expressed concern that the elderly and their caretakers will encounter great difficulty in obtaining medication to treat chronic pain.

In her second email, Ms. Matthews added her recommendation that the 7-day limit be extended to a six week supply. She expressed concern that Section 9.0 focuses on restricting the prescribing of opioid analgesics but does not address treatment for those addicted.

Exhibit 10: May 25, 2016 email from Laura Wharton, B.S., Administrative Assistant Tova Community Health, Inc.

Ms. Wharton stated that the regulations would have an adverse impact on populations requiring prescriptions longer than 7 days such as sickle cell anemia patients.

Exhibit 11: May 25, 2016 comments from John Goodill, M.D., Director, Palliative Care Education and Outreach, CCHS

Dr. Goodill stated his concern that the regulations will drive providers away from prescribing opiates leaving legitimate pain patients high and dry. Dr. Goodill suggested exempting certain patient populations, such as post-operative and trauma, cancer, and end of life/hospice care patients. He would not exempt veterinarians, pharmacists and institutional providers and asked for clarification as to what an "institutional provider" is. Dr. Goodill stated that Section 9.6 is unclear: what would trigger the 5 listed requirements? He suggested adding to Section 9.6 "document alternative treatments tried or considered" as well as risk assessment. Section 9.8 relates to general documentation, not opioids.

Exhibit 12: May 26, 2016 comments from Jeanne Chiquoine, Delaware Government Relations Director, American Cancer Society Action Network

Ms. Chiquoine commented that the regulations do not specify what analytes should be tested with respect to urine screening. She expressed concern regarding the financial burden that testing will place on patients experiencing pain. The regulations seem to apply differently to institutional v. non-institutional providers and require a patient-provider relationship. In the context of cancer, it is unclear how oncologists are categorized.

Exhibit 13: May 12, 2016 letter from John Becher, D.O. (President, American Osteopathic Association) and Anne Marie Sullivan, D.O. (President, Delaware State Osteopathic Medical Society)

Dr. Becher and Dr. Sullivan requested an amendment to Section 9.7.9 because it doesn't recognize equivalent board certifications in addiction medicine for osteopathic physicians offered by AOA. Section 9.7.9 just notes the American Board of Psychiatry and Neurology. Dr. Becher and Dr. Sullivan requested inclusion of the language: "subspecialty certification in addiction medicine from AOA."

Exhibit 14: May 27, 2016 email from Jayshree Tailor, M.D.

Dr. Tailor stated that he is a practicing primary care physician in Wilmington. The regulations should be guidelines to consider but final decisions should be made in doctors' offices. Dr. Tailor suggested investing energy into education of physicians regarding treating pain.

Exhibit 15: May 27, 2016 email from Taihitia Watson-Wilmer, LPN, Tova Community Health, Inc.

Ms. Watson-Wilmer stated that she is a nurse at a Sickle Cell Specialty Center. The maximum 7 day supply would be

difficult for this population to manage. Emergency room visits would increase.

Exhibit 16: May 27, 2016 email from Dr. Nina Anderson, Nova Community Health, Inc. Sickle Cell Specialty Center

As a provider who takes care of adults with Sickle Cell Disease, Dr. Anderson questioned whether limiting acute pain prescriptions to a 7-day supply would unduly impact sickle cell patients who live with chronic pain. This population should continue to get a 30 day supply if needed with monitoring.

Exhibit 17: May 30, 2016 email from M. Northrop

M. Northrop objected to the 7-day supply limit. It is impractical to pick up prescriptions every 7 days. M. Northrop asked whether chronic pain patients need to start over as new users and expressed concern regarding payment for urine screens and physician exams. M. Northrop recommended eliminating the urine screen if the patient is responsible and limiting physical exams to every 3 years. The proposed requirements place extra burdens on providers. Forcing physicians to stop prescribing schedule II pain medication is an overreaction to opioid deaths.

Exhibit 18: May 30, 2016 comments from Janet Kramer, M.D.

