Governor Baker Signs Legislation Designed To Address Opioid Crisis

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On Monday, March 14, 2016, Governor Baker signed into law Chapter 52 of the Acts of 2016, a comprehensive law aimed at addressing the opioid addiction crisis in Massachusetts. The new law, titled An Act Relative to Substance Use, Treatment, Education and Prevention ("Act"), establishes tighter controls over practitioners, healthcare facilities, pharmacies, insurers and other authorities relative to the evaluation and treatment of patients who are suspected of having a substance use disorder as well as the process for prescribing Schedule II and III opioid medications. Relevant provisions are highlighted below.

24-HOUR SUBSTANCE ABUSE EVALUATION (EFFECTIVE 7/1/2016)

The Act requires facilities to conduct a substance abuse evaluation of a patient who has been administered naloxone prior to arrival, or who is reasonably believed to have experienced an opiate-related overdose by the treating clinician. The evaluation must occur within 24 hours of admission or prior to discharge, whichever comes sooner, and must conclude with a diagnosis of the status and nature of the patient's substance use disorder, and if necessary, contain recommendations for further treatment. The findings and recommendations must be presented to the patient in writing and entered into the patient's medical record. The facility must notify the patient's primary care physician, if known, about the overdose and any recommendations for further treatment. Insurance coverage of the evaluation is mandated under the Act.

Patients may consent to further treatment within the facility; however, if the facility is unable to provide such services, it must refer the patient to a treatment center outside the facility. If the patient refuses treatment upon completion of the evaluation, and is otherwise medically stable, the facility may initiate discharge proceedings.

PRESCRIPTION LIMITS (EFFECTIVE IMMEDIATELY)

The Act limits the timeframe for which a practitioner may prescribe opiate medications for outpatient use. If the prescription is for the first time for an adult patient, the practitioner cannot issue a prescription for more than a 7-day supply. In the case of a minor, the practitioner cannot issue a prescription for more than a 7-day supply at any time. In addition, the practitioner must discuss with parents or guardian(s) of a minor the risks associated with opiate use and the reasons why the prescription is necessary. Exceptions to the 7-day limit are provided for the treatment of chronic pain management, pain associated with cancer or palliative care if reasons are properly documented. The limitation does not apply to medications designed for the treatment of substance abuse or opioid dependence.

PAIN MANAGEMENT TREATMENT AGREEMENT (EFFECTIVE IMMEDIATELY)

Prior to prescribing an extended-release opioid in a non-abuse deterrent form to a patient for the first time, a practitioner must evaluate a patient's current condition, medications, risk factors and history of substance abuse, as well as inform the patient and note in his/her medical record that the prescribed medication, in the practitioner's medical opinion, is an appropriate course of treatment based on the patient's medical needs. Should the practitioner recommend the use of an extended-release long-acting opioid for long-term pain management, the physician must enter into a written pain management treatment agreement with the patient, which shall be filed in the patient's electronic health record. The agreements should address the benefits and risk factors for misuse or abuse of the controlled substance according to guidelines published by the Department of Public Health.

SATELLITE EMERGENCY FACILITIES (EFFECTIVE IMMEDIATELY)

The Act amends the hospital licensure definitions by adding a "satellite emergency facility" category, which is defined as 'a health care facility that operates on a 7-day per week, 24-hour per day basis that is located off the premises of a hospital, but is listed on the license of a hospital, and is authorized to accept patients transported to the facility by ambulance." Satellite emergency facilities were previously addressed only in Department of Public Health regulations, but are now part of state statute.

VOLUNTARY NON-OPIATE DIRECTIVE (EFFECTIVE 12/1/2016)

Upon discharge from a licensed substance use disorder treatment program, patients must be provided information about the option to file a voluntary non-opiate directive form, established by the Department of Public Health, which a patient may file with their physician or other authority and which may be revoked by the patient at any time.

UNIVERSAL INTAKE FORM (TO BE AVAILABLE OCTOBER 1, 2016)

The Division of Insurance, in consultation with the Department of Public Health, the Department of Mental Health, and the Bureau of Substance Abuse Services, will develop a universal intake form to streamline the administrative process for the intake of behavioral health and substance abuse patients. The form shall be available on the Division's website no later than October 1, 2016. The Division must hold at least 4 public hearings on the development of the form.

PROVIDER EDUCATION (EFFECTIVE IMMEDIATELY)

As a prerequisite to obtaining or renewing their professional licenses, practitioners who prescribe controlled substances will be required to complete training relative to effective pain management, the risks of abuse and addiction associated with opioid medication, identification of patients at risk for substance use disorders, counseling patients about side effects, addictive nature and proper storage and disposal of prescription medications, appropriate prescription quantities for medications that have an increased risk of abuse, and opioid antagonists, overdose prevention treatments and instances in which a patient may be advised on both the use of and ways to access opioid antagonists and overdoes prevention treatments. Standards for appropriate training programs will be established by the boards of registration for each professional that requires the training.

