

**DEPARTMENT OF STATE  
DIVISION OF PROFESSIONAL REGULATION**

**1700 BOARD OF MEDICAL LICENSURE AND DISCIPLINE**

Statutory Authority: 24 Delaware Code, Sections 1713(a)(12) and 1769D (24 **Del.C.** §§1713(a)(12) & 1769D)

**24 DE Admin. Code 1700**

**PROPOSED**

**PUBLIC NOTICE**

**1700 Board of Medical Licensure and Discipline**

The Delaware Board of Medical Licensure and Discipline, pursuant to 24 **Del.C.** §§1713(a)(12) & 1769D, proposes to revise its regulations adding a new regulation clarifying the language in the Medical Practice Act pertaining to telemedicine and telehealth. Written comments should be sent to Devashree Brittingham, Executive Director of the Delaware Board of Medical Licensure and Discipline, Cannon Building, 861 Silver Lake Blvd., Dover, DE 19904. Written comments will be accepted until July 3, 2017 pursuant to 29 **Del.C.** §10118(a).

**Summary of the evidence and information submitted**

The Delaware Board of Medical Licensure and Discipline pursuant to 24 **Del.C.** §§1713(a)(12) & 1769D, proposed to revise its regulations adding a new regulation clarifying the language in the Medical Practice Act pertaining to telemedicine and telehealth.

Following publication in the Delaware *Register of Regulations* on November 1, 2016 a public hearing was held on January 3, 2017. Written comment periods were held open for thirty days, and an additional fifteen days following the public hearing. At the hearing, the Board accepted as evidence and marked as the Board's Exhibit 1 documentation of publication of the notice of the public hearing in the *News Journal* and the *Delaware State News*. During the written public comment period, comments were received from both local and national interest groups.

A comment was received from Ted Thompson, J.D., Senior Vice President of Public Policy at the Michael J. Fox Foundation for Parkinson's Research. Mr. Thompson requests the removal of language in 19.1 and 19.2 of Regulation 356 that prohibits audio-only telemedicine visits for both examination and establishment of the patient-physician relationship. His concern is that this represents a barrier to accessing healthcare via telemedicine for Parkinson's patients. The Foundation believes physicians should be able to use their training and professional judgment to make the determination about whether or not an audio-visual connection lends itself well to treatment of their Parkinson's that Nemours strongly supports 19.1 and 19.2. citing information from major medical specialty societies whose clinical practical guidelines on telemedicine indicate that both audio and visual contact are necessary to ensure quality treatment, Nemours believes that an audio-only interaction runs the risk of not providing all the necessary information to meet clinical standards of care. Nemours has conducted research studies comparing the use of real-time audio and video to audio only. One particular study led by critical care intensivist, Dr. Nicholas Slamon, reviewed more than 250 charts of transported children who had a real-time audio and video consult and found that the ED disposition fell to 26% ( $p < 0.001$ ). When providers were able to see and hear their patients rather than relying on the description of their condition over the phone, the level of care was significantly raised. Treatment recommendations could begin hours before the transport team arrived, direct admission to the intensive care unit happened more efficiently, and in some cases children seen by real-time audio and video were able to stay in their local community and avoid unnecessary transport altogether. Nemours also supports a ban on opioid prescribing via telehealth technology, with the exception of buprenorphine and naloxone prescribed for the purposes of treating drug addiction. Nemours feels both the prohibition against prescribing opioid generally and an exception for addiction treatment purposes are strategies to combat the current Delaware addiction crisis.

A comment was received from Carolyn Morris, Director of Telehealth Planning and Development for the State of Delaware. Ms. Morris indicates that a critical need exists to address the opiate epidemic impacting Delaware's population. According to a 2016 DEA report Delaware's heroin related deaths rose more than 90 percent from 2013-2014, with a 93.5 percent increase in New Castle County and an 87.5 percent increase in need across a wide area. The program allows the prescribing physician to utilize live, interactive videoconferencing to provide medication management as part of the comprehensive model of care. Since 2011, WVU has expanded this program into rural areas of the state using telemedicine to help consumers with experts at WVU online and receive comprehensive treatment. The outpatient treatment model includes screening, assessment, group therapy and medication management. Most of the program takes place in person. The medication management for some of the clinics takes place 30 minutes

per week via telemedicine in a group setting. According to telehealth coordinator Jordan Cunningham one critical element of the program is having a good relationship with local pharmacies so that processing prescriptions is smooth. Another critical element is a strong dedicated staff at the remote clinics.

Use Case 2: California-based company Bright Heart Health has established a comprehensive and integrated telemedicine modality identified as the first Telemedicine Rapid Access Opioid Use Disorder Program. The model is designed to administer counseling, manage the patient's medication and oversee therapy. Though all medical encounters and treatment sessions are provided through telemedicine, the patient must have an initial in-person assessment by a physician to establish the patient/provider relationship.

During admission and induction the physician evaluates the patient and develops a treatment plan. The patient is then walked through an in home induction process. Following this all follow-up physician encounters occur virtually via telemedicine including prescription refills, medication management and drug-screening. Quality controls include regular checks of the Prescription Drug Monitoring Program (PDMP) records] does not meet the standard of establishing a patient physician relationship...

Teledoc also requested that 19.4 be revised to read as follows:

...real time communication [unless after review of the patient's medical records] the treating physician determines that audio communication supported by store and forward transfer technology would support a diagnosis consistent with the standard of care.

### **Summary of the finding of fact**

Pursuant to discussions held at open public Board meetings, the Board proposed to adopt telemedicine and telehealth regulations to clarify Section 1769D of Title 24 after the Board became aware that, despite the clear language of the statute, certain interest groups were opining that the requirement that a physician using telemedicine technologies to provide medical care to patients located in Delaware must first provide one of four options, including "an appropriate examination in-person," as that term is used in 24 **Del.C.** §1769D(h)(1) did not actually require an in-person examination as an option. The Board finds compelling the comments of Nemours, indicating that better health care performance flows from audio and visual examination. The Board is also mindful of the large amount of comments it received regarding the ban on opioid prescribing, and the limitations this will place on substance abuse treatment. Therefore, the Board is republishing the regulations, now with the added exception for treatment of substance abuse as suggested by the Delaware Department of Substance Abuse and Mental Health. As suggested by the Medical Society of Delaware, the Board is open to revisiting the regulations periodically as telemedicine become more pervasive in medical practice.

### **Decision of the Board**

Having found that the proposed changes to the regulations are necessary as outlined herein, the Board finds that the regulations shall be republished with the addition of an exception for prescribing opioids for the treatment of substance abuse. The exact text of the regulations, as amended, are attached to this order as Exhibit A.

IT IS SO ORDERED this 4<sup>th</sup> day of April, 2017 by the Delaware Board of Medical Licensure and Discipline.