Dr. Kramer stated that the regulations should not be approved until open public hearings occur. She is a primary care physician with experience treating patients with substance abuse problems. The regulations will jeopardize patients challenged with acute or chronic pain. Dr. Kramer objected to the requirements for prescribing beyond 7 days. Physicians already provide information and discuss treatment options and the risks of treatment. The proposed regulations won't impact the availability of opioids for abuse on the street. Dr. Kramer also objected to use of the PMP in that it is a breach of health services confidentiality. The regulations threaten to decrease the availability of medications for patients who need them.

Exhibit 19: May 30, 2016 comments from Ron Dozier

With respect to Section 9.0, Mr. Dozier questioned who will pay for drug screens. He stated that trying to solve the opioid problem leads to a heroin problem. If addiction is suspected and confirmed, treatment is needed. He suggested tracking controlled substances and not pullout all of the stops.

Exhibit 20: May 31, 2016 letter from Wayne A. Smith, President and CEO, Delaware Healthcare Association

Mr. Smith stated that there is a fine line between regulating prescription habits while ensuring patient care isn't compromised. Mr. Smith noted that in Section 9.3, "institutional practitioner" isn't defined. If the intent is to exempt hospitals, that needs to be clarified. Section 9.5.3 allows more than a 7 day supply if the practitioner documents it in the patient record. Mr. Smith recommended including express language that patients with acute pain due to traumatic injuries, major surgical procedures, or advanced cancer are covered by Section 9.5.3. Many of these patients need more than 7 days of opioid pain medication. The urine drug screen requirement in Section 9.6.2 will place a financial burden on patients. Mr. Smith noted that the original proposed regulations included an exemption for hospice and cancer patients and requested that this be returned to the regulations. Addiction is not really a concern for end of life patients.

Exhibit 21: May 31, 2016 comments from Brent R. King, M.D., Enterprise Vice President, Chief Medical Officer, Physician in Chief, Nemours

Dr. King stated that in general he supports the regulations but wants to ensure that they are appropriate for the pediatric population. With respect to the definition of "chronic pain," the distinction between acute and chronic pain can blur in the pediatric population in conditions such as lupus and sickle cell disease. Dr. King recommended: "Chronic pain means continuous or nearly continuous pain more than three months in duration." With respect to the definition of "risk assessment," Dr. King noted that there is no validated tool for the pediatric population. To clarify that new tools may become available, he suggested adding "such as but not limited to." Dr. King suggested amending Section 9.5.2 to a 10 day supply so that families don't have to travel for a new prescription. With respect to Section 9.7.6, because there are no validated tools for pediatrics, Dr. King suggested adding "with the exception of minors, until a validated, pediatric risk assessment tool is available for use." Exceptions might be appropriate for hospice patients.

Exhibit 22: May 31, 2016 comments from Christopher D. Casscells, MD, Casscells Orthopaedics and Sports Medicine

Dr. Casscells stated that pain patients and prescription medications are not the root cause of gun violence, drug gangs and overdoses. The root cause is cocaine and heroin. The regulations are unenforceable except to criminalize physicians and push patients out of doctor's offices and onto the street for illegal drugs. The regulations will lead to increased expenses and inconvenience for patients and practice disruption for physicians. Access to legitimate and legal pain management will become onerous and expensive. Heroin is a gateway drug to Vicodin and Percocet and the regulations will worsen the illegal drug problem.

Exhibit 23: May 30, 2016 fax from Dotti Dunham

Ms. Dunham stated that weekly trips to the doctor and pharmacy will pose a hardship for pain patients. The drug abuse

epidemic was created by the American Medical Society and individuals with pain are being penalized.

Exhibit 24: May 31, 2016 letter from Attorney General Matthew Denn

Attorney General Denn stated that the initial concern after the regulations were first published in July 2015 was ensuring a higher level of doctor-patient communication before prescribing opiates for acute pain and ensuring a higher level of both initial communication and ongoing monitoring for doctors prescribing opiates for chronic pain. Both concerns have been addressed in the revised regulations. The regulations still allow doctors to prescribe opiates for acute care patients without PMP review or informed consent outlining the risks. However, the new regulations limit the initial prescription to 7 days absent documentation in the patient file as to a need for more than 7 days. This is a middle ground and the Attorney General supports it. Attorney General Denn suggested a return of the exemption for cancer and hospice care patients.

