SENATE, No. 2735

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED JUNE 18, 2018

Sponsored by:
Senator TROY SINGLETON
District 7 (Burlington)
Senator KRISTIN M. CORRADO
District 40 (Bergen, Essex, Morris and Passaic)

SYNOPSIS

Requires licensure of pain management clinics, establishes process to identify abnormal drug usage and prescribing practices, modifies requirements for opioid prescriptions and medication-assisted treatment, authorizes use of non-opioid advance directives, and addresses liability.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 6/19/2018)

AN ACT concerning opioid prescribing and pain management, supplementing Titles 24 and 26 of the Revised Statutes, and amending various parts of the statutory law.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. (New section) As used in sections 1 through 3 of P.L. , c. (C.) (pending before the Legislature as this bill):

"Chronic pain" means pain that persists or recurs for more than three months.

"Commissioner" means the Commissioner of Health.

"Department" means the Department of Health.

"Owner" means any person, partnership, association, or corporation listed as the owner of a pain management clinic on a licensing application submitted pursuant to section 2 of P.L. , c. (C.) (pending before the Legislature as this bill).

"Pain management clinic" means a privately-owned clinic, facility, or office, in which at least 50 percent of the patients seen by practitioners in any month are prescribed or dispensed Schedule II controlled dangerous substances for the treatment of chronic pain resulting from non-terminal conditions.

2. (New section) a. A pain management clinic shall not operate in this State, unless it possesses a valid license issued by the Department of Health pursuant to sections 1 through 3 of P.L. , c. (C.) (pending before the Legislature as this bill). No entity, and no owner or employee thereof, shall represent to the public that the entity is a pain management clinic, unless the entity is licensed to operate as a pain management clinic, as required by this section.

b. Application for a pain management clinic license shall be made in the form and manner prescribed by the department. The department shall charge such nonrefundable fees for the filing of a license application, and for any renewal thereof, as it shall establish by regulation, except that the amount of each such fee shall not exceed $2,000. An application filed under this subsection shall identify the proposed name of the pain management clinic and include any other information required by the department.

c. A pain management clinic shall not be subject to the certificate of need requirements that are ordinarily applicable to health care facilities under P.L.1971, c.136 (C.26:2H-1 et al.).

3. (New section) a. The Commissioner of Health shall adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to effectuate the

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

purposes of sections 1 through 3 of P.L. , c. (C.) (pending before the Legislature as this bill).

b. The rules and regulations adopted pursuant to this section shall identify, at a minimum:

(1) the criteria that will be used to identify a facility as a pain management clinic;

(2) the process that is to be followed by applicants seeking a pain management clinic license;

(3) the qualifications, supervision, and training requirements applicable to licensed and nonlicensed clinic personnel, and the standards and procedures that are to be followed by a clinic owner in providing supervision, direction, or control over individuals who are employed by, or associated with, the pain management clinic;

(4) the types of drugs, including muscle relaxers and opioid drugs, that may be used by practitioners at a pain management clinic to treat patients with chronic pain;

(5) requirements governing the management, operation, staffing, and equipping of pain management clinics;

(6) requirements governing the provision and coordination of patient care, and the development of a written plan of care for each patient;

(7) infection control procedures and protocols;

(8) procedures and protocols to prevent the diversion of drugs by patients, practitioners, and other employees of a pain management clinic, and to ensure the proper usage of drugs by patients;

(9) data collection, recordkeeping, and reporting requirements; and

(10) procedures and protocols that will be used to ensure that a pain management clinic is providing adequate care and treatment to, and is operating in the best interests of, its patients, including, at a minimum, procedures and protocols for the departmental inspection of pain management clinics, and for the regular review of clinic service utilization and quality of care.

4. As used in sections 5 through 10 of P.L. , c. (C.) (pending before the Legislature as this bill):

"Accepted guideline" means a care or practice guideline for pain management, which has been developed by a nationally recognized clinical or professional association, or by a specialty society or government-sponsored agency that develops guidelines based on original research or the review of existing research or expert opinions; or a policy or position statement on pain management, which is issued by any State professional licensing board having jurisdiction over health care practitioners. "Accepted guideline" does not include any guideline that is established primarily for purposes of payment, insurance coverage, or reimbursement, and which limits treatment options.

"Advisory committee" means the Advisory Committee on Drug Usage and Prescribing, established pursuant to section 9 of P.L. , c. (C.) (pending before the Legislature as this bill).

"Controlled dangerous substance" means the same as that term is defined by section 2 of P.L.1970, c.226 (C.24:21-2).

"Medical emergency" means an acute injury or illness that poses an immediate threat to the patient's life or long-term health.

"Practitioner" means a licensed physician, physician assistant, advanced practice nurse, pharmacist, or other person who is authorized to engage in the prescription, administration, or dispensing of controlled dangerous substances to patients as part of the person's authorized scope of professional practice.

"Review committee" means the Drug Usage and Prescribing Practices Review Committee established pursuant to section 10 of P.L. , c. (C.) (pending before the Legislature as this bill).

5. (New Section) a. A patient may execute an advance directive for nonopioid treatment at any time. The Commissioner of Health shall establish a nonopioid treatment advance directive form, which shall be made available on the Department of Health website. The form may be used by a patient to indicate to a practitioner that the patient does not wish to be administered or offered a prescription or medication order for any opioid drug. A patient who elects to execute a nonopioid advanced directive form shall sign the form and file it with the person's primary or attending physician, who shall include the form in the patient's medical record and note the existence of the form in the patient's prescription monitoring information, pursuant to the process established under paragraph (4) of subsection o. of section 26 of P.L.2007, c.244 (C.45:1-46). Any nonopioid treatment advance directive form that is filed by a patient, pursuant to this section, shall be transferred with the patient whenever the patient is transferred from one practitioner to another, or from one health care facility to another.

b. A patient may revoke, at any time, and through either written or oral means, any nonopioid advance directive that has been filed thereby pursuant to this section. The patient's primary or attending physician, upon receipt of the patient's request for revocation, shall ensure that the advanced directive form, earlier filed by the patient, is immediately removed from the patient's medical record, and that the associated notation in the patient's prescription monitoring information is promptly deleted.

c. A practitioner who does not have actual knowledge of a nonopioid advanced directive filed pursuant to this section, and who prescribes or administers an opioid to the patient in a medical emergency, shall not be subject to criminal or civil liability, or professional disciplinary action, for failing to act in accordance

with the directive, unless the act or omission was the result of the practitioner's gross negligence or willful misconduct.

