

ASSEMBLY, No. 796

STATE OF NEW JERSEY 219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:

Assemblyman ANTHONY S. VERRELLI

District 15 (Hunterdon and Mercer)

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

Introduced Pending Technical Review by Legislative Counsel.



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2

1 AN ACT concerning opioid prescribing and pain management,
2 supplementing Titles 24 and 26 of the Revised Statutes, and
3 amending various parts of the statutory law.
4

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

7
8 1. (New section) As used in sections 1 through 3 of P.L. ,
9 c. (C.) (pending before the Legislature as this bill):

10 “Chronic pain” means pain that persists or recurs for more than
11 three months.

12 “Commissioner” means the Commissioner of Health.

13 “Department” means the Department of Health.

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

18 “Pain management clinic” means a privately-owned clinic,
19 facility, or office, in which at least 50 percent of the patients seen
20 by practitioners in any month are prescribed or dispensed Schedule
21 II controlled dangerous substances for the treatment of chronic pain
22 resulting from non-terminal conditions.
23

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

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

40 c. A pain management clinic shall not be subject to the
41 certificate of need requirements that are ordinarily applicable to
42 health care facilities under P.L.1971, c.136 (C.26:2H-1 et al.).
43

44 3. (New section) a. The Commissioner of Health shall adopt
45 rules and regulations, pursuant to the “Administrative Procedure

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 thus is new matter.

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1 Act,” P.L.1968, c.410 (C.52:14B-1 et seq.), to effectuate the
2 purposes of sections 1 through 3 of P.L. , c. (C.) (pending
3 before the Legislature as this bill).

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

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

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

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

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

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

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

23 (7) infection control procedures and protocols;

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

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

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

36

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

39 “Accepted guideline” means a care or practice guideline for pain
40 management, which has been developed by a nationally recognized
41 clinical or professional association, or by a specialty society or
42 government-sponsored agency that develops guidelines based on
43 original research or the review of existing research or expert
44 opinions; or a policy or position statement on pain management,
45 which is issued by any State professional licensing board having
46 jurisdiction over health care practitioners. “Accepted guideline”
47 does not include any guideline that is established primarily for

1 purposes of payment, insurance coverage, or reimbursement, and
2 which limits treatment options.

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

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

8 “Medical emergency” means an acute injury or illness that poses
9 an immediate threat to the patient’s life or long-term health.

10 “Practitioner” means a licensed physician, physician assistant,
11 advanced practice nurse, pharmacist, or other person who is
12 authorized to engage in the prescription, administration, or
13 dispensing of controlled dangerous substances to patients as part of
14 the person’s authorized scope of professional practice.

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

18

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

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

45 c. A practitioner who does not have actual knowledge of a
46 nonopioid advanced directive filed pursuant to this section, and who
47 prescribes or administers an opioid to the patient in a medical
48 emergency, shall not be subject to criminal or civil liability, or

1 professional disciplinary action, for failing to act in accordance
2 with the directive, unless the act or omission was the result of the
3 practitioner's gross negligence or willful misconduct.
4

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

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

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

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

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

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

37 d. Nothing in the provisions of this section, or in any other law
38 or regulation, shall be deemed to immunize a practitioner from
39 criminal or civil liability, or from professional disciplinary action, if
40 the practitioner prescribes, administers, or dispenses a Schedule II
41 controlled dangerous substance or opioid drug in violation of the
42 provisions of section 11 of P.L.2017, c.28 (C.24:21-15.2) or any
43 other applicable law or regulation.
44

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

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

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

16

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

27

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

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

47 c. The advisory committee shall:

