



MASSACHUSETTS
MEDICAL SOCIETY

June 21, 2018

Commissioner Monica Bharel, MD, MPH
Massachusetts department of Public health
250 Washington Street
Boston, MA 02115

RE: 105 CMR 700.000 – *Implementation of M.G.L. c. 94C*

Dear Commissioner Bharel:

On behalf of our respective organizations and their members, we are pleased to provide comments on the pending revisions to *105 CMR 700.000 - Implementation of M.G.L. c. 94c*. We appreciate the Department's work to update the regulation to take into account recent legislative changes and also allow for greater flexibility with an eye toward reducing unnecessary burden, while still ensuring the intent of the regulation remains intact. We especially appreciate the recognition of the need for greater clarity on Massachusetts Controlled Substance Registration as it relates to the conduct of medical research, but have several recommendations for further revision which we hope the Department will favorably consider.

700.001: Definitions - Research Drug

As proposed, the new definition of "Research Drug" reads:

Research Drug means an investigational new drug as defined in 21 C.F.R. 312.3, or any scheduled drug, which is being used in a research study or program where it will be administered or dispensed to one or more human or animal subjects.

We believe that the inclusion of the term "any scheduled drug" in the definition of research drug is overly broad and would impose an unnecessary burden on both filers and Department staff. For example, Massachusetts is the only state in the nation where prescription drugs that are not controlled substances are included in a schedule (Schedule VI), under the proposed definition, use of these drugs in research would require approval by the Department. In addition, Schedule I drugs used in research already require a separate filing and reporting required under 105 CMR 700.009 would be duplicative.

For these reasons, we recommend that the regulation be amended to include a definition of research drug that makes a distinction between research involving humans and that involving animals, we **recommend** the following new definition:

Research Drug means i) an investigational new drug as defined in 21 C.F.R. 312.3, or the investigational use of schedule II drugs in a research study or program where it will be administered or dispensed to one or more human subjects, or ii) a DEA controlled substance used in animal or laboratory research.

105 CMR 700.009 (A) - Research Involving Controlled Substances

Proposed revisions to this section relate to filing requirements of researchers and aim to streamline the approval of research studies. The proposed changes require that the primary investigator make the necessary filing with the Department. We recommend that this section be amended to allow for additional flexibility and permit the research supervisor or department chair to file on behalf of research over which s/he has oversight. This additional change would take into account the different oversight structures of hospital research programs while still maintaining accountability.

We **recommend** the following change to the proposed revised sections:

A) Persons Covered. No person, shall carry out any research project(s) or study/ies involving any research drug unless ~~the~~ a primary investigator or a supervisor or department chair for a group of investigators for the research project(s) or study/ies applies to the Commissioner and receives authorization. ~~The~~ A primary investigator or a supervisor or department chair for a group of investigators for the research project(s) or study/ies shall provide the Commissioner (a) with satisfactory evidence of compliance with any applicable Federal law, and (b) with such information regarding the research project or study as the Commissioner requires.

(B) Information to Be Submitted. The application to carry out a research project(s) or study/ies covered by M.G.L. c. 94C, § 8 shall be submitted by ~~the~~ a primary investigator or a supervisor or department chair for a group of investigators on a form provided or approved by the Commissioner. The Commissioner may, in his or her judgment, require additional information.

Thank you for the opportunity to comment on these important regulations and we look forward to continuing to work with the Department as it considers these revisions.

Sincerely



Marci Sindell, Chief Strategy Officer and Senior Vice President of External Affairs
Atrius Health



John Erwin
Executive Director
Conference of Boston
Teaching Hospitals



Robert K. Coughlin
President & CEO
MassBio



Anuj K. Goel, Esq.
Vice President, Legal and
Regulatory Affairs
Massachusetts Health &
Hospital Association



Brendan Abel, Esq.
Legislative & Regulatory
Affairs Counsel
Massachusetts Medical
Society