



The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

Drug Control Program

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Circular: DCP 19-2-105

To: Massachusetts Retail Pharmacies and Licensed Pharmacists
Massachusetts Licensed Prescribers

From: James G. Lavery, Director, Bureau of Health Professions Licensure

Date: February 12, 2019

Re: Pharmacist Administration of Medications for the treatment of Mental Illness and Substance Use Disorder.

Purpose

Recent amendments to 105 CMR 700.000 authorize pharmacists and pharmacy interns to administer medications for treating mental illness and substance use disorder, in accordance with Department guidance.¹ The purpose of this circular letter is to provide guidance to pharmacists and pharmacy interns who choose to administer any of the approved medications. There is no requirement for pharmacists or pharmacy interns to administer these medications. This circular letter also includes guidance to prescribers whose patients are administered any of the approved medications in a pharmacy setting.

Dispensing by Administration

A pharmacist or a pharmacy intern may, without obtaining a Massachusetts Controlled Substance Registration (MCSR), dispense by administration (i.e. administer) FDA-approved mental health and substance use disorder treatment drugs included below in the "Medications Eligible for Pharmacist or Pharmacy Intern Administration" to persons 18 years or older, provided that:

- (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 Department guidelines.

¹ See: 105 CMR 700.004(B)(9)

Medications Eligible for Pharmacist or Pharmacy Intern Administration

The following are the only medications eligible to be administered, provided the medication is available in single-dose packaging and prescribed in single doses, with or without refills.

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®)

Prescriber Assessment

Prescribers must regularly re-assess the patient and prescription at appropriate intervals, such as quarterly, to be determined by the prescriber. This assessment does not preclude the issuance of valid prescriptions with available refills. If a pharmacist or pharmacy intern is presented with a prescription and has questions about the interval transpiring between assessments, routine communication with the prescriber is encouraged, but not required, prior to administration.

Training

To administer, a pharmacist or pharmacy intern must first receive training that is accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body appropriate for the medications being administered and their respective patient populations. Such training shall include learning modules on techniques for administration by injection.

CPR Certification

To administer, a pharmacist or pharmacy intern must maintain current certification in cardiopulmonary resuscitation.

Continued Competency

To administer, a pharmacist or pharmacy intern must maintain continued competency regarding the populations served, medications administered and current guidelines. Continuing education programs are one way to maintain competency.

Pre-administration patient counseling

A pharmacist or pharmacy intern must provide customary, patient counseling prior to administering a dose of an approved medication. Such counseling may include information about common side-effects, drug interactions, dietary requirements, injection site reaction and other information routinely provided to patients upon dispensing, as appropriate within the professional judgment of the pharmacist and in accordance with 247 CMR 2.00 et seq.

Administration and Dosing – Manufacturers’ Instructions

A pharmacist or pharmacy intern may only administer an eligible medication, in accordance with manufacturer approved labeling for the specific medication administered.

Administration – Medical Emergencies

To administer, a pharmacist or pharmacy intern must maintain competency in management of medical emergencies such as may arise as a result of administration of eligible medications. If emergency medical services are required, an adverse event must be immediately reported, as outlined below. Prescribers are urged to issue separate prescriptions for appropriate emergency medications, as needed.

Record Keeping

A pharmacy where any of the eligible medications are administered must maintain the following information:

- Patient consent;
- Patient screening information, including at least date of birth and other relevant vital statistics, known allergies, and other medications taken;
- Type of medication administered;
- Manufacturer;
- Lot number
- Expiration date;
- Date of administration;
- Route and site of administration;
- Pharmacist or pharmacy intern (signature or initials and title); and
- Adverse outcome, if any;
- Adverse event, if any.

Reporting Adverse Events

Any adverse events or reactions occurring as a result of a pharmacist or pharmacy intern administering a medication listed in this guidance should be appropriately communicated to the prescriber within 24 hours. If the adverse event includes one of the following outcomes, the event must be immediately reported to the prescriber.

- (i) death;
- (ii) a life-threatening outcome;
- (iii) inpatient hospitalization or prolongation of existing hospitalization;
- (iv) additional treatment, testing, or monitoring in a hospital or emergency department; or
- (v) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

If the adverse event is the result of a dispensing error or is a serious adverse drug event, the pharmacist or pharmacy intern remains responsible for reporting the event to the Board of Registration in Pharmacy, in accordance with Board regulations.

Pharmacist-Prescriber Communication

Prescribers issuing prescriptions for eligible medications and pharmacists or pharmacy interns administering these medications are strongly encouraged to engage in regular communication to ensure patient safety, continued patient progress, medication adherence and emergency management.

As a best practice, prescribers may make clear that they intend for eligible medications to be administered by a pharmacist or pharmacy intern by including the following notation on the prescription:

“for pharmacist administration”.

A pharmacist or pharmacy intern receiving a prescription for eligible medications without the notation is encouraged to contact the prescriber if, in their professional judgment, it appears the medication is intended to be administered, rather than being dispensed to the patient for administration outside the pharmacy.

Pharmacists and pharmacy interns are strongly encouraged to send administration records to prescribers as soon after administration as practical.

Prescribers are urged to issue a separate prescription for appropriate emergency medication, as needed, along with any prescription for eligible mental health or substance use disorder medications to be administered by a pharmacist or pharmacy intern. Prescribers and pharmacists are encouraged to develop an emergency medication protocol to address any emergency medication prescription needs for patients.

Privacy

A pharmacist or pharmacy intern engaged in this activity must maintain the privacy and confidentiality of any patient to whom medication is administered, in accordance with 247 CMR 2.00 et seq., and 42 CFR Part 2 as applicable, at all times during the course of dispensing and administration.

Contact Information

Questions or concerns regarding this information should be directed to The Drug Control Program: dcp.dph@state.ma.us.