These emergency rules are effective immediately (as of March 1, 2017) and will remain in effect for 60 days, and are being concurrently proposed for readoption to permit members of the regulated community and the public to submit comments concerning the rules and the intention of the Attorney General and Board to make these rules permanent. Comments may be submitted following publication of the proposal in the New Jersey Register. The official version of the Emergency Adoption and Concurrent Proposal will be published in the New Jersey Register on March 20, 2017.

LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

NEW JERSEY STATE BOARD OF DENTISTRY

Issuance of Prescriptions; Limitations on Prescribing, Administering, or Dispensing of Controlled Dangerous Substances, and Special Requirements for Management of Acute and Chronic Pain

Adopted Emergency Amendments and Concurrent Proposed Amendments: N.J.A.C. 13:30-8.18

Authorized _____ by Christopher S. Porrino, Attorney General, State of New Jersey

_____ and
_____ by Nicholas DeRobertis, DMD, President, New Jersey State Board of Dentistry

_____

Filed: , 2017, as R.

Authority: N.J.S.A. 45:1-17(b); N.J.S.A. 45:6-3.

Calendar Reference: See Summary below for explanation of exemption to calendar requirement.

Concurrent Proposal Number: PRN 2017-

Emergency Amendments Effective Date:

Emergency Amendments Expiration Date:

Submit comments by _____ to:

Jonathan Eisenmenger, Executive Director
New Jersey State Board of Dentistry
P.O. Box 45005
Newark, N.J. 07101

These emergency rules are effective immediately (as of March 1, 2017) and will remain in effect for 60 days, and are being concurrently proposed for readoption to permit members of the regulated community and the public to submit comments concerning the rules and the intention of the Attorney General and Board to make these rules permanent. Comments may be submitted following publication of the proposal in the New Jersey Register. The official version of the Emergency Adoption and Concurrent Proposal will be published in the New Jersey Register on March 20, 2017.
Or electronically at:

www.NJConsumerAffairs.gov/Proposals/

This is an emergency adoption and concurrent proposal of amendments to N.J.A.C. 13:30-8.18 concerning limitations on prescribing, administering, or dispensing of controlled dangerous substances, with specific limitations for opioid drugs, and establishing special requirements for the management of acute and chronic pain. These limitations and requirements apply to licensed dentists.

On January 18, 2017, the Attorney General advised the New Jersey State Board of Dentistry (Board) of his intention to amend existing Board regulations, pursuant to the Attorney General's rulemaking authority in N.J.S.A. 45:1-17(b), because of the imminent peril created by the epidemic of prescription opioid and heroin abuse in New Jersey. In response to this advice, the Attorney General and the Board are proposing emergency amendments establishing limitations on prescribing of controlled dangerous substances, pursuant to their respective rulemaking authority in N.J.S.A. 45:1-17(b) and 45:6-3.

On February 15, 2017, P.L. 2017, c.28 was signed into law, imposing certain restrictions on how opioids and other Schedule II controlled dangerous substances may be prescribed, including, in cases of acute pain, prohibiting a practitioner from issuing an initial prescription for an opioid drug in a quantity exceeding a five-day supply, and requiring the prescription to be for the lowest effective dose of an immediate-releasing opioid drug. However, because P.L. 2017, c.28 does not become effective until May 16, 2017, the Attorney General has determined that these amendments are necessary because the State of New Jersey is confronting a staggering public health crisis brought about by prescription opioid and heroin abuse. One reason for the

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public health emergency is the prevalence of opioid prescribing. The Attorney General believes that the adoption of these amendments on an emergency basis will substantially reduce the risk of addiction and the accumulation of opioids in the household medicine cabinets across the State. Failure to adhere to the standards set forth in the attached rule proposal will provide a basis to seek emergent action to suspend or limit licenses pending a plenary hearing, pursuant to N.J.S.A. 45:1-22, and/or for disciplinary sanctions pursuant to N.J.S.A. 45:1-21.