6. (New section) a. A practitioner acting within the scope of his or her authorized practice shall not be subject to any criminal or civil liability, or any professional disciplinary action, for prescribing, administering, or dispensing a Schedule II controlled dangerous substance or opioid drug for the purpose of alleviating or controlling a patient's pain, provided that the following conditions are satisfied:

(1) in the case of a dying patient, the practitioner acts in accordance with an accepted guideline in the discharge of a professional obligation to relieve the dying patient's pain and promote the dying patient's dignity and autonomy;

(2) in the case of a patient who is experiencing pain, but who is not dying, the practitioner acts in substantial compliance with an accepted guideline in the discharge of a professional obligation to relieve the patient's pain; and

(3) if the practitioner is an advanced practice nurse, a physician assistant, or a pharmacist, the practitioner is operating pursuant to a standing protocol or direct order of a physician.

b. For the purposes of paragraph (2) of subsection a. of this section, evidence of substantial compliance with an accepted guideline may only be rebutted by the testimony of a clinical expert. Absent such expert testimony, evidence that a practitioner has failed to fully conform to an accepted guideline in the treatment of a non-terminal patient shall not be sufficient to support any criminal, civil, or professional disciplinary action against the practitioner.

c. A practitioner shall not be subject to criminal or civil liability, or professional disciplinary action, for declining to prescribe or dispense, or for declining to continue to prescribe or dispense, any controlled dangerous substance to a patient, if the practitioner believes, in the exercise of reasonably prudent judgment, that the patient is misusing or unlawfully diverting the controlled dangerous substance.

d. Nothing in the provisions of this section, or in any other law or regulation, shall be deemed to immunize a practitioner from criminal or civil liability, or from professional disciplinary action, if the practitioner prescribes, administers, or dispenses a Schedule II controlled dangerous substance or opioid drug in violation of the provisions of section 11 of P.L.2017, c.28 (C.24:21-15.2) or any other applicable law or regulation.

7. (New section) a. A practitioner has the right to exercise his or her professional judgment to decline to prescribe, administer, or dispense a Schedule II controlled dangerous substance or opioid drug without being subject to actual or threatened acts of reprisal.

b. No person shall engage in, hire or conspire with others to engage in, or aid, abet, incite, compel, or coerce any person to engage in, any action, the purpose of which is to punish, embarrass, deny or reduce the privileges or compensation of, or cause economic loss to, a practitioner, either as a result of, or in retaliation for, the practitioner's refusal to prescribe, administer, or dispense Schedule II controlled dangerous substances or opioid drugs.

c. Any person who violates the provisions of this section shall be subject to a private right of action by the affected practitioner, and shall be liable to pay an amount that is three times the economic loss that was sustained by the practitioner as a direct and proximate result of the violation. Any practitioner who prevails in an action brought under this subsection shall also be entitled to an award of attorneys' fees and court costs.

8. (New section) The commissioner shall provide written notice to all practitioners in the State who are authorized to engage in medication-assisted treatment for opioid dependence, within 60 days after an abuse deterrent version or practitioner-administered form of buprenorphine or other medication-assisted treatment is approved by the federal Food and Drug Administration. Upon receipt of such notice, a practitioner may elect to advise any patients who are undergoing medication-assisted treatment with the drug named in the notice to switch to the abuse deterrent version or practitioner-administered form of the drug.

9. (New section) a. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety shall establish an Advisory Committee on Drug Usage and Prescribing, which shall be responsible for developing, recommending, and implementing parameters to be used in identifying abnormal or unusual controlled dangerous substance usage, prescribing, and dispensing practices in the State.

b. The advisory committee shall consist of the following members: (1) a licensed physician board certified in pain management or a related field, and recommended by the State Medical Association; (2) a licensed physician board certified in medical oncology and recommended by the State Medical Association; (3) a licensed physician board certified in palliative care and recommended by the Home Care & Hospice Association of New Jersey; (4) a licensed physician who is a member of, and is recommended by, the New Jersey Academy of Family Physicians; (5) a licensed pharmacist; (6) a licensed dentist; (7) an expert in matters of drug diversion; and (8) any other members that the Board of Pharmacy may deem to be appropriate.

c. The advisory committee shall:

(1) Establish parameters to identify abnormal or unusual controlled dangerous substance usage patterns of patients;

(2) Establish parameters to identify abnormal or unusual controlled dangerous substance prescribing and dispensing practices of practitioners;

(3) Identify and recommend training, research, or other activities and opportunities that have the potential to reduce or eliminate instances of inappropriate controlled dangerous substance usage, prescribing, and dispensing;

(4) Study the diversion of controlled dangerous substances, and make recommendations to prevent and address drug diversion, particularly in relation to Schedule II controlled dangerous substances that are prescribed for the treatment of pain, and the management of opioid addiction;

(5) Establish educational and outreach programs for health care facilities, pharmacies, practitioners, law enforcement, and other relevant parties, which programs shall provide education and advice to such entities and practitioners on the issue of controlled dangerous substance diversion, and the practices and protocols that are recommended to prevent and respond to instances of diversion.

d. The Division of Consumer Affairs shall provide administrative support to the advisory committee.

10. (New section) a. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety shall establish a Drug Usage and Prescribing Practices Review Committee to review controlled dangerous substance usage, prescribing, and dispensing practices in the State and identify abnormal or unusual patterns, in this regard.

b. The review committee shall consist of the following members: (1) two prosecuting attorneys, each from a different county in New Jersey; (2) two licensed physicians who specialize in care that requires the extensive use of controlled dangerous substances, and who are recommended by the State Medical Association and (3) a licensed pharmacist who is trained in the use and abuse of controlled dangerous substances, and who is recommended by the Board of Pharmacy.

c. The review committee, working independently, shall query the Prescription Monitoring Program database, established pursuant to section 25 of P.L.2007, c.244 (C.45:1-45), based on the parameters that have been established by the Advisory Committee on Drug Usage and Prescribing, pursuant to section 9 of P.L. , c. (C.) (pending before the Legislature as this bill). Using those parameters, the review committee shall determine whether any abnormal or unusual usage, prescribing, or dispensing patterns are evident from the data. If the review committee has reasonable cause to believe that abnormal or unusual practices are occurring in any given case, the review committee shall, as deemed to be

appropriate, document its findings and refer the case to law enforcement, or to the appropriate professional licensing board having jurisdiction over the relevant practitioners, or both.

d. (1) Whenever a professional licensing board receives a case referral under subsection c. of this section, indicating that a practitioner under its jurisdiction has engaged in abnormal or unusual prescribing or dispensing practices, the licensing board shall notify the practitioner of the case referral and take appropriate action, including, but not limited to, initiating an investigation or disciplinary action based upon the findings of the review committee.

(2) Within 30 days after the resolution of any action undertaken pursuant to this subsection, the licensing board shall report back to the review committee, indicating the actions that have been undertaken in response to the case referral, and providing its findings on the case.

