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Board of Registration in Pharmacy

Policy 2018-06: Retail Pharmacy Participation in Research Drug Studies

The Massachusetts Board of Registration in Pharmacy ("Board") would like to inform licensees of the following procedure required for Massachusetts-located Board-licensed retail pharmacy participation in research studies.

Retail pharmacies may procure, store, handle, compound, transport, and/or dispense drug products and/or drug substances for a research study pursuant to a patient specific prescription only after the **researcher** responsible for the study **has obtained** a Researcher Massachusetts Controlled Substance Registration ("MCSR") from the Drug Control Program ("DCP") for the pharmacy site participating in the research study, and the role of the participating pharmacy in the study is described in the application.

A retail pharmacy may only participate in a research study for which they are included in the approved Researcher MCSR application, and their site address is specified on the Researcher MCSR. A pharmacy may not continue to participate in a research study with an expired MCSR. Participation may only resume when the Researcher MCSR is renewed.

If the researcher wishes to include a retail pharmacy in the study protocol, the pharmacy shall provide the following to the Board:

- On pharmacy letterhead, a signed statement from the pharmacy Manager of Record including the following:
  - MA Board pharmacy license number(s);
  - Manner of prescription receipt by retail pharmacy;
  - Brief description of the nature of the drug study including route of administration;
  - Detailed description of the pharmacy's specific role in procuring, receiving, handling, storing, compounding, repackaging, labeling, recordkeeping, dispensing of study medication(s) (e.g., direct to

patient, prescriber's office, etc.), and/or any other responsibilities of the pharmacy in the study (e.g. randomization, blinding, etc.);

- A copy of the MCSR issued to the researcher specifying the pharmacy site address;
- USP/NF monograph for active pharmaceutical ingredient(s) ("API") / bulk drug substance(s) used, if applicable;
- USP/NF Compounded Preparation Monograph, if applicable;
- Valid Certificate of Analysis ("COA") for APIs / bulk drug substance(s) used, if applicable;
- An example of the product label(s);
- An example of patient prescription(s);
- A list of specific Board of Pharmacy regulations that conflict with practices included in the study protocol; and
- A signed attestation that the pharmacy maintains master formulation record(s) for all compounded medications involved in the study and said master formulation record(s) complies with Board of Pharmacy regulations, USP <795>, USP <797>, USP <800> and all other USP chapters, as applicable.

Upon receiving all required information, the Board will review submitted materials and communicate with the licensee(s) involved for further information. The licensee(s) involved may be required to appear before the Board.

Pharmacies must notify the Board when the research drug study has been terminated or if the pharmacy will no longer be participating. All documents related to drug study participation approvals and/or waivers shall be maintained by the pharmacy and shall be made available for Board inspection, upon request.

It is the pharmacy's responsibility to comply with all state and federal laws and regulations.

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