

# MARYLAND PSYCHIATRIC SOCIETY



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March 14, 2022

Jason Caplan, Director  
Office of Regulation and Policy Coordination  
Maryland Department of Health  
201 West Preston Street, Room 512  
Baltimore, MD 21201

RE: Public Comments on 10.34.41 Administration of Maintenance Injectable Medication

Dear Mr. Caplan:

The Maryland Psychiatric Society (MPS) is a state medical organization whose physician members specialize in the diagnosis, treatment, and prevention of mental illnesses including substance use disorders. Formed more than seventy years ago to support the needs of psychiatrists and their patients, MPS works to ensure available, accessible, and comprehensive quality mental health resources for all Maryland citizens; and strives through public education to dispel the stigma and discrimination of those suffering from a mental illness. As the district branch of the American Psychiatric Association covering the state of Maryland excluding the D.C. suburbs, MPS represents over 730 psychiatrists as well as physicians currently in psychiatric training.

We would like to provide the attached notes regarding your call for public comments on COMAR regulation 10.34.41, Administration of Maintenance Injectable Medication. If you have any questions, please do not hesitate to contact Meagan Floyd at [mfloyd@mdpsych.org](mailto:mfloyd@mdpsych.org).

Sincerely

Virginia Ashley, MD, President  
Maryland Psychiatric Society



(See comments in red. \* indicates an addition to text)

**.03 Requirements to Administer a Maintenance Injectable Medication—Pharmacist’s Responsibilities.**

A. Upon completion of all requirements established by the Board in this chapter, and after review of all relevant information, a pharmacist may administer a maintenance injectable medication.

B. In order to administer a maintenance injectable medication, a pharmacist shall:

- (1) Utilize and follow the Board-approved procedure set forth in Regulation .07 of this chapter to administer a maintenance injectable medication;
- (2) Refer a patient for additional care to the patient’s primary care practitioner or the authorized prescriber, if necessary;
- (3) Provide the patient and the authorized prescriber with a copy of the visit summary, including a written record of the maintenance injectable medication that was administered;
- (4) Document the encounter and maintain records pursuant to Regulation .05 of this chapter; and
- (5) Notify the authorized prescriber that the medication was administered to the specific patient and any relevant information about the patient’s condition.

C. A pharmacist shall:

- (1) Obtain written approval *\*in electronic or other form*, from the patient’s authorized prescriber prior to administering an initial dose of a maintenance injectable medication; and
- (2) Notify the patient of all fees that the patient is required to pay before administering a maintenance injectable medication.

**.04 Training Program Requirements.**

A. Except as provided in §C of this regulation, a pharmacist shall successfully complete a Board-approved training program for the administration of injectable maintenance medications prior to administering injectable maintenance medications.

B. At a minimum, a Board-approved training program consists of the following elements:

- (1) Administration of a maintenance injectable medication;
- (2) Management of the patient populations served by a pharmacist;
- (3) Knowledge of the specific maintenance injectable medications that a pharmacist may administer; and
- (4) Current guidelines *\*and (FDA) advisories* relating to the specific patient populations served by a pharmacist and the specific maintenance injectable medications that a pharmacist may administer, if applicable.

C. The training program requirement set forth in §A of this regulation is waived for a pharmacist who has undergone the training as part of a formal education program, *\*unless the training in that education program is out-of-date as regards current guidelines and (FDA) advisories*.

D. A pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern, who has successfully completed a Board-approved certification course under Health Occupations Article, §12-508, Annotated Code of Maryland, may administer a maintenance injectable medication under the direct supervision of a licensed pharmacist who meets the requirements set forth in Regulation .03 of this chapter.

**.06 Patient Information and Consent.**

A. A pharmacist that administers a maintenance injectable medication shall:

- (1) Obtain a paper or electronic consent form signed by the patient, or the patient’s legal guardian, that authorizes the pharmacist to administer the maintenance injectable medication;
- (2) Provide the patient, or the patient’s legal guardian, with a copy of the consent form for future reference upon request;



(3) Provide the patient, or the patient's legal guardian, and the authorized prescriber with a copy of the visit summary, including a written record of the maintenance injectable medication that was administered; and

(4) Notify the patient of the need to attend any upcoming appointments the patient has scheduled with the *\*authorized prescriber, \*or the need to schedule a visit with the patient's primary care practitioner or the authorized prescriber*, for additional care.

B. The administering pharmacist shall:

(1) Disclose their credentials on the consent form; and

(2) Provide every patient with notification of the fee for service prior to administration.

*\*(3) Inform the patient of their right to decline administration of the medication by the pharmacist*

#### **.07 Standard Procedures.**

A. Before a pharmacist administers a maintenance injectable medication, a pharmacist shall have and maintain a written procedure for any maintenance injectable medication that may be administered.

B. A pharmacist shall administer a maintenance injectable medication in accordance with the written procedure, including:

(1) Recording and maintaining the prescription files in accordance with Regulation .05 of this chapter;

(2) Reviewing and screening for the following:

(a) Indications;

(b) Precautions;

(c) Contraindications; and

(d) Allergies;

(3) Reviewing the process for handling adverse reactions, including but not limited to:

(a) Acute anaphylactic reactions; and

(b) Other acute emergencies;

(4) Following injection or administration procedures;

(5) Advising the patient of post-administration procedures, including waiting requirements; and

(6) Documenting and maintaining a maintenance injectable medication record, including:

(a) Patient's:

(i) Name;

(ii) Date of birth;

(iii) Address;

(iv) Consent form;

(v) Authorized *\*prescriber's name*; and

(vi) Administering pharmacist's name and license number;

(b) Administration:

(i) Date;

(ii) Dose;

(iii) Site; and

(iv) Route;

(v) *\*Post-administration adverse events, if any*

(c) Maintenance injectable medication:

(i) Name, generic or brand;

(ii) Manufacturer;

(iii) Lot number; and

(iv) Expiration date;

(d) *\*Written notification, \*in electronic or other form, via the visit summary or otherwise, to the authorized prescriber that the patient received a specific maintenance injectable medication including \*adverse events, if any; and*

(e) Verification that the prescription is:

# MARYLAND PSYCHIATRIC SOCIETY



(i) Not for the patient's initial dose, if applicable; or  
(ii) For the patient's initial dose and the patient's record contains documented approval from the authorized prescriber.

*D. The pharmacist shall:*

- (1) Sign and date the standard procedure at least annually;
- (2) Make the standard procedure available for inspection by the Board, *\*authorized prescriber, or patient upon request; and*
- (3) Review and update the standard procedure as necessary, *\*based on changes in current guidelines, (FDA) advisories, applicable state and federal laws and regulation.*