

DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
Statutory Authority: 24 Delaware Code, Section 1713(a)(12) (24 **Del.C.** §1713(a)(12))
24 **DE Admin. Code** 1700

FINAL

ORDER

1700 Board of Medical Licensure and Discipline

After due notice in the *Register of Regulations* and two Delaware newspapers, a public hearing was held on October 2, 2012 at a scheduled meeting of the Delaware Board of Medical Licensure and Discipline (the "Board") to receive comments regarding proposed changes to the Board's rules and regulations. The Board deliberated on the proposed amendments on November 13, 2012.

The Board proposed changes to its rules and regulations, specifically, Regulation 31 - Use of Controlled Substances for the Treatment of Pain - to address concerns related to the applicability of the regulation to the treatment of acute pain. The amendments clarify that the primary focus of the regulation is the use of controlled substances in the treatment of chronic pain. Instead of stating that the regulations "are" applicable to the use of controlled substances in the treatment of acute pain, the proposed amendments provide that the regulations "may be applicable to prescribing controlled substances for the treatment of acute pain when clinically appropriate." The amendments also give the Board discretion to refer to current clinical practice guidelines and/or expert review in approaching cases involving the management of pain.

The amendments to Regulation 31.8.1 require that the medical records contain documentation of the patient's interim history and "physical examination." The amendments Regulation 31.8.2 require that the medical records contain documentation of the patient's vital signs "as clinically appropriate" Finally, Regulation 31.10.4 clarifies the definition of a "licensed practitioner" for purposes of the regulations.

SUMMARY OF THE EVIDENCE AND INFORMATION SUBMITTED

Board Exhibit 1, the *News Journal* Affidavit of Publication, and Board Exhibit 2, the *Delaware State News* Affidavit of Publication, were made a part of the record.

The Board did not receive any written or oral public comment opposed to the proposed regulations. Nitin Rao, Medical Society of Delaware, submitted an e-mail dated October 2, 2012 to the Board's Executive Director which stated in relevant part that the amendments came from the Medical Society and that the Medical Society stands by them. He indicated that he wanted to formally support the changes in writing since he could not attend the meeting.

FINDINGS OF FACT WITH RESPECT TO THE EVIDENCE AND INFORMATION SUBMITTED

The public was given notice and an opportunity to provide the Board with comments in writing and by testimony at the public hearing on the proposed amendments to the Board's Rules and Regulations. The Board held multiple publicly noticed committee meetings and a properly noticed public hearing to give practitioners a chance to comment on the proposed regulations. In addition, the Board held the record open for a minimum of 15 days following the public hearing in accordance with 29 **Del.C.** §10118(a) to enable the public to submit additional written public comment. No additional written comment was submitted during the extended comment period.

The Board finds that amendments to the regulations are necessary to clarify the applicability of the regulation to the treatment of acute pain.

THE LAW

Pursuant to 24 **Del.C.** §1713(a)(12) the Board has statutory authority to promulgate regulations clarifying specific statutory sections of its statute.

DECISION AND EFFECTIVE DATE

The Board hereby adopts the amendments to Regulation 31 as effective 10 days following publication of this Order in the *Register of Regulations*.

TEXT AND CITATION

The text of Regulation 32 remains as published in *Register of Regulations*, Vol. 16, Issue 3, on September 1, 2012.

IT IS SO ORDERED this 13th day of November, 2012.

BOARD OF MEDICAL LICENSURE AND DISCIPLINE

Stephen Cooper, M.D., President	Raymond Moore, Public Member
Gregory Adams, M.D., Vice-President	Joseph Parise, D.O.
Evelyn Ayala, Public Member	George Brown, Public Member
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Leslie C. Ramsey, Public Member	Daryl Sharman, M.D.
Vincent Lobo, D.O.	Malvine Richard, Ed.D., Public Member
Vonda Calhoun, Public Member	Mary Ryan, Public Member

1700 Board of Medical Licensure and Discipline

1.0 Scope

These rules and regulations apply to all applicants for a license to practice medicine in the State, whether by examination or endorsement, and to all physicians practicing medicine within the State, whether licensed or unlicensed.

2.0 Definitions

"Board" means the State Board of Medical Practice.

"Courtesy Applicant" means an individual who is being allowed to take the FLEX or USMLE examination in Delaware, but is a candidate for licensure in another of the United States.

"ECFMG" means the Educational Council for Foreign Medical Graduates.

"Emergency Care" means an unplanned and unstructured medical intervention by any individual, whether or not licensed to practice medicine and surgery in the State of Delaware, which, if not immediately provided, would likely result in either loss of life or subsequent permanent impairment.

"Fifth Pathway" means a path to licensure under which an applicant has not met the requirements for licensure under 24 **Del.C.** §1720 because of failure to receive an M.D., D.O., or equivalent degree although the applicant has completed the course of academic study required by the medical school attended. Such an applicant may be licensed by the Board if the applicant meets the requirements of Section 26 of these Regulations.

"FLEX Examination" means the Federation Licensing Examination as promulgated by the Federation of State Medical Boards of the United States, Inc.

"Foreign Medical School" means any medical school located outside of the United States or Canada.

"Institutional License" means a certificate to practice medicine as outlined under 24 **Del.C.** §1725(a)(2).

"NBME" means National Board of Medical Examiners.

"NBOME" means National Board of Osteopathic Medical Examiners.

"SPEX" is the Special Proficiency Examination.

"USMLE" means United States Medical Licensing Examination. which has replaced (FLEX) and (NBME) as the only allopathic examination given in the USA since 1994.

"VQE" means Visa Qualifying Examination as mandated by Public Law 94-484.

3.0 Licensure by Examination

3.1 All candidates for regular licensure by examination are required to pass the FLEX.

National Boards, SPEX or USMLE as outlined below:

3.1.1 Any applicant who originally took the FLEX or National Board Examination prior to June 1985 must achieve a weighted average of 75 to be eligible for licensure. An applicant who took and failed the FLEX exam more than three times prior to June 1985 will not be eligible for licensure by examination for reciprocity, unless the candidate completes one further year of training acceptable to the Board. In that case, one further examination will be required, namely the SPEX examination.

- 3.1.2 The Board, at its discretion, may create hybrid examination sequences for individuals who have not completed old examination sequences when they were discontinued. These must be in keeping with sequences recommended by USMLE.
- 3.2 Applications for examination must be completed and in the office of the Board of Medical Practice, Dover, Delaware 60 days prior to the examination.
- 3.3 The required fee must be submitted with the application to take the examination. The fee is not refundable and is subject to change.
- 3.4 Applicants who are graduates of medical schools outside the continental United States (or Canada) must present a photostat copy of their medical school diploma with a notarized translation from a translating organization acceptable to the Board.
- 3.5 There is a limit of 40 candidates at each examination, the number being changeable at the Board's discretion.

4.0 Licensure by Endorsement

- 4.1 Qualifications for consideration of licensure by endorsement are the same as the requirements for licensure by examination.
- 4.2 Acceptable candidates for endorsement granted to:
 - 4.2.1 All candidates for licensure by endorsement must meet the qualifications for primary licensure in Delaware. (10/5/82)
 - 4.2.2 Certain persons licensed in other states: Doctors with valid state licenses by examination from other jurisdictions may be licensed at the discretion of the Board if this examination took place before January, 1973.
- 4.3 Completed applications for licensure by endorsement must be received in the office of the Board of Medical Practice, 861 Silver Lake Blvd., Dover, Delaware fourteen (14) days prior to a scheduled meeting.
- 4.4 Applications for licensure by endorsement must be completed by the State Board which issued the original license.
- 4.5 A fee of \$150 must be submitted with the completed application to be considered for reciprocity.
- 4.6 A surcharge of \$15 must be submitted by candidates from Canada to defray the verification fee levied by the Medical Council of Canada.

5.0 Institutional Licenses

- 5.1 Pursuant to 24 **Del.C.** §1725(a)(2), the Board will issue, without examination, institutional licenses to qualified physicians who will be employed as interns, residents, house physicians or fellows by an accredited hospital operated within this State. The Board will also issue, without examination, institutional licenses to qualified physicians who will be employed as staff physicians in a medical institution operated in this State by any governmental unit.
- 5.2 Interns, Residents, House Physicians and Fellows Employed by Accredited Hospitals.
 - 5.2.1 Any physician who will be employed as an intern, resident, house physician, or fellow by a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Hospital Association may apply for an institutional license. Application may be made on forms provided by the Board. Such applications shall include:
 - 5.2.1.1 An affidavit of the chief administrative officer of said hospital certifying that the individual will be employed by the hospital and meets all requirements for licensure specified in 24 **Del.C.** §1720(a)(1) through (a)(6), excluding 24 **Del.C.** §1720(a)(4) for those physicians who will be employed as interns or residents.
 - 5.2.1.2 An affidavit of the physician seeking licensure certifying that he meets all the requirements for licensure specified in 24 **Del.C.** §1720(a)(1) through (a)(6) excluding 24 **Del.C.** §1720(a)(4), if the physician will be employed as an intern or resident.
 - 5.2.1.3 An affidavit of the physician seeking licensure certifying that he intends to limit himself solely to practice within the hospital, or the performance of such medical duties outside the hospital which may be assigned to him as part of a resident training program.
 - 5.2.1.4 Any physician applying for an institutional license who is to be employed by an accredited hospital as a house physician or fellow must submit proof that he completed a year of internship or its equivalent in an institution in Canada or the United States, which has been approved by the American Medical Association or the American Osteopathic Association.

- 5.2.2 An applicant for an institutional license who will be employed as a house physician or fellow in an accredited hospital shall be interviewed by a member of the Board prior to the Board's consideration of his application.
- 5.2.3 After reviewing the application for institutional licensure made by a physician who is to be employed by an accredited hospital and after considering the interview of such applicant, if necessary, the Board may, in its discretion grant an institutional license without examination if the applicant meets all applicable requirements for institutional licensure.
- 5.2.4 A physician who is to be employed by an accredited hospital as an intern, resident, house physician or fellow who was not a citizen of the United States at the time he enrolled in medical school outside of the United States must present a photostatic copy of his permanent ECFMG or VQE results.
- 5.2.5 Interns, residents, house physicians or fellows employed by accredited hospitals who have been granted institutional licenses shall be specifically limited to the practice of medicine within the hospital wherein they are employed, except that interns or residents may perform such medical duties outside of the hospital which may be assigned to them as part of an internship or residency training program, provided such outside duties are performed under the supervision of a regularly licensed physician.
- 5.2.6 Residents who are registered in training programs outside of Delaware and who rotate through programs in institutions in Delaware for over one month are required to obtain an institutional license.
- 5.2.7 Institutional licenses issued pursuant to these rules shall expire on the day on which the holder ceases to be employed by the employer hospital. Both the holder and the employer hospital shall notify the Secretary of the Board immediately, but not later than three days after they cease their employment relationship.
- 5.2.8 Valid institutional licenses shall be renewed every year upon payment of a \$15.00 fee by the holder thereof.
- 5.2.9 No institutional license granted to an employee of an accredited hospital after April 7, 1981 shall be valid for a period of more than five years after the date it was originally issued, unless in the opinion of the Board, exigent circumstances exist which warrant the re-issuance of the institutional license. Such reissued institutional license shall be valid for a period of time deemed appropriate by the Board. All institutional licenses granted prior to April 7, 1981 shall remain effective until such time as the physician to whom the license was issued shall leave the employ of the accredited hospital which sponsored the physician's request for an institutional license. Effective September 1, 1989, no institutional license issued by the Board will be renewed at the end of the first year of issuance unless the holder has passed at least one part of the FLEX examination or at least one part of the National Board examination.
- 5.2.10 Effective September 1, 1989, no institutional license issued by the Board will be renewed at the end of the first year of issuance unless the holder has passed at least one part of the FLEX examination or at least one part of the National Board Examination.
- 5.3 Staff Physicians Employed by a Governmental Institution.
 - 5.3.1 Any physician who will be employed as a staff physician by a governmental institution may apply for an institutional license. Application may be made on forms provided by the Board. Such application shall include:
 - 5.3.1.1 An affidavit of the chief administrative officer of said institution certifying that the individual will be employed by the institution and meets all the requirements for license specified in 24 **Del.C.** §1720(a)(1) through (a)(6).
 - 5.3.1.2 An affidavit of the physician seeking licensure certifying that he meets all the requirements for licensure specified in 24 **Del.C.** §1720(a)(1) through (a)(6).
 - 5.3.1.3 An affidavit of the physician seeking licensure certifying that he intends to limit himself solely to practice within the institution.
 - 5.3.1.4 Any physician applying for an institutional license who is to be employed by a governmental institution must first have completed a year internship or its equivalent in an institution in Canada or the United States which has been approved by the American Medical Association or the American Osteopathic Association.
 - 5.3.2 An applicant for an institutional license who will be employed by a governmental institution shall be interviewed by one member of the Board prior to the Board's consideration of his application.
 - 5.3.3 After reviewing the application for institutional licensure made by a physician who is to be employed by a government institution and after considering the interview of such applicant, the Board may, in its discretion, grant an institutional license without examination if the applicant meets all applicable requirements for institutional license.