These amendments have been adopted on an emergency basis and became effective upon acceptance for filing by the Office of Administrative Law (see N.J.S.A. 52:14B-4(c) as implemented by N.J.A.C. 1:30-6.5(b)). Concurrently, the provisions of this emergency adoption are proposed for readoption pursuant to the rulemaking requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. The readopted amendments will be effective upon acceptance for filing by the Office of Administrative Law (N.J.A.C. 1:30-6.5(d)) if filed on or prior to the expiration date of the emergency amendments.

Because these are emergency amendments published in accordance with N.J.S.A. 52:14B-4(c), this rulemaking is excepted from the rulemaking calendar requirement under N.J.A.C. 1:30-3.3(a)3.

The agency emergency adoption and concurrent proposal follows:

Summary

The abuse of prescription drugs has reached epidemic proportions nationwide. Moreover, according to the National Institute on Drug Abuse (NIDA), research now suggests

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that abuse of prescription pain relievers may actually open the door to heroin use. Most alarmingly, the 2016 American Society of Addiction Medicine (ASAM) Facts and Figures notes that "four in five new heroin users started out misusing prescription painkillers."

New Jersey is not immune. Prescription opioid and heroin abuse is growing at an alarming rate among the citizens of New Jersey. A 2014 report from the Governor's Council on Alcoholism and Drug Abuse noted a startling rise in the rate of patient admissions to drug addiction treatment centers of more than 200% over the past five years, and nearly 700% over the past decade. Heroin and opioid admissions accounted for 49 percent of all substance abuse admissions in New Jersey in 2014, the highest in at least a decade, according to data from the State Division of Mental Health and Addiction Services. There were 781 heroin-related overdose deaths in New Jersey in 2014, according to data by the State Division of Criminal Justice. That is more than twice as many as in 2010. And, as observed in the July 2013 report from the State of New Jersey Commission of Investigation, staggering amounts of legitimate medicines manufactured by major pharmaceutical companies and intended for those needing relief from the pain of disease and injury have been diverted into criminal enterprises founded on drug abuse and addiction. New Jersey's opioid and heroin epidemic, like those facing many states across the nation, shows no signs of abating. In 2014, there were 1,306 drug-related deaths; in 2015, that number increased to 1,587. Naloxone administrations in 2014 numbered 5,174. In 2015, that number rose to 7,222. With the expansion of programs for first responders, the Attorney General fully expects that number to be exceeded this year. According to the New Jersey Division of Mental Health and Addiction Services, in 2014, there were 28,653 patients in treatment for opioids; by 2015 that number had risen to 35,529.

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One reason for the public health emergency we face today is the prevalence of opioid prescribing. The March 2016 Guideline for Prescribing Opioids for Chronic Pain, issued by the Centers for Disease Control and Prevention (CDC), noted these alarming findings: 1) nationally, an estimated 20 percent of patients presenting to physician offices with non-cancer pain symptoms, pain-related diagnoses, or acute and chronic pain reportedly receive an opioid prescription; 2) in 2013, an estimated 1.9 million persons abused or were dependent on opioid pain medication; 3) having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder; 4) in the past decade, death rates associated with opioid pain medication have increased markedly; 5) a long term (13 years) study concluded that, of the patients receiving opioids for chronic non-cancer pain, one in 550 patients died from an opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages of more than 200 morphine milligram equivalents died from opioid-related overdose; and 6) most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily dosages.

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from an overdose related to opioid pain medication in the United States. Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths. The Drug Abuse Warning Network estimated that more than 420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on

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prescription opioid pain medication. Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder, highlighting the value of guidance on safer prescribing practices for clinicians.

The prevalence of opioid prescribing for pediatric populations is of particular concern, with a large proportion of adolescents commonly prescribed opioid pain medications for conditions such as headache and sports injuries. An estimated 20% of adolescents with currently prescribed opioid medications report using them intentionally to get high or increase the effects of alcohol or other drugs. Research suggests that misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use.

As set forth in the CDC Guideline, "the clinical evidence review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use." In addition, "experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion." As noted in the CDC Guideline, experts agree that when opioids are needed for acute pain, prescribers "should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use." "Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of three to five days or three to seven days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected

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course of severe acute pain for most acute pain syndromes seen in primary care." The CDC recommends that prescribers "should not prescribe additional opioids to patients 'just in case' pain continues longer than expected" but rather "should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly."

