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Circular Letter: DHCQ 17-1-666

TO: Pharmaceutical Drug Manufacturers

FROM: Eric Sheehan, Director, Bureau of Health Care Safety and Quality
James Lavery, Director, Bureau of Health Professions Licensure

DATE: January 18, 2017

RE: Massachusetts Drug Stewardship Program

The purpose of this Circular Letter is to inform manufacturers of pharmaceutical drugs regarding their obligations under M.G.L. c. 94H – *The Drug Stewardship Program*.

As set out in M.G.L. c. 94H, the Drug Stewardship Program took effect January 1, 2017. Within 180 days of the issuance of this Circular Letter, every manufacturer of covered drugs, as defined below, must file a plan to operate a Drug Stewardship Program with the Department of Public Health ("Department"). The plan will be subject to the approval of the Department. Manufacturers of covered drugs will need to file annually thereafter.

Who Must File?

Any entity that manufactures one or more controlled substances under a U.S. Food and Drug Administration manufacturer's license (excluding institutional pharmacies as defined in M.G.L. c. 112, § 39D and wholesalers licensed pursuant to M.G.L. c. 112, § 36B); and that sells or distributes any "covered drug" to consumers in the Commonwealth, whether directly or through a wholesaler, retailer, or other agent, must file a plan with the Department.

A "covered drug" is any brand name or generic Schedule II or Schedule III opioid drug, and benzodiazepines. The following items are specifically excluded from the definition of "covered drug":

(i) Drugs intended for use solely in veterinary care.

(ii) Cosmetic products as defined in 21 U.S.C. § 301 et seq., the U.S. Food, Drug & Cosmetic Act.

(iii) Drugs compounded under a specialty license pursuant to M.G.L. c. 112, §§ 39G through 39J.

(iv) Hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in accordance with M.G.L. c. 94C, § 27A through 39J.

(v) Drugs approved and used primarily for medication-assisted substance use disorder treatment.

What is a Drug Stewardship Program?

A Drug Stewardship Program collects, secures, transports and safely disposes of unwanted drugs. An "unwanted drug" is a covered drug, as defined above, that is:

(i) No longer wanted or intended to be consumed, or which is abandoned, discarded, expired or surrendered by the person to whom it was prescribed; or

(ii) Voluntarily deposited at collection points co-located with a law enforcement agency.

Plans can be filed, financed and operated either individually, or by a group of manufacturers. **A Drug Stewardship Program must be fully financed by the filing drug manufacturer or group of manufacturers.**

A Drug Stewardship Program plan must include, but is not limited to:

- A collection system to provide convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs; provided, however, that the collection system may accept any covered drug and any other prescription drug in a pill formulation regardless of its schedule, brand or source of manufacture. The collection system must include at least 2 of the following methods, at least one of which must be methods (i) or (ii) below:

  (i) A mail-back program that provides prepaid and preaddressed packaging for a pharmacy to distribute when filling a prescription for a covered drug or upon request by a consumer;

  (ii) Collection kiosks;

  (iii) Drop-off day events at regional locations convenient to the public; or

  (iv) In-home disposal methods that render a product safe from misuse and that comply with applicable controlled substance regulations and environmental safety regulations.

- Adequate provisions for the security of unwanted drugs throughout the collection process and the safety of any person involved in monitoring, staffing or servicing the stewardship program.

- A plan for public outreach and education about the Drug Stewardship Program.

- A plan for the manufacturer or stewardship organization that provides the operational and administrative costs associated with the program; provided, however, that no point-of-sale, point-of-collection, processing fees or other drug cost increases may be charged to individual consumers to recoup program costs.

- An attestation that the program shall comply with all applicable state and federal requirements for the collection, security, transport and disposal of drug products, including any requirements established by rule or regulation of either the U.S. Drug Enforcement Administration or the U.S. Environmental Protection Agency.

- A list of all manufacturers participating in the proposed plan and the amount each will contribute to the plan financing. Each manufacturer must also identify all covered drug products sold in the Commonwealth during calendar year 2016, and the number of units of each.

A Drug Stewardship Program need not provide for disposal of the following drugs:

- Drugs from a non-residential source, such as waste or unused drug products from a pharmacy, hospital or health clinic or other commercial sources; and

- Drug products seized by law enforcement officers in the course of their law enforcement duties.

The Department may approve or disapprove a Drug Stewardship Program in whole or in part.

Are There Any Alternatives to Filing a Drug Stewardship Program Plan?

Pursuant to M.G.L. c. 94H, § 6, the Department will develop an alternative plan for compliance beginning January 1, 2018. For the first year, the Department will not make an alternative plan available as an option, and manufacturers of covered drugs must file their own individual or group plan.

When to File:

Upon issuance of this letter, the Department will begin accepting plans from manufacturers. All manufacturers of covered drugs must file an individual or joint plan by no later than180 days of the issuance of this notice. Failure to comply is subject to fine.

Where to File:

Plans must be submitted electronically to **drugstewardship@massmail.state.ma.us**. Program-related questions may be sent to the same address.