- 1 (1) Establish parameters to identify abnormal or unusual
2 controlled dangerous substance usage patterns of patients;
 - 3 (2) Establish parameters to identify abnormal or unusual
4 controlled dangerous substance prescribing and dispensing practices
5 of practitioners;
 - 6 (3) Identify and recommend training, research, or other
7 activities and opportunities that have the potential to reduce or
8 eliminate instances of inappropriate controlled dangerous substance
9 usage, prescribing, and dispensing;
 - 10 (4) Study the diversion of controlled dangerous substances, and
11 make recommendations to prevent and address drug diversion,
12 particularly in relation to Schedule II controlled dangerous
13 substances that are prescribed for the treatment of pain, and the
14 management of opioid addiction;
 - 15 (5) Establish educational and outreach programs for health care
16 facilities, pharmacies, practitioners, law enforcement, and other
17 relevant parties, which programs shall provide education and advice
18 to such entities and practitioners on the issue of controlled
19 dangerous substance diversion, and the practices and protocols that
20 are recommended to prevent and respond to instances of diversion.
- 21 d. The Division of Consumer Affairs shall provide
22 administrative support to the advisory committee.
23
- 24 10. (New section) a. The Director of the Division of Consumer
25 Affairs in the Department of Law and Public Safety shall establish a
26 Drug Usage and Prescribing Practices Review Committee to review
27 controlled dangerous substance usage, prescribing, and dispensing
28 practices in the State and identify abnormal or unusual patterns, in
29 this regard.
- 30 b. The review committee shall consist of the following
31 members: (1) two prosecuting attorneys, each from a different
32 county in New Jersey; (2) two licensed physicians who specialize in
33 care that requires the extensive use of controlled dangerous
34 substances, and who are recommended by the State Medical
35 Association and (3) a licensed pharmacist who is trained in the use
36 and abuse of controlled dangerous substances, and who is
37 recommended by the Board of Pharmacy.
- 38 c. The review committee, working independently, shall query
39 the Prescription Monitoring Program database, established pursuant
40 to section 25 of P.L.2007, c.244 (C.45:1-45), based on the
41 parameters that have been established by the Advisory Committee
42 on Drug Usage and Prescribing, pursuant to section 9 of
43 P.L. , c. (C.) (pending before the Legislature as this bill).
44 Using those parameters, the review committee shall determine
45 whether any abnormal or unusual usage, prescribing, or dispensing
46 patterns are evident from the data. If the review committee has
47 reasonable cause to believe that abnormal or unusual practices are
48 occurring in any given case, the review committee shall, as deemed

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

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

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

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

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

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

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

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

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

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

19

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (2) the reasons why the prescription is necessary;

25 (3) alternative treatments that may be available; and

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

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

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

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

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

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

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

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

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

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

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

41 g. As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

43 "Pain management specialist" means a licensed physician who is
44 board certified in pain management or a related field.

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

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

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

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

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

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

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

26

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

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

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

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

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

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

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

39

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

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

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

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

17 b. "Health care service" means the preadmission, outpatient,
18 inpatient, and postdischarge care provided in or by a health care
19 facility, and such other items or services as are necessary for such
20 care, which are provided by or under the supervision of a physician
21 for the purpose of health maintenance organizations, diagnosis, or
22 treatment of human disease, pain, injury, disability, deformity, or
23 physical condition, including, but not limited to, nursing service,
24 home care nursing, and other paramedical service, ambulance
25 service, service provided by an intern, resident in training or
26 physician whose compensation is provided through agreement with
27 a health care facility, laboratory service, medical social service,
28 drugs, biologicals, supplies, appliances, equipment, bed and board,
29 but excluding services provided by a physician in his private
30 practice, except as provided in sections 7 and 12 of P.L.1971, c.136
31 (C.26:2H-7 and C.26:2H-12), or by practitioners of healing solely
32 by prayer, and services provided by first aid, rescue and ambulance
33 squads as defined in the "New Jersey Highway Traffic Safety Act of
34 1987," P.L.1987, c.284 (C.27:5F-18 et seq.).

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

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

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

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

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

- 1 h. (Deleted by amendment, P.L.1991, c.187).
- 2 i. "Department" means the Department of Health.
- 3 j. "Commissioner" means the Commissioner of Health.
- 4 k. "Preliminary cost base" means that proportion of a hospital's
5 current cost which may reasonably be required to be reimbursed to
6 a properly utilized hospital for the efficient and effective delivery of
7 appropriate and necessary health care services of high quality
8 required by such hospital's mix of patients. The preliminary cost
9 base initially may include costs identified by the commissioner and
10 approved or adjusted by the commission as being in excess of that
11 proportion of a hospital's current costs identified above, which
12 excess costs shall be eliminated in a timely and reasonable manner
13 prior to certification of the revenue base. The preliminary cost base
14 shall be established in accordance with regulations proposed by the
15 commissioner and approved by the board.
- 16 l. (Deleted by amendment, P.L.1992, c.160).
- 17 m. "Provider of health care" means an individual (1) who is a
18 direct provider of health care service in that the individual's primary
19 activity is the provision of health care services to individuals or the
20 administration of health care facilities in which such care is
21 provided and, when required by State law, the individual has
22 received professional training in the provision of such services or in
23 such administration and is licensed or certified for such provision or
24 administration; or (2) who is an indirect provider of health care in
25 that the individual (a) holds a fiduciary position with, or has a
26 fiduciary interest in, any entity described in subparagraph b(ii) or
27 subparagraph b(iv); provided, however, that a member of the
28 governing body of a county or any elected official shall not be
29 deemed to be a provider of health care unless he is a member of the
30 board of trustees of a health care facility or a member of a board,
31 committee or body with authority similar to that of a board of
32 trustees, or unless he participates in the direct administration of a
33 health care facility; or (b) received, either directly or through his
34 spouse, more than one-tenth of his gross annual income for any one
35 or more of the following:
- 36 (i) Fees or other compensation for research into or instruction in
37 the provision of health care services;
- 38 (ii) Entities engaged in the provision of health care services or in
39 research or instruction in the provision of health care services;
- 40 (iii) Producing or supplying drugs or other articles for
41 individuals or entities for use in the provision of or in research into
42 or instruction in the provision of health care services;
- 43 (iv) Entities engaged in producing drugs or such other articles.
- 44 n. "Private long-term health care facility" means a nursing
45 home, skilled nursing home, or intermediate care facility presently
46 in operation and licensed as such prior to the adoption of the 1967
47 Life Safety Code by the Department of Health in 1972 and which