The proposed amendments set forth steps a licensee must take when prescribing, dispensing, or administering a controlled dangerous substance. The amendments establish special requirements when prescribing a Schedule II controlled dangerous substance for pain or any opioid drug; for the treatment of chronic pain; and the prescribing of opioid drugs for the treatment of acute pain. The Attorney General believes that these amendments will substantially reduce the risk of addiction and the accumulation of opioids in household medicine cabinets across the State, stockpiles that are ripe for diversion.

Currently, N.J.A.C. 13:30-8.18 sets forth the requirement to issue written prescriptions on New Jersey Prescription Blanks and to comply with State and Federal laws concerning the prescribing of controlled dangerous substances. The proposed amendments to N.J.A.C. 13:30-8.18 set forth limitations on prescribing, administering, or dispensing of controlled dangerous substances, and special requirements for the management of acute and chronic pain, and to amend the title of the rule to reflect these changes. Proposed new subsection (a) sets forth the definitions for the rule. Definitions are provided for the terms "acute pain," "chronic pain," "initial prescription," "licensee," and "palliative care." The term "chronic pain" is consistent with the definition as found in the prescription monitoring program (PMP) regulations at N.J.A.C. 13:45A-35. The term "acute pain" differs from that found in the PMP regulations by

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specifying that it is pain that the licensee reasonably expects to last only a short period of time, and excludes 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. "Licensee" is defined as a licensed dentist who is currently authorized to prescribe drugs in the course of professional practice. "Palliative care" is defined as care provided to an individual suffering from an incurable progressive illness that is expected to end in death, which is designed to decrease the severity of pain, suffering, and other distressing symptoms, and the expected outcome of which is to enable the individual to experience an improved quality of life. This definition is consistent with the definition of "palliative care" under Department of Human Services' regulations concerning decision-making for the terminally ill, set forth at N.J.A.C. 10:48B-2.1.

Existing subsections (a) and (b) are proposed for recodification as subsections (b) and (c). Proposed amendments to recodified subsection (c) require compliance with the PMP regulations at N.J.A.C. 13:45A-35 and specify that N.J.A.C. 13:45H refers to the controlled dangerous substances regulations.

Proposed new subsection (d) specifies the actions a licensee must perform when prescribing, dispensing, or administering controlled dangerous substances. A licensee must take a thorough medical history of the patient that reflects the nature, frequency, and severity of any pain; the patient's history of substance use or abuse; and the patient's experience with non-opioid medication and non-pharmacological pain management approaches. In addition, licensees must develop a treatment plan, which includes the nature, frequency, and severity of any pain expected after a dental procedure or associated with dental conditions and identifies the objectives by which treatment success is to be evaluated, and any further diagnostic evaluations

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or other treatments planned, with particular attention focused on determining the cause of the patient's pain. The proposed amendments also require the licensee to conduct a comprehensive dental examination and to access and consider relevant PMP information in accordance with the PMP rules at N.J.A.C. 13:45A-35. In addition, the proposed amendments require that the licensee prepare a patient record that reflects the history, the findings on examination, any relevant PMP data, the treatment plan, and the complete name of the controlled dangerous substance, the dosage, strength, and quantity of the controlled dangerous substance, and the instructions as to frequency of use.

Proposed subsection (e) provides that licensees may prescribe Schedule II controlled dangerous substances in a quantity not to exceed a 30-day supply, which shall be at the lowest effective dose as determined by the directed dosage and frequency of dosage. The prescribing of opioids in any schedule is subject to the limitations set forth in proposed subsection (i).