Karyl Rattay, M.D., President

Leslie C. Ramsey, Public Member (absent)

Joseph M. Parise, D.O. (absent)

Stephen G. Cooper, M.D.

Gregory D. Adams, M.D.

Garrett H. Colmorgen, M.D.

Sharon Williams-Mayo, Public Member

Georges A. Dahr, M.D.

Malvine Richard, Public Member

Barry L. Baskt, D.O.

Stephen Lawless, M.D. (absent)

Mary K. Ryan, Public Member

Bryan Villar, M.D.

N.C. Vasuki, Public Member

Mary Lomax, Public Member

Vonda Calhoun, Public Member (absent)

### **1700 Board of Medical Licensure and Discipline**

#### **1.0 Scope**

These rules and regulations apply to all persons possessing, applying for or required to have a license or certificate or other authorization or approval which the Board of Medical Licensure and Discipline is empowered to issue or grant.

#### **2.0 Definitions**

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

**"Accredited Hospital"** means a medical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Hospital Association.

**"Board"** means the Board of Medical Licensure and Discipline.

**"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.

**"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. §1722(a)(2).

**"LCME"** means the examination given by the Medical Council of Canada.

**"National Boards"** means the examination administered by the National Board of Medical Examiners.

**"NBME"** means National Board of Medical Examiners.

**"NBOME"** means National Board of Osteopathic Medical Examiners.

**"SPEX"** is the Special Proficiency Examination.

**"United States"** means the 50 States and its territories or possessions.

**"USMLE"** means United States Medical Licensing Examination.

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

### 3.0 Licensure by Examination

All candidates for licensure by examination are required to pass the USMLE, National Boards, FLEX or SPEX as outlined below:

#### 3.1 FLEX Examination:

3.1.1 If FLEX was taken before June, 1985 applicant must have successfully passed a FLEX examination (Component 1 and Component 2) and have attained a passing score of a weighted average of seventy-five (75). After June, 1985 a passing score of 75 must have been obtained on Component 1 and Component 2.

3.1.2 LCME is the equivalent to FLEX Component 1 and 2.

#### 3.2 USMLE Examination:

3.2.1 The USMLE is designed to supersede and replace the FLEX and the National Boards. If completed prior to the year 2000 acceptable combinations are acceptable with a score of 75:

3.2.1.1 National Board Part I or USMLE Part 1 and

3.2.1.2 National Board Part II or USMLE Part 2 and

3.2.1.3 National Board Part III or USMLE Part 3

Or

3.2.1.4 FLEX Component 1 and USMLE Step 3

Or

3.2.1.5 National Board Part 1 and USMLE Step 1 and

3.2.1.6 National Board Part 11 and USMLE Step 2 and

3.2.1.7 FLEX Component 2

3.2.2 Passing Step 1, Step 2, and Step 3 of the examination must occur within 7 years. There shall be no more than six attempts to pass each Step without demonstration of additional experience acceptable to the Board.

3.3 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.

### 4.0 Institutional Certificates

The Board may issue institutional certificates to qualified persons who may be employed as post graduate trainees (interns, residents, or fellows) or house physicians by an accredited hospital operated within this State. The Board will also issue institutional certificates to qualified persons who will be employed as staff physicians in a medical institution operated in this State by any governmental institution.

#### 4.1 Post Graduate Trainees Employed by Accredited Hospitals

4.1.1 Any applicant applying for and institutional certificate shall include with the application:

4.1.1.1 An affidavit of the applicant certifying that

4.1.1.1.1 He or she meets all the requirements for licensure specified in 24 **Del.C.** §1720(b)(1) through (b)(6) excluding (b)(3); and

4.1.1.1.2 He or she intends to limit him or her selves solely to practice within the hospital, or the performance of such medical duties outside the hospital which may be assigned to them as part of a post graduate training program.

4.1.1.2 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(b)(1) through (b)(6), excluding (b)(3).

4.1.2 A person who is to be employed by an accredited hospital as a post graduate trainee who was not a citizen of the United States at the time he or she enrolled in medical school outside of the United States must present a photocopy of his or her permanent ECFMG Certificate or VQE results.

4.1.3 Post graduate trainees employed by accredited hospitals who have been granted institutional certificates shall be specifically limited to the practice of medicine within the hospital where they are employed, except that they may perform such medical duties outside the hospital which may be assigned to them as part of their postgraduate training program, provided such outside duties are performed under the supervision of a physician with a Certificate to Practice Medicine in the State of Delaware.

4.1.4 Postgraduate trainees 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 certificate.

4.1.5 Institutional certificates issued pursuant to these rules shall expire on the day on which the holder ceases to be employed by the employer hospital. If the employment relationship is prematurely terminated, both the holder and the Chief Administrative Officer of the employer hospital shall notify the Executive Director of the Board in writing not later than three days after the employment relationship is terminated.

4.1.6 Institutional certificates shall be renewed every year upon payment of a fee determined by the Division of Professional Regulation.

4.1.7 No institutional certificate issued to a post graduate trainee will be renewed at the end of the first year of issuance unless the trainee has passed at least one component of the FLEX examination or at least one part of the National Board Examination or the USMLE Step 1.

#### 4.2 Staff Physicians Employed by a Governmental Institution.

4.2.1 Any physician who will be employed as a staff physician by a governmental institution shall include with the application:

4.2.1.1 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).

4.2.1.2 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).

4.2.1.3 An affidavit of the physician seeking licensure certifying that he intends to limit himself solely to practice within the institution.

4.2.2 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.

4.2.3 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.

4.2.4 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 Executive Director of the Board in writing not later than three days after the employment relationship is terminated.

4.2.5 Valid institutional licenses shall be renewed every year upon payment of a fee determined by the Division of Professional Regulation.

### 5.0 Personal Interviews

5.1 As part of the application process for certification, a personal interview is required and will not be conducted until the completed application of the candidate has been received in the Board's Office.

- 5.2 Electronic Interviews via video-conferencing means satisfy the requirement for a personal interview provided the interviewer is able to view the applicant and the applicant's photo identification.
- 5.3 The President of the Board has the power to waive the personal interview when the President considers it a hardship for the candidate. Distance alone is not considered a hardship.

## **6.0 Consulting Physician**

Consultation may be done telephonically, electronically or in person. Consultation shall ordinarily consist of a history and physical examination, review of records and imaging pathology or similar studies. Consultation includes providing opinions and recommendations. An active Delaware certificate is required of any out of state physician who comes into Delaware to perform a consultation more than twelve (12) times per year. A physician who comes into Delaware to perform consultations must be actively licensed in another State or country on a full and unrestricted basis. Any consultations done for teaching and/or training purposes may include active participation in procedures and treatment, whether surgical or otherwise, provided a Delaware licensed physician remains responsible as the physician of record, and provided the patient is not charged a fee by the consultant.