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

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

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

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

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

14

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

17 8. A board may refuse to admit a person to an examination₂ or
18 may refuse to issue₂ or may suspend or revoke₂ any certificate,
19 registration or license issued by the board₂ upon proof that the
20 applicant or holder of such certificate, registration₂ or license:

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

24 b. Has engaged in the use or employment of dishonesty, fraud,
25 deception, misrepresentation, false promise₂ or false pretense;

26 c. Has engaged in gross negligence, gross malpractice or gross
27 incompetence which damaged or endangered the life, health,
28 welfare, safety₂ or property of any person;

29 d. Has engaged in repeated acts of negligence, malpractice₂ or
30 incompetence;

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

33 f. Has been convicted of, or engaged in acts constituting, any
34 crime or offense involving moral turpitude or relating adversely to
35 the activity regulated by the board. For the purpose of this
36 subsection a judgment of conviction or a plea of guilty, non vult,
37 nolo contendere₂ or any other such disposition of alleged criminal
38 activity shall be deemed a conviction;

39 g. Has had his authority to engage in the activity regulated by
40 the board revoked or suspended by any other state, agency₂ or
41 authority for reasons consistent with this section;

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

44 i. Is incapable, for medical or any other good cause, of
45 discharging the functions of a licensee in a manner consistent with
46 the public's health, safety₂ and welfare;

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

- 1 applications, as required **【to be filed with】** by the Department of
2 Environmental Protection;
- 3 k. Has violated any provision of P.L.1983, c.320 (C.17:33A-
4 1 et seq.) or any insurance fraud prevention law or act of another
5 jurisdiction, or has been adjudicated, in civil or administrative
6 proceedings, of a violation of P.L.1983, c.320 (C.17:33A-1 et seq.),
7 or has been subject to a final order, entered in civil or
8 administrative proceedings, that imposed civil penalties under that
9 act against the applicant or holder;
- 10 l. Is presently engaged in drug or alcohol use that is likely to
11 impair the ability to practice the profession or occupation with
12 reasonable skill and safety. For purposes of this subsection, the
13 term "presently" means at this time or any time within the previous
14 365 days;
- 15 m. Has engaged in abnormal or unusual controlled dangerous
16 substance prescribing or dispensing practices, as indicated by a
17 report of, or a case referral from, the Drug Usage and Prescription
18 Practices Review Committee established pursuant to section 10 of
19 P.L. , c. (C.) (pending before the Legislature as this bill),
20 or has otherwise prescribed or dispensed controlled dangerous
21 substances indiscriminately **【or】**, without good cause, or in any
22 case where the applicant or holder knew or should have known that
23 the substances were to be used for unauthorized consumption or
24 distribution;
- 25 n. Has permitted an unlicensed person or entity to perform an
26 act for which a license or certificate of registration or certification
27 is required by the board, or has aided and abetted an unlicensed
28 person or entity in performing such an act;
- 29 o. **【Advertised】** Has advertised fraudulently in any manner.
- 30 The division is authorized, for purposes of facilitating
31 determinations concerning licensure eligibility, to require the
32 fingerprinting of each applicant in accordance with applicable State
33 and federal laws, rules, and regulations. Each applicant shall submit
34 the applicant's name, address, and written consent to the director for
35 a criminal history record background check to be performed. The
36 division is authorized to receive criminal history record information
37 from the State Bureau of Identification in the Division of State
38 Police and the Federal Bureau of Investigation. Upon receipt of
39 such notification, the division shall forward the information to the
40 appropriate board, which shall make a determination regarding the
41 issuance of licensure. The applicant shall bear the cost for the
42 criminal history record background check, including all costs of
43 administering and processing the check, unless otherwise provided
44 for by an individual enabling act. The Division of State Police shall
45 promptly notify the division in the event an applicant or licensee,
46 who was the subject of a criminal history record background check

1 pursuant to this section, is convicted of a crime or offense in this
2 State after the date the background check was performed.