Proposed new subsection (f) provides that, prior to issuing the first prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, and then again prior to issuing the third prescription, the licensee must discuss with the patient the reasons why the medication is being prescribed, the possible alternative treatments, and the risks associated with the medication. With respect to opioid drugs, the discussion must also include the risks of addiction, physical or psychological dependence, and overdose associated with opioid drugs, the danger of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the requirements for proper storage and disposal. The Division of Consumer Affairs will make guidance materials available on its website that may be used by licensees to help facilitate the required discussion. The licensee is required to include a note in the patient

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record that this discussion took place. The rule also provides that when the patient is under 18 years of age and is not an emancipated minor the discussion is with, and the written acknowledgement is from, the patient's parent or guardian. With respect to the treatment of minors, the rule provides, consistent with P.L. 2017, c.8, which became effective on February 6, 2017, that, if the prescription is for an opioid drug which is a Schedule II controlled dangerous substance, the licensee shall have the required discussion prior to the issuance of each prescription, and shall include a note in the patient record that the discussion took place.

Proposed new subsection (g) establishes the requirement for a licensee to enter into a pain management agreement with a patient when issuing the third prescription for a Schedule II controlled dangerous substance for pain or any opioid drug. Subsection (g) also sets forth the requirements for the pain management agreement, which must be signed and dated by the licensee and patient prior to the issuance of the third prescription for the ongoing treatment of pain using a Schedule II controlled dangerous substance or any opioid drug. The agreement must document the understanding of both the licensee and the patient concerning the patient's pain management plan; establish the patient's rights in association with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, storage and disposal of Schedule II controlled dangerous substances and any opioid drugs, including any restrictions on the refill of or the acceptance of such prescriptions from other licensees or prescribers; identify the specific medications and other modes of treatment that are included as part of the treatment plan; specify the measures the licensee may employ to monitor the patient's compliance, such as random specimen screens and pill counts; and delineate the process for terminating the agreement, including the consequences if the licensee has reason to believe that

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the patient is not complying with the terms of the agreement. The Division of Consumer Affairs will provide sample pain management agreements on its website for use by licensees.

Proposed new subsection (h) sets forth the requirements for the management of chronic pain using controlled dangerous substances. The licensee must review, at least every three months, the course of treatment, new information about the etiology of the pain, and the patient's progress toward treatment objectives, and document the results of that review. The licensee is required to assess the patient prior to the issuance of each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and to document the results of that assessment. In addition, the licensee must make periodic reasonable efforts to either stop the use of the controlled dangerous substance, taper the dosage, try other drugs or utilize alternative treatment modalities to reduce the potential for abuse or the development of physical or psychological dependence, and document, with specificity, the efforts undertaken by the licensee consistent with the paragraph. The proposed amendments also require licensees to access relevant PMP information; monitor compliance with the pain management agreement, and any recommendation that the patient seek a referral, and discuss with the patient any breaches, and document within the patient record the plan after that discussion; conduct random urine screens at least once every 12 months; refer the patient to a pain management or addiction specialist for independent evaluation or treatment to achieve treatment objectives, if those objectives are not being met; and for those patients who are being prescribed an opioid drug to treat chronic pain, advise the patient of the availability of an opioid antidote. Overall, the amendments to this subsection are designed to increase licensee

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involvement and vigilance when prescribing for the treatment of chronic pain, and to ensure that the patient record reflects active pain management procedures.

Proposed new subsections (i) and (j) are specific to the prescribing of opioid drugs for the treatment of acute pain. Proposed new subsection (i) sets forth the limitations on the quantities of opioid drugs for the treatment of acute pain issued in an initial prescription. The rule is intended to infuse into the licensee/patient relationship a need for consultation after the expected course of recovery and prior to issuing additional prescriptions. As noted above, the CDC recommends that prescribers "should not prescribe additional opioids to patients 'just in case' pain continues longer than expected" but rather "should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly." Moreover, as specifically set forth in subsection (*l*), this rule is not to be construed to limit a licensee's professional judgment to issue subsequent prescriptions for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.