### **18 DE Reg. 898 (05/01/15)**

## **7.0 Issuance and Renewal of License; Requirements for Physicians Re-entering Practice**

- 7.1 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.
- 7.2 Renewal may be effected by:
  - 7.2.1 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](http://www.dpr.delaware.gov);
  - 7.2.2 providing other information as may be required by the Board to ascertain the licensee's good standing;
  - 7.2.3 attesting on the renewal application to the completion of continuing education as required by the Board's rules and regulations;
  - 7.2.4 payment of fees as determined by the Division of Professional Regulation.
- 7.3 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 8.2.1 – 8.2.4 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.
- 7.4 No physician will be permitted to renew his/her license after the expiration of the one-year period.
- 7.5 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 8.7.
- 7.6 No physician shall practice medicine in the State of Delaware during the period of time that his/her Delaware license has expired.
- 7.7 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:
  - 7.7.1 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
  - 7.7.2 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.

## **8.0 Dishonorable or Unethical Conduct (24 Del.C. §1731(b)(3))**

- 8.1 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:
  - 8.1.1 A pattern of performance of unnecessary medical procedures.
  - 8.1.2 Exploitation of the doctor/patient privilege for personal gain or sexual gratification.
  - 8.1.3 Sexual impropriety including, but not limited to, sexually suggestive behavior, gestures, expressions, statements and failure to respect a patient's privacy.
  - 8.1.4 Fraudulent billing for medical services.

- 8.1.5 Intentional falsification of records maintained for controlled substances and non-controlled drugs.
- 8.1.6 Fraudulent advertising.
- 8.1.7 Willfully failing to treat a person under the physician's care who requires such treatment.
- 8.1.8 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.
- 8.1.9 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.
- 8.1.10 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.
- 8.1.11 Failure to comply with administrative requirements of the Board including failure to comply with continuing medical education requirements.
- 8.1.12 Failure to comply with the Board's regulations governing the use of controlled substances for the treatment of pain.
- 8.1.13 Failure to adequately maintain and properly document patient records.
- 8.1.14 Failure to provide access to patient records.
- 8.1.15 Inappropriate or disruptive behavior as defined in the AMA code of ethics.
- 8.1.16 Any other act tending to bring discredit upon the profession.

## **9.0 Medical Treatment Rendered During Patient Transport in an Emergency Vehicle**

A physician or other healthcare provider regulated by the Board who has not been granted a certificate or license in the State of Delaware may render care or treatment to a patient in an emergency vehicle which is in transit in the State of Delaware provided such healthcare provider is certified or licensed in the state from which the emergency vehicle departed, or the state to which the emergency vehicle is destined.

## **10.0 Board Reporting of Disciplinary Action**

- 10.1 Upon the Board taking any disciplinary action against a physician written notification of the disciplinary action taken by the Board shall be forwarded to the following agencies or individuals:
  - 10.1.1 Federation of State Medical Boards.
  - 10.1.2 Medical Boards in other states in which the physician is licensed to practice medicine.
  - 10.1.43 The Medical Society of Delaware.
  - 10.1.54 Delaware Osteopathic Medical Society.
  - 10.1.65 Director of the Division of Revenue.
  - 10.1.76 Director of the Division of Public Health.
  - 10.1.87 National Practitioner Data Bank.
  - 10.1.98 All Hospitals and Managed Care Entities in Delaware.

## **11.0 Delegation of Responsibilities to Non-physicians**

- 11.1 This section does not apply to physician assistant practice. Regulations governing the practice of physician assistants may be found in Section 13.0 of these regulations.
  - 11.1.1 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.
  - 11.1.2 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.
  - 11.1.3 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.

- 11.1.4 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.
- 11.1.5 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.
- 11.1.6 Any exemptions from the requirements specified above previously issued under former Regulation 20.1.6 will continue in effect and must be renewed by the Board every two years. No exemption will be renewed 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.
- 11.1.7 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. §1702(12) of the Medical Practice Act), and would be subject to disciplinary action by the Board.

## **12.0 Continuing Medical Education**

- 12.1 Pursuant to the provisions of 24 Del.C. §1713(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 (AMA) or equivalent courses approved by the American Osteopathic Association (AOA) 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.
- 12.2 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 approved by the AMA or equivalent courses approved by the AOA. 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.
- 12.3 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.

## **13.0 Physician Assistants**

### **13.1 Definitions:**

- 13.1.1 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:
  - 13.1.1.1 Definition of Physician Assistants
  - 13.1.1.2 Criteria for Licensure
  - 13.1.1.3 Licensure Fee
  - 13.1.1.4 Prohibited Practices
  - 13.1.1.5 Discipline
  - 13.1.1.6 Scope of Practice
  - 13.1.1.7 Supervision of Physician Assistants

- 13.1.1.7.1 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.** §1770A(3).
- 13.1.1.7.2 No supervising physician may supervise more than 4 physician assistants at any given time unless granted an exemption by the Board. As provided in 24 **Del.C.** §1771(f) and (h) 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.
- 13.1.1.7.3 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.

13.1.2 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).

## 13.2 Biennial Renewal of License

- 13.2.1 Physician Assistants must renew their license on a biennial basis by payment of appropriate fees as established by 24 **Del.C.** §1774A.
- 13.2.2 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.

## 13.3 Prescriptive Authority

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

- 13.3.1.1 Prescriptive authority is a delegated medical service by the supervising physician.
- 13.3.1.2 Prescriptive authority will be practice specific of the supervising physician.
- 13.3.1.3 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.
- 13.3.1.4 PAs will be assigned a provider identifier number as outlined by the Division of Professional Regulation.
- 13.3.1.5 Controlled Substances registration will be as follows:
  - 13.3.1.5.1 PAs must register with the Drug Enforcement Agency (DEA) and use such DEA number for controlled substance prescriptions.
  - 13.3.1.5.2 PAs must register biennially with the Secretary of the Department of Health and Social Services in accordance with 16 **Del.C.** §4732(a).
- 13.3.1.6 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:
  - 13.3.1.6.1 The name and phone number of the prescriber;
  - 13.3.1.6.2 The name and strength of the drug prescribed;
  - 13.3.1.6.3 The quantity of the drug prescribed;

- 13.3.1.6.4 The directions for the use of the drug;
- 13.3.1.6.5 Date of issue.
- 13.3.1.7 PA prescriptions must include the Division of Professional Regulation provider identifier number.
- 13.3.1.8 PA prescriptions for a controlled substance must include the PAs DEA number, as well as the Division of Professional Regulation provider identifier number.
- 13.3.1.9 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).