3 For purposes of this act:

4 "Completed application" means the submission of all of the
5 information designated on the checklist, adopted pursuant to section
6 1 of P.L.1991, c.421 (C.13:1D-101), for the class or category of
7 permit for which application is made.

8 "Permit" has the same meaning as defined in section 1 of
9 P.L.1991, c.421 (C.13:1D-101).
10 (cf: P.L.2003, c.199, s.31)

11

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

14 26. Access to prescription information.

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

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

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

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

46 (2) a review to identify whether a violation of law or regulation
47 or a breach of the applicable standards of practice by any person

1 may have occurred, including, but not limited to, diversion of a
2 controlled dangerous substance. If the division determines that
3 such a violation or breach may have occurred, the division shall
4 notify the appropriate law enforcement agency or professional
5 licensing board, and provide the prescription monitoring
6 information required for an investigation.

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

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

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

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

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

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

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

38 (4) The division shall provide online access to prescription
39 monitoring information to as many medical or dental residents as
40 are authorized by a faculty member of a medical or dental teaching
41 facility to access that information and for whom the practitioner is
42 responsible for the use or misuse of that information. The director
43 shall establish, by regulation, the terms and conditions under which
44 a faculty member of a medical or dental teaching facility may
45 delegate that authorization, including procedures for authorization
46 and termination of authorization, provisions for maintaining
47 confidentiality, provisions regarding the duration of a medical or
48 dental resident's authorization to access prescription monitoring

1 information, and such other matters as the division may deem
2 appropriate.

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

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

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

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

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

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

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

- 1 i. The division may provide online access to prescription
2 monitoring information, or may provide access to prescription
3 monitoring information through any other means deemed
4 appropriate by the director, to the following persons:
- 5 (1) authorized personnel of the division or a vendor or
6 contractor responsible for maintaining the Prescription Monitoring
7 Program;
- 8 (2) authorized personnel of the division responsible for
9 administration of the provisions of P.L.1970, c.226 (C.24:21-1 et
10 seq.), and authorized members of the Drug Usage and Prescribing
11 Practices Review Committee responsible for conducting the reviews
12 required by section 10 of P.L. , c. (C.) (pending before the
13 Legislature as this bill);
- 14 (3) the State Medical Examiner, a county medical examiner, a
15 deputy or assistant county medical examiner, or a qualified
16 designated assistant thereof, who certifies that the request is for the
17 purpose of investigating a death pursuant to P.L.1967, c.234
18 (C.52:17B-78 et seq.);
- 19 (4) a controlled dangerous substance monitoring program in
20 another state with which the division has established an
21 interoperability agreement, or which participates with the division
22 in a system that facilitates the secure sharing of information
23 between states;
- 24 (5) a designated representative of the State Board of Medical
25 Examiners, New Jersey State Board of Dentistry, State Board of
26 Nursing, New Jersey State Board of Optometrists, State Board of
27 Pharmacy, State Board of Veterinary Medical Examiners, or any
28 other board in this State or another state that regulates the practice
29 of persons who are authorized to prescribe or dispense controlled
30 dangerous substances, as applicable, who certifies that the
31 representative is engaged in a bona fide specific investigation of a
32 designated practitioner or pharmacist whose professional practice
33 was or is regulated by that board;
- 34 (6) a State, federal, or municipal law enforcement officer who is
35 acting pursuant to a court order and certifies that the officer is
36 engaged in a bona fide specific investigation of a designated
37 practitioner, pharmacist, or patient. A law enforcement agency that
38 obtains prescription monitoring information shall comply with
39 security protocols established by the director by regulation;
- 40 (7) a designated representative of a state Medicaid or other
41 program who certifies that the representative is engaged in a bona
42 fide investigation of a designated practitioner, pharmacist, or
43 patient;
- 44 (8) a properly convened grand jury pursuant to a subpoena
45 properly issued for the records; and
- 46 (9) a licensed mental health practitioner providing treatment for
47 substance abuse to patients at a residential or outpatient substance
48 abuse treatment center licensed by the Division of Mental Health