(3) Nothing in this subsection shall be deemed to prohibit a professional licensing board from initiating an investigation into the prescribing or dispensing practices of a practitioner under its jurisdiction, or from initiating disciplinary action against a practitioner for unusual or abnormal prescribing or dispensing patterns, based on information that is received from sources other than the review committee.

e. (1) The review committee shall submit a quarterly report to the Commissioner of Health, and to the Director of the Division of Consumer Affairs in the Department of Law and Public Safety, describing its findings and recommendations on the issue of abnormal or unusual drug usage, prescribing, and dispensing, as provided in this subsection. Upon receipt of each quarterly report, the Division of Consumer Affairs shall ensure that copies of the report are promptly made available to each professional licensing board having jurisdiction over practitioners in the State.

(2) Each report filed pursuant to this subsection shall: (a) contain aggregated, de-identified information on the unusual or abnormal usage, prescribing, or dispensing practices that the review committee has identified during the reporting period; (b) include specific reference to the ways in which the identified practices exceed, or have failed to comply with, the parameters identified by the advisory committee, pursuant to section 9 of P.L. , c. (C.) (pending before the Legislature as this bill); (c) indicate the number of cases that were referred, during the reporting period, to law enforcement or a professional licensing board for resolution, pursuant to subsection c. of this section; (d) summarize the disciplinary actions that were undertaken by professional licensing boards in response to such case referrals, to the extent such information has been reported pursuant to subsection d. of this section; (e) identify trends in the data, and evaluate changes that have occurred since previous reports were filed; and (f) provide

recommendations and strategies for reducing or eliminating incidences of abnormal or unusual controlled substance usage, prescribing, and dispensing in the State.

(3) Any reports filed under this subsection shall be maintained by the review committee for a period of five years after the date of filing.

f. Based on the reports that are filed pursuant to subsection e. of this section, the Department of Health and each appropriate professional licensing board shall communicate with practitioners about the strategies that should be used in the future to more effectively manage patient medications, as recommended by the review committee.

g. The Division of Consumer Affairs in the Department of Law and Public Safety shall provide administrative support to the review committee, and shall establish procedures and protocols to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted, and maintained by the review committee is not disclosed, except as authorized by this section.

11. Section 11 of P.L.2017, c.28 (C.24:21-15.2) is amended to read as follows:

11. a. A practitioner shall not issue an initial prescription for an opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a quantity exceeding a five-day supply for treatment of acute pain. Any prescription for acute pain pursuant to this subsection shall be for the lowest effective dose of immediate-release opioid drug.

b. Prior to issuing an initial prescription of a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a course of treatment for acute or chronic pain, a practitioner shall:

(1) take and document the results of a thorough medical history, including the patient's experience with non-opioid medication and non-pharmacological pain management approaches and substance abuse history;

(2) conduct, as appropriate, and document the results of a physical examination;

(3) develop a treatment plan, with particular attention focused on determining the cause of the patient's pain;

(4) access relevant prescription monitoring information under the Prescription Monitoring Program pursuant to section 8 of P.L.2015, c.74 (C. 45:1-46.1); and

(5) limit the supply of any opioid drug prescribed for acute pain to a duration of no more than five days as determined by the directed dosage and frequency of dosage.

c. No less than four days after issuing the initial prescription pursuant to subsection a. of this subsection, the practitioner, after

consultation with the patient, may issue a subsequent prescription for the drug to the patient in any quantity that complies with applicable State and federal laws, provided that:

(1) the subsequent prescription would not be deemed an initial prescription under this section;

(2) the practitioner determines the prescription is necessary and appropriate to the patient's treatment needs and documents the rationale for the issuance of the subsequent prescription; and

(3) the practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination.

d. Prior to issuing the initial prescription of a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a course of treatment for acute pain, and prior to issuing a prescription at the outset of a course of treatment for chronic pain, a practitioner shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to:

(1) the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;

(2) the reasons why the prescription is necessary;

(3) alternative treatments that may be available; and

(4) risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines or alcohol with opioids, can result in fatal respiratory depression.

The practitioner shall also indicate to the patient the quantity of the opioid drug that is being prescribed, and advise the patient that the patient may ask the dispenser to fill the prescription in a lesser amount.

The practitioner shall include a note in the patient's medical record that the patient or the patient's parent or guardian, as applicable, has discussed with the practitioner the risks of developing a physical or psychological dependence on the controlled dangerous substance and alternative treatments that may be available. The Division of Consumer Affairs shall develop and make available to practitioners guidelines for the discussion required pursuant to this subsection.

e. Prior to the commencement of an ongoing course of treatment for chronic pain with a Schedule II controlled dangerous substance or any opioid, the practitioner shall consider referring the patient to a pain management clinic or pain management specialist,

and discuss with the patient the benefits of receiving treatment from a pain management clinic or pain management specialist, as well as the risks that may be associated with the patient's failure to seek such specialized pain treatment. If no referral to a pain management clinic or pain management specialist is made, and the patient elects to remain under the practitioner's care for the purposes of ongoing pain management, the practitioner shall note this fact in the patient's medical record, and shall enter into a pain management agreement with the patient before commencing any ongoing course of treatment with any Schedule II controlled dangerous substance or opioid drug. As part of the pain management agreement, the patient shall agree to: (1) only obtain prescriptions for Schedule II controlled dangerous substances or opioid medications from the practitioner named in the agreement; (2) only fill those prescriptions at the pharmacy named in the agreement; and (3) notify the practitioner named in the agreement within 72 hours after the patient receives any emergency treatment involving the administration of a Schedule II controlled dangerous substance or opioid medication.

f. When a Schedule II controlled dangerous substance or any other prescription opioid drug is continuously prescribed for three months or more for chronic pain, the practitioner shall:

(1) review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document the results of that review;

(2) assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment;

(3) periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence and document with specificity the efforts undertaken;

(4) review the Prescription Drug Monitoring information in accordance with section 8 of P.L.2015, c.74 (C. 45:1-46.1); and

(5) monitor compliance with the pain management agreement and any recommendations that the patient seek a referral.

g. As used in this section:

"Acute pain" means pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. "Acute pain" does not include chronic pain, pain being treated as part of cancer care, hospice or other end of life care, or pain being treated as part of palliative care.

"Chronic pain" means pain that persists or recurs for more than three months.

"Initial prescription" means a prescription issued to a patient who:

(1) has never previously been issued a prescription for the drug or its pharmaceutical equivalent; or

(2) was previously issued a prescription for, or used or was administered the drug or its pharmaceutical equivalent, but the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent.

When determining whether a patient was previously issued a prescription for, or used or was administered a drug or its pharmaceutical equivalent, the practitioner shall consult with the patient and review the patient's medical record and prescription monitoring information.