## 14.0 Paramedic Certification

### 14.1 Qualifications

- 14.1.1 Upon notification of the receipt of an application signed by the applicant accompanied by a letter of recommendation from the Paramedic Administrator of the Office of Emergency Medical Services (OEMS), the Board of Medical Licensure and Discipline (Board) may grant initial certification pursuant to 16 **Del.C.** §9809(a) to a paramedic whose application establishes that the applicant has meet all of the following course requirements and standards.
- 14.1.2 Current registration as a paramedic by the National Registry of Emergency Medical Technicians, or proof of employment as a Delaware Paramedic continually since before January 1, 1990; and,
- 14.1.3 Current course completion cards or approval of an equivalent level of instruction by the State EMS Medical Director in each of the following:
  - 14.1.3.1 CPR (Cardio-pulmonary Resuscitation at the healthcare provider level)
  - 14.1.3.2 ACLS (Advanced Cardiac Life Support)
  - 14.1.3.3 PALS (Pediatric Advanced Life Support)
  - 14.1.3.4 PHTLS (Pre-hospital Trauma Life Support) or BTLS-Advanced (Basic Trauma Life Support).
- 14.1.4 Certification by the Paramedic Administrator that the applicant, upon a valid offer of employment and/or an affiliation with an OEMS approved advanced life support service, has satisfactory completed such written and practical examinations as determined by the State EMS Medical Director.

### 14.2 Recertification

- 14.2.1 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 Delaware 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:
  - 14.2.1.1 Current registration as an Emergency Medical Technician-Paramedic with the National Registry of Emergency Medical Technicians (except for those paramedics who have been continuously employed as a Delaware Paramedic since before January 1, 1990).
  - 14.2.1.2 Delaware and Nationally Registered Paramedics must meet National Registry requirements for recertification. The applicant must successfully complete the following:
    - 14.2.1.2.1 Forty-eight (48) hours of an EMT-Paramedic Refresher Education Program approved by the State EMS Medical Director.
    - 14.2.1.2.2 Twenty-four (24) hours of continuing medical education approved by the State EMS Medical Director.
    - 14.2.1.2.3 Possession of current course completion cards or approval of an equivalent level of instruction by the State EMS Medical Director in each of the following disciplines. There cannot be a lapse in course completion cards in any of the referenced disciplines at any time during the recertification/re-registration cycle.
    - 14.2.1.2.4 CPR (Cardio-pulmonary Resuscitation at the healthcare provider level)
    - 14.2.1.2.5 ACLS (Advanced Cardiac Life Support)
    - 14.2.1.2.6 PALS (Pediatric Advanced Life Support)
    - 14.2.1.2.7 PHTLS (Pre-hospital Trauma Life Support) or BTLS-Advanced (Basic Trauma Life Support).
    - 14.2.1.2.8 Current certification of the following:
      - 14.2.1.2.8.1 That the applicant has demonstrated competency in the management of stable and unstable patients presenting with medical and/or traumatic emergencies by the State and respective agency Medical Director.
      - 14.2.1.2.8.2 That the applicant has successfully completed such interviews and competency evaluations as required by the State EMS Medical Director.

14.2.1.2.8.3 That the applicant is employed and/or affiliated with an OEMS recognized advanced life support service.

**15.0 Crimes Substantially Related to the Practice of Medicine, Respiratory Care, Acupuncture, Genetic Counseling, Polysomnography and Physicians Assistants**

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, Acupuncture, Genetic Counseling and Physician Assistants in the State of Delaware without regard to the place of conviction:

15.1 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.

15.2 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**

- 15.2.1 §601. Offensive touching;
- 15.2.2 §602. Menacing (felony);
- 15.2.3 §603. Reckless endangering in the second degree;
- 15.2.4 §604. Reckless endangering in the first degree;
- 15.2.5 §605. Abuse of a pregnant female in the second degree;
- 15.2.6 §606. Abuse of a pregnant female in the first degree;
- 15.2.7 §611. Assault in the third degree;
- 15.2.8 §612. Assault in the second degree;
- 15.2.9 §613. Assault in the first degree;
- 15.2.10 §614. Assault on a sports official.
- 15.2.11 §615. Assault by abuse or neglect;
- 15.2.12 §621. Terroristic threatening;
- 15.2.13 §622. Hoax device;
- 15.2.14 §625. Unlawfully administering drugs;
- 15.2.15 §626. Unlawfully administering controlled substance or counterfeit substance or narcotic drugs;
- 15.2.16 § 628 Vehicular assault in the third degree;
- 15.2.17 §628. Vehicular assault in the second degree;
- 15.2.18 §629. Vehicular assault in the first degree;
- 15.2.19 §630. Vehicular homicide in the second degree;
- 15.2.20 §630A. Vehicular homicide in the first degree;
- 15.2.21 §631. Criminally negligent homicide;
- 15.2.22 §632. Manslaughter;
- 15.2.23 §633. Murder by abuse or neglect in the second degree;
- 15.2.24 §634. Murder by abuse or neglect in the first degree;
- 15.2.25 §635. Murder in the second degree;
- 15.2.26 §636. Murder in the first degree;
- 15.2.27 §645. Promoting suicide.

**Abortion and Related Offenses**

- 15.2.28 §651. Abortion;
- 15.2.29 §653. Issuing abortifacient articles.

### Sexual Offenses

- 15.2.30 §763. Sexual harassment;
- 15.2.31 §764. Indecent exposure in the second degree;
- 15.2.32 §765. Indecent exposure in the first degree;
- 15.2.33 §766. Incest;
- 15.2.34 §767. Unlawful sexual contact in the third degree;
- 15.2.35 §768. Unlawful sexual contact in the second degree;
- 15.2.36 §769. Unlawful sexual contact in the first degree;
- 15.2.37 §770. Rape in the fourth degree;
- 15.2.38 §771. Rape in the third degree;
- 15.2.39 §772. Rape in the second degree;
- 15.2.40 §773. Rape in the first degree;
- 15.2.41 §774. Sexual extortion;
- 15.2.42 §775. Bestiality;
- 15.2.43 §776. Continuous sexual abuse of a child;
- 15.2.44 §777 Dangerous crime against a child;
- 15.2.45 §777A Sex offender unlawful conduct against a child;
- 15.2.46 §778 Sexual abuse of a child by a person in a position of trust, authority or supervision in the first degree;
- 15.2.47 §778A Sexual abuse of a child by a person in a position of trust, authority or supervision in the second degree;
- 15.2.48 §780. Female genital mutilation.

### Kidnapping and Related Offenses

- 15.2.49 §781. Unlawful imprisonment in the second degree;
- 15.2.50 §782. Unlawful imprisonment in the first degree;
- 15.2.51 §783. Kidnapping in the second degree;
- 15.2.52 §783A. Kidnapping in the first degree;
- 15.2.53 §785. Interference with custody;

### Coercion

- 15.2.54 §791. Acts constituting coercion (where injury or property damage occurs).