- 5.3.4 Physicians applying for an institutional license who are to be employed by a governmental institution and who were not citizens of the United States at the time they enrolled in medical school outside the United States must present a photostatic copy of his/her permanent ECFMG or VQE certificate.
- 5.3.5 Physicians granted institutional licenses to practice medicine in governmental institutions shall be specifically limited to the practice of medicine within the governmental institution wherein the holder is employed.
- 5.3.6 Institutional licenses shall expire on the day on which the holder ceases to be employed by the employer institution. Both the holder and the employer institution shall notify the Secretary of the Board immediately, but not later than three days after they cease their employment relationship.
- 5.3.7 Valid institutional licenses shall be renewed every year upon payment of a \$15.00 fee by the holder thereof.
- 5.3.8 No institutional license granted after April 7, 1981 shall be valid for a period of more than five years after the date it was originally issued, unless in the opinion of the Board, exigent circumstances exist which warrant the reissuance of the institutional license. Such reissued institutional license shall be valid for a period of time deemed appropriate by the board. All institutional licenses granted prior to April 7, 1982 shall remain effective until such time as the physician to whom the license was issued shall leave the employ of the institution which sponsored the physician's request for an institutional license.
- 5.3.9 Effective September 1, 1989, no institutional license issued by the Board will be renewed at the end of the first year of issuance unless the holder has passed at least one part of the FLEX examinations or at least one part of the National Board examination.

6.0 Temporary License

- 6.1 A temporary license may be issued by the President, Vice President, or Secretary of the Board.
- 6.2 A temporary license will not be issued unless the applicant has passed the National Board Examination, the FLEX examination or an examination given by a Board of Examiners of any other of the United States before January 1973, or the examination given by the Medical Council of Canada.

7.0 Personal Interviews

- 7.1 A personal interview is required to obtain a permanent license, by examination or endorsement.
- 7.2 Personal interviews will not be granted until the completed application of the candidate has been received at the Board's Office in Dover, Delaware.
- 7.3 The President of the Board has the power to waive the personal interview when the President considers it a hardship for the candidate.

8.0 Malpractice Investigations

- 8.1 The Board will not be obligated to investigate every malpractice claim settled or adjudicated prior to September 1976.
- 8.2 The Board will not be obligated to investigate malpractice claims, adjudicated to final judgment when the decision was rendered for the defendant.

9.0 Meetings

- 9.1 Regular meetings of the Board will be held at least eight times a year. at a place designated by the Board.

10.0 Confidentiality of Records

- 10.1 The public records of the Board of Medical Practice are available for inspection and copying at the Office of the Board, Dover, Delaware, during the regular business hours of the Division of Professional Regulation (8:00 A.M. to 4:30 P.M.) The request for inspection or copies shall be made on a form approved by the Board. Requests to inspect Board records will be granted immediately whenever possible. If it is not possible to grant the request immediately, or when the records requested are in active use or in storage, an appointment will be set up for the requester to inspect the records within five (5) working days. A copy of any record of the Board shall be provided according to procedures and at a cost set by the Division of Professional Regulation.
- 10.2 Confidential records consist of:
 - 10.2.1 Completed application for endorsement.
 - 10.2.2 Completed application for examination.
 - 10.2.3 Results of all examinations for FLEX.

- 10.2.4 All documents and results of examinations ordered when investigating complaints under 24 Del.C. §1730(a).
- 10.2.5 All hearings shall be private unless requested to be open to the public by the respondent. (24 Del.C. §1734(b).)
- 10.2.6 Reports of a hearing will be private unless the Board, in its judgment decides it will serve the best interest of the public by publication. (24 Del.C. §1734(g).
- 10.2.7 Minutes of the Board that contain test results or investigation data.
- 10.2.8 Disclosures to the Board suggesting a physician is so impaired that he or she may be unable to practice medicine and surgery with reasonable skill and safety.
- 10.2.9 Disclosures of changes in hospital privileges or disciplinary actions taken by Medical Societies.
- 10.2.10 Disclosures of malpractice claims settled or adjudicated to final judgment (24 Del.C. §1728(a)(b)(c).
- 10.2.11 Transcripts of proceedings under 24 Del.C. §1734(e).
- 10.2.12 Completed applications for institutional and temporary licenses and documents submitted in support of such applications.

11.0 Investigation Procedures

- 11.1 Whenever a complaint is lodged against a physician, the physician shall be informed as to the nature of the complaint and given a copy of the complaint as soon as, in the opinion of the Board, such notification will not impede the investigation.
- 11.2 He or she shall be notified of the disposition of the complaint no later than the next regularly scheduled Board meeting. If, however, an investigation has been ordered, this notification will be deferred until the recommendation of the investigation committee has been received. If a hearing on the complaint has been directed, the respondent shall be served personally with the complaint not less than 30 days or more than 60 days prior to the hearing on the complaint.

12.0 Consulting Physician

An active license is required of any out-of-state physician who is regularly available for consultation on an unlimited basis, whether in an institutional setting, off-ice or home. An active license is not required if a physician licensed in another state or country comes into Delaware to perform a consultation no more than six times a year. Consultation shall ordinarily consist of a history and physical examination, review of records and imaging studies and providing opinions and recommendations. Any consultations done for teaching and/or training purposes may include active participation in procedures, whether surgical or otherwise, provided a Delaware licensed physician remains responsible as the surgeon of record, and provided the patient is not charged a fee by the consultant.

13.0 Actions Regarding Physicians Which Should Be Reported to the Board

The following disciplinary actions against physicians should be reported:

- 13.1 By hospitals:
 - 13.1.1 Dismissal from the staff.
 - 13.1.2 Denial of staff appointment or reappointment.
 - 13.1.3 Permanent curtailment of privileges by action of the governing body.
- 13.2 By Medical Societies:
 - 13.2.1 Expulsion from the organization.
 - 13.2.2 Censure.

14.0 Issuance and Renewal of License; Requirements for Physicians Re-entering Practice

- 14.1 Each license shall be renewed biennially. The failure of the Board to notify a licensee of his/her expiration date and subsequent renewals does not, in any way, relieve the licensee of the requirement to renew his/her registration/license pursuant to the Board's regulations and 24 Del.C. Ch. 17.
- 14.2 Renewal may be effected by:
 - 14.2.1 filing a renewal application prescribed by the Board and provided by the Division of Professional Regulation. License renewal must be accomplished online at www.dpr.delaware.gov;
 - 14.2.2 providing other information as may be required by the Board to ascertain the licensee's good standing;

14.2.3 attesting on the renewal application to the completion of continuing education as required by the Board's rules and regulations;

14.2.4 payment of fees as determined by the Division of Professional Regulation.

14.3 Failure of a licensee to renew his/her license shall cause his/her license to expire. A physician whose license has expired may renew his/her license within one year after the expiration date upon fulfilling items 14.2.1 – 14.2.4 above, certifying that he/she has not practiced medicine in Delaware while his/her license has expired, and paying any renewal fees and a late fees determined by the Division of Professional Regulation.

14.4 No physician will be permitted to renew his/her license after the expiration of the one-year period.

14.5 The former licensee may re-apply under the same conditions that govern applicants for new licensure under 24 Del.C. Ch. 17 and meeting any requirements for re-entry to practice established under Board Rule 14.7.

14.6 No physician shall practice medicine in the State of Delaware during the period of time that his/her Delaware license has expired.

14.7 A physician seeking to obtain an initial license who has not been engaged in the clinical practice of medicine within the three (3) years immediately preceding the application shall be required to demonstrate clinical competency as follows:

14.7.1 completing an approved practice assessment program that is both clinical and didactic in nature. Approved physician re-entry programs are listed on the Board's website. Programs not on the list must be submitted to the Board for approval. A physician who completes a program not on the list without first obtaining Board approval does so at his or her own risk that the program may not be approved by the Board; and

14.7.2 demonstrating that the applicant for licensure or renewal has kept current with continuing medical education meeting the requirements of the Board's rules and regulations.

16 DE Reg. 330 (09/01/12)

15.0 Dishonorable or Unethical Conduct (24 Del.C. §1731(b)(3))

15.1 The phrase "dishonorable or unethical conduct likely to deceive, defraud, or harm the public" as used in 24 Del.C. 1731(b)(3) shall include, but not be limited to, the following specific acts:

15.1.1 A pattern of performance of unnecessary medical procedures.

15.1.2 Exploitation of the doctor/patient privilege for personal gain or sexual gratification.

15.1.3 Fraudulent billing for medical services.

15.1.4 Intentional falsification of records maintained for controlled substances and non-controlled drugs.

15.1.5 Fraudulent advertising.

15.1.6 Willfully failing to treat a person under the physician's care who requires such treatment.

15.1.7 Intentional release of confidential information gained as a result of the doctor/patient privilege, unless such release was authorized by the patient or required by subpoena.

15.1.8 Conviction of a misdemeanor involving moral turpitude.

15.1.9 Payment of a fee by a physician to another physician who has referred the patient to him, unless the fee is in proportion to work actually performed by the referring physician.

15.1.10 Any other act tending to bring discredit upon the profession.

15.1.11 Willful failure to disclose to a patient that a referring physician has the financial interest in an ancillary testing or treatment facility outside of the physician's office.

16.0 Emergency Medical Service

A physician who has not been granted a certificate to practice medicine in the State of Delaware may render medical care or treatment to a patient in an emergency vehicle which is in transit in the State of Delaware provided such physician is licensed to practice medicine in the state from which the emergency vehicle departed, or the state to which the emergency vehicle is destined. Medical care or treatment undertaken in the State of Delaware prior to the patient's entry into an emergency vehicle or after the patient's exit from the emergency vehicle must be undertaken by a fully licensed Delaware physician. or under the supervision of such physician.

15 DE Reg. 1766 (06/01/12)

17.0 Reporting Disciplinary Action

17.1 Upon the board taking any disciplinary action against a physician, other than private censure, written notification of the disciplinary action taken by the Board shall be forwarded to the following agencies or individuals:

- 17.1.1 Federation of State Medical Boards.
 - 17.1.2 Medical Boards in other states in which the physician is licensed to practice medicine.
 - 17.1.3 Hospitals at which the physician holds staff privileges.
 - 17.1.4 The Medical Society of Delaware.
 - 17.1.5 Delaware Osteopathic Medical Society.
 - 17.1.6 Director of the Division of Revenue.
 - 17.1.7 Director of the Division of Public Health.
 - 17.1.8 National Practitioner Data Bank.
 - 17.1.9 All Hospitals and Managed Care Entities in Delaware.
- 17.2 Only written notification setting forth disciplinary action other than private censure taken by the Board and the specific grounds for that action shall be released to representative news media. Opinions issued by the Board concerning disciplinary action, other than private censure, will be forwarded to licensing boards in other states in which the physician is licensed to practice medicine and hospitals at which the physician holds staff privileges.

15 DE Reg. 1766 (06/01/12)

18.0 Activation Of- Inactive Registration

All licensees who apply for an active registration more than six months after an inactive registration was originally issued to them shall be charged a fee of \$50 to defray the cost of processing the application for activation of the registration. No such fee shall be charged to licensees who apply to reactivate their registration within six months after the inactive registration was originally issued to them.

15 DE Reg. 1766 (06/01/12)

19.0 Temporary Licensure under 24 Del.C. §1725(a)(1)

Physicians requesting temporary license under the provisions of 24 **Del.C.** §1725(a)(1) shall complete an application for such temporary license. The application shall be accompanied by a letter from the physician who is temporarily ill or who will be temporarily absent from the state. The letter shall set out the dates of expected absences or expected date of return to practice. The applicant for temporary license shall be granted a temporary license if he has been licensed in another state and has achieved scores on the professional licensure examination which would entitle him to full licensure.