PRESCRIPTION MONITORING PROGRAM (EFFECTIVE 10/15/2016)

Practitioners will be required to utilize the Prescription Drug Monitoring Program prior to the issuance of prescriptions for Schedule II or III narcotics.

PARTIAL FILL OF PRESCRIPTIONS (EFFECTIVE IMMEDIATELY)

Physicians must consult with their patients regarding the quantity of the opioid prescription and the patient's option to request a lesser amount, as well as the risks. Prescriptions must include a notation that the patient may, upon request, fill any amount not to exceed the recommended full quantity indicated. Registered pharmacists must dispense a lesser quantity of the Schedule II opioid if requested by the patient, with any leftover amount to be void. The division of insurance shall develop and implement regulations providing that there shall be no financial penalty for a patient's choice to receive a lesser quantity of an opioid contained in Schedule II or III.

MONTHLY REPORTING OF SUBSTANCE EXPOSED NEWBORNS AND CHILDREN (EFFECTIVE IMMEDIATELY)

The monthly reporting requirements for acute hospitals are amended to include the number of newborns identified as having been exposed to, and the number and specific causes of hospitalizations of children under the age of 11 caused by ingestion of, a "Schedule I or Schedule II controlled substance under chapter 94C or those controlled substances in Schedule III under said chapter 94C that the drug formulary commission, established by section 13 of chapter 17, has determined have a heightened level of public health risk due to the drug's potential for abuse and misuse." These provisions replace the previous reporting requirements of infants exposed to and children hospitalized due to ingestion of schedule II – schedule VI controlled substances.

PRESCRIBING TRENDS (EFFECTIVE 12/1/2016)

Under the Act, the Department of Public Health will be required to determine the annual mean and median quantity and volume of Schedules II and III opiate prescriptions. Prescribers who exceed the mean or median values within their category will be sent a notice of their percentile ranking. The first distribution of said reports will occur no later than March 1, 2017. Practitioners may also request their percentile ranking. The rankings will be confidential and not considered part of the public record, admissible as evidence in criminal or civil proceedings, or be used as the sole basis for investigation by a licensure board. The Department of Public Health may provide de-identified information for statistical research or educational purposes.

OTHER PROVISIONS:

- The Act provides for civil liability protection for any person who administers naloxone in an attempt to render emergency care, except in cases of gross negligence or willful or wanton misconduct.
- Requirements for certain pamphlets at pharmacies have been amended to include a specific reference to opiates.
- A definition for "extended-release long-acting opioid" is now included in the Controlled Substances Act.
- Within 12 months, the Health Policy Commission, in consultation with the Department of Public Health and the Department of Mental Health, shall study the availability of health care providers that serve patients with dual diagnoses of substance use disorder and mental illness in both inpatient and outpatient settings.
- The Department of Public Health must amend its regulations to provide that discharge planning include information on FDA-approved medication assisted treatment, and the availability of such treatments in each geographic region.
- The Department of Public Health, in collaboration with other agencies, will develop an education and referral training program to enable municipal police officers to obtain information regarding referral to treatment for individuals seeking help at a local police department.
- Contact information for all insurance payers will be posted on the Massachusetts behavioral health access website.
- The Drug Formulary Commission must publish by September 1, 2016 a list of FDA-approved alternatives to opioid medication for pain management that have less potential for abuse.
- The Department of Public Health must promulgate regulations relative to the advertising of opiates, benzodiazepines, and narcotics by practitioners on their premises.

- The Act creates a drug stewardship program, effective January 1, 2017, to collect, secure, transport and dispose of unwanted drugs. The program will be financed by pharmaceutical manufacturers.
- The Board of Registration in Pharmacy is required to establish a rehabilitation program to assist registered pharmacists whose competency has been impaired due to substance use disorders to return to practice.
- The Act establishes a special commission to study and make recommendations by December 1, 2016 regarding the incorporation of additional professional training regarding safe and effective pain treatment and prescribing practices.
- The Act establishes a special commission to examine the feasibility of creating a pain management access program to increase access to pain management for patients in need of comprehensive resources, with a report and any proposed legislation to be submitted by November 1, 2016.
- The Act establishes a special commission to study and investigate the effectiveness of state licensed addiction treatment centers and to make policy recommendations for enhancing the accessibility, utilization and effectiveness such services, with a report and any proposed legislation to be submitted by January 1, 2017.
- Public schools are required to develop a policy addressing substance use prevention and education. Schools will be required to conduct verbal screenings for substance use disorders on all students in two grades.

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