Commonwealth of Massachusetts
Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

Dispensing Procedures for Pharmacists – A Strategy to Minimize Potential Drug Shortages

Request to Promulgate Emergency Regulations at 105 CMR 722.000

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Overview

- Background
  - Overview of need
  - Current regulations
- Proposed Regulations
  - Authority given by regulations
  - Conditions for waiver
- Public Comment Summary
  - Testimonies
  - DPH Response
  - DPH request that PHC approve the emergency amendments as newly amended

Background

Overview of Need

- Multi-State Meningitis Outbreak
- Overview of Compounding
  - New England Compounding Center/Ameridose Actions
- Board of Pharmacy Actions – Emergency Regulations
- Concern for Drug Shortages
  - No concrete reports at present
  - Collaboration with MHA and hospitals

Current Regulations

- 105 CMR 722.090 restricts hospital pharmacies from dispensing medications to anyone other than the hospital's patients and staff.
- DPH has received requests to waive these requirement.
- DPH currently has no authority to grant a waiver.
- The amendment to 105 CMR 722.000 adds a new section authorizing the Commissioner, or the Commissioner's designee, to waive requirements imposed by 105 CMR 722.000 during temporary drug shortage or other emergencies.

Proposed Regulations

Previously Proposed Authority

The proposed regulation authorizes the Commissioner, or the Commissioner's designee, to grant time-limited waivers to any requirements imposed by 105 CMR 722.000 when:

(1) The Commissioner determines that there is an emergency that affects public health and safety;

(2) Waiver of a requirement will alleviate the emergency;

(3) Waiver of a requirement will not jeopardize the health or safety of patients; and

(4) The emergency is expected to be temporary in nature.

Commensurate with waiver authority under other regulations.

Conditions

- Temporary waivers granted under this new section may be accompanied by conditions with which the registrant must comply.

- Failure to comply with the conditions of a waiver may result in immediate termination of the waiver.

Public Comment

Public Comment

- Proposed amendment presented to the Public Health Council on November 21, 2012
- Public Hearing held on December 20, 2012
- Written testimony accepted until December 21, 2012
  - Two written testimonies received
  - No oral testimonies presented

Summary of Public Comment

- Written testimonies received from Massachusetts Hospital Association (MHA) and Berkshire Health Systems (BHS)
- Written testimony was mostly supportive

Specific requests:

- use the waiver language in 105 CMR 130 (hospital licensure)
- remove the time-limited nature of the waiver
- broaden the scope of the waiver specifically to meet the ongoing needs of critical access hospitals

DPH Response to Public Comment

Hospital licensure request: the waiver addresses a controlled substances issue, which is heavily restricted and cannot be afforded the same flexibility as in licensing situations

Remove time limitation: waiver must be time-limited because its purpose is to address short-term emergencies. Further, a hospital pharmacy must not act in any way that would require it to have a manufacturer's license unless it does in fact have such a license.

Broaden the scope of the waiver for critical needs: DPH amended the proposed language to allow for a long-term or permanent waiver for situations of critical need, as well as, broadened the general applicability of the waiver to include a situation of critical need that may not rise to the level of an emergency

Newly Proposed Authority

The proposed regulation authorizes the Commissioner, or the Commissioner's designee, to grant time-limited waivers to any requirements imposed by 105 CMR 722.000 when:

(1) The Commissioner determines that there is an emergency **or other situation of critical need** that affects public health and safety;

(2) Waiver of a requirement will alleviate the emergency;

(3) Waiver of a requirement will not jeopardize the health or safety of patients; and

(4) The emergency is expected to be temporary in nature**, except in the case of a critical access hospital or similarly situated facility**

Commensurate with waiver authority under other regulations.

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