15 DE Reg. 1766 (06/01/12)

20.0 Delegation of Responsibilities to Non-physicians

- 20.1 The Board of Medical Licensure and Discipline feels it is appropriate to issue new regulations that recognize the changing relationship between physicians and non-physician associates, and to give guidelines to licensed physicians with regard to delegating physician responsibilities to non-physician associate. The sole purpose in doing so is to protect the public interest by maintaining the highest possible quality of medical care. The Board's decision to issue exemptions from the requirements that follow, is in recognition that it is within the public interest that certain ongoing and pre-existent practices should not be abruptly terminated. This section does not apply to physician assistant practice. Regulations governing the practice of physician assistants may be found in Section 24.0 of these regulations.
- 20.1.1 Any physician who delegated medical responsibility to a non-physician is responsible for that individual's medical activities and must provide adequate supervision. No function may be delegated to a non-physician who by statute or professional regulation is prohibited from performing that function. Supervision may be direct or indirect depending upon the type of medical responsibility delegated. The delegating physician cannot be involved in patient care in name only.
 - 20.1.2 For the purpose of clarification, the terms "guidelines", "standing orders", "protocols", and "algorithms" are synonymous in their application under these regulations. Hereafter, the term "standing orders" will be used. Standing orders must not be used to make a medical diagnosis or to prescribe medication or other "therapeutics". Non-prescription medications, however, may be initiated by standing orders if these standing orders have been approved by the responsible delegating physician. Emergency care as defined in the Medical Practice Act is exempt from these regulations.
 - 20.1.3 Direct supervision requires the delegating physician to be physically on the premises and to perform an evaluation or give a consultation. Direct supervision is required if a medical diagnosis is rendered or a treatment plan involving prescription medications is to be instituted.

- 20.1.4 Indirect supervision requires the physician to be either physically present on the premises or readily available by an electronic device. Readily available necessitates the ability to become physically present within thirty minutes of notification if the situation warrants such action. Indirect supervision is required whenever a non-physician evaluates a patient, initiates a non-prescription medication or therapeutic, or renews a previously prescribed medication or therapeutic. Direct supervision (as defined above) required whenever a controlled substance is renewed. A non-physician may follow a physician-initiated standing order under the indirect supervision of the physician, providing the standing order does not call for the initiation of a prescription drug or therapeutic.
- 20.1.5 The Board considers it to be appropriate and good medical procedure for all responsible physicians who choose to have their patients followed by non-physician associates to personally re-evaluate at least every three months any patient receiving controlled substances, or at least every six months any patient receiving other prescription medications or therapeutics.
- 20.1.6 The Board may issue exemptions from the requirements specified above in cases of activities wherein the dispensing of prescription drugs or other therapeutics has occurred without direct supervision of a licensed physician, if such activity has taken place on a regular ongoing basis prior to the enactment of the regulations. Such exemptions will be considered by petition and must be renewed by the Board every two years. No exemption will be issued by the Board until it reaches the determination that the training and experience of the non-physician associate involved is adequate. Procedural safeguards must be in place to ensure the safe dispensing of drugs and other therapeutics. All exemptions must be judged by the Board not to endanger the public health of the citizens of Delaware.
- All standing orders proposed by the petitioner must be reviewed by a joint committee composed of three members of the Board or its designees and three members or designees from the regulatory board responsible for the licensure of the nonphysician associate.
- 20.1.7 A supervising physician who fails to adhere to these regulations would be considered to be permitting the unauthorized practice of medicine (as defined under 24 **Del.C.** §1703(2)(12) of the Medical Practice Act), and would be subject to disciplinary action by the Board.

15 DE Reg. 1766 (06/01/12)

21.0 Continuing Medical Education

Pursuant to the provisions of 24 **Del.C.** §1730(d) the Board adopts the following regulation regarding requirements for continuing medical education as a prerequisite for renewal of registrations to practice medicine in the State of Delaware. Prior to renewal of registrations to practice medicine in this State a physician must be prepared to supply the Board with proof that he has completed forty (40) hours per registration period of continuing medical education in Category I courses approved by the American Medical Association or the American Osteopathic Association since the time of the physician's last renewal of his registration. Individuals enrolled in approved medical or osteopathic resident or fellowship training programs may be requested to submit proof of satisfactory participation in lieu of approved continuing medical education credits. Certification by the Medical Society of Delaware that a physician has completed such continuing medical education since the time of his last renewal of his registration shall be acceptable proof of completion of these requirements.

A physician who is renewing his registration for the first time and who has been licensed to practice medicine in Delaware for more than one year shall be prepared to supply the Board with proof that he has completed twenty hours of continuing medical education in Category I courses. A physician who is renewing his registration for the first time and who has been licensed to practice medicine in Delaware for less than one year shall not be required to meet any continuing medical education requirements until the time of the next subsequent renewal of his registration.

This regulation shall be applicable only to renewal of registrations occurring after July 1, 1985.

The Board may, upon application from the physician, waive the requirements of the regulation for good cause shown. The Board will consider good cause to have been shown if the lack of compliance with this regulation was due to causes beyond the physician's control.

15 DE Reg. 1766 (06/01/12)

22.0 Use of Controlled Substances

22.1 Schedule II - Controlled Stimulants

- 22.1.1 A physician shall not utilize Schedule II amphetamine, sympathomimetic amine or compound, derivative, congener or analog thereof (hereinafter collectively referred to as "controlled stimulant") for any purpose except:

- 22.1.1.1 The treatment of narcolepsy;
- 22.1.1.2 The treatment of abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), or related disorders of childhood;
- 22.1.1.3 The treatment of intractable seizure disorders or drug induced brain dysfunction;
- 22.1.1.4 The differential diagnostic psychiatric evaluation of depression;
- 22.1.1.5 The treatment of depression shown to be refractory to other therapeutic modalities. including pharmacological approaches, such as tricyclic antidepressants or MAO inhibitors;
- 22.1.1.6 As adjunctive therapy in the treatment of chronic severe pain, or chronic severe pain accompanied by depression, in terminal stages of diseases which are accompanied by severe pain;
- 22.1.1.7 The clinical investigation of the effects of such drugs, in which case the physician shall submit to the Board a written investigation protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the physician shall, within sixty days following the conclusion of the investigation, submit to the Board a written report detailing the findings and conclusions of the investigation.

22.1.2 A physician shall not utilize a Schedule II controlled stimulant for purposes of weight reduction or control.

22.1.3 A physician may use a Schedule II controlled stimulant when properly indicated for any purpose listed in 22.1.1 of this rule, provided that all the following conditions are met:

- 22.1.3.1 Before initiating treatment utilizing a Schedule II controlled stimulant, the physician obtains personally or there is included in the patient's file a thorough history, the results of a thorough recent physical examination of the patient, and he rules out the existence of any recognized contraindications to the use of the controlled stimulant to be utilized.
- 22.1.3.2 The physician shall not utilize any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists.
- 22.1.3.3 The physician shall not utilize any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant.
- 22.1.3.4 The physician shall not initiate or shall discontinue utilizing all controlled stimulants immediately upon ascertaining or having reason to believe that the patient has a history of, or shows propensity for, alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.
- 22.1.3.5 If it is believed that paragraph 23.1.3.4 may apply, the physician may use a Schedule II controlled stimulant for a purpose listed in 23.1.1 of this rule, provided that simultaneously a monitoring and a therapeutic program is started to detect and control further abuse.
If continued abuse occurs the Schedule II stimulant shall be discontinued.
If demonstrated that such abuse has ended, the Schedule II controlled stimulant may again be used for the purposes listed in 23.1.1 of this rule.
(A monitoring program should be frequent and performed at random intervals and consist of the appropriate blood or urine testing.)

22.2 Schedule III or IV Controlled Substances; Utilization for Weight Reduction

22.2.1 A physician shall not dispense a Schedule III or IV controlled substance for weight reduction but may prescribe a Schedule III or IV controlled substance for purposes of weight reduction if it has a Food and Drug Administration (FDA) approved indication for this purpose and then only in accordance with all of the provisions of this rule.

22.2.2 A physician may prescribe a Schedule III or IV controlled substance for purposes of weight reduction in the treatment of obesity only as an adjunct, in accordance with the FDA approved labeling for the product, in a regimen of weight reduction based on caloric restriction, provided that all of the following conditions are met;

- 22.2.2.1 Before initiating treatment with a Schedule III or IV controlled substance, the physician determines through review of his own records of prior treatment, or through review of the records of prior treatment which another physician or weight loss program has provided to the physician, that the patient, by written document, has made a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling behavior modification, and exercise, with the utilization of controlled substances, and that said treatment has been ineffective.
- 22.2.2.2 Before initiating treatment with a Schedule III or IV controlled substance, the physician obtains a thorough history, performs a thorough physical examination of the patient and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized.

- 22.2.2.3 The physician shall not prescribe any Schedule III or IV controlled substance when he knows or has reason to believe that a recognized contraindication to its use exists, including:
 - 22.2.2.3.1 That the patient has developed tolerance (a decreasing contribution of the drug toward further weight loss) to the anorectic effects of the controlled substance being utilized, or
 - 22.2.2.3.2 That the patient has a history of, or shows a propensity for alcohol or drug abuse, or
 - 22.2.2.3.3 That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.
- 22.2.2.4 The physician shall not prescribe any Schedule III or IV controlled substance in the treatment of a patient who he knows or should know is pregnant.
- 22.2.2.5 Long Term Therapy with Schedule III or IV Controlled Substances for Weight Reduction:
 - 22.2.2.5.1 Short term therapy with Schedule III or IV substances for weight reduction has not been found to be effective for long term obesity management.
 - 22.2.2.5.2 Long term therapy may be considered if the provisions of this rule (23.2.1, 23.2.2) have been met as well as the following:
 - 22.2.2.5.2.1 Periodic assessment of efficacy, compliance with, and tolerance of the medical regimen with medical judgement made as to need for dosage adjustment or discontinuation, or an additional Schedule III or IV substance.
 - 22.2.2.5.2.2 Medication is to be used as an adjunctive method to a program of nutrition education, exercise and behavior modification.

22.3 Definitions

- 22.3.1 A "thorough history" shall consist of a history that includes a recording and evaluation of the history of the present illness and indication for the use of the scheduled medication; evaluation of previous medication use; history of mental or emotional disturbances; and of contraindications of the use of the medication. When used for weight control, the history shall also include in addition a recording and evaluation of previous attempts at weight reduction and evaluation of the dietary state.
- 22.3.2 A "thorough physical examination" shall consist of the measurement of the height, weight, blood pressure and pulse, and also include examination of the general appearance of the skin, head, eyes, nose and throat, neck and thyroid, chest (heart and lungs), abdomen and extremities. When used for weight control, in addition, a measurement of weight, blood pressure and pulse shall be made at each visit. As part of the physical examination, the following laboratory studies are to be performed. In adults (above 18 years): (1) CBC, (2) SMA-12 or similar study, (3) routine urinalysis. In children (below 18 years): (1) CBC, (2) routine urinalysis. In addition, when used for weight control, a T-4 and if the patient is over forty years of age, a 12 lead EKG are to be obtained.
- 22.3.3 "Knowledge of pregnancy" in a female patient will be determined by obtaining the current menstrual history as means of determining the possibility of pregnancy. If there is uncertainty as to the possibility of pregnancy, a negative serum pregnancy test will be obtained before initiating treatment, or treatment will be initiated only on the second or third day of the next menstrual period.

22.4 Violations

A violation of this rule may be considered unprofessional conduct as defined in 24 **Del.C.** §1731(b)(6), (11), (17).

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23.0 Consultants

- 23.1 Consultants for specific patients.

Pursuant to 24 **Del.C.** §1726 consulting physicians licensed in any of the United States or foreign countries may come into Delaware in consultation with any person licensed to practice medicine in the State regarding a particular patient.
- 23.2 Consulting physicians as part of a foreign exchange educational program.

