

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE G: WASTE DISPOSAL
CHAPTER II: ENVIRONMENTAL PROTECTION AGENCY

PART 889
MEDICATION TAKEBACK PROGRAM

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AUTHORITY: Implementing and authorized by Section 22.55(1) of the Environmental Protection Act [415 ILCS 5/22.55(1)].

SOURCE: Adopted at 42 Ill. Reg. 6364, effective May 1, 2018.

SUBPART A: GENERAL

Section 889.100 Purpose and Applicability

- a) The purpose of this Part is to establish a medication takeback program, pursuant to Section 22.55(1) of the Act, *to ensure that there are pharmaceutical product disposal options regularly available for residents across the State.* [415 ILCS 5/22.55(1)]
- b) This Part applies to any person that accepts pharmaceutical products at a household waste drop-off point in accordance with Section 22.55(c) of the Act and that the Agency has selected to arrange for the disposal of accepted pharmaceutical products.
- c) Nothing in this Part shall prevent any person from accepting pharmaceutical products at a household waste drop-off point in accordance with Section 22.55(c) of the Act or any other location and arranging for the disposal of accepted pharmaceutical products in accordance with applicable State and federal law.

Section 889.105 Definitions

Except as stated in this Section, or unless a different meaning of a word or term is clear from the context, the definitions of words or terms in this Part shall be the same as that applied to the same words or terms in Title I or Title V of the Environmental Protection Act.

"Act" means the Environmental Protection Act [415 ILCS 5].

"Agency" means the Illinois Environmental Protection Agency. [415 ILCS 5/3.105]

"Controlled substance" means a controlled substance as defined in the Illinois Controlled Substances Act [720 ILCS 570]. [415 ILCS 5/22.55(b)]

"Household waste" means waste generated from a single residence or multiple residences. [415 ILCS 5/22.55(b)]

"Household waste drop-off point" means the portion of a site or facility used solely for the receipt and temporary storage of household waste. [415 ILCS 5/22.55(b)]

"Medication takeback location" means a household waste drop-off point that accepts pharmaceutical products for which the Agency has agreed to make disposal arrangements.

"Operator" means a person responsible for the operation and maintenance of a household waste drop-off point at which pharmaceutical products are accepted.

"Owner" means a person who has an interest, directly or indirectly, in land, including a leasehold interest, on which a person operates or maintains a medication takeback who operates or maintains that medication takeback location.

"Person" means individual, trust, firm, joint stock company, joint venture, consortium, commercial entity, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, or any interstate body, including the United States government and each department, agency and instrumentality of the United States. [415 ILCS 5/58.2]

"Pharmaceutical product" means a medicine or a product containing medicine. A pharmaceutical product may be sold by prescription or over the counter.

"Pharmaceutical product" does not include medicine or a product that contains a radioactive component. [415 ILCS 5/22.55(b)]

Section 889.110 Compliance with Applicable Law

Any person subject to this Part must comply with all applicable State and federal laws and regulations, including but not limited to State and federal laws and regulations that govern the collection and disposal of controlled substances and other pharmaceutical products or State and federal regulations that require pharmaceutical product manufacturers to provide a product stewardship program or product takeback program as part of a managed risk evaluation and mitigation strategy.

Section 889.115 Severability

If any Section, subsection, sentence or clause of this Part is judged invalid, that adjudication shall not affect the validity of this Part as a whole or any Section, subsection, sentence or clause of this Part not judged invalid.

SUBPART B: APPLICATION, SELECTION AND OPERATION

Section 889.200 Application

- a) Any person seeking to have the Agency arrange for the disposal of pharmaceutical products accepted at a medication takeback location must submit to the Agency an application requesting that the Agency arrange for the disposal.
- b) Applications must be on the forms prescribed by the Agency. The application must include:
 - 1) The name and address of the medication takeback location;
 - 2) The name and address of the operator of the medication takeback location;
 - 3) The name and telephone number of the operator of the medication takeback location;
 - 4) The name and address of the owner of the site on which the medication takeback location is located;
 - 5) The geographic area served by the medication takeback location;
 - 6) The population of the geographic area served by the medication takeback location, according to the most recent decennial census;
 - 7) The dates and times that pharmaceutical products will be accepted at the medication takeback location;
 - 8) The volume of pharmaceutical products accepted at the medication takeback location during the preceding calendar year, if applicable; and

- 9) The requested duration of Agency-sponsored disposal.