Proposed new subsection (i) provides that the initial prescription for an opioid drug for treatment of acute pain shall not exceed a five-day supply, as determined by the directed dosage and frequency of dosage. An "initial prescription" is defined as a prescription issued to a patient who has never previously been issued a prescription for the drug or its pharmaceutical equivalent, or who was previously issued a prescription for the drug or its pharmaceutical equivalent more than one year prior to the date the current prescription is being issued. When determining whether a patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the licensee must consult with the patient, review prescription

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monitoring information and, to the extent they are available to the licensee, review the patient's dental and medical records. The initial prescription shall be for the lowest effective dose of an immediate-release opioid drug. The rule further provides that a licensee shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid. No less than four days after issuing the initial prescription, upon request of the patient, a licensee may issue a subsequent prescription for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription. Prior to issuing the subsequent prescription the licensee must consult with the patient. The consultation may be in person, via telephone, or via other means of direct communication. After the consultation, the licensee, in the exercise of professional judgment, must determine that an additional days' supply of the prescribed opioid drug is necessary and appropriate to the patient's treatment needs, and does not present an undue risk of abuse, addiction, or diversion. The licensee is required to document the rationale for the authorization in the patient record. Subparagraph (i)4 provides that subsequent prescriptions for an additional days' supply of the prescribed opioid drug must be tailored to the patient's expected need at the stage of recovery, and in no case may the quantity exceed a 30-day supply. The proposed amendments do not alter existing requirements under the controlled dangerous substances regulations at N.J.A.C. 13:45H-7.8(d), which permit a pharmacist to dispense a controlled dangerous substance in an amount adequate to treat the patient during an emergency period not to exceed 72 hours. The requirements of subsection (h) concerning the treatment of chronic pain apply once the pain persists for three or more consecutive months.

Proposed new subsection (j) provides that a when a licensee issues an initial prescription for an opioid drug for the treatment of acute pain, the licensee shall indicate on the prescription

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that it is an initial prescription for the treatment of acute pain. Proposed new subsection (k) specifies that the requirements for prescribing controlled dangerous substances set forth in subsections (f) through (j) do not apply to a prescription for a patient who is currently in active treatment for cancer, or receiving hospice care from a licensed hospice, or is receiving 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.

Proposed new subsection (*l*) specifies that this rule is not to be construed to limit a licensee's professional judgment to issue subsequent prescriptions for an opioid drug in a quantity consistent with subsection (i)4 for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.

Because these are emergency amendments published in accordance with N.J.S.A. 52:14B-4(c), this rulemaking is excepted from the rulemaking calendar requirement under N.J.A.C. 1:30-3.3(a)3.

Social Impact

The proposed amendments will have a positive social impact by substantially reducing the risk of addiction and the accumulation of opioids in household medicine cabinets across the State, stockpiles that are ripe for diversion. In addition, the proposed amendments will provide clear standards for licensees who prescribe, dispense, or administer controlled dangerous substances.

Economic Impact

The proposed amendments may have an economic impact upon licensed dentists and

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their patients to the extent there are costs associated with the requirement for a licensee to consult with the patient to authorize an additional days' supply of opioid drugs for acute pain. In addition, the proposed amendments may have an economic impact upon patients and pharmacies to the extent that there are costs associated with co-payments, co-insurance or deductibles for an initial prescription issued consistent with requirements imposed under the proposed amendments. Patients may also experience costs associated with the required urine screenings and referrals to a pain management or addiction specialist. The costs, if any, will vary based upon third-party payor benefit plans, and are outweighed by the interest in reducing the risk of opioid and heroin addiction, and protecting the public health and safety.

The CDC Guideline notes that yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids; $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids; and $20.4 billion for direct and indirect costs related to opioid-related overdose alone.

Federal Standards Statement

A Federal standards analysis is not required because the proposed amendments are governed by N.J.S.A. 45:6-1 et seq. To the extent that the CDC Guideline may be viewed as establishing and setting forth federal standards and requirements for the prescribing and dispensing of opioid drugs, the proposed amendments are consistent with these standards.

Jobs Impact

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The proposed amendments may result in the creation of jobs in the State to the extent that additional employment opportunities may be created for pain management specialists as a result of the requirement in the proposed amendments that a licensed dentist must refer a patient to such specialists when treatment objectives are not being met.

Agriculture Industry Impact

The proposed amendments will have no impact on the agriculture industry in the State.