A physician licensed to practice medicine in a foreign country ("foreign physician") who comes to Delaware to participate in an organized exchange program with any hospital in this State may do so as a consultant if meeting the following requirements and with the following restrictions;

 - 23.2.1 The Chief Administrative Officer of the hospital must submit an affidavit stating that the foreign physician will be engaged in an exchange program with his institution and must attach to said affidavit copies of the physician's diploma from medical school, license to practice medicine in his home country, evidence of any board certifications and certification that the physician is currently licensed and in good standing in his home country.

- 23.2.2 The chief of the medical service on which such foreign physician shall receive training shall submit an affidavit stating that he is a licensed physician in the State of Delaware, will either personally, or through another physician licensed to practice in Delaware, at all times supervise the foreign physician and will establish procedures within the institution to ensure that the foreign physician will at no time be providing patient care without direct supervision by a physician licensed in Delaware.
- 23.2.3 No foreign physician shall be permitted to provide patient care independent of direct supervision by a physician licensed to practice in Delaware.
- 23.2.4 Permission to be a foreign consultant under 24.2 of this regulation is granted only upon the Board receiving the affidavits and documentation required above and the Board notifying the institution of the Board's approval of such program. This permission shall be for one year and shall expire one year from the date that the foreign physician arrives at the institution and is not renewable.
- 23.2.5 Any violation of this regulation or any provision of the Medical Practice Act or the Board's regulations will subject the foreign physician to revocation of this privilege after a hearing. Any such violation may also result in disciplinary action being taken against the chief of the medical service who was overall supervisor or any licensee who was supervising the foreign physician at the time of the violation.

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24.0 Physician's Assistants

24.1 Definitions:

24.1.1 Rules and Regulations governing Physician Assistant (PA) practice in the State of Delaware. For information relative to the following categories refer to 24 **Del.C.** Ch. 17:

24.1.1.1 Definition of Physician Assistants

24.1.1.2 Criteria for Licensure

24.1.1.3 Licensure Fee

24.1.1.4 Prohibited Practices

24.1.1.5 Discipline

24.1.1.6 Scope of Practice

24.1.1.7 Supervision of Physician Assistants

24.1.1.7.1 The supervising physician cannot be involved in patient care in name only and must provide adequate supervision. The supervising physician must be available for consultation, during the patient encounter, when necessary as defined under supervision in the 24 **Del.C.** Ch. 17 §1770A (3).

24.1.1.7.2 No supervising physician may supervise more than 2 physician assistants at any given time unless granted an exemption by the Board. As provided in 24 **Del.C.** §1771 (e) and (i) the Board may increase or decrease the number of physician assistants being supervised. The Board may issue an exemption to increase the number of physician assistants supervised by a physician upon written application filed by the supervising physician demonstrating good cause for the request. Requests for exemption will be considered on a case-by-case basis. The requesting physician has the burden of demonstrating that the granting of an exemption will not endanger the public health, safety, or welfare.

24.1.1.7.3 Any physician desiring to supervise an assistant who will perform acupuncture upon a patient shall make a medical evaluation of the patient and determine that acupuncture treatment is medically appropriate prior to the commencing of any acupuncture treatment by a physician assistant. Such evaluation will be made on the patient's initial contact with the physician without referral. A physician assistant employed by a physician for the purpose of administering an acupuncture treatment to patients shall not administer such treatment unless an initial evaluation by the physician has been made. In addition, no subsequent acupuncture treatments of a patient shall occur unless the physician has requested such treatment. No physician shall supervise a physician assistant who administers acupuncture treatment to patients unless the physician is proficient in the field of acupuncture and has assured himself that the physician assistant is also proficient in the administration of acupuncture treatment. A physician assistant who administers acupuncture treatment to patients at the direction of a physician shall administer such treatment only within the physical confines of the physician's office at such times when the physician is physically present on the premises and immediately available for consultation.

24.1.2 Legend - For the purpose of these rules and regulations the term "legend" is defined as any drug containing the statement "Caution: Federal law prohibits dispensing without prescription" required by

section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act as part of the labeling of all prescription drugs (and only such drugs). A "legend" drug is thus a prescription drug, III.B.3 and 24 **Del.C.** §2502(22).

24.2 Biennial Renewal of License

24.2.1 Physician Assistants must renew their license on a biennial basis by payment of appropriate fees as established by 24 **Del.C.** §1774A.

24.2.2 Completion of required renewal form, and submission of documentation of one hundred (100) hours of Continuing Medical Education (CME), 50 hours of Category 1 during every 2 year cycle. A licensee who submits proof of holding current certification from the NCCPA shall be deemed to have met this requirement.

24.3 Prescriptive Authority

24.3.1 Prescriptive authority for the therapeutic drugs and treatments will include the following:

24.3.1.1 Prescriptive authority is a delegated medical service by the supervising physician.

24.3.1.2 Prescriptive authority will be practice specific of the supervising physician.

24.3.1.3 PAs may prescribe legend medication including Schedule II-V controlled substances, (as defined in the Controlled Substance Act). parenteral medications, medical therapeutics, devices and diagnostics.

24.3.1.4 PAs will be assigned a provider identifier number as outlined by the Division of Professional Regulation.

24.3.1.5 Controlled Substances registration will be as follows:

24.3.1.5.1 PAs must register with the Drug Enforcement Agency (DEA) and use such DEA number for controlled substance prescriptions.

24.3.1.5.2 PA's must register biennially with the Secretary of the Department of Health and Social Services in accordance with 16 **Del.C.** §4732(a).

24.3.1.6 Prescriptions must include the printed or legibly handwritten name of the PA. Prescriptions shall be written in accordance with 17 **Del.C.** §1764A and shall contain the following information clearly typed or written:

24.3.1.6.1 The name and phone number of the prescriber;

24.3.1.6.2 The name and strength of the drug prescribed;

24.3.1.6.3 The quantity of the drug prescribed;

24.3.1.6.4 The directions for the use of the drug;

24.3.1.6.5 Date of issue.

24.3.1.7 PA prescriptions must include the Division of Professional Regulation provider identifier number.

24.3.1.8 PA prescriptions for a controlled substance must include the PA's DEA number, as well as the Division of Professional Regulation provider identifier number.

24.3.1.9 As a delegated authority by the supervising physician PAs may request and issue professional samples of legend and over-the-counter medications. Professional samples must be labeled in compliance with 24 **Del.C.** §2522(c).

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25.0 Fifth Pathway

An applicant who does not meet the usual educational requirements for licensure may apply through the "Fifth Pathway" if the following conditions are met:

25.1 The applicant has studied medicine at a medical school outside the United States or Canada which was approved by the government of the country where the medical school is located to confer a doctorate of medicine and surgery or its equivalent. The medical school must have been approved during the applicant's entire period of study. and be listed in the World Health Organization Directory;

25.2 The applicant has successfully completed all academic requirements of a matriculated student of that school for a diploma conferring a doctorate of medicine and surgery or its equivalent including any clinical rotations but who has not received the degree due to an additional requirement such as social service;

25.3 All clinical clerkship rotations served in the United States or Canada as part of training received in a medical college or school must be conducted in an institution that is a formal part (primary hospital) of a medical college or school or has a formal affiliation with a medical college or school approved by the appropriate accrediting body of the American Osteopathic Association or the American Medical Association or such clinical rotation must be served in a hospital which has. at the time the rotation is served, a residency training approved by the Accreditation Counsel for Graduate Medical Education in the area of the clinical rotation;

- 25.4 The applicant has successfully completed a one year program of supervised clinical training under the direction of a medical school approved by the Liaison Committee on Medical Education and has submitted a certificate attesting to the satisfactory completion of the program by the sponsoring medical school;
- 25.5 The applicant has completed the post graduate hospital training required by the Board of all applicants for licensure;
- 25.6 The applicant has passed the examination(s) required by the Board of all applicants for licensure.

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26.0 Requirements for Independent Practice/Prescriptive Authority for Advanced Practice Nurses (APN)

26.1 Definitions

26.1.1 Collaborative Agreement - Includes

- 26.1.1.1 A true collegial agreement between two parties where mutual goal setting, access, authority, and responsibility for actions belong to individual parties and there is a conviction to the belief that this collaborative agreement will continue to enhance patient outcomes and
- 26.1.1.2 A written document that outlines the process for consultation and referral between an Advanced Practice Nurse (APN) and a licensed physician, dentist, podiatrist or licensed Delaware health care delivery system. This document can include, but not be limited to, written verification of health care facility approved clinical privileges or a health care facility approved job description of the APN. If the agreement is with a licensed Delaware health care delivery system, the individual will have to show that the system will supply appropriate medical back-up for purposes of consultation and referral.

26.1.2 National Certification - That credential earned by an Advanced Practice Nurse who has met requirements of a Board approved certifying agency. The agencies so approved include:

- 26.1.2.1 American Academy of Nurse Practitioners
- 26.1.2.2 American Nurses' Credentialing Center
- 26.1.2.3 American Association of Nurse Anesthetists Council on Certification of Nurse Anesthetists
- 26.1.2.4 American Association of Nurse Anesthetists Council on Recertification of Nurse Anesthetists
- 26.1.2.5 National Certification Corporation for Obstetric, Gynecological and Neonatal Nursing Specialties
- 26.1.2.6 National Certification Board of Pediatric Nurse Practitioners and Nurses
- 26.1.2.7 ACNM Certification Council. Inc.

26.1.3 Pharmacology/Therapeutics - refers to any course, program, or offering that would include, but not be limited to, the identification of individual and classes of drugs, their indications and contraindications, their likelihood of success, their dosages, their side effects and their interactions. It also encompasses clinical judgment skills and decision making. These skills may be based on thorough interviewing, history taking, physical assessment, test selection and interpretation, patho-physiology, epidemiology, diagnostic reasoning, differentiation of conditions, treatment decisions, case evaluation and nonpharmacological interventions.

26.1.4 Prescription Order - includes the prescription date, the name of the patient, the name, address, area of specialization and business telephone number of the advanced practice nurse prescriber, the name, strength, quantity, directions for use, and number of refills of the drug product or device prescribed, and must bear the signature and prescriber ID number of the advanced practice nurse prescriber, and when applicable, practitioner's DEA number. There must be lines provided to show whether the prescription must be dispensed as written or substitution is permitted.

26.2 Requirements for Independent Practice/Prescriptive Authority

An APN applicant for independent practice and/or independent prescriptive authority shall:

- 26.2.1 Be an Advanced Practice Nurse (APN) holding a current permanent license issued by the Board of Nursing (BON). If the individual does not hold national certification, eligibility will be determined on a case by case basis.
- 26.2.2 Submit a copy of the current collaborative agreement to the Joint Practice Committee (JPC). The collaborative agreement(s) shall include arrangements for consultation and/or referral and/or hospitalization complementary to the area of the nurse's independent practice.
- 26.2.3 Show evidence of the equivalent of at least a thirty hour advanced pharmacology and therapeutics program within the five years prior to application for independent practice and/or independent prescriptive authority. This may be a comprehensive continuing education program or a three credit, semester long graduate level course. CRNAs may meet this requirement by submitting evidence of thirty hours of pharmacology/therapeutics related continuing education offerings within the five years prior to application

for independent practice and/or independent prescriptive authority. The thirty hours may also occur during the generic APN program as integrated content as long as this can be documented to the JPC. All offerings will be reviewed and approved by the JPC.

- 26.2.4 Demonstrate how submitted continuing education offerings relate to pharmacology and therapeutics within their area of specialty. This can be done by submitting the program titles to show content and dates attended. If the JPC questions the relevance of the offerings, the applicant must have available program descriptors, and/or learner objectives, and/or program outlines for submission to the JPC for its review and approval.

26.3 Application

- 26.3.1 Names and credentials of qualified applicants will be forwarded to the Joint Practice Committee for approval and then forwarded to the Board of Medical Practice for review and final approval.

26.4 Prescriptive Authority

- 26.4.1 APNs may prescribe legend medications including Schedule II - V controlled substances, (as defined in the Controlled Substance Act), parenteral medications, medical therapeutics, devices and diagnostics.
- 26.4.2 APNs will be assigned a provider identifier number as outlined by the Division of Professional Regulation.
- 26.4.3 Controlled Substances registration will be as follows:
 - 26.4.3.1 APNs must register with the Drug- Enforcement Agency and use such DEA number for controlled substance prescriptions.
 - 26.4.3.2 APNs must register biennially with the Secretary of the Department of Health and Social Services in accordance with 16 **Del.C.** §4732(a).
- 26.4.4 APNs may request and issue professional samples of legend and over-the-counter medications that must be labeled in compliance with 24 **Del.C.** §2536(C).