- 15.3 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

- 15.3.1 §801. Arson in the third degree;
- 15.3.2 §802. Arson in the second degree;
- 15.3.3 §803. Arson in the first degree;

### Criminal Trespass and Burglary

- 15.3.4 §820. Trespassing with intent to peer or peep into a window or door of another;
- 15.3.5 §824. Burglary in the third degree;
- 15.3.6 §825. Burglary in the second degree;
- 15.3.7 §826. Burglary in the first degree;
- 15.3.8 §826A. Home invasion;
- 15.3.9 §828. Possession of burglar's tools or instruments facilitating theft;

### Robbery

- 15.3.10 §831. Robbery in the second degree;
- 15.3.11 §832. Robbery in the first degree.
- 15.3.12 §835. Carjacking in the second degree;
- 15.3.13 §836. Carjacking in the first degree;

### Theft and Related Offenses

- 15.3.14 §840. Shoplifting; class G felony;
- 15.3.15 §840A. Use of illegitimate retail sales receipt or Universal Product Code Label (felony);
- 15.3.16 §841. Theft (felony);
- 15.3.17 §841A. Theft of a motor vehicle;

15.3.18 §841B. Theft: Organized retail crime (felony);  
15.3.19 § 841C. Possession or theft of a prescription form or a pad;  
15.3.20 §842. Theft; lost or mislaid property; mistaken delivery (felony);  
15.3.21 §843. Theft; false pretense (felony);  
15.3.22 §844. Theft; false promise (felony);  
15.3.23 §845. Theft of services (felony);  
15.3.24 §846. Extortion;  
15.3.25 §848. Misapplication of property (felony);  
15.3.26 §849. Theft of rented property (felony);  
15.3.27 §850. Use, possession, manufacture, distribution and sale of unlawful telecommunication and access devices (felony);  
15.3.28 §851. Receiving stolen property;  
15.3.29 §854. Identity theft;  
15.3.30 §860. Possession of shoplifter's tools or instruments facilitating theft;

#### Forgery and Related Offenses

15.3.31 §861. Forgery; (felony);  
15.3.32 §862. Possession of forgery devices;

#### Offenses Involving Falsification of Records

15.3.33 §871. Falsifying business records;  
15.3.34 §872. Falsifying business records;  
15.3.35 §873. Tampering with public records in the second degree;  
15.3.36 §876. Tampering with public records in the first degree;  
15.3.37 §877. Offering a false instrument for filing;  
15.3.38 §878. Issuing a false certificate;

#### Frauds on Creditors

15.3.39 §891. Defrauding secured creditors;  
15.3.40 §892. Fraud in insolvency;  
15.3.41 §893. Interference with levied-upon property;

#### Other Frauds and Cheats

15.3.42 §900. Issuing a bad check (felony);  
15.3.43 §903. Unlawful use of credit card;  
15.3.44 §903A. Reencoder and scanning devices;  
15.3.45 §906. Deceptive business practices;  
15.3.46 §907. Criminal impersonation;  
15.3.47 §907A. Criminal impersonation, accident related;  
15.3.48 §907B. Criminal impersonation of a police officer, firefighter, EMT, paramedic, fire police;  
15.3.49 §908. Unlawfully concealing a will;  
15.3.50 §909. Securing execution of documents by deception;  
15.3.51 §910. Debt adjusting;  
15.3.52 §911. Fraudulent conveyance of public lands;  
15.3.53 §912. Fraudulent receipt of public lands;  
15.3.54 §913. Insurance fraud;  
15.3.55 §913A. Health care fraud;  
15.3.56 §916. Home improvement fraud;  
15.3.57 §917. New home construction fraud;

#### Computer Related Offenses

15.3.58 §932. Unauthorized access (felony);  
15.3.59 §933. Theft of computer services (felony);  
15.3.60 §934. Interruption of computer services (felony);  
15.3.61 §935. Misuse of computer system information (felony);  
15.3.62 §936. Destruction of computer equipment (felony);

- 15.3.63 §937. Unrequested or unauthorized electronic mail or use of network or software to cause same (felony);
- 15.3.64 §938. Failure to promptly cease electronic communication upon request (felony).

Offenses Relating to Marriage

- 15.3.65 §1001. Bigamy;
- 15.3.66 §1003. Bigamous marriage contracted outside the State.

- 15.4 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

- 15.4.1 §1100. Dealing in children;
- 15.4.2 §1101. Abandonment of child;
- 15.4.3 §1102. Endangering the welfare of a child;
- 15.4.4 §1105. Crime against a vulnerable adult;
- 15.4.5 §1106. Unlawfully dealing with a child;
- 15.4.6 §1107. Endangering children;
- 15.4.7 §1108. Sexual exploitation of a child;
- 15.4.8 §1109. Dealing in child pornography;
- 15.4.9 §1111. Possession of child pornography;
- 15.4.10 §1112. Sexual offenders; prohibitions from school zones.
- 15.4.11 §1112A. Sexual solicitation of a child;
- 15.4.12 §1114. Body-piercing; tattooing or branding;
- 15.4.13 §1114A. Tongue-splitting;
- 15.4.14 §1116. Sale or distribution of tobacco products to minors;
- 15.4.15 §1117. Notice;
- 15.4.16 §1325. Cruelty to animals;
- 15.4.17 §1325A. The unlawful trade in dog or cat by-products (class A misdemeanor);
- 15.4.18 §1326. Animals; fighting and baiting prohibited (felony);
- 15.5 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

- 15.5.1 §1201. Bribery;
- 15.5.2 §1203. Receiving a bribe;
- 15.5.3 §1207. Improper influence;
- 15.5.4 §1211. Official misconduct;
- 15.5.5 §1212. Profiteering.

Perjury and related offenses

- 15.5.6 §1221. Perjury in the third degree;
- 15.5.7 §1222. Perjury in the second degree;
- 15.5.8 §1223. Perjury in the first degree;
- 15.5.9 §1233. Making a false written statement;
- 15.5.10 §1239. Wearing a disguise during the commission of a felony;
- 15.5.11 §1240. Terroristic threatening of public officials or public servants;
- 15.5.12 §1241. Refusing to aid a police officer;
- 15.5.13 §1243. Obstructing fire-fighting operations;
- 15.5.14 §1244. Hindering prosecution;
- 15.5.15 §1245. Falsely reporting an incident;
- 15.5.16 §1246. Compounding a crime;
- 15.5.17 §1249. Abetting the violation of driver's license restrictions;
- 15.5.18 §1250. Offenses against law-enforcement animals (Class A misdemeanor and felony);
- 15.5.19 §1252. Escape in the second degree;
- 15.5.20 §1253. Escape after conviction;

- 15.5.21 §1254. Assault in a detention facility;
- 15.5.22 §1257. Resisting arrest (felony);
- 15.5.23 §1257A. Use of an animal to avoid capture;
- 15.5.24 §1259. Sexual relations in detention facility;
- 15.5.25 §1260. Misuse of prisoner mail.