1 and Addiction Services in the Department of Human Services, who
2 certifies that the request is for the purpose of providing health care
3 to a current patient or verifying information with respect to a patient
4 or practitioner, and who furnishes the division with the written
5 consent of the patient for the mental health practitioner to obtain
6 prescription monitoring information about the patient. The director
7 shall establish, by regulation, the terms and conditions under which
8 a mental health practitioner may request and receive prescription
9 monitoring information. Nothing in sections 25 through 30 of
10 P.L.2007, c.244 (C.45:1-45 through C.45:1-50) shall be construed
11 to require or obligate a mental health practitioner to access or check
12 the prescription monitoring information in the course of treatment
13 beyond that which may be required as part of the mental health
14 practitioner's professional practice.

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

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

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

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

46 n. Nothing shall be construed to prohibit the division from
47 obtaining unsolicited automated reports from the program or
48 disseminating such reports to pharmacists, practitioners, mental

1 health care practitioners, and other licensed health care
2 professionals.

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

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

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

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

46 p. The division shall take steps to ensure that appropriate
47 channels of communication exist to enable any licensed health care
48 professional, licensed pharmacist, mental health practitioner,

1 pharmacy permit holder, or other practitioner who has online access
2 to the Prescription Monitoring Program pursuant to this section to
3 seek or provide information to the division related to the provisions
4 of this section.

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

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

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

21

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

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29 17. This act shall take effect immediately.

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STATEMENT

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

46 A pain management clinic is defined under the bill as a privately-
47 owned clinic, facility, or office, in which at least 50 percent of the
48 patients seen by practitioners in any month are prescribed or

1 dispensed a Schedule II controlled dangerous substance for the
2 treatment of chronic pain resulting from non-terminal conditions.
3 The Commissioner of Health would be required to adopt rules and
4 regulations governing the licensure of these clinics, including, but
5 not limited to, rules establishing the license application process,
6 imposing management, operation, and staffing requirements,
7 identifying the types of drugs that may be used by patients of these
8 clinics, providing inspection protocols, and establishing procedures
9 to be used in the inspection of clinics and the evaluation of
10 utilization rates and quality of care. The bill provides that a pain
11 management clinic will not be subject to the certificate of need
12 requirements that are ordinarily applicable to health care facilities
13 under the "Health Care Facilities Planning Act," P.L.1971, c.136
14 (C.26:2H-1 et al.).

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

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

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

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

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

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

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

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

38 The bill would impose certain new requirements in association
39 with a practitioner's prescription of an opioid drug for the purposes
40 of pain management. Specifically, under the bill, a practitioner
41 prescribing opioid medication would be required: 1) the first time
42 an opioid is prescribed, to indicate to the patient the quantity of the
43 opioid drug that is being prescribed, and to advise the patient that
44 the prescription may be filled in a lesser amount; and 2) before
45 commencing an ongoing course of opioid treatment for chronic
46 pain, to consider referring the patient to a pain management clinic
47 or pain management specialist, and to discuss, with the patient, the
48 benefits of choosing such option, and the risks associated with

1 failure to choose such option. If a referral for specialized pain
2 treatment is not made, and the patient elects to remain in the
3 practitioner's care for the purpose of ongoing pain management, the
4 patient must agree, as part of the patient's pain management
5 agreement, to: 1) only obtain prescriptions for Schedule II
6 controlled dangerous substances or opioid medications from the
7 practitioner named in the agreement; 2) only fill those prescriptions
8 at the pharmacy listed in the agreement; and 3) notify the
9 practitioner named in the agreement within 72 hours after the
10 patient receives emergency treatment with Schedule II controlled
11 dangerous substances or opioid drugs.

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

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

45 The advisory committee would be required to: 1) establish the
46 parameters that are to be used in identifying abnormal or unusual
47 drug usage, prescribing, and dispensing patterns in the State; 2)
48 identify training and research opportunities that can reduce

1 inappropriate CDS usage, prescribing, and dispensing; 3) study
2 drug diversion and develop recommendations to reduce instances of
3 diversion; and 4) establish educational and outreach programs to
4 provide education and advice to health care facilities and
5 practitioners, as well as law enforcement, on the issue of CDS
6 diversion and the recommended practices and protocols that can be
7 used to prevent and respond to instances of diversion.

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