24 Del. Admin. Code CSA 9.0

CSA 9.0. Safe Prescribing of Opioid Analgesics

Currentness

<Section effective until April 11, 2017. See, also, section effective April 1, 2017.>

9.1 Preamble: This Section provides requirements for the prescribing of opioid analgesics in order to address potential prescription drug overdose, abuse, and diversion and encourage the proper and ethical treatment of pain. Pursuant to the requirements of this Section, the practitioner can meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care.

9.2 License and DEA registration required: To prescribe opioid analgesics in Delaware, the practitioner must be licensed in this state and registered with the U.S. Drug Enforcement Administration and must comply with all applicable federal and state regulations. Out-of-state practitioners, who are prescribing controlled substances to patients in Delaware, must hold active licensure and registration in their home states. Practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances.

9.3 Definitions:

9.3.1 "**Acute Care**" means the treatment of Acute Pain, as defined in subsection 9.3.2.

9.3.2 "**Acute Pain**" means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time limited. For the purpose of this Regulation, Acute Pain is less than three months in duration.

9.3.3 "**Acute pain episode**" means a discrete period of pain that usually follows some sort of injury to the body and generally dissipates when the injury heals.

9.3.4 "**Addiction**" means a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental

factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

9.3.5 "**Chronic Care**" means the treatment of Chronic Pain, as defined in subsection 9.3.6.

9.3.6 "**Chronic Pain**" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years. For the purpose of this Regulation, Chronic Pain means continuous or nearly continuous pain more than three months in duration.

9.3.7 "**Opioid Analgesic**" means a drug that is used to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (synthetic drugs). Examples include: morphine, codeine, fentanyl, meperidine, and methadone. For purposes of this regulation, it does not include, unless specifically designated as controlled under 16 Del.C. § 4711, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

9.3.8 "**PMP**" means the Delaware Prescription Monitoring Program.

9.3.9 "**Practitioner**" means a physician, dentist, podiatrist, nurse practitioner, physician assistant or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to prescribe a controlled substance in the course of professional practice but does not include veterinarians.

9.3.10 "**Risk Assessment**" means utilizing a tool appropriate for the patient, such as but not limited to, the Screener and Opioid Assessment for Patients with Pain ("SOAPP"), Opioid Risk Tool ("ORT"), or Screening, Brief Intervention and Referral to Treatment ("SBIRT"), which are designed for predicting the likelihood that a patient will abuse or misuse a prescribed controlled substance based on past behavior, genetic predispositions, social or environmental factors, or other risks.

9.3.11 "**Substance Abuse**" means using a controlled substance without a legitimate medical need, for the purpose of altering one's emotional experience.

9.3.12 "**Substance Misuse**" means using a controlled substance in a way that is not prescribed.

9.3.13 "**Treatment Agreement**" means a written agreement, signed by the practitioner and the patient (or the patient's proxy), which shall become part of the patient's medical record. The Treatment Agreement may include, at the practitioner's discretion:

• The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

• Reasons for which medication therapy may be re-evaluated, tapered or discontinued, including but not limited to, violation of the Treatment Agreement or lack of effectiveness;

• The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;

• The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;

• Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan, a referral to a pain specialist, or referral to an addiction treatment program; and

• The requirement that fluid drug screens be performed at random intervals at the practitioner's discretion, but not less than every six months.

9.4 Practitioner-patient relationship: A practitioner may not prescribe opioid analgesics unless a practitioner-patient relationship has been established, or the practitioner is seeing the patient in lieu of the patient's prescribing practitioner on a limited basis and on the practitioner's request or behalf.

9.5 First time, outpatient prescription for Acute Pain; maximum seven-day supply.

9.5.1 When issuing a prescription for an opioid analgesic to an adult patient for outpatient use for the first time, for an Acute Pain Episode, a practitioner may not issue a prescription for more than a seven-day supply.

9.5.2 A practitioner may not issue a prescription for an opioid analgesic to a minor for more than a seven-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opioid use and the reasons why the prescription is necessary.