#### Offenses Relating to Judicial and Similar Proceedings

- 15.5.26 §1261. Bribing a witness;
- 15.5.27 §1262. Bribe receiving by a witness;
- 15.5.28 §1263. Tampering with a witness;
- 15.5.29 §1263A. Interfering with child witness.
- 15.5.30 §1264. Bribing a juror;
- 15.5.31 §1265. Bribe receiving by a juror;
- 15.5.32 §1266. Tampering with a juror;
- 15.5.33 §1267. Misconduct by a juror;
- 15.5.34 §1269. Tampering with physical evidence;
- 15.5.35 §1271A. Criminal contempt of a domestic violence protective order;
- 15.5.36 §1273. Unlawful grand jury disclosure.

- 15.6 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 individual's ability to make health care decisions or advise upon health care related matters for other individuals.

#### Disorderly Conduct and Related Offenses

- 15.6.1 §1302. Riot;
- 15.6.2 §1303. Disorderly conduct; funeral or memorial service (felony);
- 15.6.3 §1304. Hate crimes;
- 15.6.4 §1312. Aggravated harassment;
- 15.6.5 §1312A. Stalking;
- 15.6.6 §1313. Malicious interference with emergency communications;
- 15.6.7 §1331. Desecration;
- 15.6.8 §1332. Abusing a corpse;
- 15.6.9 §1333. Trading in human remains and associated funerary objects.
- 15.6.10 §1335. Violation of privacy;
- 15.6.11 §1338. Bombs, incendiary devices, Molotov cocktails and explosive devices;
- 15.6.12 §1339. Adulteration;
- 15.6.13 §1340. Desecration of burial place.

#### Offenses Involving Public Indecency

- 15.6.14 §1342. Prostitution;
- 15.6.15 §1343. Patronizing a prostitute prohibited.
- 15.6.16 §1351. Promoting prostitution in the third degree;
- 15.6.17 §1352. Promoting prostitution in the second degree;
- 15.6.18 §1353. Promoting prostitution in the first degree;
- 15.6.19 §1355. Permitting prostitution;

#### Obscenity

- 15.6.20 §1361. Obscenity (felony);
- 15.6.21 §1365. Obscene literature harmful to minors.

- 15.7 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**:

- 15.7.1 §4751. Prohibited acts A;
- 15.7.2 §4752. Prohibited acts B;

- 15.7.3 §4752A.Unlawful delivery of noncontrolled substance.
- 15.7.4 §4753. Prohibited acts C.
- 15.7.5 §4753A.Trafficking in marijuana, cocaine, illegal drugs, methamphetamines, L.S.D., or designer drugs.
- 15.7.6 §4754. Prohibited acts D;
- 15.7.7 §4754A.Possession and delivery of noncontrolled prescription drug.
- 15.7.8 §4755. Prohibited acts E;
- 15.7.9 §4756. Prohibited acts;
- 15.7.10 §4757. Hypodermic syringe or needle; delivering or possessing; disposal; exceptions;
- 15.7.11 §4761. Distribution to persons under 21 years of age;
- 15.7.12 §4761A. Purchase of drugs from minors;
- 15.7.13 §4767. Distribution, delivery, or possession of controlled substance within 1,000 feet of school property;
- 15.7.14 §4768. Distribution, delivery or possession of controlled substance in or within 300 feet of park, recreation area, church, synagogue or other place of worship.

#### Offenses Involving Drug Paraphernalia

- 15.7.15 §4774(b) and (c). (convictions for manufacture and sale and delivery to a minor in violation of §4771
- 15.8 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

- 15.8.1 §1442. Carrying a concealed deadly weapon;
- 15.8.2 §1443. Carrying a concealed dangerous instrument;
- 15.8.3 §1444. Possessing a destructive weapon;
- 15.8.4 §1445. Unlawfully dealing with a dangerous weapon (felony);
- 15.8.5 §1446. Unlawfully dealing with a switchblade knife (felony);
- 15.8.6 §61446A. Manufacture of undetectable knives (felony);
- 15.8.7 §1447. Possession of a deadly weapon during commission of a felony;
- 15.8.8 §1447A. Possession of a firearm during commission of a felony;
- 15.8.9 §1448. Possession and purchase of deadly weapons by persons prohibited;
- 15.8.10 §1448A. Criminal history record checks for sales or firearms;
- 15.8.11 §1449. Wearing body armor during commission of felony;
- 15.8.12 §1450. Receiving a stolen firearm;
- 15.8.13 §1451. Theft of a firearm;
- 15.8.14 §1452. Unlawfully dealing with knuckles-combination knife;
- 15.8.15 §1454. Giving a firearm to person prohibited;
- 15.8.16 §1455. Engaging in a firearms transaction on behalf of another;
- 15.8.17 §1456. Unlawfully permitting a minor access to a firearm;
- 15.8.18 §1457. Possession of a weapon in a Safe School and Recreation Zone;
- 15.8.19 §1458. Removing a firearm from the possession of a law enforcement officer;
- 15.8.20 §1459. Possession of a weapon with a removed, obliterated or altered serial number;
- 15.8.21 §1471. Prohibited acts (felony).

#### Offenses Involving Organized Crime and Racketeering

- 15.8.22 §1504. Criminal Penalties for Organized Crime & Racketeering

#### Offenses Involving Intimidation of Victims or Witnesses

- 15.8.23 §3532. Acts of Intimidation (Class E felony);
- 15.8.24 §3533. Aggravated act of intimidation (Class D felony);
- 15.8.25 §3534. Attempt to intimidate.