26.5 Prescriptive Writing

- 26.5.1 All prescription orders will be written as defined by the Delaware Board of Pharmacy as defined in Section 1.4.

26.6 Renewal

- 26.6.1 Maintain current APN licensure.
- 26.6.2 Maintain competency through a minimum of fifteen hours of JPC approved pharmacology and therapeutics continuing education within the area of specialization and licensure per biennium.

26.7 Disciplinary Proceedings

- 26.7.1 Complaints against an APN will be forwarded to the Division of Professional Regulation. A complaint related to independent practice/prescriptive authority will be referred to the Joint Practice Committee for review and disposition and then forwarded to the Board of Medical Practice for review and final approval in an expeditious manner.
- 26.7.2 All other complaints regarding APNs will continue to be under the sole jurisdiction of the Board of Nursing.

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27.0 Paramedic Certification

27.1 Qualifications

Upon notification of the receipt of an application signed by the applicant and the Paramedic Administrator of the Office of Emergency Medical Services, the Board of Medical Practice (Board) may grant initial certification pursuant to 16 **Del.C.** §9809(a) to a paramedic whose application establishes that the applicant has met all of the following course requirements and standards.

- 27.1.1 Current registration as a paramedic by the National Registry of Emergency Medical Technicians, or proof of employment as a Delaware Paramedic continually since January 1, 1990; and,
- 27.1.2 Current certification in each of the following:
 - 27.1.2.1 CPR (Cardio-pulmonary Resuscitation at the healthcare provider level),
 - 27.1.2.2 ACLS (Advanced Cardiac Life Support),
 - 27.1.2.3 PALS (Pediatric Advanced Life Support),
 - 27.1.2.4 PHTLS (Pre-hospital Trauma Life Support) or BTLS (Basic Trauma Life Support; and,
- 27.1.3 Certification by a paramedic administrator and the state paramedic medical director that the applicant has satisfactorily completed a field evaluation period while employed by a state approved paramedic service and demonstrated the ability to competently manage a variety of stable and unstable patients presenting with medical and/or traumatic emergencies in accordance with standard treatment protocol and established practices.

27.2 Recertification

Such initial certification by the Board will be valid for a period of either one (1) or two (2) years depending upon the applicant's position in the recertification cycle and may be renewed thereafter for two-year (2) periods upon application in writing to the Board accompanied by a certification from the paramedic administrator establishing that the applicant has met all of the following requirements:

- 27.2.1 Satisfactory completion of a 48-hour EMT-paramedic Refresher Training Program that is in accordance with the requirements of the Department of Transportation Paramedic Refresher National Standard Curriculum and approved by the state paramedic administrator.
- 27.2.2 Satisfactory completion of 12 hours per year of continuing education or 24 hours of continuing education over a two-year period to comply with National Registry of Emergency Medical Technicians' Paramedic Curriculum and approved by the state paramedic administrator.
- 27.2.3 Possession of current certification in each of the following:
 - 27.2.3.1 CPR (Cardio-pulmonary Resuscitation at the healthcare provider level);
 - 27.2.3.2 ACLS (Advanced Cardiac Life Support),
 - 27.2.3.3 PALS (Pediatric Advanced Life Support);
 - 27.2.3.4 PHTLS (Pre-hospital Trauma Life Support); or
 - 27.2.3.5 BTLS (Basic Trauma Life Support).
- 27.2.4 Current national registration as an emergency medical technician-paramedic (except for those paramedics who have been continuously employed as a Delaware paramedic since January 1, 1990); and,
- 27.2.5 Current certification of competency by the state and respective county paramedic medical directors and employment by a state or county paramedic service.

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28.0 Crimes Substantially Related to the Practice of Medicine and the Practice of Licensed Respiratory Care and Practice as a Licensed Physician's Assistant

The Board finds that for purposes of licensing, renewal, reinstatement and discipline, the conviction of any of the following crimes, or of the attempt to commit or a conspiracy to commit or conceal the following crimes or substantially similar crimes in another state or jurisdiction, is deemed to be substantially related to the practice of Medicine, Respiratory Care and Physician's Assistants in the State of Delaware without regard to the place of conviction:

- 28.1 For the purposes of this section the following definitions shall apply:

"Conviction" means a verdict of guilty by whether entered by a judge or jury, or a plea of guilty or a plea of nolo contendere or other similar plea such as a "Robinson" or "Alford" plea unless the individual has been discharged under §4218 of Title 11 of the Delaware Code (probation before judgment) or under §1024 of Title 10 (domestic violence diversion program) or by §4764 of Title 16 (first offenders controlled substances diversion program).

"Jurisdiction" Substantially similar crimes in another State or Jurisdiction including all crimes prohibited by or punishable under Title 18 of the United States Code Annotated (U.S.C.A.) such as, but not limited to, Federal Health Care offenses.

- 28.2 Any crime which involves the use of physical force or violence toward or upon the person of another and shall include by way of example and not of limitation the following crimes set forth in Title 11 of the **Delaware Code Annotated**:

Assaults and Related Offenses

- 28.2.1 §601. Offensive touching;
- 28.2.2 §602. Menacing;
- 28.2.3 §603. Reckless endangering in the second degree;
- 28.2.4 §604. Reckless endangering in the first degree;
- 28.2.5 §605. Abuse of a pregnant female in the second degree;
- 28.2.6 §606. Abuse of a pregnant female in the first degree;
- 28.2.7 §611. Assault in the third degree;
- 28.2.8 §612. Assault in the second degree;
- 28.2.9 §613. Assault in the first degree;
- 28.2.10 §614. Assault on a sports official.
- 28.2.11 §615. Assault by abuse or neglect;

28.2.12 §621. Terroristic threatening;
28.2.13 §625. Unlawfully administering drugs;
28.2.14 §626. Unlawfully administering controlled substance or counterfeit substance or narcotic drugs;
28.2.15 §627. Prohibited acts as to substances releasing vapors or fumes;
28.2.16 §628. Vehicular assault in the second degree;
28.2.17 §629. Vehicular assault in the first degree;
28.2.18 §630. Vehicular homicide in the second degree;
28.2.19 §630A. Vehicular homicide in the first degree;
28.2.20 §631. Criminally negligent homicide;
28.2.21 §632. Manslaughter;
28.2.22 §633. Murder by abuse or neglect in the second degree;
28.2.23 §634. Murder by abuse or neglect in the first degree;
28.2.24 §635. Murder in the second degree;
28.2.25 §636. Murder in the first degree;
28.2.26 §645. Promoting suicide.

Abortion and Related Offenses

28.2.27 §651. Abortion;
28.2.28 §653. Issuing abortifacient articles.

Sexual Offenses

28.2.29 §763. Sexual harassment;
28.2.30 §764. Indecent exposure in the second degree;
28.2.31 §765. Indecent exposure in the first degree;
28.2.32 §766. Incest;
28.2.33 §767. Unlawful sexual contact in the third degree;
28.2.34 §768. Unlawful sexual contact in the second degree;
28.2.35 §769. Unlawful sexual contact in the first degree;
28.2.36 §770. Rape in the fourth degree;
28.2.37 §771. Rape in the third degree;
28.2.38 §772. Rape in the second degree;
28.2.39 §773. Rape in the first degree;
28.2.40 §776. Sexual extortion;
28.2.41 §777. Bestiality;
28.2.42 §778. Continuous sexual abuse of a child;
28.2.43 §780. Female genital mutilation.

Kidnapping and Related Offenses

28.2.44 §781. Unlawful imprisonment in the second degree;
28.2.45 §782. Unlawful imprisonment in the first degree;
28.2.46 §783. Kidnapping in the second degree;
28.2.47 §783A. Kidnapping in the first degree;
28.2.48 §785. Interference with custody;

Coercion

28.2.49 §791. Acts constituting coercion;

28.3 Any crime which involves dishonesty or false, fraudulent or aberrant behavior and shall include by way of example and not of limitation the following crimes listed in Title 11 of the **Delaware Code Annotated**:

Arson and Related Offenses

28.3.1 §801. Arson in the third degree;
28.3.2 §802. Arson in the second degree;
28.3.3 §803. Arson in the first degree;
28.3.4 §804. Reckless burning or exploding;
28.3.5 §805. Cross or religious symbol burning;

Criminal Trespass and Burglary

28.3.6 §820. Trespassing with intent to peer or peep into a window or door of another;
28.3.7 §821. Criminal trespass in the third degree;
28.3.8 §822. Criminal trespass in the second degree;
28.3.9 §823. Criminal trespass in the first degree;
28.3.10 §824. Burglary in the third degree;
28.3.11 §825. Burglary in the second degree;
28.3.12 §826. Burglary in the first degree;
28.3.13 §828. Possession of burglar's tools or instruments facilitating theft;

Robbery

28.3.14 §831. Robbery in the second degree;
28.3.15 §832. Robbery in the first degree.
28.3.16 §835. Carjacking in the second degree;
28.3.17 §836. Carjacking in the first degree;

Theft and Related Offenses

28.3.18 §840. Shoplifting; class G felony;
28.3.19 §840A. Use of illegitimate retail sales receipt or Universal Product Code Label.
28.3.20 §841. Theft;
28.3.21 §842. Theft; lost or mislaid property; mistaken delivery.
28.3.22 §843. Theft; false pretense.
28.3.23 §844. Theft; false promise.
28.3.24 §845. Theft of services.
28.3.25 §846. Extortion;
28.3.26 §848. Misapplication of property;
28.3.27 §849. Theft of rented property;
28.3.28 §850. Use, possession, manufacture, distribution and sale of unlawful telecommunication and access devices.
28.3.29 §851. Receiving stolen property;
28.3.30 §853. Unauthorized use of a vehicle;
28.3.31 §854. Identity theft;
28.3.32 §859. Larceny of livestock;
28.3.33 §860. Possession of shoplifter's tools or instruments facilitating theft;

Forgery and Related Offenses

28.3.34 §861. Forgery; class F felony;
28.3.35 §862. Possession of forgery devices;

Offenses Involving Falsification of Records

28.3.36 §871. Falsifying business records;
28.3.37 §872. Falsifying business records;
28.3.38 §873. Tampering with public records in the second degree;
28.3.39 §876. Tampering with public records in the first degree;
28.3.40 §877. Offering a false instrument for filing;
28.3.41 §878. Issuing a false certificate;

Bribery Not Involving Public Servants

28.3.42 §881. Bribery;
28.3.43 §882. Bribe receiving;

Frauds on Creditors

28.3.44 §891. Defrauding secured creditors;
28.3.45 §892. Fraud in insolvency;
28.3.46 §893. Interference with levied-upon property;

Other Frauds and Cheats

28.3.47 §900. Issuing a bad check;
28.3.48 §903. Unlawful use of credit card;

28.3.49 §903A. Reencoder and scanning devices;
28.3.50 §906. Deceptive business practices;
28.3.51 §907. Criminal impersonation;
28.3.52 §907A. Criminal impersonation, accident related;
28.3.53 §907B. Criminal impersonation of a police officer;
28.3.54 §908. Unlawfully concealing a will;
28.3.55 §909. Securing execution of documents by deception;
28.3.56 §910. Debt adjusting;
28.3.57 §911. Fraudulent conveyance of public lands;
28.3.58 §912. Fraudulent receipt of public lands;
28.3.59 §913. Insurance fraud;
28.3.60 §913A. Health care fraud;
28.3.61 §914. Use of consumer identification information;
28.3.62 §915. Use of credit card information;
28.3.63 §915A. Credit and debit card transaction receipts;
28.3.64 §916. Home improvement fraud;
28.3.65 §917. New home construction fraud;

Offenses Relating to Recorded Devices

28.3.66 §920. Transfer of recorded sounds;
28.3.67 §921. Sale of transferred recorded sounds;
28.3.68 §922. Improper labeling;

Computer Related Offenses

28.3.69 §932. Unauthorized access.
28.3.70 §933. Theft of computer services.
28.3.71 §934. Interruption of computer services.
28.3.72 §935. Misuse of computer system information.
28.3.73 §936. Destruction of computer equipment.
28.3.74 §937. Unrequested or unauthorized electronic mail or use of network or software to cause same.
28.3.75 §938. Failure to promptly cease electronic communication upon request.