Regulatory Flexibility Analysis

Currently, the Board licenses approximately 8,780 dentists. If these licensees are considered "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., then the following analysis applies.

The proposed amendments will impose new recordkeeping and compliance requirements upon dentists who issue prescriptions for controlled dangerous substances. These requirements are discussed in the Summary statement above. No additional professional services will be needed to comply with the proposed amendments. The costs of compliance with the proposed amendments are discussed in the Economic Impact above. The proposed amendments should be uniformly applied to all dentists who are authorized to prescribe drugs in order to ensure the health, safety and welfare of the general public. Therefore, no differing compliance requirements for any licensee are provided based upon the size of the business.

Housing Affordability Impact Analysis

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The proposed amendments will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the regulations would evoke a change in the average costs associated with housing because the proposed amendments concern the prescribing, administering, or dispensing of controlled dangerous substances.

Smart Growth Development Impact Analysis

The proposed amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the regulations would evoke a change in housing production in Planning areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the proposed amendments concern the prescribing, administering, or dispensing of controlled dangerous substances.

Full text of the proposed amendments follows (additions indicated in **bold face, thus,** deletions in brackets [thus]:

SUBCHAPTER 8. General Provisions

13:30-8.18 Issuance of prescriptions; NJPBs; [controlled dangerous substances] **limitations on prescribing, dispensing, or administering controlled dangerous substances; special requirements for management of acute and chronic pain**

(a) The following words and terms when used in this rule, shall have the following meanings, unless the context clearly indicates otherwise:

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"Acute pain" means the pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the licensee 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 for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically.

"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 the drug or its pharmaceutical equivalent, and 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 a drug or its pharmaceutical equivalent, the licensee shall consult with the patient, review prescription monitoring information and, to the extent they are available, review the patient's dental and medical records.

"Licensee" means a licensed dentist who is currently authorized to prescribe drugs in the course of professional practice.

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"Palliative care" means care provided to an individual suffering from an incurable progressive illness that is expected to end in death, which is designed to decrease the severity of pain, suffering, and other distressing symptoms, and the expected outcome of which is to enable the individual to experience an improved quality of life.

[(a)] **(b)** (No change to text.)

[(b)] **(c)** Licensees issuing prescriptions for controlled dangerous substances shall comply with all State and Federal laws concerning the issuance of such prescriptions, including **the** requirements **of the controlled dangerous substances regulations** set forth at N.J.A.C. 13:45H **and the prescription monitoring program regulations at N.J.A.C. 13:45A-35.**

(d) When prescribing, dispensing, or administering controlled dangerous substances, a licensee shall:

1. Take a thorough medical history of the patient which reflects the nature, frequency, and severity of any pain being experienced before or after a dental procedure, the patient's history of substance use or abuse, and the patient's experience with non-opioid medication and non-pharmacological pain management approaches;

2. Conduct a comprehensive dental examination;

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3. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L.2015, c.74 (C. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;

4. Develop a treatment plan, which includes the nature, frequency, and severity of any pain expected after a dental procedure or associated with dental conditions and identifies the objectives by which treatment success is to be evaluated, such as pain relief and improved function, and any further diagnostic evaluations or other treatments planned, with particular attention focused on determining the cause of the patient's pain; and

5. Include in the patient's dental record the medical history, including the information described in subparagraph (d)1 above, the findings on examination, any relevant PMP data, and the treatment plan, as well as:

i. The complete name of the controlled substance;

ii. The dosage, strength and quantity of the controlled substance; and

iii. The instructions as to frequency of use.

(e) With respect to Schedule II controlled dangerous substances, unless the prescribing of opioids is subject to limitations as set forth in subsection (i), a licensee may authorize a quantity, not to exceed a 30-day supply, which shall be at the lowest effective dose as

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determined by the directed dosage and frequency of dosage. The prescribing of opioids in any schedule is subject to limitations as set forth in subsection (i).