#### Other Crimes

- 15.8.26 §907. Interference with officer or inspector;
- 15.8.27 §908. Failure of licensee to file report;
- 15.8.28 Title 7 §1717. Unauthorized acts against a service guide or seeing eye dog.
- 15.8.29 Title 11 §2403. Manufacture, possession or sale of intercepting device;
- 15.8.30 §2410. Breaking and entering, etc. to place or remove equipment;

- 15.8.31 §2412. Obstruction, impediment or prevention of interception;
- 15.8.32 §2422. Divulging contents of communications;
- 15.8.33 §8523. Penalties [for violation of reporting provision re: SBI];
- 15.8.34 §8562. Penalties [for failure of child-care provider to obtain information required under §8561 or for those providing false information]
- 15.8.35 §8572. Penalties [for providing false information when seeking employment in a public school]
- 15.8.36 §9016. Filing false claim [under Victims' Compensation Fund].
- 15.8.37 Title 12 §210. Alteration, theft or destruction of Will.
- 15.8.38 Title 16 §1136. Abuse or neglect of a patient or resident of a nursing facility.
- 15.8.39 Title 21 §2118A. Unlawful possession or manufacture of proof of insurance;
- 15.8.40 §2133. Penalties; jurisdiction of justices of the peace.
- 15.8.41 §2315. False statements;
- 15.8.42 §2316. Altering or forging certificate of title, manufacturer's certificate of origin, registration sticker or vehicle identification plate;
- 15.8.43 §2620. False statements; incorrect or incomplete information;
- 15.8.44 §2703. License to operate a motorcycle, motorbike, etc.;
- 15.8.45 §2710. Issuance of a Level 1 Learner's Permit and Class D operator's license to persons under 18 years of age;
- 15.8.46 §2722. Restricted licenses based on driver's physical limitations;
- 15.8.47 §2751. Unlawful application for or use of license or identification card;
- 15.8.48 §2752. False statements;
- 15.8.49 §2756. Driving vehicle while license is suspended or revoked; penalty;
- 15.8.50 §2760. Duplication, reproduction, altering, or counterfeiting of driver's licenses or identification cards.
- 15.8.51 Title 23 §2302. Operation of a vessel or boat while under the influence of intoxicating liquor and/or drugs;
- 15.8.52 §2305. Penalties; jurisdiction.
- 15.8.53 §4177. Driving a vehicle while under the influence or with a prohibited alcohol content; evidence; arrests; and penalties.
- 15.8.54 §4177M. Operating a commercial motor vehicle with a prohibited blood alcohol concentration or while impaired by drugs;
- 15.8.55 §4201. Duty of driver involved in accident resulting in property damage or injury;
- 15.8.56 §4202. Duty of driver involved in accident resulting in injury or death to any person;
- 15.8.57 §4203. Duty to report accidents; evidence;
- 15.8.58 §4204. Report of damaged vehicles; cars involved in fatal accidents;
- 15.8.59 §4604. Possession of motor vehicle master keys, manipulative keys, key-cutting devices, lock picks or lock picking devices and hot wires;
- 15.8.60 §6420. Odometers penalties;
- 15.8.61 §6704. Receiving or transferring stolen vehicle;
- 15.8.62 §6705. Removed, falsified or unauthorized identification number on vehicle, bicycle or engine; removed or affixed license/registration plate with intent to misrepresent identity;
- 15.8.63 §6707. Penalty;
- 15.8.64 §6709. Removal of warranty or certification stickers; vehicle identification plates; confidential vehicle identification numbers;
- 15.8.65 §6710. Unlawful possession of assigned titles, assigned registration cards, vehicle identification plates and warranty stickers.
- 15.8.66 Title 30 §571. Attempt to evade or defeat tax;
- 15.8.67 §572. Failure to collect or pay over tax;
- 15.8.68 §573. Failure to file return, supply information or pay tax;
- 15.8.69 §574. Fraud and false statements;
- 15.8.70 §576. Misdemeanors.
- 15.8.71 Title 31 §1007. Fraudulent acts penalties;
- 15.8.72 §3913. Welfare violations [knowing or reckless abuse of an infirm adult]
- 15.9 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.

- 15.10 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).

#### **16.0 Patient Records; Fee Schedule for Copies**

- 16.1 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
- 16.2 The fees set forth in section 30.1 above shall apply whether the records are produced in paper or electronic format.
- 16.3 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.
- 16.4 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.

#### **17.0 Disciplinary Guidelines [Authority: 24 Del.C. §1713 (f)]**

- 17.1 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.
- 17.2 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.
- 17.3 Negligence is an act or omission that deviates from accepted standards of practice in the medical community
- 17.3.1 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)
- 17.3.2 Pattern of Negligence – a range from 1 year probation to suspension with reinstatement after proof of satisfactory improvement - §1731(b)(11)
- 17.4 Incompetence is failing to exercise appropriate professional judgment or failing to utilize skill to a degree showing a lack of general competence.
- 17.4.1 Incompetence in Practice – practice reviewed by organization of the Board's choice and a range from 1 year probation to revocation - §1731(b)(11)
- 17.4.2 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
- 17.4.3 Incompetent Acts of Supervision – range from \$1,000 fine to \$1,000 fine and letter of reprimand - §1731(b)(10)

- 17.5 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.
- 17.5.1 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)(11); §1731(b)(19)
- 17.5.2 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)
- 17.5.3 Unjustified Failure to Cooperate – a range from 6 months probation to 6 months suspension - §1731(b)(16); §1731(b)(17)
- 17.6 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.
- 17.6.1 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)
- 17.6.2 Felony Sexual Offenses – revocation - §1731(a)
- 17.7 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.
- 17.7.1 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.
- 17.7.2 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.
- 17.7.3 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:
- 17.7.3.1 failing to employ disrobing or draping practices that respect the patient's privacy (except in the case of examination in an emergency setting);
- 17.7.3.2 examination or touching of a patient's genital region without donning gloves without clinical justification;
- 17.7.3.3 inappropriate comments to a patient about the patient's body, sexual orientation, or potential sexual performance during the examination; and
- 17.7.3.4 performing an intimate examination without clinical justification
- 17.7.4 Sexual misconduct may include, but is not limited to, physical contact such as:
- 17.7.4.1 touching breasts, genitals, or other body part without clinical justification; and
- 17.7.4.2 offering clinical services or prescriptions in exchange for sexual favors.
- 17.7.5 Sexual Relations with a Patient - a range from 6 months suspensions to revocation
- 17.7.6 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)