Offenses Relating to Marriage

28.3.76 §1001. Bigamy;
28.3.77 §1003. Bigamous marriage contracted outside the State.

28.4 Any crime which involves misuse or abuse of children or animals and shall include by way of example and not of limitation the following crimes listed in Title 11 of the **Delaware Code Annotated**:

Child Welfare; Sexual Offenses, Animal Offenses

28.4.1 §1100. Dealing in children;
28.4.2 §1101. Abandonment of child;
28.4.3 §1102. Endangering the welfare of a child;
28.4.4 §1105. Endangering the welfare of an incompetent person;
28.4.5 §1106. Unlawfully dealing with a child;
28.4.6 §1107. Endangering children;
28.4.7 §1108. Sexual exploitation of a child;
28.4.8 §1109. Unlawfully dealing in child pornography;
28.4.9 §1111. Possession of child pornography;
28.4.10 §1112. Sexual offenders; prohibitions from school zones.
28.4.11 §1112A. Sexual solicitation of a child;
28.4.12 §1113. Criminal non-support and aggravated criminal non-support.
28.4.13 §1114. Body-piercing; tattooing or branding;
28.4.14 §1114A. Tongue-splitting;
28.4.15 §1116. Sale or distribution of tobacco products to minors;
28.4.16 §1117. Notice;

28.4.17 §1119. Distribution of cigarettes through vending machines;
28.4.18 §1120. Distribution of tobacco products;
28.4.19 §1124. Purchase or receipt of tobacco products by minor;
28.4.20 §1325. Cruelty to animals;
28.4.21 §1325A. The unlawful trade in dog or cat by-products;
28.4.22 §1326. Animals; fighting and baiting prohibited;
28.4.23 §1327. Maintaining a dangerous animal;

- 28.5 Any crime which involves offenses against the public order the commission of which may tend to bring discredit upon the profession and which are thus substantially related to one's fitness to practice such profession and shall include by way of example and not of limitation the following crimes listed in Title 11 of the **Delaware Code Annotated**:

Bribery and Improper Influence

28.5.1 §1201. Bribery;
28.5.2 §1203. Receiving a bribe;
28.5.3 §1205. Giving unlawful gratuities;
28.5.4 §1206. Receiving unlawful gratuities;
28.5.5 §1207. Improper influence;
28.5.6 §1211. Official misconduct;
28.5.7 §1212. Profiteering.

Perjury and related offenses

28.5.8 §1221. Perjury in the third degree;
28.5.9 §1222. Perjury in the second degree;
28.5.10 §1223. Perjury in the first degree;
28.5.11 §1233. Making a false written statement;
28.5.12 §1239. Wearing a disguise during the commission of a felony;
28.5.13 §1240. Terroristic threatening of public officials or public servants;
28.5.14 §1241. Refusing to aid a police officer;
28.5.15 §1243. Obstructing fire-fighting operations;
28.5.16 §1244. Hindering prosecution;
28.5.17 §1245. Falsely reporting an incident;
28.5.18 §1246. Compounding a crime;
28.5.19 §1248. Obstructing the control and suppression of rabies;
28.5.20 §1249. Abetting the violation of driver's license restrictions;
28.5.21 §1250. Offenses against law-enforcement animals;
28.5.22 §1251. Escape in the third degree;
28.5.23 §1252. Escape in the second degree;
28.5.24 §1253. Escape after conviction;
28.5.25 §1254. Assault in a detention facility;
28.5.26 §1257A. Use of an animal to avoid capture;
28.5.27 §1259. Sexual relations in detention facility;
28.5.28 §1260. Misuse of prisoner mail.

Offenses Relating to Judicial and Similar Proceedings

28.5.29 §1261. Bribing a witness;
28.5.30 §1262. Bribe receiving by a witness;
28.5.31 §1263. Tampering with a witness;
28.5.32 §1263A. Interfering with child witness.
28.5.33 §1264. Bribing a juror;
28.5.34 §1265. Bribe receiving by a juror;
28.5.35 §1266. Tampering with a juror;
28.5.36 §1267. Misconduct by a juror;
28.5.37 §1269. Tampering with physical evidence;
28.5.38 §1271. Criminal contempt;

28.5.39 §1271A. Criminal contempt of a domestic violence protective order;

28.5.40 §1273. Unlawful grand jury disclosure.

- 28.6 Any crime which involves offenses against a public health order and decency which may tend to bring discredit upon the profession, specifically including the below listed crimes from Title 11 of the **Delaware Code Annotated** which evidence a lack of appropriate concern for the safety and well being of another person or persons in general or sufficiently flawed judgment to call into question the individuals ability to make health care decisions or advise upon health care related matters for other individuals.

Disorderly Conduct and Related Offenses

28.6.1 §1301. Disorderly conduct;

28.6.2 §1302. Riot;

28.6.3 §1304. Hate crimes;

28.6.4 §1311. Harassment;

28.6.5 §1312. Aggravated harassment;

28.6.6 §1312A. Stalking;

28.6.7 §1313. Malicious interference with emergency communications;

28.6.8 §1315. Public intoxication;

28.6.9 §1316. Registration of out-of-state liquor agents;

28.6.10 §1320. Loitering on property of a state-supported school, college or university;

28.6.11 §1321. Loitering

28.6.12 §1322. Criminal nuisance;

28.6.13 §1323. Obstructing public passages;

28.6.14 §1324. Obstructing ingress to or egress from public buildings;

28.6.15 §1331. Desecration;

28.6.16 §1332. Abusing a corpse;

28.6.17 §1333. Trading in human remains and associated funerary objects.

28.6.18 §1335. Violation of privacy;

28.6.19 §1338. Bombs, incendiary devices, Molotov cocktails and explosive devices;

28.6.20 §1339. Adulteration;

28.6.21 §1340. Desecration of burial place.

Offenses Involving Public Indecency

28.6.22 §1341. Lewdness;

28.6.23 §1342. Prostitution;

28.6.24 §1343. Patronizing a prostitute prohibited.

28.6.25 §1351. Promoting prostitution in the third degree;

28.6.26 §1352. Promoting prostitution in the second degree;

28.6.27 §1353. Promoting prostitution in the first degree;

28.6.28 §1355. Permitting prostitution;

Obscenity

28.6.29 §1361. Obscenity; acts constituting;

28.6.30 §1365. Obscene literature harmful to minors;

28.6.31 §1366. Outdoor motion picture theatres;

Offenses Involving Gambling

28.6.32 §1403. Advancing gambling in the first degree;

28.6.33 §1404. Providing premises for gambling;

28.6.34 §1405. Possessing a gambling device; class A misdemeanor.

28.6.35 §1406. Being concerned in interest in keeping any gambling device;

28.6.36 §1407. Engaging in a crap game;

28.6.37 §1411. Unlawfully disseminating gambling information.

- 28.7 Any crime which involves the illegal possession or the misuse or abuse of narcotics, or other addictive substances and those non-addictive substances with a substantial capacity to impair reason or judgment and shall include by way of example and not of limitation the following crimes listed in Chapter 47 of Title 16 of the Delaware Code Annotated:

- 28.7.1 §4751. Prohibited acts A;
- 28.7.2 §4752. Prohibited acts B;
- 28.7.3 §4752A. Unlawful delivery of noncontrolled substance.
- 28.7.4 §4753. Prohibited acts C.
- 28.7.5 §4753A. Trafficking in marijuana, cocaine, illegal drugs, methamphetamines, L.S.D., or designer drugs.
- 28.7.6 §4754. Prohibited acts D;
- 28.7.7 §4754A. Possession and delivery of noncontrolled prescription drug.
- 28.7.8 §4755. Prohibited acts E;
- 28.7.9 §4756. Prohibited acts;
- 28.7.10 §4757. Hypodermic syringe or needle; delivering or possessing; disposal; exceptions;
- 28.7.11 §4758. Keeping drugs in original containers.
- 28.7.12 §4761. Distribution to persons under 21 years of age;
- 28.7.13 §4761A. Purchase of drugs from minors;
- 28.7.14 §4767. Distribution, delivery, or possession of controlled substance within 1,000 feet of school property;
- 28.7.15 §4768. Distribution, delivery or possession of controlled substance in or within 300 feet of park, recreation area, church, synagogue or other place of worship.
- 28.8 Any crime which involves the misuse or illegal possession or sale of a deadly weapon or dangerous instrument and shall include by way of example and not of limitation the following crimes listed in Title 11 of the **Delaware Code Annotated**:
 - Offenses Involving Deadly Weapons and Dangerous Instruments
 - 28.8.1 §1442. Carrying a concealed deadly weapon;
 - 28.8.2 §1443. Carrying a concealed dangerous instrument;
 - 28.8.3 §1444. Possessing a destructive weapon;
 - 28.8.4 §1445. Unlawfully dealing with a dangerous weapon;
 - 28.8.5 §1446. Unlawfully dealing with a switchblade knife;
 - 28.8.6 §1447. Possession of a deadly weapon during commission of a felony;
 - 28.8.7 §1447A. Possession of a firearm during commission of a felony;
 - 28.8.8 §1448. Possession and purchase of deadly weapons by persons prohibited;
 - 28.8.9 §1448A. Criminal history record checks for sales or firearms;
 - 28.8.10 §1449. Wearing body armor during commission of felony;
 - 28.8.11 §1450. Receiving a stolen firearm;
 - 28.8.12 §1451. Theft of a firearm;
 - 28.8.13 §1452. Unlawfully dealing with knuckles-combination knife;
 - 28.8.14 §1453. Unlawfully dealing with martial arts throwing star;
 - 28.8.15 §1454. Giving a firearm to person prohibited;
 - 28.8.16 §1455. Engaging in a firearms transaction on behalf of another;
 - 28.8.17 §1456. Unlawfully permitting a minor access to a firearm;
 - 28.8.18 §1457. Possession of a weapon in a Safe School and Recreation Zone;
 - 28.8.19 §1458. Removing a firearm from the possession of a law enforcement officer;
 - 28.8.20 §1459. Possession of a weapon with a removed, obliterated or altered serial number;
 - 28.8.21 §1471. Prohibited acts.
 - Offenses Involving Drug Paraphernalia
 - 28.8.22 §4774. Penalties.
 - Offenses Involving Organized Crime and Racketeering
 - 28.8.23 §1504. Criminal Penalties for Organized Crime & Racketeering
 - Offenses Involving Intimidation of Victims or Witnesses
 - 28.8.24 §3532. Acts of Intimidation: Class E felony
 - 28.8.25 §3533. Aggravated act of intimidation, Class D felony
 - Other Crimes
 - 28.8.26 Title 3 §1041. Willfully or maliciously starting fires; Carelessly Starting Fires;
 - 28.8.27 §1043. Setting fire to woodland; Unseasonable Marsh Burning.
 - 28.8.28 Title 4 §901. Offenses carrying penalty of imprisonment for 3 to 6 months;

28.8.29 §902. Offenses carrying penalty of fine of \$500 to \$1,000 or imprisonment of 3 to 6 months on failure to pay fine;

28.8.30 §903. Offenses carrying penalty of fine of not more than \$100 imprisonment for 1 month on failure to pay fine;

28.8.31 §904. Offenses concerning certain persons;

28.8.32 §905. Unlicensed manufacture of alcoholic liquor; Possession of still, apparatus, mash, etc., by unlicensed person;

28.8.33 §906. Transportation or shipment;

28.8.34 §907. Interference with officer or inspector;

28.8.35 §908. Failure of licensee to file report;

28.8.36 §909. Violation of rules respecting liquor taxes.

28.8.37 Title 7 §1717. Unauthorized acts against a service guide or seeing eye dog.

28.8.38 Title 11 §2403. Manufacture, possession or sale of intercepting device;

28.8.39 §2410. Breaking and entering, etc. to place or remove equipment;

28.8.40 §2412. Obstruction, impediment or prevention of interception;

28.8.41 §2422. Divulging contents of communications;

28.8.42 §3532. Act of intimidation;

28.8.43 §3533. Aggravated act of intimidation;

28.8.44 §3534. Attempt to intimidate;

28.8.45 §8523. Penalties [for violation of reporting provision re: SBI];

28.8.46 §8562. Penalties [for failure of child-care provider to obtain information required under §8561 or for those providing false information]

28.8.47 §8572. Penalties [for providing false information when seeking employment in a public school]

28.8.48 §9016. Filing false claim [under Victims' Compensation Fund].

