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Board of Registration in Pharmacy

Policy 2019-07: Pilot Projects in Pharmacy Practice

I. Introduction

The Board of Registration in Pharmacy ("Board") would like to inform licensees of the procedures to be followed in applying for approval of a pilot project for innovative applications in the practice of pharmacy. In reviewing projects, the Board will give priority to projects that expand pharmaceutical care services which contribute to positive patient outcomes.

II. Rules

The Board's approval of pilot projects may include the granting of an exception to the regulations adopted under 247 CMR but may not include an exception from any law relating to the practice of pharmacy. Such exception to the regulations shall be for a specified period of time not exceeding 18 months unless otherwise approved by the Board.

Pilot projects may not:

1. expand the definition of the practice of pharmacy as provided in MGL c. 112 §§ 24(A) through 42(A); or
2. include therapeutic substitution or substitution of medical devices used in patient care.

III. Request Process

A licensee who wishes the Board to consider approval of a pilot project shall submit a petition including at least the following information:

1. Name, address, telephone number, email address, and license number of the licensee responsible for overseeing the project;
2. Site of the pilot project if different from the pharmacy location, as well as the pharmacy license number, as applicable;

3. A detailed summary of the proposed pilot project including:
 - a. Goals, hypothesis, and/or objectives;
 - b. Full explanation of the project, how it will be conducted, and how it will optimize the provision of pharmaceutical care to patients;
 - c. Time frame including the proposed start date and length. Such time frame may not exceed 18 months unless otherwise approved by the Board;
 - d. Background information and/or literature review to support the proposal;
 - e. Regulation(s) that will have to be waived in order to complete the project and a request to waive such regulation(s), as applicable;
 - f. Procedures and safeguards to be used during the project to ensure that the health and safety of the public are not compromised; and
 - g. List of performance metrics (e.g., volume, quality-related events, etc.).

After the petition for a pilot project is received:

1. The Board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for Board consideration for any reason, Board staff will communicate with the licensee to discuss and request additional documentation.
2. Once Board staff has determined that the petition is complete and appropriate, the licensee shall present the pilot project to the Board at a regularly scheduled meeting. Board staff will notify the licensee of the date and time to appear.

IV. Approval Requirements

If the applicant fails to adhere to the requirements set forth by the Board, the Board reserves the right to discontinue or suspend the pilot project.

All documents related to the pilot project and waivers, if applicable, shall be maintained by the pharmacy and shall be made available for Board inspection, upon request.

Please direct any questions to: Pharmacy.Admin@mass.gov