- 17.7.7 Sexual Harassment Associated with Practice (employees) – education on sexual harassment and a \$1,000 fine and a letter of reprimand
- 17.8 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.
  - 17.8.1 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
  - 17.8.2 Other Wrongful Transactions - education on billing and a \$1,000 fine and letter of reprimand
- 17.9 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)
- 17.10 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.
  - 17.10.1 Not cooperating with remediation or non-remediable - a range from 6 months suspension to indefinite suspension until treatment is deemed to be effective
  - 17.10.2 Appears remediable but discipline needed - appropriate treatment with probation and/or suspension until remediation is proven to the Board
- 17.11 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.
  - 17.11.1 Failure to comply with other administrative requirements of the Board – \$1,000 fine and letter of reprimand - §1763; §1769; §1769A
  - 17.11.2 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.
  - 17.11.3 Violation of a Board Order (§1731(b)(17)) – Suspension until compliance of Board Order is accomplished to revocation
- 17.12 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.
  - 17.12.1 No legitimate medical purpose – education in pharmacology and a range from a letter of reprimand to suspension - §1731(b)(6)
  - 17.12.2 Failure to follow requirements – \$1,000 fine and/or a letter of reprimand – §1731(b)(21)
  - 17.12.3 Failure to follow the Board's Regulations 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
- 17.13 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.
  - 17.13.1 False documentation/alteration – a range from \$2,000 fine and letter of reprimand to 6 months probation
  - 17.13.2 Poor documentation - letter of reprimand
  - 17.13.3 Confidentiality Issues/HIPAA – education on confidentiality/HIPAA and letter of reprimand - §1731(b)(12)
  - 17.13.4 Problems with access to patient records which impedes continuity of care - letter of reprimand - §1761
  - 17.13.5 Notice requirement of Office Closure – letter of reprimand – §1761
  - 17.13.6 Practice Abandonment – Suspension to revocation
  - 17.13.7 Falsely Documenting a Death Certificate - a range from \$2,000 fine and letter of reprimand to 6 months probation - §1731(b)(20)
- 17.14 Aggravating (worsening) factors when determining the degree of discipline, the board may consider certain factors, including but not limited to the following:
  - 17.14.1 Prior Disciplinary Offenses
  - 17.14.2 Past Disciplinary Record
  - 17.14.3 Frequency of Acts
  - 17.14.4 Nature and (extreme) gravity of the allegation

- 17.14.5 False evidence, false statements, other deceptive practices during disciplinary process or proceedings and during the investigative process
- 17.14.6 Dishonest or selfish motive
- 17.14.7 Motivation; criminal dishonest; or personal gain
- 17.14.8 Different multiple offenses
- 17.14.9 Failing to comply with rules or orders
- 17.14.10 Refusal to acknowledge wrongful nature of conduct and vulnerability of the victim
- 17.14.11 Intentional
- 17.14.12 Abuse of trust
- 17.14.13 Consensus about blameworthiness of conduct
- 17.14.14 No consent of patient/Against patient's will
- 17.14.15 Age capacity or vulnerability of patient or victim of licensee's misconduct
- 17.14.16 Severe injury caused by misconduct
- 17.14.17 Potential for injury ensuing from act
- 17.14.18 Practitioner present competence in medical skills
- 17.14.19 Pattern of misconduct
- 17.14.20 Illegal conduct
- 17.14.21 Heinousness of actions
- 17.14.22 Ill repute upon profession
- 17.14.23 Public's perception of protection
- 17.15 Mitigating (lessening) factors when determining the degree of discipline, the board may consider certain factors, including but not limited to the following:
  - 17.15.1 Absence of prior disciplinary record
  - 17.15.2 Single act
  - 17.15.3 Nature and (minimal) gravity of the allegation
  - 17.15.4 Voluntary restitution or other actions taken to remedy the misconduct
  - 17.15.5 Remorse and/or consciousness of wrongful conduct
  - 17.15.6 Absence of dishonest or selfish motive
  - 17.15.7 Timely good faith effort to rectify consequences of misconduct
  - 17.15.8 Interim rehabilitation
  - 17.15.9 Remoteness of prior offenses
  - 17.15.10 Length of time that has elapsed since misconduct
  - 17.15.11 Inadvertent
  - 17.15.12 Consent of patient
  - 17.15.13 No apparent vulnerability of patient
  - 17.15.14 No significant injury caused by misconduct
  - 17.15.15 No significant potential for injury ensuing from act
  - 17.15.16 No evidence of motivation of criminal; dishonest or personal gain
  - 17.15.17 Mental or physical health; weak health; cancer
  - 17.15.18 Personal circumstances
  - 17.15.19 Present fitness of the practitioner
  - 17.15.20 Potential for successful rehabilitation
  - 17.15.21 Practitioner's present competence in medical skills
  - 17.15.22 Personal problems (if there is a connection to violation)
  - 17.15.23 Emotional problems (If there is a connection to violation)
  - 17.15.24 Isolated incident unlikely to reoccur
  - 17.15.25 Public's perception of protection
- 17.16 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.

## **18.0 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](http://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 may be applicable to prescribing controlled substances for 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.

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

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

- 18.1.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain,
- 18.1.1.2 underlying or coexisting diseases or conditions,

- 18.1.1.3 the effect of the pain on physical and psychological function, and history of substance abuse,
- 18.1.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.
- 18.2 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.
- 18.3 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.
- 18.4 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:
  - 18.4.1 urine/serum medication levels screening when requested;
  - 18.4.2 number and frequency of all prescription refills; and
  - 18.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement).
  - 18.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.
- 18.5 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:
  - 18.5.1 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.
  - 18.5.2 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.
  - 18.5.3 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.
- 18.6 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,
- 18.7 Medical Records- The practitioner shall keep accurate and complete records. The entire record must, include the:
  - 18.7.1 medical history and physical examination,
  - 18.7.2 diagnostic, therapeutic and laboratory results,
  - 18.7.3 evaluations and consultations,
  - 18.7.4 documentation of etiology;
  - 18.7.5 treatment objectives,
  - 18.7.6 discussion of risks and benefits,
  - 18.7.7 informed consent,
  - 18.7.8 treatments,
  - 18.7.9 medications (including date, type, dosage and quantity prescribed),
  - 18.7.10 instructions and agreements, and
  - 18.7.11 periodic review.
- 18.8 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:
  - 18.8.1 interim history and physical examination,
  - 18.8.2 vital signs as clinically appropriate,
  - 18.8.3 assessment of progress, and

#### 18.8.4 medication plan.

18.9 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.

18.10 The following terms are defined as follows:

18.10.1 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.

18.10.2 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.

18.10.3 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.

18.10.4 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).

18.10.5 Pain- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

18.10.6 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.

18.10.7 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.

18.10.8 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.

18.10.9 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.

16 DE Reg. 1085 (04/01/13)

18 DE Reg. 898 (05/01/15)

#### **19.0 Telemedicine**

19.1 A remote, audio-only examination is not an "appropriate in-person examination" as that term is used in 24 Del.C. §1769D(h)(1).

19.2 A remote, audio-only interaction does not meet the standards of establishing a patient-physician relationship pursuant to 24 Del.C. §1769D(h)(4).

19.3 No opioid prescribing is permitted via telemedicine with the exception of addiction treatment programs offering medication assisted treatment that have received a Division of Substance Abuse and Mental Health (DSAMH) waiver to use telemedicine through DSAMH's licensure or renewal process as outlined in 16 DE Admin. Code 6001 Substance Abuse Facility Licensing Standards Sec. 4.15. All other controlled substance prescribing utilizing telemedicine is held to the same standards of care and requisite practice as prescribing for in-person visits.

19.4 For diagnosis using audio and visual communications, the audio and visual communications must be live, real-time communications.

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

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

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

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

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

16 DE Reg. 1085 (04/01/13)

18 DE Reg. 898 (05/01/15)