28.8.49 Title 12 §210. Alteration, theft or destruction of Will.

28.8.50 Title 16 §1136. Abuse or neglect of a patient or resident of a nursing facility.

28.8.51 Title 21 §2118A. Unlawful possession or manufacture of proof of insurance;

28.8.52 §2133. Penalties; jurisdiction of justices of the peace.

28.8.53 §2315. False statements;

28.8.54 §2316. Altering or forging certificate of title, manufacturer's certificate of origin, registration sticker or vehicle identification plate;

28.8.55 §2620. False statements; incorrect or incomplete information;

28.8.56 §2703. License to operate a motorcycle, motorbike, etc.;

28.8.57 §2710. Issuance of a Level 1 Learner's Permit and Class D operator's license to persons under 18 years of age;

28.8.58 §2722. Restricted licenses based on driver's physical limitations;

28.8.59 §2751. Unlawful application for or use of license or identification card;

28.8.60 §2752. False statements;

28.8.61 §2756. Driving vehicle while license is suspended or revoked; penalty;

28.8.62 §2760. Duplication, reproduction, altering, or counterfeiting of driver's licenses or identification cards.

28.8.63 Title 23 §2302. Operation of a vessel or boat while under the influence of intoxicating liquor and/or drugs;

28.8.64 §2305. Penalties; jurisdiction.

28.8.65 Title 24 §903. Sale to persons under 21 or intoxicated persons.

28.8.66 Title 29 §3107. Motor vehicle safety-responsibility; False statements;

28.8.67 §4175A. Reckless driving;

28.8.68 §4177. Driving a vehicle while under the influence or with a prohibited alcohol content; evidence; arrests; and penalties.

28.8.69 §4177M. Operating a commercial motor vehicle with a prohibited blood alcohol concentration or while impaired by drugs;

28.8.70 §4183. Parking areas for vehicles being used by persons with disabilities;

28.8.71 §4198J. Bicycling on highways under influence of drugs or alcohol;

28.8.72 §4198O. Operation of electric personal assistive mobility devices (EPAMD);

- 28.8.73 §4201. Duty of driver involved in accident resulting in property damage or injury;
- 28.8.74 §4202. Duty of driver involved in accident resulting in injury or death to any person;
- 28.8.75 §4203. Duty to report accidents; evidence;
- 28.8.76 §4204. Report of damaged vehicles; cars involved in fatal accidents;
- 28.8.77 §4604. Possession of motor vehicle master keys, manipulative keys, key-cutting devices, lock picks or lock picking devices and hot wires;
- 28.8.78 §6420. Odometers penalties;
- 28.8.79 §6702. Driving vehicle without consent of owner;
- 28.8.80 §6704. Receiving or transferring stolen vehicle;
- 28.8.81 §6705. Removed, falsified or unauthorized identification number on vehicle, bicycle or engine; removed or affixed license/registration plate with intent to misrepresent identity;
- 28.8.82 §6707. Penalty;
- 28.8.83 §6709. Removal of warranty or certification stickers; vehicle identification plates; confidential vehicle identification numbers;
- 28.8.84 §6710. Unlawful possession of assigned titles, assigned registration cards, vehicle identification plates and warranty stickers.
- 28.8.85 Title 30 §571. Attempt to evade or defeat tax;
- 28.8.86 §572. Failure to collect or pay over tax;
- 28.8.87 §573. Failure to file return, supply information or pay tax;
- 28.8.88 §574. Fraud and false statements;
- 28.8.89 §576. Misdemeanors.
- 28.8.90 Title 31 §1007. Fraudulent acts penalties;
- 28.8.91 §3913. Welfare violations [knowing or reckless abuse of an infirm adult]
- 28.9 Any crime which is a violation of Title 24, Chapter 17 (Delaware Medical Practices Act) as it may be amended from time to time or of any other statute which requires the reporting of a medical situation or condition to state, federal or local authorities or a crime which constitutes a violation of the Medical Practice Act of the state in which the conviction occurred or in which the physician is licensed.
- 28.10 The Board reserves the jurisdiction and authority to modify this regulation as and if it becomes necessary to either add or delete crimes including such additions as may be required on an emergency basis under 29 **Del.C.** §10119 to address imminent peril to the public health, safety or welfare. The Board also specifically reserves the jurisdiction to review any crime committed by an applicant for licensure as a physician and to determine whether to waive the disqualification under 24 **Del.C.** §1720(d).

15 DE Reg. 1766 (06/01/12)

29.0 Patient Records; Fee Schedule for Copies

- 29.1 A patient requesting of a copy of his or her own medical records to be transferred to another physician or to be obtained on their own behalf may be charged a reasonable fee not to exceed the fees set forth in the schedule below, excluding the actual cost of postage or shipping if the records are mailed:
 - \$2.00 per page for pages 1-10
 - \$1.00 per page for pages 11-20
 - \$0.90 per page for pages 21-60
 - \$0.50 per page for pages 61 and above
- 29.2 The fees set forth in section 30.1 above shall apply whether the records are produced in paper or electronic format.
- 29.3 The full cost of reproduction may be charged for copies of records not susceptible to photostatic reproduction, such as radiology films, models, photographs or fetal monitoring strips.
- 29.4 Payment of all costs may be required in advance of release of the records except for records requested to make or complete an application for a disability benefits program.

13 DE Reg. 680 (11/01/09)

15 DE Reg. 1766 (06/01/12)

77 Del. Laws c. 319, § 1.

30.0 Disciplinary Guidelines [Authority: 24 Del.C. §1713 (f)]

- 30.1 Purpose: The Legislature has created the Board of Medical Licensure and Discipline to assure the protection of the public from persons who do not meet the minimum requirements for safe practice or who pose a danger to the public. Pursuant to 24 **Del.C.** §1713(f), the Board provides the disciplinary guidelines it will apply to licensees regulated under 24 **Delaware Code**, Chapter 17, after a full investigation and at the conclusion of a hearing after finding violations of the Board's statute and/or regulations. The purpose of this rule is to notify applicants of the ranges of penalties which may be imposed unless the Board finds grounds to deviate from the guidelines due to aggravating or mitigating circumstances (Rules 31.12 and 31.13). The practice of medicine is already subject to both civil and criminal penalties. Recognizing its role as protector of the public's health, safety, and welfare, the Board offers these guidelines as a means to improve the quality of medical care and not to enforce the penal code, a responsibility left to law enforcement and to the courts. The purpose of imposing discipline is to sanction licensees for violation; deter them from future violations; to offer opportunities for rehabilitation when appropriate; and to dissuade other applicants and licensees from committing disciplinable offenses.
- 30.2 Violations and Range of Penalties: When imposing discipline, the Board shall act in accordance with the following disciplinary guidelines and shall impose a penalty within the range corresponding to the violations unless grounds to deviate are found. The following identification of categories of offenses and summary explanations are intended to be descriptive only; the full language of each statutory provision cited must be consulted in order to determine the conduct included.
- 30.3 Negligence is an act or omission that deviates from accepted standards of practice in the medical community
- 30.3.1 Gross Negligence – a range from 1 year probation with education to 1 year suspension with reinstatement upon proof of improvement in practice proficiency - §1731(b)(11)
- 30.3.2 Pattern of Negligence – a range from 1 year probation to suspension with reinstatement after proof of satisfactory improvement - §1731(b)(11)
- 30.4 Incompetence is failing to exercise appropriate professional judgment or failing to utilize skill to a degree showing a lack of general competence.
- 30.4.1 Incompetence in Practice – practice reviewed by organization of the Board's choice and a range from 1 year probation to revocation - §1731(b)(11)
- 30.4.2 Failure to Use Skill or Judgment - practice reviewed by an organization of the Board's choice and a range from \$1,000 fine to 6 months probation
- 30.4.3 Incompetent Acts of Supervision – range from \$1,000 fine to \$1,000 fine and letter of reprimand - §1731(b)(10)
- 30.5 Misconduct is that conduct which is recognized to be unsafe or improper by the ethical and competent members of the profession. The term also includes, but is not limited to, general conduct that is dishonorable or unprofessional and that is not addressed in other categories within these guidelines, and includes acts prohibited by policies expressed in legislation.
- 30.5.1 General Misconduct - a range from \$1,000 fine to 6 months suspension - §1731(b)(1); §1731 (b)(3); §1731(b)(4); §1731(b)(5); §1731(b)(9); §1731(b)(19)
- 30.5.2 Willful Failure to Report – minimum \$5,000 fine and/or 6 months probation - §1731(b)(13); §1731(b)(14); §1731(b)(15); §1731(b)(22)
- 30.5.3 Unjustified Failure to Cooperate – a range from 6 months probation to 6 months suspension - §1731(b)(16); §1731(b)(17)
- 30.6 Criminal Conduct is conduct which violates rules and statutes that define conduct prohibited by the government. Such unprofessional conduct reflects upon the licensee's fitness and qualifications to practice in the healthcare field and detracts from the trust of the public.
- 30.6.1 Crimes Substantially Related – a range from 90 days probation to suspension with reinstatement only after proof satisfactory to the board of practice improvement, not to be less than any court-ordered sanctions – §1731(b)(2)
- 30.6.2 Felony Sexual Offenses – revocation - §1731(a)
- 30.7 Sexual Misconduct – These guidelines cannot define or foresee all the possible scenarios of sexual misconduct. The professional boundary required between physician and patient is based upon the fiduciary relationship in which the patient entrusts his or her welfare to the physician, reflects the physician's respect for the patient. That boundary, once crossed, severely impacts the patient's well-being on an individual basis, and causes distrust to other professional relationships in general. Sexual misconduct is a harmful example of a boundary violation, occurring in multiple contexts and involving a wide range of behaviors. Sexual misconduct includes but is not limited to, sexual impropriety towards a patient, sexual conduct towards patients, sexual harassment in the workplace facilitating a hostile work environment, sexual conduct between supervisors and subordinates, the commission of sexual assault and other sexual crimes.

- 30.7.1 Sexual involvement can occur in circumstances involving two consenting adults. However, sexual involvement with a current patient is considered misconduct. It is the responsibility of the physician to transfer the patient's care to another health care provider if they foresee a romantic or sexual relationship developing.
- 30.7.2 Sexual involvement with former patients is misconduct when the licensee exploits knowledge or information obtained from the previous physician-patient relationship. Sexual or romantic relationships between physicians and their patients may exploit the vulnerability of the patient and may obscure the physician's objective judgment concerning the patient's health care. Sexual misconduct between a physician and a patient is never diagnostic or therapeutic. Romantic or intimate relationships may impede the physician's ability to confront the patient about noncompliance with treatment or to bring up unpleasant medical information. Physicians must set aside their own needs or interests in the service of addressing the patient's needs. The physician-patient relationship depends upon the ability of the patient to have absolute confidence and trust in the physician, and a patient has the right to believe that a physician is dedicated solely to the patient's best interests. When considering action related to sexual involvement with a former patient the Board should consider the extent, if any, to which the (medical provider) exploited the previous patient-provider relationship.
- 30.7.3 Sexual impropriety may include, but is not limited to, sexually suggestive behavior, gestures, expressions, statements, and it may include failing to respect a patient's privacy such as in the following examples:
 - 30.7.3.1 failing to employ disrobing or draping practices that respect the patient's privacy (except in the case of examination in an emergency setting);
 - 30.7.3.2 examination or touching of a patient's genital region without donning gloves without clinical justification;
 - 30.7.3.3 inappropriate comments to a patient about the patient's body, sexual orientation, or potential sexual performance during the examination; and
 - 30.7.3.4 performing an intimate examination without clinical justification
- 30.7.4 Sexual misconduct may include, but is not limited to, physical contact such as:
 - 30.7.4.1 touching breasts, genitals, or other body part without clinical justification; and
 - 30.7.4.2 offering clinical services or prescriptions in exchange for sexual favors.
- 30.7.5 Sexual Relations with a Patient - a range from 6 months suspensions to revocation
- 30.7.6 Sexual Impropriety Involving Current Patients – education on boundary issues and a range of minimum \$1,000 fine to maximum \$10,000 fine to suspension - §1731(b)(23)
- 30.7.7 Sexual Harassment Associated with Practice (employees) – education on sexual harassment and a \$1,000 fine and a letter of reprimand
- 30.8 Billing/Business Issues, includes but is not limited to, charging grossly exorbitant fees for services, failure to report laboratory costs and failure to disclose to the patient a financial interest.
 - 30.8.1 Financial Exploitation of Patients or Fraud of Others – a range from a minimum \$1,000 fine to 6 months probation - §1731(b)(8); §1731(b)(18); §1769
 - 30.8.2 Other Wrongful Transactions - education on billing and a \$1,000 fine and letter of reprimand
- 30.9 False Advertising, includes but is not limited to, false or prohibited statements, exploitation, or economic injury – \$1,000 fine and letter of reprimand - §1731(b)(7); §1731(b)(8)
- 30.10 Impairment is a condition which renders the licensee unable to practice medicine with reasonable skill or safety. Impaired licensees are not only at risk of causing patient harm but are also at risk of causing significant personal endangerment. Impairments include drug abuse, alcohol abuse, and mental or physical conditions that impede the licensee's ability to practice with reasonable skill and safety.
 - 30.10.1 Not cooperating with remediation or non-remediable - a range from 6 months suspension to indefinite suspension until treatment is deemed to be effective
 - 30.10.2 Appears remediable but discipline needed - appropriate treatment with probation and/or suspension until remediation is proven to the Board
- 3.11 Administrative Misconduct is conduct that fails to adhere to the standards required for the regulation of the profession. All licensees in their practice have not only professional medical requirements but administrative requirements that are integral to their performance as a licensed physician. Administrative misconduct includes, but is not limited to, disregard of continuing medical education requirements.
 - 30.11.1 Failure to comply with other administrative requirements of the Board – \$1,000 fine and letter of reprimand - §1763; §1769; §1769A
 - 30.11.2 Failure to comply with CME requirements - \$1,000 fine and requirement to complete CME within 60 days and license suspended until CME completed, if not completed within 60 days.