"Pain management agreement" means a written contract or agreement that is executed between a practitioner and a patient, prior to the commencement of treatment for chronic pain using a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41), as a means to:

(1) prevent the possible development of physical or psychological dependence in the patient;

(2) document the understanding of both the practitioner and the patient regarding the patient's pain management plan;

(3) establish the patient's rights in association with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of Schedule II controlled dangerous substances, including any restrictions on the refill of prescriptions or the acceptance of Schedule II prescriptions from practitioners;

(4) identify the specific medications and other modes of treatment, including physical therapy or exercise, relaxation, or psychological counseling, that are included as a part of the pain management plan;

(5) specify the measures the practitioner may employ to monitor the patient's compliance, including but not limited to random specimen screens and pill counts; and

(6) delineate the process for terminating the agreement, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement.

<u>“Pain management specialist” means a licensed physician who is board certified in pain management or a related field.</u>

"Practitioner" means a medical doctor, doctor of osteopathy, dentist, optometrist, podiatrist, physician assistant, certified nurse midwife, or advanced practice nurse, acting within the scope of

practice of their professional license pursuant to Title 45 of the Revised Statutes.

h. This section shall not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

i. Every policy, contract or plan delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, and every contract purchased by the School Employees' Health Benefits Commission or State Health Benefits Commission, on or after the effective date of this act, that provides coverage for prescription drugs subject to a co-payment, coinsurance or deductible shall charge a co-payment, coinsurance or deductible for an initial prescription of an opioid drug prescribed pursuant to this section that is either:

(1) proportional between the cost sharing for a 30-day supply and the amount of drugs the patient was prescribed; or

(2) equivalent to the cost sharing for a full 30-day supply of the opioid drug, provided that no additional cost sharing may be charged for any additional prescriptions for the remainder of the 30-day supply.

(cf: P.L.2017, c.341, s.1)

12. Section 5 of P.L.1970, c.334 (C.26:2G-25) is amended to read as follows:

5. a. The commissioner shall adopt, amend, promulgate and enforce such rules, regulations and minimum standards for the treatment of patients of narcotic and substance use disorder treatment centers as may be reasonably necessary to accomplish the purposes of P.L.1970, c.334 (C.26:2G-21 et seq.). Such narcotic and substance use disorder treatment centers may be classified into two or more classes with appropriate rules, regulations and minimum standards for each such class. No narcotic or drug abuse treatment center, transitional sober living home, halfway house, or other residential aftercare facility shall be permitted to deny admission to a prospective client on the basis that the person is currently receiving medication assisted treatment for a substance use disorder administered by a licensed treatment provider, including but not limited to methadone, buprenorphine, naltrexone, or any other medication approved by the Food and Drug Administration for the treatment of a substance use disorder.

b. The rules and regulations adopted pursuant to this section shall, at a minimum:

(1) require a transitional sober living home, halfway house, or other residential aftercare facility to provide notice to a patient's

spouse, parent, legal guardian, designated next of kin, or other designated emergency contact, whenever the patient voluntarily withdraws, or is involuntarily evicted from, such facility, provided that: (1) such notice is provided in a manner that is consistent with federal requirements under 42 CFR Part 2 and federal HIPAA requirements under 45 CFR Parts 160 and 164; and (2) the patient, if an adult, has not withheld consent for such notice or expressly requested that notification not be given. If a patient who is not incapacitated withholds consent for such notice, or expressly requests that notification not be given, the department shall require the patient's wishes to be respected unless the patient is a minor child or adolescent, in which case, the department shall require the minor's parent, legal guardian, designated next of kin, or other designated emergency contact to be notified, provided that such notification is not inconsistent with, and would not violate, federal requirements under 42 CFR Part 2 and federal HIPAA requirements under 45 CFR Parts 160 and 164; and

(2) require an opioid treatment program to: (a) display the entity's current license in a prominent location, and in the view of patients, in the area where services are provided; (b) ensure that prescribers in the program exercise control over, and maintain the security of, their prescription blanks and any other method used for prescribing medication, and provide written notice to the commissioner and appropriate law enforcement agencies within 24 hours after any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment; (c) maintain a record of each patient's medical history, substance use disorder diagnosis, plan of treatment, response to treatment, the date on which any medications were prescribed or administered, the name of the prescriber, and the dosage amount of each prescribed or administered drug; and (c) require prescribers in the program, when prescribing more than 16 milligrams of buprenorphine to a single patient, to note the clinical reason for the dosage in the patient's medical record, and, when prescribing any amount of buprenorphine to a female patient, to consult with the patient's obstetrical or gynecological provider in determining the appropriate dosage amount.

(cf: P.L.2017, c.256, s.1)

13. Section 2 of P.L.1971, c.136 (C.26:2H-2) is amended to read as follows:

2. The following words or phrases, as used in this act, shall have the following meanings, unless the context otherwise requires:

a. "Health care facility" means the facility or institution, whether public or private, that is engaged principally in providing services for health maintenance organizations, diagnosis, or treatment of human disease, pain, injury, deformity, or physical condition, including, but not limited to, a general hospital, special

hospital, mental hospital, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, pain management clinic, dispensary, home health care agency, residential health care facility, dementia care home, and bioanalytical laboratory (except as specifically excluded hereunder), or central services facility serving one or more such institutions but excluding institutions that provide healing solely by prayer and excluding such bioanalytical laboratories as are independently owned and operated, and are not owned, operated, managed, or controlled, in whole or in part, directly or indirectly by any one or more health care facilities, and the predominant source of business of which is not by contract with health care facilities within the State of New Jersey and which solicit or accept specimens and operate predominantly in interstate commerce.

b. "Health care service" means the preadmission, outpatient, inpatient, and postdischarge care provided in or by a health care facility, and such other items or services as are necessary for such care, which are provided by or under the supervision of a physician for the purpose of health maintenance organizations, diagnosis, or treatment of human disease, pain, injury, disability, deformity, or physical condition, including, but not limited to, nursing service, home care nursing, and other paramedical service, ambulance service, service provided by an intern, resident in training or physician whose compensation is provided through agreement with a health care facility, laboratory service, medical social service, drugs, biologicals, supplies, appliances, equipment, bed and board, but excluding services provided by a physician in his private practice, except as provided in sections 7 and 12 of P.L.1971, c.136 (C.26:2H-7 and C.26:2H-12), or by practitioners of healing solely by prayer, and services provided by first aid, rescue and ambulance squads as defined in the "New Jersey Highway Traffic Safety Act of 1987," P.L.1987, c.284 (C.27:5F-18 et seq.).

c. "Construction" means the erection, building, or substantial acquisition, alteration, reconstruction, improvement, renovation, extension, or modification of a health care facility, including its equipment, the inspection and supervision thereof; and the studies, surveys, designs, plans, working drawings, specifications, procedures, and other actions necessary thereto.

d. "Board" means the Health Care Administration Board established pursuant to this act.