9.5.3 Notwithstanding subsections 9.5.1 and 9.5.2, if, in the professional medical judgment of a practitioner, more than a seven-day supply of an opiate is required to treat the adult or minor patient's acute medical condition, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition. The condition triggering the prescription of an opiate for more than a seven-day supply shall be documented in the patient's medical record, the practitioner shall query the PMP to obtain a prescription history, and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition and comply with subsections 9.6.4 and 9.6.5.

9.6 Subsequent prescriptions. After the first time outpatient prescription, or after the patient has been issued outpatient prescription(s) totaling up to a seven day supply, prior to issuing a subsequent prescription for an opioid analgesic for Acute Pain, the practitioner must perform an appropriate evaluation of the patient's medical history and condition, including the following:

9.6.1 Query the PMP to obtain a prescription history for the first subsequent prescription that goes beyond the initial 7-day period and, for any subsequent prescriptions after that, the PMP shall be queried at the discretion of the practitioner unless otherwise required;

9.6.2 Administer a fluid drug screen, at the discretion of the practitioner;

9.6.3 Conduct a physical examination which must include a documented discussion between the practitioner and patient to: Elicit relevant history, explain the risks and benefits of opioid analgesics and possible alternatives to the use of opioid analgesics, identify other treatments tried or considered, and determine whether opioid analgesics are contra-indicated;

9.6.4 Obtain an Informed Consent form, signed by the patient (or the patient's proxy), that must include information regarding the drug's potential for addiction, abuse, and misuse; and the risks associated with the drug of life-threatening respiratory depression; overdose as a result of accidental exposure potentially fatal, especially in children; neonatal opioid withdrawal symptoms; and potentially fatal overdose when interacting with alcohol; and other potentially fatal drug/drug interactions, such as benzodiazepines; and

9.6.5 Schedule and undertake periodic follow-up visits and evaluations of the patient to monitor and assess progress toward goals in the treatment plan and modify the treatment plan, as necessary. The practitioner must determine whether to continue the treatment of pain with an opioid analgesic, whether there is an available alternative, whether to refer the patient for a pain management or substance abuse consultation.

9.7 Chronic Pain patients. In addition to the requirements of subsection 9.6, the practitioner must adhere to the following additional requirements for Chronic Pain patients:

9.7.1 Query the PMP at least every six months, more frequently if clinically indicated, or whenever the patient is also being prescribed a benzodiazepine;

9.7.2 Query the PMP whenever the patient is assessed to potentially be at risk for substance abuse or misuse or demonstrates such things as loss of prescription(s), requests for early refills or similar behavior;

9.7.3 Administer fluid drug screens at least once every six months;

9.7.4 Obtain a signed Treatment Agreement, pursuant to subsection 9.3.13;

9.7.5 Conduct a Risk Assessment as defined in subsection 9.3.10;

9.7.6 Document in the patient's medical record alternative treatment options that have been tried by the patient, including non-pharmacological treatments, and their adequacy with respect to providing sufficient management of pain;

9.7.7 Make efforts to address psychiatric and medical comorbidities concurrently, rather than sequentially, when concurrent treatment is clinically feasible; and

9.7.8 At the practitioner's discretion, seek a case review and consult with, or otherwise refer the patient to, a state-licensed physician who holds a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology or an addiction certification from the American Board of Addiction Medicine or an addiction specialist if any of the following occur:

9.7.8.1 Adulterated drug tests;

9.7.8.2 Diversion of prescribed medications; or

9.7.8.3 The patient has obtained controlled substances elsewhere without disclosure to the physician, as evidenced by PMP data.

9.8 Practitioners treating the following patients are exempted from the requirements of this Regulation:

9.8.1 Hospice care patients;

9.8.2 Active cancer treatment patients;

9.8.3 Patients experiencing cancer-related pain;

9.8.4 Terminally ill/palliative care patients; and

9.8.5 Hospital patients, during the hospital stay, including any prescription issued at the time of discharge, so long as that discharge prescription is for a quantity of a 7-day supply or less.

Credits

Adopted April 11, 2014; Aug. 11, 2016. Amended April 1, 2017.

Current with amendments included in the Delaware Register of Regulations, Volume 21, Issue 3, dated September 1, 2017.

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