Exhibit 25: May 31, 2016 letter from Adam Raben, MD, President, Delaware Society for Clinical Oncology, Helen F. Graham Cancer Center, CCHS

Dr. Raben requested the exclusion of cancer patients from the regulations' requirements. Care of cancer patients involves both acute and chronic treatment. Additional requirements will increase the burdens already experienced by cancer patients and will disrupt the work flow of oncology specialists, which will result in reluctance to prescribe opioid analgesics.

Exhibit 26: May 31, 2016 letter from Katie Duensing, J.D., Assistant Director for Legislative and Regulatory Affairs, State Pain Policy Advocacy Network, American Academy of Pain Management

Ms. Duensing noted that Section 9.7.3 states that chronic pain patients must undergo urine drug screens every six months. The result will be that a patient's ability to receive treatment for pain will be dependent on drug screens insurance won't pay for. Delaware Medicaid limits the coverage of urine screens to situations where there is an acute change in the patient's physical or mental status. Ms. Duensing suggested aligning Section 9.7.3 with Section 9.6.2, allowing for practitioner discretion, or align Section 9.7.3 with the Medicaid rules. With respect to Section 9.5.2, the language pertaining to first time prescriptions for minors needs to be revised; the regulation doesn't say "first time."

Exhibit 27: May 31, 2016 letter from Dorothy Moore, M.D., President, Richard Henderson, M.D., Vice President and Randeep Kahlon, M.D., Treasurer, Medical Society of Delaware

Dr. Moore, Dr. Henderson and Dr. Kahlon, on behalf of the Medical Society of Delaware ("MSD"), commented that the State needs a comprehensive strategy addressing the many facets of the drug abuse and diversion crisis. Behavior change can be better affected by specialty-specific prescribing guidelines as opposed to one size fits all restrictive regulations. The regulations target prescribers and track patients. The 7-day limit has no scientific basis.

MSD offered specific comments, including the following: In Section 4.2.3, a definition of "narcotic dependent person" is needed. Section 9.3.2 provides that acute pain "is less than 3 months in duration." Some disease or post-surgery recoveries use pain medication beyond 3 months. MSD recommended amended language to the effect that acute pain can continue for up to six months. With respect to Section 9.3.9, veterinarians, pharmacists and pharmacies should not be exempted. The term "institutional practitioner" needs clarification. In Section 9.5, the maximum supply for acute pain should be increased from 7 days to 14 days because patients are not always seen in a week post procedure. With respect to Section 9.6, "subsequent prescriptions," it is unrealistic to expect every patient to be seen in person in the office for every single refill request after procedures. MSD suggested that Section 9.6.1 be amended to state that a PMP query be mandated for prescriptions beyond 3 months from procedures, not for every refill during normal, acute recovery. MSD suggested, in Section 9.6.2, a change from "urine" drug screen to "fluid" drug screen to allow for future advances in medical technology. MSD suggested that Section 9.6.5, requiring the practitioner to schedule and undertake periodic follow up visits, may not apply to hospitalists, who care for and discharge patients with outpatient prescriptions but refer the patient back to the primary caregiver. MSD requested a change in Section 9.7.3 from "[a]dminister urine drug screens at least once every six months" to "at the prescriber's discretion but a minimum of twice a year." Section 9.7.5 is duplicative of Section 9.3.13 and should be stricken. In Section 9.7.7, the word "each" should be deleted, with respect to documenting other forms of treatment tried by the patient. Section 9.8, pertaining to "medical records" is unnecessary and should be deleted. The exemption for hospice and cancer patients should be put back into the regulations to avoid increased patient suffering.