e. (Deleted by amendment, P.L.1998, c.43).

f. "Government agency" means a department, board, bureau, division, office, agency, public benefit, or other corporation, or any other unit, however described, of the State or political subdivision thereof.

g. (Deleted by amendment, P.L.1991, c.187).

h. (Deleted by amendment, P.L.1991, c.187).

i. "Department" means the Department of Health.

j. "Commissioner" means the Commissioner of Health.

k. "Preliminary cost base" means that proportion of a hospital's current cost which may reasonably be required to be reimbursed to a properly utilized hospital for the efficient and effective delivery of appropriate and necessary health care services of high quality required by such hospital's mix of patients. The preliminary cost base initially may include costs identified by the commissioner and approved or adjusted by the commission as being in excess of that proportion of a hospital's current costs identified above, which excess costs shall be eliminated in a timely and reasonable manner prior to certification of the revenue base. The preliminary cost base shall be established in accordance with regulations proposed by the commissioner and approved by the board.

l. (Deleted by amendment, P.L.1992, c.160).

m. "Provider of health care" means an individual (1) who is a direct provider of health care service in that the individual's primary activity is the provision of health care services to individuals or the administration of health care facilities in which such care is provided and, when required by State law, the individual has received professional training in the provision of such services or in such administration and is licensed or certified for such provision or administration; or (2) who is an indirect provider of health care in that the individual (a) holds a fiduciary position with, or has a fiduciary interest in, any entity described in subparagraph b(ii) or subparagraph b(iv); provided, however, that a member of the governing body of a county or any elected official shall not be deemed to be a provider of health care unless he is a member of the board of trustees of a health care facility or a member of a board, committee or body with authority similar to that of a board of trustees, or unless he participates in the direct administration of a health care facility; or (b) received, either directly or through his spouse, more than one-tenth of his gross annual income for any one or more of the following:

(i) Fees or other compensation for research into or instruction in the provision of health care services;

(ii) Entities engaged in the provision of health care services or in research or instruction in the provision of health care services;

(iii) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research into or instruction in the provision of health care services;

(iv) Entities engaged in producing drugs or such other articles.

n. "Private long-term health care facility" means a nursing home, skilled nursing home, or intermediate care facility presently in operation and licensed as such prior to the adoption of the 1967 Life Safety Code by the Department of Health in 1972 and which

has a maximum 50-bed capacity and which does not accommodate Medicare or Medicaid patients.

o. (Deleted by amendment, P.L.1998, c.43).

p. "State Health Planning Board" means the board established pursuant to section 33 of P.L.1991, c.187 (C.26:2H-5.7) to conduct certificate of need review activities.

q. "Integrated health care" means the systematic coordination of general and behavioral healthcare. This care may address mental illnesses, substance use disorders, health behaviors including their contributions to chronic medical illnesses, life stressors and crises, stress-related physical symptoms, and ineffective patterns of health care utilization.

(cf: P.L.2017, c.294, s.2)

14. Section 8 of P.L.1978, c.73 (C.45:1-21) is amended to read as follows:

8. A board may refuse to admit a person to an examination, or may refuse to issue, or may suspend or revoke, any certificate, registration or license issued by the board, upon proof that the applicant or holder of such certificate, registration, or license:

a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or misrepresentation;

b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise, or false pretense;

c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety, or property of any person;

d. Has engaged in repeated acts of negligence, malpractice, or incompetence;

e. Has engaged in professional or occupational misconduct as may be determined by the board;

f. Has been convicted of, or engaged in acts constituting, any crime or offense involving moral turpitude or relating adversely to the activity regulated by the board. For the purpose of this subsection a judgment of conviction or a plea of guilty, non vult, nolo contendere, or any other such disposition of alleged criminal activity shall be deemed a conviction;

g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, agency, or authority for reasons consistent with this section;

h. Has violated or failed to comply with the provisions of any act or regulation administered by the board;

i. Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety, and welfare;

j. Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with, such

applications, as required [to be filed with] by the Department of Environmental Protection;

k. Has violated any provision of P.L.1983, c.320 (C.17:33A-1 et seq.) or any insurance fraud prevention law or act of another jurisdiction, or has been adjudicated, in civil or administrative proceedings, of a violation of P.L.1983, c.320 (C.17:33A-1 et seq.), or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under that act against the applicant or holder;

l. Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subsection, the term "presently" means at this time or any time within the previous 365 days;

m. Has engaged in abnormal or unusual controlled dangerous substance prescribing or dispensing practices, as indicated by a report of, or a case referral from, the Drug Usage and Prescription Practices Review Committee established pursuant to section 10 of P.L. , c. (C.) (pending before the Legislature as this bill), or has otherwise prescribed or dispensed controlled dangerous substances indiscriminately [or], without good cause, or in any case where the applicant or holder knew or should have known that the substances were to be used for unauthorized consumption or distribution;

n. Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the board, or has aided and abetted an unlicensed person or entity in performing such an act;

o. [Advertised] Has advertised fraudulently in any manner.

The division is authorized, for purposes of facilitating determinations concerning licensure eligibility, to require the fingerprinting of each applicant in accordance with applicable State and federal laws, rules, and regulations. Each applicant shall submit the applicant's name, address, and written consent to the director for a criminal history record background check to be performed. The division is authorized to receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation. Upon receipt of such notification, the division shall forward the information to the appropriate board, which shall make a determination regarding the issuance of licensure. The applicant shall bear the cost for the criminal history record background check, including all costs of administering and processing the check, unless otherwise provided for by an individual enabling act. The Division of State Police shall promptly notify the division in the event an applicant or licensee, who was the subject of a criminal history record background check pursuant to this section, is convicted of a crime or offense in this State after the date the background check was performed.

For purposes of this act:

"Completed application" means the submission of all of the information designated on the checklist, adopted pursuant to section 1 of P.L.1991, c.421 (C.13:1D-101), for the class or category of permit for which application is made.

"Permit" has the same meaning as defined in section 1 of P.L.1991, c.421 (C.13:1D-101).