(f) Prior to issuing the first prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, a licensee 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 reasons why the medication is being prescribed, the possible alternative treatments and the risks associated with the medication. With respect to opioid drugs, the discussion shall include, but not be limited to, the risks of addiction, physical or psychological dependence, and overdose associated with opioid drugs and the danger of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and requirements for proper storage and disposal.

i. If the patient is under 18 years of age and is not an emancipated minor, the licensee shall have the discussion required in section (f) prior to the issuance of each subsequent prescription for any opioid drug which is a Schedule II controlled dangerous substance.

ii. In addition to the requirements of subparagraph (i), the licensee shall reiterate the discussion required in section (f) prior to issuing the third prescription of the course of treatment for a Schedule II controlled dangerous substance for pain or any opioid drug.

iii. The licensee shall include a note in the patient record that the required discussion(s) took place.

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(g) At the time of issuance of the third prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, the licensee shall enter into a pain management agreement with the patient. The pain management agreement shall be a written contract or agreement that is executed between a licensee and a patient, that is signed and dated prior to the issuance of the third prescription for the ongoing treatment of pain using a Schedule II controlled dangerous substance or any opioid drug, and which shall:

1. Document the understanding of both the licensee and the patient regarding the patient's pain management plan;

2. 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 and disposal of Schedule II controlled dangerous substances and any opioid drugs, including any restrictions on the refill or acceptance of such prescriptions from licensees and other prescribers;

3. Identify the specific medications and other modes of treatment, including physical therapy or exercise, relaxation, or psychological counseling, that are included as part of the treatment plan;

4. Specify the measures the licensee may employ to monitor the patient's compliance, including but not limited to, random specimen screens and pill counts; and

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5. Delineate the process for terminating the agreement, including the consequences if the licensee has reason to believe that the patient is not complying with the terms of the agreement.

(h) When controlled dangerous substances are continuously prescribed for management of chronic pain, the licensee 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 issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment;

3. Make periodic reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled dangerous substance, taper the dosage, try other drugs such as nonsteroidal anti-inflammatories, or utilize alternative 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. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L. 2015, c.74 (C. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;

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5. Monitor compliance with the pain management agreement and any recommendations that the patient seek a referral and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by licensees or other prescribers, and document within the patient's record the plan after that discussion;

6. Conduct random urine screens at least once every 12 months;

7. For those patients being prescribed an opioid drug to treat chronic pain, advise the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, of the availability of an opioid antidote; and

8. Refer the patient to a pain management or addiction specialist for independent evaluation or treatment in order to achieve treatment objectives if those objectives are not being met.

(i) A licensee shall not issue an initial prescription for an opioid drug for treatment of acute pain in a quantity exceeding a five-day supply as determined by the directed dosage and frequency of dosage. The initial prescription shall be for the lowest effective dose of an immediate-release opioid drug. A licensee shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid. No less than four days after issuing the initial prescription, upon request of the patient, a licensee may issue a subsequent prescription for an opioid drug for the continued

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treatment of acute pain associated with the condition that necessitated the initial prescription provided the following conditions are met:

1. The licensee consults (in person, via telephone, or other means of direct communication) with the patient;

2. After the consultation with the patient, the licensee, in the exercise of professional judgment, determines that an additional days' supply of the prescribed opioid drug is necessary and appropriate to the patient's treatment needs and does not present an undue risk of abuse, addiction, or diversion;

3. The licensee documents the rationale for the authorization in the patient record;

4. The subsequent prescription for an additional days' supply of the prescribed opioid drug is tailored to the patient's expected need at the stage of recovery, as determined in paragraph 2 above, and:

i. Any subsequent prescription for an additional days' supply shall not exceed a 30-day supply.

(j) When a licensee issues an initial prescription for an opioid drug for the treatment of acute pain, the licensee shall so indicate it on the prescription.

(k) The requirements for prescribing controlled dangerous substances set forth in subsections (f) through (j) shall not apply to a prescription for a patient who is currently in active treatment for cancer, or receiving hospice care from a licensed

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hospice, or receiving 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.

(*l*) Nothing in subsection (i) shall be construed to limit a licensee's professional judgment to authorize a subsequent prescription for an opioid drug in a quantity consistent with subsection (i)4 for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.