Exhibit 28: May 23, 2016 letter from Robert Winter, M.D. and Arlen D. Stone, M.D., Go Care at Abby Medical, Abby Family Practice

Dr. Winter and Dr. Stone expressed support for the comments and concerns presented by MSD and offered additional items for consideration. The term "Medical Aid Unit" should be included in terminology when discussing urgent and emergency care centers. If acute care is 7-14 days and chronic care is after 3 months, what is the plan for intervening weeks? Insurers won't pay for office drug testing and the costs can't be sustained by the practice. Chronic non-cancer pain is not addressed. Consulting with a pain management specialist isn't practical. The treatment of addiction is not addressed in the regulations. There is limited access to substance abuse treatment in Delaware. The regulations will cause many

PCPs to be more reluctant to prescribe narcotics appropriately.

Exhibit 29: May 31, 2016 letter from Tabassum Salam, MD, FACP, Governor, Delaware Chapter of the American College of Physicians, Senior Physician Advisor for Population Health, CCHS

Dr. Salam, an internal medicine physician, stated that education needs to be the cornerstone of initiatives. Pain management doesn't solely equate to the prescribing of opiates. The PMP needs improvement. Sections 9.5.3 and 9.6 are unduly burdensome. Forcing re-assessment within 7 days is premature; this should be changed to 14 days or one refill without a face to face visit.

Exhibit 30: May 31, 2016 email from Donna Gregory Burch

Ms. Burch stated that checking the PMP and twice a year urine screenings are reasonable proposals. She objected to a maximum 7 day supply for acute injuries. This should be left to the physician. As an alternative, doctors can be required to undergo yearly opioid training.

Exhibit 31: May 31, 2016 email from Hadassah Futrell

Miss Futrell asked that Sickle Cell patients be exempted from the regulations.

Exhibit 32: May 28, 2016 letter from Richard Bounds, M.D., John Powell, M.D. and Jonathan McGhee, D.O., Delaware ACEP (American College of Emergency Physicians)

Dr. Bounds, Dr. Powell and Dr. McGhee stated that there is a need to balance the opioid diversion and abuse problem with compassionate pain control. Emergency centers are often the only access patients have to care. Checking the PMP interrupts work flow. A more user friendly PMP interface is needed. They support exempting acute conditions from the time consuming regulations in Section 9.6. They support MSD's proposal of specialty-specific prescribing guidelines.

Secretary of State's Findings and Conclusions

Pursuant to 16 **Del.C.** §4731(a), the Secretary has the statutory authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State.

The proposed Section 9.0 is the result of many discussions by the Controlled Substance Advisory Committee at properly noticed, public meetings. All members of the public were welcome to attend these meetings and offer comments. A public hearing was held on July 29, 2015 and at that time members of the public were afforded the opportunity to present testimony and written comments. With respect to the proposed rules and regulations published on May 1, 2016, the written comment period was held open for 30 days. The 32 comments submitted have been summarized herein and have been thoroughly considered by the Secretary in making further revisions to Section 9.0 attached hereto as Exhibit A.

The purpose of Section 9.0 is to address the state-wide health crisis caused by the abuse and diversion of opioid analgesics. Section 9.0 sets forth minimum requirements for the treatment of both acute and chronic pain. Further, Section 9.0 is designed to enable practitioners to meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care. Comments that the requirements in Section 9.0 are overly burdensome are not persuasive. Given the risks posed by opioid abuse, and the number of deaths resulting from opioid overdose, the required steps are basic practice requirements to ensure the safety of patients and the public.

Many of the written comments submitted are based on the incorrect assumption that the maximum seven-day supply language applies to all forms of pain management. Section 9.5 states clearly that the maximum seven-day supply limit is applicable to a first-time, outpatient prescription for acute pain. In addition, Section 9.5.3 gives the practitioner the discretion to prescribe more than a seven-day supply if, in the practitioner's professional medical judgment, more than a seven-day supply is required to treat the patient's acute medical condition, as long as the rationale is documented in the patient file and the PMP is queried to obtain a prescription history. There are separate requirements for subsequent prescriptions in Section 9.6 and for the treatment of chronic pain in Section 9.7.

