MHA SUMMARY DOCUMENT:

Statutory and Regulatory Changes Related to Substance Use Disorder Evaluations, and the Administration, Prescribing, and Dispensing of Opioids and Other Medications of Potential Misuse

February 21, 2019

This document summarizes important state and federal updates to laws and regulations relating to substance use disorder evaluations (SUDE), the state's prescription monitoring program (MassPAT), professional licensure, and new Medicare Part D Opioid Prescribing Requirements, among other related topics.

If you have questions about any of these provisions, please contact Leigh Simons Youmans, MHA's Director of Behavioral Health & Healthcare Policy, at **lyoumans@mhalink.org** or (781) 262-6026.

Substance Use Disorder Evaluations

One of Massachusetts' previous opioid laws, Chapter 52 of the Acts of 2016, requires any patient arriving in an emergency department (ED) or a satellite emergency facility (SEF), who is experiencing an overdose or who was administered naloxone before arriving, to undergo a substance use disorder evaluation (SUDE) within 24 hours. Chapter 208 of the Acts of 2018 made several updates to SUDEs. As a result, on February 14, the Department of Public Health (DPH) released **this circular letter** to hospitals. Additionally, MHA, in collaboration with the Massachusetts College of Emergency Physicians (MACEP), has released **these updated joint guidelines** on SUDEs. The statutory changes include:

- Adding several provider types to those that are able to perform SUDEs;
- Allowing treatment for a substance use disorder, including Medication for Addiction Treatment (MAT), to occur both during or after an SUDE;
- Requiring that if the patient is in need of and agrees to further treatment following discharge, then the acute care hospital or SEF must directly connect the patient with a community-based program prior to discharge or within a reasonable time following discharge when the community-based program is available; and
- Requiring that acute care hospitals, SEFs, or emergency service programs record the overdose and SUDE in the patient's electronic medical record (EMR) and that these entities make the SUDE available to other providers and facilities through a secure EMR or information system.

Additionally, the SUDE statute requires five criteria that must be part of the SUDE and incorporated into the hospital medical record. While providers are able to develop their own form or process for obtaining this information, the Massachusetts Behavioral Health

Partnership (MBHP) has developed two forms that are used by all emergency service programs. These forms are comprehensive assessments for both mental health and substance use disorder evaluations; **this form is for adult populations** and **this form is for youth**. Nothing precludes a provider from developing a format or process within their own EMR or other system.

Proposed MassPAT Regulatory Changes

Chapter 208 and the subsequent Chapter 425 of the Acts of 2018 made changes to the Massachusetts prescription monitoring program (PMP), commonly referred to as MassPAT. These changes are related to the use of MassPAT data in an EMR or other secure electronic system, the use of the PMP before prescribing benzodiazepines, and how data can be shared with law enforcement officials.

- **MassPAT Data and EMRs**
    - The draft regulations allow MassPAT data to be accessed through a secure EMR or other secure electronic system as authorized in a written agreement with DPH. The agreement with DPH allows the creation and maintenance of a summary of patient-specific data in that patient's EMR as a clinical note associated with the specific clinical encounter. The data may be used only for the purpose of diagnosis, treatment or coordinating care, and cannot be retained separately from the clinical note.

    - The draft regulations also allow DPH to enter into data use agreements with healthcare facilities so that the facilities can integrate secure software or other information systems with their EMR to perform compilation, data analysis or visualization of data for the purposes of diagnosis, treatment, or coordinating care of the practitioner's patient as long as the data use agreements comply with DPH guidelines related to security protocols, terms and conditions of use established by the Commissioner, and DPH regulations related to Standards for Prescription Format and Security in Massachusetts.

- **MassPAT and Benzodiazepines:**
    - As described in **this November 2018 MHA Advisory**, Chapter 208 updates Massachusetts General Laws Chapter 94C, the Controlled Substances Act, to require prescribers to check MassPAT before every prescription for a benzodiazepine. Previously, DPH regulation required that MassPAT be checked prior to issuing a benzodiazepine to a patient for the *first time*.

    - DPH also suggests clinicians consider prescribing naloxone to patients to who the clinician is prescribing a benzodiazepine.

- **MassPAT and Data Availability to Law Enforcement:** Chapter 425 of the Acts of 2018, signed into law in January, updated the list of entities/personnel that MassPAT data may be released to upon request. The data may be released to:
    - Personnel of the United States Attorney or a federal agency, office of the attorney general, a district attorney's office if the data request is made in connection with a *bona fide* specific controlled substance or additional drug-related investigation and is in accordance with federal law or

accompanied by relevant probably cause warrant or civil investigative demand;

- Personnel of the Medicaid fraud control unit within the office of the attorney general if the data request is made in connection with a *bona fide* specific controlled substance or additional drug related investigation; or

- Personnel within the office of a district attorney if the data request is made in connection with a *bona fide* investigation into the cause and manner of death of an individual suspected of a drug overdose as long as the data provided in this manner is limited to the prescription information of the individual suspected of the drug overdose.

A red-lined version of the draft regulations is **available here**. DPH plans to hold a public hearing on these regulations on March 8, 2019 at 2 p.m. in the Public Health Council Room, DPH, 250 Washington Street, Boston.

This **March 2018 MHA Advisory** contains guidance on exemptions from MassPAT requirements.

