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Circular Letter: DCP 23-04-120

Commissioner Tel: 617-624-6000 www.mass.gov/dph

то:	Pharmacy Collectors, Reverse Distributors, and Long Term Care Facilities
FROM:	David Johnson, Director, Drug Control Program David Sencabaugh, Executive Director, Board of Registration in Pharmacy
DATE:	May 2, 2023
RE:	Procedures Regarding Drug Disposal Receptacles Located in Long Term Care Facilities

The purpose of this Circular Letter is to inform Massachusetts pharmacies registered with the federal government as collectors (Pharmacy Collectors), and reverse distributors working with them to service drug disposal receptacles (DRs) maintained in Long Term Care Facilities (LTCFs), regarding safety and security measures required by the Drug Control Program (DCP) and the Board of Registration in Pharmacy (BORP). These requirements are in addition to those set by federal law and regulations.¹

Federally registered Pharmacy Collectors may choose to locate DRs in LTCFs, and to contract with federally registered reverse distributors to remove and destroy filled DR liners. DCP and BORP encourage such arrangements, as they can greatly reduce the impact of drug destruction on the local environment; increase the safety and security of the drug disposal process; and reduce the staff time required for LTCFs to comply with state and federal laws regarding drug destruction.

To place a DR in a LTCF a Pharmacy Collector must also apply for and receive a waiver from the Massachusetts Department of Department of Environmental Protection for that activity: <u>https://www.mass.gov/how-to/apply-for-a-waste-medications-collection-waiver</u>

Federal regulations also specify the options for staffing the installation, removal, transfer, and storage of DR inner liners.² BORP and DCP require that Pharmacy Collectors and LTCFs utilize the option which

¹ Retail pharmacies and hospitals/clinics with on-site pharmacies may modify their federal registrations to obtain authorization to be a "collector". 21 CFR 1301.51(b), 1317.40(a). A reverse distributor is a person registered with the federal government as a reverse distributor pursuant to 21 CFR §1317.15. *See, 105 CMR 700.001*. Reverse distributors doing business in the Commonwealth of Massachusetts must register with the Drug Control Program pursuant to 105 CMR 700(A)(4)(j).

² 21 CFR 1317.80(c).

staffs those functions with both an employee of the Pharmacy Collector and a supervisor-level employee of the LTCF.

The LTCF employee must be the Director of Nursing. However, if an LTCF needs to utilize a different staff position for this purpose, the facility must request a waiver from DCP which requests permission to utilize a specific alternative staff position for this purpose and explain why the Director of Nursing is not available for this protocol. The LTCF must receive a written waiver from DCP before utilizing the requested alternative staffing. Please review 105 CMR 700.140 regarding the representations which must be made in the waiver application. The waiver request should be sent to DCP at DCP.DPH@mass.gov.

The Pharmacy Collector must contract with a reverse distributor for the disposal of the collected medications. Once the filled liner is removed from the DR, arrangements for the transfer of the sealed liner to the reverse distributor either by direct pick up or delivery by a designated common carrier must be made immediately. The liner must be secured in the LTCF until transferred to the reverse distributor in accordance with 21 CFR 1317.05(c)(2)(iv).

Reverse distributor and LTCF questions should be addressed to the Drug Control Program at: <u>dcp.dph@mass.gov</u>

Pharmacy Collector questions should be addressed to the DEA at: 1-800-882-9539 or <u>DEA.Registration.Help@dea.gov</u>

Board of Registration in Pharmacy: pharmacy.admin@mass.gov