



The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

250 Washington Street

Boston, MA 02108-4619

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JOHN W. POLANOWICZ
SECRETARY

LAUREN A. SMITH, MD, MPH
INTERIM COMMISSIONER

NOTICE OF PUBLIC HEARING

Notice is hereby given pursuant to M.G.L. c. 30A, §2, that the Department of Public Health will hold a public hearing on proposed amendments to 105 CMR 700.000 related to the implementation of M.G.L. c. 94C (Controlled Substances Act). The Department is proposing to update the regulations to enhance the Massachusetts Prescription Monitoring Program (PMP) in order to fulfill the statutory mandates of Chapter 244 of the Acts of 2012 and improve public health and safety.

The hearing will be held on Friday, March 22, 2013, at 10:00 a.m. in the Public Health Council Room, Second Floor, Department of Public Health, 250 Washington Street, Boston, Massachusetts. Speakers are requested to provide a copy of their oral testimony. The Department encourages all interested parties to submit testimony electronically to the following address:

Reg.Testimony@state.ma.us. Please submit electronic testimony as an attached Word document or as text within the body of an email and type "Prescription Monitoring Program 2013" in the subject line. All submissions must include the sender's full name and address. The Department will post all electronic testimony that complies with these instructions on its website. Parties who are unable to submit electronic testimony should mail submissions to LouAnn Stanton, Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, MA 02108. All testimony must be submitted by 5:00 p.m. on Friday, March 29, 2013.

A copy of the proposed amendments may be viewed on the Department's website or obtained from LouAnn Stanton, Office of the General Counsel, at 617-624-5220.

2013 FEB 16 PM 12:00

REGISTRATION DIVISION
STATE

SMALL BUSINESS IMPACT STATEMENT

In order to accurately predict the impact the adoption, amendment, or repeal of a regulation will have on small businesses, the promulgating authority must conduct a thorough analysis that not only considers the potential effects of the action but also quantifies the costs, if any, associated with each. The questions below are designed to aid promulgating authorities in conducting their analysis.

Agency Submitting Regulation: Department of Public Health

Subject Matter of Regulation: Controlled Substances--Prescription Monitoring Program

Regulation No: 105 CMR 700.000

Statutory Authority: Ch. 244, Acts of 2012

Other Agencies Affected: Boards of registration in medicine, dentistry, podiatry, and nursing

Other Regulations That May Duplicate or Conflict with the Regulation: N/A

Describe the Scope and Objectives of the Regulation: The objective of 105 CMR 700.000 is to implement the requirements of G.L. c. 94C (Controlled Substances Act). The sections being amended are related specifically to the Prescription Monitoring Program (PMP). The amendments fulfill the requirements of the legislation and require that certain health care providers utilize the PMP before seeing a new patient.

Business Industry(ies) Affected by the Regulation: Ambulatory Healthcare Services

Types of Businesses Included in the Industry(ies): Offices of Physicians, offices of dentists, offices of podiatrists

Total Number of Small Businesses Included in the Regulated Industry(ies) *Please see the attached guidance documents for assistance determining the total number of small businesses:* The types of businesses that will be most affected by this amendment are physician practices, dental practices, and podiatry practices. (Other health care providers write prescriptions, but do not have independent prescriptive authority.) According to the SBA web site, there are 24 medical practices listed as small businesses within the 621111 NAICS code, 6 dental practices in the 621210 code, and 1 podiatry practice in the 621391 code. However, it is likely that most of these kinds of practices do not self report as small businesses. According to the web site of the Board of Registration in Medicine, there are approximately 35,000 licensed physicians in MA, almost all of whom write prescriptions. According to the Board of Registration in Dentistry, there are approximately 7,000 licensed dentists in MA and presumably most of those write prescriptions. According to the Board of Registration in Podiatry, there are 554 licensed podiatrists in MA.

Number of Small Businesses Potentially Subject to the Proposed Regulation: Because so few ambulatory health care practices are registered as small businesses, the number of small businesses affected is difficult to calculate.

Effective Date Used In Cost Estimate: No cost associated with these amendments

Yes	No	<i>*Note: For each question, please answer "yes" or "no" and offer a brief explanation. Please describe any facts, data, views, arguments, or other input from small businesses, organizations or any other sources that were used to quantify the impacts outlined below.</i>

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to create, file, or issue additional reports?
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures? Although not specifically required by the regulation, providers will likely need to record their use of the PMP in the patient record.
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Will small businesses have to provide additional administrative oversight? Only if they choose to authorize delegate users of the PMP.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to hire additional employees in order to comply with the proposed regulation?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are performance standards more appropriate than design standards?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will the regulation have the effect of creating additional taxes and/or fees for small businesses?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can the regulation provide for less stringent compliance or reporting requirements for small businesses?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can the compliance or reporting requirements be consolidated or simplified for small businesses?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can performance standards for small businesses replace design or operational standards?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses?
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Were any small businesses or small business organizations contacted during the preparation of this document? If so, please describe.</p> <p>Not directly, but representatives of the boards of registration that license these professionals were consulted.</p>