Voluntary Non-Opioid Directives

Chapter 52 of the Acts of 2016 required DPH to develop a voluntary non-opioid directive (VNOD) form with the intent of indicating to practitioners that a patient shouldn't be administered or offered a prescription or medication order for an opioid. Earlier this year, the Bureau of Substance Addiction Services developed **this form** for patients and providers to use to indicate when a patient does not want to be administered an opioid.

For full details on practitioner and facility requirements relative to VNODs, please see this **February 2017 MHA Advisory**.

Pharmacist and Pharmacy Intern Administration of Medications for the Treatment of Mental Illness and Substance Use Disorder

DPH's Bureau of Health Professions Licensure on February 12 released **this circular letter** on pharmacist administration of medications for the treatment of mental illness and substance use disorder. Pursuant to DPH regulations 105 CMR 700.000, *Implementation of Massachusetts General Laws chapter 94C,* pharmacists and pharmacy interns are able to administer a specific list of FDA-approved mental health and substance use disorder medications to persons 18 years or older if:

a) The pharmacist or pharmacy intern is authorized to dispense controlled substances, in accordance with M.G.L. c. 112;
b) Administration is conducted pursuant to a valid prescription;
c) The pharmacist or pharmacy intern does not administer the first dose of such medication the person receives;
d) The prescription is subject to reassessment by the prescriber at appropriate intervals, as determined by the prescriber; and
e) The activity is conducted in accordance with DPH guidelines.

The medications eligible to be administered by a pharmacist or pharmacy intern are:

- Long Acting Injectable Antipsychotics (LAIs)
  - Aripiprazole (Abilify Maintena®)
  - Aripiprazole lauroxil (Aristada®)
  - Fluphenazine decanoate (Prolixin decanoate®)
  - Haloperidol decanoate (Haldol decanoate®)
  - Paliperidone palmitate (Invega Sustenna®)
  - Paliperidone palmitate (Invega Trinza®)
  - Risperidone (Risperdal Consta®)

- Long Acting Injectable Medication for Substance Use Disorders
  - Naltrexone (Vivitrol®)

Additional requirements related to prescriber assessment, training, continued competency, pre-administration patient counseling, administration, recordkeeping, and reporting adverse events are detailed in the circular letter.

Gabapentin Dispensing

The Massachusetts Board of Pharmacy recently sent a communication on instances when a pharmacy may dispense Gabapentin or a controlled substance in Schedules II through V without customer identification.

If the pharmacist has reason to believe that the failure to dispense the medication would result in a serious hardship for the patient, the pharmacist may dispense it without identification if:

a) the reason is documented; and
b) the patient or agent of the patient prints his or her name and address on the reverse side of the prescription and signs his or her name; or in the case of an electronic prescription, provides an electronic signature; and
c) the pharmacist enters "cust signed rx" in the PMP customer ID field (AIR05) rather than leaving the field blank.

Additional instructions can be found in the **PMP Data Submission Guide**.

E-Prescribing

Chapter 208 requires electronic-only prescribing standard for controlled substances by all providers in all settings by January 2020. Exceptions to exclusive e-prescribing include temporary technological or electrical failure, emergency situations, prescriptions that can't be issued electronically under federal or state law, and prescriptions issued outside Massachusetts.

DPH anticipates amending its regulation in order to implement these requirements and MHA will continue to work with DPH and MHA members as the regulatory process moves forward.

Existing requirements for Schedule I-V and Schedule VI e-prescribing systems are detailed in **this DPH regulation 105 CMR 721.030**.

New Medicare Part D Opioid Prescribing Requirements

CMS finalized new policies for Medicare drug plans to follow starting in January 2019, including safety alerts when opioid prescriptions are dispensed at the pharmacy, and drug management programs for patients determined to be at-risk for misuse of opioids or other frequently misused medications.

The new safety alerts include:

- a seven-day limit for opioid prescriptions for patients who are opioid naïve;
- an opioid care coordination alert when a patient presents an opioid prescription at a pharmacy and the patient's cumulative morphine milligram equivalent (mme) across all opioid prescriptions meets or exceeds 90 mme;
- an alert when there is concurrent opioid and benzodiazepine use or duplicative long-active opioid therapy; and
- an optional alert when a patient's cumulative opioid daily dosage reaches 200 MME.

Exceptions to these new requirements include: residents of long-term care facilities, those in hospice care, patients receiving palliative or end-of-life care, and patients being treated for active cancer-related pain. Medication for addiction treatment, including buprenorphine, should not be affected by these changes.

Additional information on the safety alerts and drug management programs as they apply to prescribers, pharmacists, and patients, **is here**.

MAT in Emergency Departments

Chapter 208 also requires acute care hospitals and satellite emergency facilities to have the capacity to initiate opioid agonist therapy to patients after an opioid-related overdose, and directly connect such patients to continuing treatment prior to discharge. MHA, in collaboration with MACEP, released these **Guidelines for Medication for Addiction Treatment for Opioid Use Disorder within the Emergency Department** in January to assist acute care hospitals in implementing a Medication for Addiction Treatment program in their emergency departments or satellite emergency facilities.

If you have any questions about any of these provisions, please contact Leigh Simons Youmans, MHA's Director of Behavioral Health & Healthcare Policy at **lyoumans@mhalink.org** or (781-262-6026).