There are also objections to the "at least once every six months" drug screen requirement. Those objections address patient cost. Section 9.0 does not specify the method of drug screening and does not require that the screening be done through lab testing. More importantly, none of the commentators challenge the essential information obtained through drug screens. Through drug screening, the practitioner can determine whether the patient is using other narcotics, either prescribed by other practitioners or obtained illegally, or is not taking the prescribed medication. Such information is key to ensuring patient safety and detecting possible diversion. Similarly, objections to utilization of the PMP do not consider the importance of the information obtained.

A number of commentators request that the exemption for hospice and cancer patients be returned to the regulation. The argument that addiction and diversion are not significant issues for these populations is persuasive and the exemption is included in the revised regulation.

Comments regarding the definition of "practitioner" in Section 9.3.9 have been given weight and this section has been revised to clarify that the only practice at issue in these regulations is prescribing. Consequently, references to pharmacists, pharmacies and institutional practitioners have been removed. Veterinarians are excluded from the definition of

"practitioner" in that the patient practices specified in the regulation have no applicability to animals.

Due to the lack of clarity identified by a number of commentators, the reference to "institutional practitioner" has been stricken. The treatment of patients while hospitalized is addressed in Section 9.8.5. Specifically, hospital patients, during the hospital stay, are exempt from the requirements, so long as the discharge prescription is for a quantity of a 7-day supply or less.

Finally, numerous comments of a technical nature have been incorporated into the revised regulation. For example, Section 4.2.3, referencing "narcotic dependent person," has been revised. The term "urine drug screen" has been amended to "fluid drug screen." The section pertaining to records has been stricken. Section 9.7.5, referencing treatment agreements, has been stricken as duplicative of Section 9.3.13. Section 9.7.8 has been broadened to state that the practitioner may seek a case review and consult with an "addiction specialist." Section 9.6 has been revised to clarify the requirements for a subsequent prescription, after the first-time outpatient prescription.

Therefore, based on the extensive public comment addressing both substantive and more technical issues, the proposed Section 9.0 published on May 1, 2016 is stricken and the Secretary proposes the revised Section 9.0 attached hereto as Exhibit A.

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 engaged in substance abuse or misuse, as defined in subsections 9.3.11 and 9.3.12, for the purpose of continuing his such person's dependence upon such drugs, unless otherwise authorized by law.

4.3 Manner of Issuance of Prescriptions. All prescriptions for controlled substances shall be dated on the day when issued and shall bear the full name and address of the patient, and the name, address, telephone number and registration number of the practitioner. A practitioner may sign a prescription in the same manner as 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 Safe Prescribing of Opioid Analgesics

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

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

9.3 Definitions:

9.3.1 "Acute Care" means the treatment of Acute Pain, as defined in subsection 9.3.2.

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

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

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

9.3.5 "Chronic Care" means the treatment of Chronic Pain, as defined in subsection 9.3.6.

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

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

9.3.8 "PMP" means the Delaware Prescription Monitoring Program.

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

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

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

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

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

- The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
- Reasons for which medication therapy may be re-evaluated, tapered or discontinued, including but not limited to, violation of the Treatment Agreement or lack of effectiveness;
- The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;
- The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;
- Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan, a referral to a pain specialist, or referral to an addiction treatment program; and
- The requirement that fluid drug screens be performed at random intervals at the practitioner's discretion, but not less than every six months.

