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LEGAL ALERT

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The Substance Use Disorders Law, P. L. 2017, c. 28, Imposes New Requirements and Limitations on Prescribing of Controlled Dangerous Substances, and Special Requirements for the Management of Acute and Chronic Pain.

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- For purposes of the new law, "Practitioner" means an individual currently licensed, registered, certified, or otherwise authorized to prescribe drugs in the course of professional practice, to include physicians, podiatrists, physician assistants, certified nurse midwives and advanced practice nurses, acting within the scope of practice of his or her professional license, registration or certification.

- A practitioner shall not issue an initial prescription for an opioid drug in a quantity exceeding a five-day supply for treatment of **acute pain**. Any prescription for acute pain pursuant to this law shall be for the lowest effective dose of an immediate-release opioid drug.

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

- Prior to issuing an initial prescription for a Schedule II controlled dangerous substance or any other opioid drug in a course of treatment for **acute or chronic pain**, a practitioner must: (1) take and document the results of a thorough medical history, including the patient's experience with non-opioid medication and non-pharmacological pain management approaches and substance abuse history; (2) conduct, as appropriate, and document the results of a physical examination; (3) develop a treatment plan, with particular attention focused on determining the cause of the patient's pain; (4) access relevant prescription monitoring information under the Prescription Monitoring Program; and (5) limit the supply of any opioid drug prescribed for acute pain to a duration of no more than five days as determined by the directed dosage and frequency of dosage.

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"Initial prescription" is defined as 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, but the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent. When determining whether the patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the practitioner shall consult with the patient and review the patient's medical records and prescription monitoring information.

- No less than four days after issuing the initial prescription, the practitioner, after consultation with the patient, may issue a subsequent prescription for the drug to the patient, provided that: (1) the subsequent prescription would not be deemed an initial prescription; (2) the practitioner determines the prescription is necessary and appropriate to the patient's treatment needs and documents the rationale for the issuance of the subsequent prescription; and (3) the practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination.

- Prior to issuing the initial prescription of a Schedule II controlled dangerous substance or any other opioid drug in a course of treatment for acute or chronic pain, and again prior to issuing the third prescription of the course of treatment, a practitioner must discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to: (1) the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants; (2) the reasons why the prescription is necessary; (3) alternative treatments that may be available; and (4) risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines or alcohol with opioids, can result in fatal respiratory depression. The practitioner must include a note in the patient's medical record that such discussion took place.

- At the time of the issuance of the third prescription for an opioid drug, the practitioner must enter into a **pain management agreement with the patient**.

- The **pain management agreement** is a written contract or agreement that is to be executed between a practitioner and a patient, prior to the commencement of treatment for chronic pain using a Schedule II controlled dangerous substance or any other opioid drug as a means to: (1) prevent the possible development of physical or psychological dependence in the patient; (2) document the understanding of both the practitioner and the patient regarding the patient's

pain management plan; (3) establish the patient's rights in association with the treatment, and the patient's obligations in relation to the responsible use, discontinuation, and storage of the drug, and any restrictions on refill; (4) identify the specific medications and other modes of treatment that are included as a part of the pain management plan; (5) specify the measures the practitioner may employ to monitor the patient's compliance, including but not limited to random specimen screens and pill counts; and (6) delineate the process for terminating the agreement, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement.

- When a Schedule II controlled dangerous substance or any other prescription opioid drug is continuously prescribed for three months or more for chronic pain, the practitioner must: (1) review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document the results of that review; (2) assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment; (3) periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence and document with specificity the efforts undertaken; (4) review the Prescription Drug Monitoring information; and (5) monitor compliance with the pain management agreement and any recommendations that the patient seek a referral.

- Except in the case of an initial prescription, a practitioner may prescribe a Schedule II controlled dangerous substance for the use of a patient in any quantity which does not exceed a 30-day supply at the lowest effective dose. The practitioner must document the diagnosis and the medical need for the prescription in the patient's medical record. Except in the case of an initial prescription, a practitioner may also issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance, provided that the following conditions are met: (1) each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice; (2) the practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription; (3) the practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and (4) the practitioner complies with all other applicable State and federal laws and regulations.

- These requirements do not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a

resident of a long term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

- Because this law does not become effective until May 16, 2017, the Attorney General and the State Board of Medical Examiners implemented emergency rules, effective as of March 1, 2017. The emergency rules implement the above provisions of the new law immediately, and also provide that failure to adhere to the standards set forth in the new rules will provide a basis for the Attorney General and the Board to seek emergent action to suspend or limit a practitioner's license.

The law also imposes continuing education requirements, including at least one credit for educational programs or topics concerning prescription opioid drugs, responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. The continuing educational requirements apply to physicians, dentists, optometrists, podiatrists, physician assistants, certified nurse midwives, nurses and pharmacists.