(cf: P.L.2003, c.199, s.31)

15. Section 26 of P.L.2007, c.244 (C.45:1-46) is amended to read as follows:

26. Access to prescription information.

a. The division shall maintain procedures to ensure patient privacy and confidentiality **[**of patients**]**, and to ensure that any patient information collected, recorded, transmitted, **[**and**]** or maintained is not disclosed, except as permitted in this section **[**, including**]** . Such procedures shall include, but not be limited to, the use of a password-protected system for maintaining this patient information **[**and**]**; the permitting of access thereto as authorized under sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50) **[**,**]** ; and a requirement that a person **[**as**]** listed in subsection h. or i. of this section provide affirmation of the person's intent to comply with the provisions of sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50) as a condition of accessing the information.

b. The prescription monitoring information submitted to the division shall be confidential, and shall not be subject to public disclosure under P.L.1963, c.73 (C.47:1A-1 et seq.), or P.L.2001, c.404 (C.47:1A-5 et al.).

c. The division shall review the prescription monitoring information provided by a pharmacy permit holder pursuant to sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50). The review shall include, but not be limited to:

(1) a review to identify whether any person is obtaining a prescription in a manner that may be indicative of misuse, abuse, or diversion of a controlled dangerous substance. The director shall establish guidelines regarding the terms "misuse," "abuse," and "diversion" for the purposes of this review. When an evaluation of the information indicates that a person may be obtaining a prescription for the same or a similar controlled dangerous substance from multiple practitioners or pharmacists during the same time period, the division may provide prescription monitoring information about the person to practitioners and pharmacists; and

(2) a review to identify whether a violation of law or regulation or a breach of the applicable standards of practice by any person may have occurred, including, but not limited to, diversion of a controlled dangerous substance. If the division determines that

such a violation or breach may have occurred, the division shall notify the appropriate law enforcement agency or professional licensing board, and provide the prescription monitoring information required for an investigation.

d. (Deleted by amendment, P.L.2015, c.74)

e. (Deleted by amendment, P.L.2015, c.74)

f. (Deleted by amendment, P.L.2015, c.74)

g. (Deleted by amendment, P.L.2015, c.74)

h. (1) A practitioner shall register to access prescription monitoring information upon initial application for, or renewal of, the practitioner's CDS registration.

(2) The division shall provide to a pharmacist who is employed by a current pharmacy permit holder online access to prescription monitoring information for the purpose of providing health care to a current patient or verifying information with respect to a patient or a prescriber.

(3) The division shall provide to a practitioner who has a current CDS registration online access to prescription monitoring information for the purpose of providing health care to a current patient or verifying information with respect to a patient or a prescriber. The division shall also grant online access to prescription monitoring information to as many licensed health care professionals as are authorized by a practitioner to access that information and for whom the practitioner is responsible for the use or misuse of that information, subject to a limit on the number of such health care professionals as deemed appropriate by the division for that particular type and size of professional practice, in order to minimize the burden to practitioners to the extent practicable while protecting the confidentiality of the prescription monitoring information obtained. The director shall establish, by regulation, the terms and conditions under which a practitioner may delegate that authorization, including procedures for authorization and termination of authorization, provisions for maintaining confidentiality, and such other matters as the division may deem appropriate.

(4) The division shall provide online access to prescription monitoring information to as many medical or dental residents as are authorized by a faculty member of a medical or dental teaching facility to access that information and for whom the practitioner is responsible for the use or misuse of that information. The director shall establish, by regulation, the terms and conditions under which a faculty member of a medical or dental teaching facility may delegate that authorization, including procedures for authorization and termination of authorization, provisions for maintaining confidentiality, provisions regarding the duration of a medical or dental resident's authorization to access prescription monitoring information, and such other matters as the division may deem appropriate.

(5) (a) The division shall provide online access to prescription monitoring information to :

(i) as many certified medical assistants as are authorized by a practitioner to access that information and for whom the practitioner is responsible for the use or misuse of that information ;

(ii) as many medical scribes working in a hospital's emergency department as are authorized by a practitioner to access that information and for whom the practitioner is responsible for the use or misuse of that information; and

(iii) as many licensed athletic trainers working in a clinical setting as are authorized by a practitioner to access that information and for whom the practitioner is responsible for the use or misuse of that information.

(b) The director shall establish, by regulation, the terms and conditions under which a practitioner may delegate authorization pursuant to subparagraph (a) of this paragraph , including procedures for authorization and termination of authorization, provisions for maintaining confidentiality, provisions regarding the duration of a certified medical assistant's , medical scribe's, or licensed athletic trainer's authorization to access prescription monitoring information, and provisions addressing such other matters as the division may deem appropriate.

(6) The division shall provide online access to prescription monitoring information to as many registered dental assistants as are authorized by a licensed dentist to access that information and for whom the licensed dentist is responsible for the use or misuse of that information. The director shall establish, by regulation, the terms and conditions under which a licensed dentist may delegate that authorization, including procedures for authorization and termination of authorization, provisions for maintaining confidentiality, provisions regarding the duration of a registered dental assistant's authorization to access prescription monitoring information, and such other matters as the division may deem appropriate.

(7) A person listed in this subsection, as a condition of accessing prescription monitoring information pursuant thereto, shall certify that the request is for the purpose of providing health care to a current patient or verifying information with respect to a patient or practitioner. Such certification shall be furnished through means of an online statement or alternate means authorized by the director, in a form and manner prescribed by rule or regulation adopted by the director. If the information is being accessed by an authorized person using an electronic system authorized pursuant to subsection q. of this section, the certification may be furnished through the electronic system.

i. The division may provide online access to prescription monitoring information, or may provide access to prescription

monitoring information through any other means deemed appropriate by the director, to the following persons:

(1) authorized personnel of the division or a vendor or contractor responsible for maintaining the Prescription Monitoring Program;

(2) authorized personnel of the division responsible for administration of the provisions of P.L.1970, c.226 (C.24:21-1 et seq.), and authorized members of the Drug Usage and Prescribing Practices Review Committee responsible for conducting the reviews required by section 10 of P.L. , c. (C.) (pending before the Legislature as this bill);

(3) the State Medical Examiner, a county medical examiner, a deputy or assistant county medical examiner, or a qualified designated assistant thereof, who certifies that the request is for the purpose of investigating a death pursuant to P.L.1967, c.234 (C.52:17B-78 et seq.);

(4) a controlled dangerous substance monitoring program in another state with which the division has established an interoperability agreement, or which participates with the division in a system that facilitates the secure sharing of information between states;

(5) a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, State Board of Nursing, New Jersey State Board of Optometrists, State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this State or another state that regulates the practice of persons who are authorized to prescribe or dispense controlled dangerous substances, as applicable, who certifies that the representative is engaged in a bona fide specific investigation of a designated practitioner or pharmacist whose professional practice was or is regulated by that board;

(6) a State, federal, or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner, pharmacist, or patient. A law enforcement agency that obtains prescription monitoring information shall comply with security protocols established by the director by regulation;

(7) a designated representative of a state Medicaid or other program who certifies that the representative is engaged in a bona fide investigation of a designated practitioner, pharmacist, or patient;

(8) a properly convened grand jury pursuant to a subpoena properly issued for the records; and