- 30.11.3 Violation of a Board Order (§1731(b)(17)) – Suspension until compliance of Board Order is accomplished to revocation
- 30.12 Inappropriate Prescribing is prescribing that fails to follow medically accepted standards to ensure the patients health and safety. It includes, but is not limited to, misconduct as the failure to follow required procedures that have been established to ensure prescriptions are legitimate, prescribing to family or friends who suffer from addiction or misuse, diversion for self use, and criminal trafficking in dangerous drugs.
 - 30.12.1 No legitimate medical purpose – education in pharmacology and a range from a letter of reprimand to suspension - §1731(b)(6)
 - 30.12.2 Failure to follow requirements – \$1,000 fine and/or a letter of reprimand – §1731(b)(21)
 - 30.12.3 Failure to follow Federation of State Medical Boards' Model Policy for the Use of Controlled Substances for the Treatment of Pain - education in pharmacology of pain management and a range from \$1,000 fine and probation to revocation
- 30.13 Patient Records Violations – Patient records consist of documentation that reflects the physician-patient relationship and any misuse of the documentation constitutes a patient records violation. Failure to adequately maintain patient records includes, but is not limited to, misconduct such as the failure to adequately document evaluation and/or treatment of the patient, failure to adequately maintain or store the records, and failure to allow the patient or the patient's authorized representative access to the records.
 - 30.13.1 False documentation/alteration – a range from \$2,000 fine and letter of reprimand to 6 months probation
 - 30.13.2 Poor documentation - letter of reprimand
 - 30.13.3 Confidentiality Issues/HIPPA – education on confidentiality/HIPAA and letter of reprimand - §1731(b)(12)
 - 30.13.4 Problems with access to patient records which impedes continuity of care - letter of reprimand - §1761
 - 30.13.5 Notice requirement of Office Closure – letter of reprimand – §1761
 - 30.13.6 Practice Abandonment – Suspension to revocation
 - 30.13.7 Falsely Documenting a Death Certificate - a range from \$2,000 fine and letter of reprimand to 6 months probation - §1731(b)(20)
- 30.14 Aggravating (worsening) factors when determining the degree of discipline, the board may consider certain factors, including but not limited to the following:
 - 30.14.1 Prior Disciplinary Offenses
 - 30.14.2 Past Disciplinary Record
 - 30.14.3 Frequency of Acts
 - 30.14.4 Nature and (extreme) gravity of the allegation
 - 30.14.5 False evidence, false statements, other deceptive practices during disciplinary process or proceedings and during the investigative process
 - 30.14.6 Dishonest or selfish motive
 - 30.14.7 Motivation; criminal dishonest; or personal gain
 - 30.14.8 Different multiple offenses
 - 30.14.9 Failing to comply with rules or orders
 - 30.14.10 Refusal to acknowledge wrongful nature of conduct and vulnerability of the victim
 - 30.14.11 Intentional
 - 30.14.12 Abuse of trust
 - 30.14.13 Consensus about blameworthiness of conduct
 - 30.14.14 No consent of patient/Against patient's will
 - 30.14.15 Age capacity or vulnerability of patient or victim of licensee's misconduct
 - 30.14.16 Severe injury caused by misconduct
 - 30.14.17 Potential for injury ensuing from act
 - 30.14.18 Practitioner present competence in medical skills
 - 30.14.19 Pattern of misconduct
 - 30.14.20 Illegal conduct
 - 30.14.21 Heinousness of actions
 - 30.14.22 Ill repute upon profession
 - 30.14.23 Public's perception of protection

- 30.15 Mitigating (lessening) factors when determining the degree of discipline, the board may consider certain factors, including but not limited to the following:
- 30.15.1 Absence of prior disciplinary record
 - 30.15.2 Single act
 - 30.15.3 Nature and (minimal) gravity of the allegation
 - 30.15.4 Voluntary restitution or other actions taken to remedy the misconduct
 - 30.15.5 Remorse and/or consciousness of wrongful conduct
 - 30.15.6 Absence of dishonest or selfish motive
 - 30.15.7 Timely good faith effort to rectify consequences of misconduct
 - 30.15.8 Interim rehabilitation
 - 30.15.9 Remoteness of prior offenses
 - 30.15.10 Length of time that has elapsed since misconduct
 - 30.15.11 Inadvertent
 - 30.15.12 Consent of patient
 - 30.15.13 No apparent vulnerability of patient
 - 30.15.14 No significant injury caused by misconduct
 - 30.15.15 No significant potential for injury ensuing from act
 - 30.15.16 No evidence of motivation of criminal; dishonest or personal gain
 - 30.15.17 Mental or physical health; weak health; cancer
 - 30.15.18 Personal circumstances
 - 30.15.19 Present fitness of the practitioner
 - 30.15.20 Potential for successful rehabilitation
 - 30.15.21 Practitioner's present competence in medical skills
 - 30.15.22 Personal problems (if there is a connection to violation)
 - 30.15.23 Emotional problems (If there is a connection to violation)
 - 30.15.24 Isolated incident unlikely to reoccur
 - 30.15.25 Public's perception of protection
- 30.16 Applicability: These guidelines are applicable to all professions or occupations regulated under the Medical Practice Act. The guidelines will be construed to apply to any substantially similar violations or offenses under the specific statutory or regulatory provisions applicable to those professions or occupations regardless of whether the code section or regulation is specifically referenced herein.

15 DE Reg. 537 (10/01/11)

15 DE Reg. 1766 (06/01/12)

31.0 Use of Controlled Substances for the Treatment of Pain: Purpose

The Board has adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" ("Model Policy"). These regulations have been developed to define specific requirements applicable to pain control, particularly related to the use of controlled substances, to alleviate licensed practitioners' uncertainty, to encourage better pain management, and to minimize practices that deviate from the appropriate standard of care and lead to abuse and diversion. Licensed practitioners should familiarize themselves with the Model Policy available online at www.dpr.delaware.gov. To the extent there are any inconsistencies between these regulations and the Model Policy, these regulations shall control.

The principles of quality medical practice dictate that citizens of Delaware have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The inappropriate treatment of pain includes a wide spectrum of issues that do not provide treatment appropriate to the patients' specific needs.

The diagnosis and treatment of pain is integral to the practice of medicine. Licensed practitioners view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. Licensed practitioners should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. These regulations are primarily directed to the treatment of chronic pain but ~~are may be~~ applicable to prescribing controlled substances for ~~other conditions as well~~ the treatment of acute pain when clinically appropriate.

Inappropriate pain treatment may result from the practitioner's lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate

pain management is the treating practitioner's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board may refer to current clinical practice guidelines and/or expert review in approaching cases involving the management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the licensed practitioner. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Licensed practitioners should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and alone are not the same as addiction.

The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes can pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, these regulations mandate that licensed practitioners incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Licensed practitioners should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a licensed practitioner-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the licensed practitioner's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will take disciplinary action against a licensed practitioner for deviating from these regulations unless contemporaneous medical records document reasonable cause for deviation. The practitioner's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

31.1 The following criteria must be used when evaluating the treatment of chronic pain, including the use of controlled substances but may be applicable to prescribing controlled substances for the treatment of acute pain when clinically appropriate:

31.1.1 Evaluation of the Patient- A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:

- 31.1.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain,
- 31.1.1.2 underlying or coexisting diseases or conditions,
- 31.1.1.3 the effect of the pain on physical and psychological function, and history of substance abuse,
- 31.1.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.

31.2 Treatment Plan- A written treatment plan is required and must state goals and objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan must address whether treatment modalities or a rehabilitation program are necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. After treatment begins, the practitioner must adjust drug therapy to the individual medical needs of each patient.

31.3 Informed Consent - The practitioner must discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.

31.4 Agreement for Treatment- If the patient is at high risk for medication abuse or has a history of substance abuse, the practitioner must use a written agreement between the practitioner and patient outlining patient responsibilities, including;

- 31.4.1 urine/serum medication levels screening when requested;
- 31.4.2 number and frequency of all prescription refills; and
- 31.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement).
- 31.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.

- 31.5 Periodic Review- The licensed practitioner shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Periodic review shall include, at a minimum, evaluation of the following:
- 31.5.1 continuation or modification of controlled substances for pain management therapy depending on the practitioner's evaluation of the patient's progress toward treatment goals and objectives.
 - 31.5.2 satisfactory response to treatment as indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.
 - 31.5.3 if the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
- 31.6 Consultation- The practitioner shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder requires extra care, monitoring, documentation and may require consultation with or referral to an expert in the management of such patients. At a minimum, practitioners who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients,
- 31.7 Medical Records- The practitioner shall keep accurate and complete records. The entire record must, include the:
- 31.7.1 medical history and physical examination,
 - 31.7.2 diagnostic, therapeutic and laboratory results,
 - 31.7.3 evaluations and consultations,
 - 31.7.4 documentation of etiology;
 - 31.7.5 treatment objectives,
 - 31.7.6 discussion of risks and benefits,
 - 31.7.7 informed consent,
 - 31.7.8 treatments,
 - 31.7.9 medications (including date, type, dosage and quantity prescribed),
 - 31.7.10 instructions and agreements, and
 - 31.7.11 periodic review.
- 31.8 Records should remain current and be maintained in an accessible manner and readily available for review. Each practitioner should include documentation appropriate for each visit's level of care and will include the:
- 31.8.1 interim history and physical examination,
 - 31.8.2 vital signs as clinically appropriate,
 - 31.8.3 assessment of progress, and
 - 31.8.4 medication plan.
- 31.9 Compliance with Controlled Substances Laws and Regulations- To prescribe, dispense or administer controlled substances, the practitioner must be licensed in the state and comply with all applicable federal and state regulations. Licensed practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances as well as applicable state regulations.
- 31.10 The following terms are defined as follows:
- 31.10.1 Acute Pain- Acute pain is 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.
 - 31.10.2 Addiction- Addiction is 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.
 - 31.10.3 Chronic Pain- Chronic pain is 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.

- 31.10.4 Licensed Practitioner - Licensed practitioner means those licensed individuals with prescriptive authority regulated under the Medical Practice Act including, but not limited to, physicians, physician assistants and nurse practitioners, except as exempted by 16 Del.C. §4798(b)(9).
- 31.10.5 Pain- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
- 31.10.6 Physical Dependence- Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.
- 31.10.7 Pseudo addiction- The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.
- 31.10.8 Substance Abuse- Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.
- 31.10.9 Tolerance- Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

15 DE Reg. 1184 (02/01/12)

15 DE Reg. 1766 (06/01/12)

16 DE Reg. 651 (12/01/12) (Final)