- 9.4 Practitioner-patient relationship: A practitioner may not prescribe opioid analgesics unless a practitioner-patient relationship has been established, or the practitioner is seeing the patient in lieu of the patient's prescribing practitioner on a limited basis and on the practitioner's request or behalf.
- 9.5 First time, outpatient prescription for Acute Pain; maximum seven-day supply.
- 9.5.1 When issuing a prescription for an opioid analgesic to an adult patient for outpatient use for the first time, for an Acute Pain Episode, a practitioner may not issue a prescription for more than a seven-day supply.
- 9.5.2 A practitioner may not issue a prescription for an opioid analgesic to a minor for more than a seven-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opioid use and the reasons why the prescription is necessary.
- 9.5.3 Notwithstanding subsections 9.5.1 and 9.5.2, if, in the professional medical judgment of a practitioner, more than a seven-day supply of an opiate is required to treat the adult or minor patient's acute medical condition, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition. The condition triggering the prescription of an opiate for more than a seven-day supply shall be documented in the patient's medical record, the practitioner shall query the PMP to obtain a prescription history, and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition and comply with subsections 9.6.4 and 9.6.5.
- 9.6 Subsequent prescriptions. After the first time outpatient prescription, or after the patient has been issued outpatient prescription(s) totaling up to a seven day supply, prior to issuing a subsequent prescription for an opioid analgesic for Acute Pain, the practitioner must perform an appropriate evaluation of the patient's medical history and condition, including the following:
- 9.6.1 Query the PMP to obtain a prescription history for the first subsequent prescription that goes beyond the initial 7-day period and, for any subsequent prescriptions after that, the PMP shall be queried at the discretion of the practitioner unless otherwise required;
- 9.6.2 Administer a fluid drug screen, at the discretion of the practitioner;
- 9.6.3 Conduct a physical examination which must include a documented discussion between the practitioner and patient to: Elicit relevant history, explain the risks and benefits of opioid analgesics and possible alternatives to the use of opioid analgesics, identify other treatments tried or considered, and determine whether opioid analgesics are contra-indicated;
- 9.6.4 Obtain an Informed Consent form, signed by the patient (or the patient's proxy), that must include information regarding the drug's potential for addiction, abuse, and misuse; and the risks associated with the drug of life-threatening respiratory depression; overdose as a result of accidental exposure potentially fatal, especially in children; neonatal opioid withdrawal symptoms; and potentially fatal overdose when interacting with alcohol; and other potentially fatal drug/drug interactions, such as benzodiazepines; and
- 9.6.5 Schedule and undertake periodic follow-up visits and evaluations of the patient to monitor and assess progress toward goals in the treatment plan and modify the treatment plan, as necessary. The practitioner must determine whether to continue the treatment of pain with an opioid analgesic, whether there is an available alternative, whether to refer the patient for a pain management or substance abuse consultation.
- 9.7 Chronic Pain patients. In addition to the requirements of subsection 9.6, the practitioner must adhere to the following additional requirements for Chronic Pain patients:
- 9.7.1 Query the PMP at least every six months, more frequently if clinically indicated, or whenever the patient is also being prescribed a benzodiazepine;
- 9.7.2 Query the PMP whenever the patient is assessed to potentially be at risk for substance abuse or misuse or demonstrates such things as loss of prescription(s), requests for early refills or similar behavior;
- 9.7.3 Administer fluid drug screens at least once every six months;
- 9.7.4 Obtain a signed Treatment Agreement, pursuant to subsection 9.3.13;
- 9.7.5 Conduct a Risk Assessment as defined in subsection 9.3.10;
- 9.7.6 Document in the patient's medical record alternative treatment options that have been tried by the patient, including non-pharmacological treatments, and their adequacy with respect to providing sufficient management of pain;
- 9.7.7 Make efforts to address psychiatric and medical comorbidities concurrently, rather than sequentially, when concurrent treatment is clinically feasible; and
- 9.7.8 At the practitioner's discretion, seek a case review and consult with, or otherwise refer the patient to, a state-licensed physician who holds a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology or an addiction certification from the American Board of Addiction Medicine or an addiction specialist if any of the following occur:
- 9.7.8.1 Adulterated drug tests;

9.7.8.2 Diversion of prescribed medications; or

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

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

9.8.1 Hospice care patients;

9.8.2 Active cancer treatment patients;

9.8.3 Patients experiencing cancer-related pain;

9.8.4 Terminally ill/palliative care patients; and

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

910.0 Procedures for Adoption of Regulations

910.1 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.

910.1.1 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.

910.2 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.

910.3 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 than 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.

910.4 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.

101.0 Severability

101.1 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.

101.2 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:

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

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

15 DE Reg. 891 (12/01/11)

16 DE Reg. 1198 (05/01/13)

17 DE Reg. 992 (04/01/14)

20 DE Reg. 31 (07/01/16) (Prop.)