(9) a licensed mental health practitioner providing treatment for substance abuse to patients at a residential or outpatient substance abuse treatment center licensed by the Division of Mental Health and Addiction Services in the Department of Human Services, who certifies that the request is for the purpose of providing health care

to a current patient or verifying information with respect to a patient or practitioner, and who furnishes the division with the written consent of the patient for the mental health practitioner to obtain prescription monitoring information about the patient. The director shall establish, by regulation, the terms and conditions under which a mental health practitioner may request and receive prescription monitoring information. Nothing in sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50) shall be construed to require or obligate a mental health practitioner to access or check the prescription monitoring information in the course of treatment beyond that which may be required as part of the mental health practitioner's professional practice.

j. A person listed in subsection i. of this section, as a condition of obtaining prescription monitoring information pursuant thereto, shall certify the reasons for seeking to obtain that information. Such certification shall be furnished through means of an online statement or alternate means authorized by the director, in a form and manner prescribed by rule or regulation adopted by the director.

k. The division shall offer an online tutorial for those persons listed in subsections h. and i. of this section, which shall, at a minimum, include: how to access prescription monitoring information; the rights of persons who are the subject of this information; the responsibilities of persons who access this information; a summary of the other provisions of sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50) and the regulations adopted pursuant thereto, regarding the permitted uses of that information and penalties for violations thereof; and a summary of the requirements of the federal health privacy rule set forth at 45 CFR Parts 160 and 164 and a hypertext link to the federal Department of Health and Human Services website for further information about the specific provisions of the privacy rule.

l. The division may request and receive prescription monitoring information from prescription monitoring programs in other states and may use that information for the purposes of sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50). When sharing data with programs in another state, the division shall not be required to obtain a memorandum of understanding unless required by the other state.

m. The director may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research, or educational purposes, in accordance with the provisions of sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50).

n. Nothing shall be construed to prohibit the division from obtaining unsolicited automated reports from the program or disseminating such reports to pharmacists, practitioners, mental health care practitioners, and other licensed health care professionals.

o. (1) A current patient of a practitioner may request from that practitioner that patient's own prescription monitoring information that has been submitted to the division pursuant to sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50). A parent or legal guardian of a child who is a current patient of a practitioner may request from that practitioner the child's prescription monitoring information that has been submitted to the division pursuant to sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50).

(2) Upon receipt of a request pursuant to paragraph (1) of this subsection, a practitioner or health care professional authorized by that practitioner may provide the current patient or parent or legal guardian, as the case may be, with access to or a copy of the prescription monitoring information pertaining to that patient or child.

(3) The division shall establish a process by which a patient, or the parent or legal guardian of a child who is a patient, may request a pharmacy permit holder that submitted prescription monitoring information concerning a prescription for controlled dangerous substances for that patient or child to the division, pursuant to sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50), to correct information that the person believes to have been inaccurately entered into that patient's or child's prescription profile. Upon confirmation of the inaccuracy of any such entry into a patient's or child's prescription profile, the pharmacy permit holder shall be authorized to correct any such inaccuracies by submitting corrected information to the division pursuant to sections 25 through 30 of P.L.2007, c.244 (C.45:1-45 through C.45:1-50). The process shall provide for review by the Board of Pharmacy of any disputed request for correction, which determination shall be appealable to the director.

(4) The division shall establish a process, pursuant to which a practitioner may make a notation, in a patient’s prescription monitoring information, to indicate that the patient has executed an advance directive for nonopioid treatment, as provided by subsection a. of section 4 of P.L. , c. (C.) (pending before the Legislature as this bill). The division shall also establish a process for prompt removal of the notation whenever the patient revokes such an advance directive, pursuant to subsection b. of section 4 of P.L. , c. (C.) (pending before the Legislature as this bill). The division shall implement an education and outreach program to inform health care practitioners about the processes established pursuant to this paragraph.

p. The division shall take steps to ensure that appropriate channels of communication exist to enable any licensed health care professional, licensed pharmacist, mental health practitioner, pharmacy permit holder, or other practitioner who has online access to the Prescription Monitoring Program pursuant to this section to

seek or provide information to the division related to the provisions of this section.

q. (1) The division may make prescription monitoring information available on electronic systems that collect and display health information, such as an electronic system that connects hospital emergency departments for the purpose of transmitting and obtaining patient health data from multiple sources, or an electronic system that notifies practitioners of information pertaining to the treatment of overdoses; provided that the division determines that any such electronic system has appropriate security protections in place.

(2) Practitioners who are required to access prescription monitoring information pursuant to section 8 of P.L.2015, c.74 (C.45:1-46.1) may discharge that responsibility by accessing one or more authorized electronic systems into which the prescription monitoring information maintained by the division has been integrated.

(cf: P.L.2017, c.341, s.3)

16. The Commissioner of Health, and the Director of the Division of Consumer Affairs in the Department of Law and Public Safety, in consultation with each other, shall adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to implement the provisions of sections 4 through 14 of this act.

17. This act shall take effect immediately.

STATEMENT

This bill would address a number of issues in the realm of opioid-based pain treatment, and the treatment of opioid dependency. Specifically, the bill would: require the licensure of pain management clinics; establish a process, and two committees, to identify and respond to abnormal and unusual drug usage and prescribing patterns in the State; modify certain requirements in association with the prescribing of opioid medications and the provision of medication-assisted treatment; authorize the use of advance directives for nonopioid treatment; and address the liability of, and retributive actions directed against, health care practitioners who are involved in the prescription, administration, or dispensation of opioid medications.

A pain management clinic is defined under the bill as a privately-owned clinic, facility, or office, in which at least 50 percent of the patients seen by practitioners in any month are prescribed or dispensed a Schedule II controlled dangerous substance for the treatment of chronic pain resulting from non-terminal conditions.

The Commissioner of Health would be required to adopt rules and regulations governing the licensure of these clinics, including, but not limited to, rules establishing the license application process, imposing management, operation, and staffing requirements, identifying the types of drugs that may be used by patients of these clinics, providing inspection protocols, and establishing procedures to be used in the inspection of clinics and the evaluation of utilization rates and quality of care. The bill provides that a pain management clinic will not be subject to the certificate of need requirements that are ordinarily applicable to health care facilities under the "Health Care Facilities Planning Act," P.L.1971, c.136 (C.26:2H-1 et al.).

The bill authorizes a patient, at any time, to execute an advance directive for nonopioid treatment, which would notify health care practitioners that the patient does not wish to be prescribed, administered, or dispensed any opioid medications. An advance directive form would need to be: 1) filed by the patient with the patient's primary or attending physician; 2) included in the patient's medical record and noted in the patient's prescription monitoring program (PMP) information; and 3) transferred with the patient whenever the patient is transferred from one practitioner to another, or from one health care facility to another. A patient would be authorized to revoke the advance directive at any time, in which case, the hard-copy form would be removed from the patient's medical record, and the notation on the patient's prescription monitoring information would be deleted. A practitioner who lacks actual knowledge of the existence of an advance directive for nonopioid treatment would not be liable for failing to act in accordance with the directive in a medical emergency, unless the practitioner acts with gross negligence or willful misconduct.