Section 889.205 Agency Action

- a) Subject to appropriation, the Agency may provide for the disposal of pharmaceutical products accepted at one or more medication takeback locations selected pursuant to subsection (b).
- b) Subject to appropriation, the Agency will review applications submitted in accordance with this Section and select applicants for whom the Agency will provide for the disposal of accepted pharmaceutical products. In making its selection, the Agency will consider site-specific factors, including but not limited to:
 - 1) The geographic location of the medication takeback location;
 - 2) The geographic area served by the medication takeback location;
 - 3) The population of the area served by the medication takeback location, according to the most recent decennial census;
 - 4) The volume of pharmaceutical products accepted at the medication takeback location during the previous calendar year, if applicable;
 - 5) The names and locations of other known entities that collect pharmaceutical products within a 25 mile radius of the medication takeback location; and
 - 6) The estimated cost to the Agency of accepting and disposing the pharmaceutical products collected at the medication takeback location.
- c) The Agency will inform selected applicants, in writing, of the Agency's decision. Written notifications made under this subsection (c) will include, but not be limited to, the following information:
 - 1) The date on which the Agency will first arrange for the disposal of accepted pharmaceutical products;
 - 2) The duration of the Agency's disposal arrangement;
 - 3) The volume of pharmaceutical products accepted at the medication takeback location for which the Agency will make disposal arrangements; and

- 4) The Agency-provided method of disposal for the accepted pharmaceutical products.
- d) The Agency will post on its website a list of all selected medication takeback locations. The Agency will also post on its website the location of other known sites that accept pharmaceutical products for disposal.

Section 889.210 Operating Requirements

- a) Medication takeback locations must be located at a site or facility where pharmaceutical products are lawfully sold, distributed or dispensed. This subsection (a) *does not apply to household waste drop-off points operated by a government or by an association or other organization of government.* [415 ILCS 5/22.55(c)(2)(A)]
- b) *The location of acceptance of pharmaceutical products at the medication takeback location must be clearly identified.* [415 ILCS 5/22.55(c)(3)]
- c) Pharmaceutical products that are accepted at medication takeback locations may only be accepted in accordance with the Act, this Part, and other applicable law. Pharmaceutical products accepted at the medication takeback location *must be accepted only from private individuals.* Pharmaceutical products *must not be accepted from other persons, including, but not limited to, owners and operators of rented or leased residences where the household waste was generated, commercial haulers, and other commercial, industrial, agricultural and government operations or entities.* [415 ILCS 5/22.55(c)(4)]
- d) Pharmaceutical products accepted at the medication takeback location *must be managed separately* from all other household waste accepted at the medication takeback location *prior to its packaging for off-site transfer.* [415 ILCS 5/22.55(c)(5)]
- e) Security of Accepted Pharmaceutical Products
 - 1) Pharmaceutical products must be accepted and managed *in a manner that protects against releases of the pharmaceutical products, prevents nuisances, and otherwise protects human health and the environment.* [415 ILCS 5/22.55(c)(7)]
 - 2) Accepted pharmaceutical products must be properly secured *to prevent unauthorized public access to the pharmaceutical products, including, but not limited to, preventing access to the pharmaceutical products during the non-business hours of the site or facility on which the household waste drop-off point is located.* [415 ILCS 5/22.55(c)(7)]

- 3) Accepted pharmaceutical products must not be stored *for longer than 90 days after receipt, except as otherwise approved by the Agency in writing.* [415 ILCS 5/22.55(c)(6)]
- f) A copy of the sign developed by the Agency in accordance with Section 22.55(j) of the Act must be clearly posted at the medication takeback location. The Agency will make a copy of the sign available for downloading from its website.

Section 889.215 Records

- a) The operator of any medication takeback location must maintain records that identify the volume of pharmaceutical products accepted for Agency arranged disposal.
- b) Records maintained pursuant to subsection (a) must be kept and made available to the Agency. The medication takeback location must have the appropriate equipment on the premises to provide readily retrievable information in the course of an on-site inspection. A hard copy printout must be provided to the Agency, upon request, within 48 hours. These records must be maintained for a minimum of three calendar years after the date of acceptance.

Section 889.220 Termination

- a) Operator Notification
 - 1) Any operator of a medication takeback location that ceases to accept pharmaceutical products for Agency arranged disposal must submit a written notification to the Agency within 30 days after the date the collection terminates.
 - 2) At a minimum, the written notification required by subsection (a)(1) must state:
 - A) the date acceptance of pharmaceutical products for Agency arranged disposal was terminated;
 - B) the volume of pharmaceutical products accepted for Agency arranged disposal prior to collection termination.
- b) The Agency may terminate disposal arrangements made pursuant to this Part for any reason, including but not limited to the operation of a medication takeback location in violation of Section 22.55(c) of the Act. The Agency will provide written notice of termination to the operator of the medication takeback location.