The bill would establish immunity from liability for practitioners who operate, in accordance with their scopes of practice, in prescribing, administering, or dispensing Schedule II controlled dangerous substances or opioid drugs for the purpose of alleviating or controlling pain. Specifically, the bill would provide that a practitioner acting within the scope of his or her authorized practice will not be subject to any criminal or civil liability, or any professional disciplinary action, for prescribing, administering, or dispensing a Schedule II controlled dangerous substance or opioid drug for the purpose of alleviating or controlling a patient's pain, provided that the following conditions are satisfied:

1) in the case of a dying patient, the practitioner acts in accordance with an accepted guideline in the discharge of a professional obligation to relieve the dying patient's pain and promote the dying patient's dignity and autonomy;

2) in the case of a patient who is experiencing pain, but who is not dying, the practitioner acts in substantial compliance with an

accepted guideline in the discharge of a professional obligation to relieve the patient's pain; and

3) if the practitioner is an advanced practice nurse, a physician assistant, or a pharmacist, the practitioner is operating pursuant to a standing protocol or direct order of a physician.

In the case of a non-terminal patient, evidence of substantial compliance with an accepted guideline may only be rebutted by the testimony of a clinical expert. Absent such expert testimony, evidence that a practitioner has failed to fully conform to an accepted guideline in the treatment of a non-terminal patient would not be sufficient to support any criminal, civil, or professional disciplinary action against the practitioner.

The bill would further provide that a practitioner may not be subject to criminal or civil liability, or professional disciplinary action, for declining to prescribe or dispense, or for declining to continue to prescribe or dispense, any controlled dangerous substance to a patient, if the practitioner believes, in the exercise of reasonably prudent judgment, that the patient is misusing or unlawfully diverting the controlled dangerous substance.

The bill would also specify that practitioners have the right to exercise their professional judgment in declining to prescribe, administer, or dispense Schedule II controlled dangerous substances or opioid drugs, without being subject to actual or threatened acts of reprisal. The bill would prohibit any person from engaging in, hiring or conspiring with others to engage in, or aiding, abetting, inciting, compelling, or coercing any other person to engage in, any action, the purpose of which is to punish, embarrass, deny or reduce the privileges or compensation of, or cause economic loss to, a practitioner, either as a result of, or in retaliation for, the practitioner's refusal to prescribe, administer, or dispense such drugs. Any person who violates this prohibition would be subject to a private right of action by the affected practitioner, and may be liable for three times the amount of economic loss suffered by the practitioner as direct and proximate cause of the violation, together with attorneys' fees and court costs.

The bill would impose certain new requirements in association with a practitioner's prescription of an opioid drug for the purposes of pain management. Specifically, under the bill, a practitioner prescribing opioid medication would be required: 1) the first time an opioid is prescribed, to indicate to the patient the quantity of the opioid drug that is being prescribed, and to advise the patient that the prescription may be filled in a lesser amount; and 2) before commencing an ongoing course of opioid treatment for chronic pain, to consider referring the patient to a pain management clinic or pain management specialist, and to discuss, with the patient, the benefits of choosing such option, and the risks associated with failure to choose such option. If a referral for specialized pain treatment is not made, and the patient elects to remain in the

practitioner's care for the purpose of ongoing pain management, the patient must agree, as part of the patient's pain management agreement, to: 1) only obtain prescriptions for Schedule II controlled dangerous substances or opioid medications from the practitioner named in the agreement; 2) only fill those prescriptions at the pharmacy listed in the agreement; and 3) notify the practitioner named in the agreement within 72 hours after the patient receives emergency treatment with Schedule II controlled dangerous substances or opioid drugs.

The bill would also impose certain new requirements in association with the provision of medication-assisted treatment for opioid dependence. Specifically, the bill would require the Commissioner of Health, as part of its general authority over substance use disorder treatment facilities, to adopt certain specific rules and regulations applicable to opioid treatment programs (OTPs). Such rules would require an OTP to: 1) display the entity's license in a prominent location in the service area; 2) ensure that prescribers maintain control over their prescription blanks and other prescribing methods, and provide prompt notice to the commissioner and law enforcement whenever there is a theft or loss of a prescription blank or other breach of a prescribing method; 3) maintain certain patient treatment records; and 4) require practitioners, when prescribing more than 16 milligrams of buprenorphine to a single patient, to note the clinical reasons for the dosage in the patient's medical record, and, when prescribing buprenorphine to a female patient, to consult with the patient's obstetrical or gynecological provider in determining the appropriate dosage amount. The Commissioner of Health would also be required to notify relevant practitioners, within 60 days after an abuse deterrent version or practitioner-administered version of buprenorphine or other medication-assisted treatment becomes available, so that the practitioners may advise their patients to switch to the abuse deterrent or practitioner-administered form of the drug.

Finally, the bill would establish a procedure, pursuant to which the State can identify abnormal or unusual drug usage, prescribing, and dispensing practices taking place in NJ, and appropriately redress such issues. Specifically, the bill would require the Director of the Division of Consumer Affairs in the Department of Law and Public Safety to establish two separate committees – the Advisory Committee on Drug Usage and Prescribing, and the Drug Usage and Prescribing Practices Review Committee – to engage in this work.

The advisory committee would be required to: 1) establish the parameters that are to be used in identifying abnormal or unusual drug usage, prescribing, and dispensing patterns in the State; 2) identify training and research opportunities that can reduce inappropriate CDS usage, prescribing, and dispensing; 3) study drug diversion and develop recommendations to reduce instances of

diversion; and 4) establish educational and outreach programs to provide education and advice to health care facilities and practitioners, as well as law enforcement, on the issue of CDS diversion and the recommended practices and protocols that can be used to prevent and respond to instances of diversion.

The review committee would be responsible for using the parameters identified by the advisory committee to query the State's PMP database, in order to determine whether any abnormal or unusual usage, prescribing, or dispensing patterns are evident from the data. If the review committee has reasonable cause to believe that such practices are occurring in any given case, the review committee would need to document its findings and refer the case to law enforcement or the appropriate professional licensing board, or both. A professional licensing board that receives a case referral from the review committee would be required to take appropriate action, including, but not limited to, initiating an investigation or undertaking disciplinary action against the practitioner, and would need to report back to the review committee within 30 days after the resolution of the case. The review committee would also be required to submit a de-identified report, on a quarterly basis, to the Department of Health and the Division of Consumer Affairs, describing its findings and recommendations on the issue of abnormal or unusual drug usage, prescribing, and dispensing. The Division of Consumer Affairs would be required to promptly forward the report to all relevant professional licensing boards. The bill would require the Department of Health and each relevant professional licensing board to use these reports to communicate with practitioners about the strategies that should be used in the future to more effectively manage patient medications.