

RCW 69.48.050 Drug take-back program approval—Program modifications. (1) By July 1, 2019, a program operator must submit a proposal for the establishment and implementation of a drug take-back program to the department for approval. Proposals from new entities seeking to become a program operator after July 1, 2019, may be submitted as provided in subsection (7) of this section. The department shall approve a proposed program if the applicant submits a completed application, the proposed program meets the requirements of subsection (2) of this section, and the applicant pays the appropriate proposal review fee established by the department under RCW 69.48.120. The department may approve drug take-back programs proposed by one or more program operators consistent with the provisions of this section.

(2) To be approved by the department, a proposed drug take-back program, independent of any other operating program, must:

- (a) Identify and provide contact information for the program operator and each participating covered manufacturer;
- (b) Identify and provide contact information for the authorized collectors for the proposed program, as well as the reasons for excluding any potential authorized collectors from participation in the program;
- (c) Provide for a collection system that complies with RCW 69.48.060;
- (d) Ensure that physical collection sites are the primary method of collection across the state and that methods of supplementing physical collection site service are the secondary methods for collection as required by RCW 69.48.060(3) (b) through (d). A drug take-back program's use of supplemental mail-back distribution locations or periodic collection events in any areas underserved by physical collection sites may provide collection services to no more than 15 percent of the state's residents;
- (e) Provide for a handling and disposal system that complies with RCW 69.48.080;
- (f) Identify any transporters and waste disposal facilities that the program will use;
- (g) Adopt policies and procedures to be followed by persons handling covered drugs collected under the program to ensure safety, security, and compliance with regulations adopted by the United States drug enforcement administration, as well as any applicable laws;
- (h) Ensure the security of patient information on drug packaging during collection, transportation, recycling, and disposal;
- (i) Promote the program by providing consumers, pharmacies, and other entities with educational and informational materials as required by RCW 69.48.070;
- (j) Demonstrate adequate funding for all administrative and operational costs of the drug take-back program, with costs apportioned among participating covered manufacturers;
- (k) Set long-term and short-term goals with respect to collection amounts and public awareness; and
- (l) Consider: (i) The use of existing providers of pharmaceutical waste transportation and disposal services; (ii) separation of covered drugs from packaging to reduce transportation and disposal costs; and (iii) recycling of drug packaging.

(3) (a) No later than one hundred twenty days after receipt of a drug take-back program proposal, the department shall either approve or reject the proposal in writing to the applicant. The department may extend the deadline for approval or rejection of a proposal for good

cause. If the department rejects the proposal, it shall provide the reason for rejection.

(b) No later than ninety days after receipt of a notice of rejection under (a) of this subsection, the applicant shall submit a revised proposal to the department. The department shall either approve or reject the revised proposal in writing to the applicant within ninety days after receipt of the revised proposal, including the reason for rejection, if applicable.

(c) If the department rejects a revised proposal, the department may:

(i) Require the program operator to submit a further revised proposal;

(ii) Develop and impose changes to some or all of the revised proposal to address deficiencies;

(iii) Require the covered manufacturer or covered manufacturers that proposed the rejected revised proposal to participate in a previously approved drug take-back program; or

(iv) Find the covered manufacturer out of compliance with the requirements of this chapter and take enforcement action as provided in RCW 69.48.110.

(4) The program operator must fully implement an approved drug take-back program no later than one hundred eighty days after approval of the proposal by the department.

(5) (a) Proposed changes to an approved drug take-back program that substantially alter program operations must have prior written approval of the department. A program operator must submit to the department such a proposed change in writing at least fifteen days before the change is scheduled to occur. Changes requiring prior approval of the department include changes to participating covered manufacturers, collection methods, achievement of the service convenience goal described in RCW 69.48.060, policies and procedures for handling covered drugs, education and promotion methods, and selection of disposal facilities.

(b) For changes to a drug take-back program that do not substantially alter program operations, a program operator must notify the department at least seven days before implementing the change. Changes that do not substantially alter program operations include changes to collection site locations, methods for scheduling and locating periodic collection events, and methods for distributing prepaid, preaddressed mailers.

(c) A program operator must notify the department of any changes to the official point of contact for the program no later than fifteen days after the change. A program operator must notify the department of any changes in ownership or contact information for participating covered manufacturers no later than ninety days after such change.

(6) By July 1, 2024, and every four years thereafter, all program operators must submit an updated proposal to the department describing any substantive changes to program elements described in subsection (2) of this section. The department shall approve or reject the updated proposal using the process described in subsection (3) of this section.

(7) (a) On July 1, 2021, the department will begin the review of new proposals received by that date from entities seeking to become a program operator.

(b) Beginning July 1, 2024, and every four years thereafter, the department will review new proposals from entities seeking to become a program operator.

(c) The department shall approve a proposal if it meets the requirements in subsection (2) of this section and the applicant pays the appropriate fee established by the department under RCW 69.48.120. The department must approve or reject proposals received using the process provided in subsection (3) of this section.

(8) (a) If there is a single approved drug take-back program at any time and that program operator intends to leave the program for any reason, participating manufacturers must find a new entity to take over operations of the existing program without a break in program services. The new entity may not make changes to the operations of the approved program, which must be consistent with the proposal as it was approved by the department under this section, or each covered manufacturer or group of covered manufacturers must identify a new program operator to develop a new program proposal. The department must accept new proposals from potential program operators for a minimum of four months from the date the department is notified of the program operator intending to cease operations, or until a proposal is approved by the department. The department may approve a proposal if it meets the requirements in subsection (2) of this section and the applicant pays the appropriate fee established by the department under RCW 69.48.120. The department must approve or reject proposals received using the process described in subsection (3) of this section.

(b) If there is a single approved drug take-back program, and that program operator leaves the program and participating manufacturers do not identify a program operator to take over the approved program as provided in (a) of this subsection, all covered manufacturers must participate in a new approved drug take-back program as soon as one is approved.

(9) If there is more than one approved drug take-back program, and a program operator for a drug take-back program leaves the program for any reason and the covered manufacturers participating in that program fail to identify a new entity to take over operations of the existing program without a break in program services as described in subsection (8) (a) of this section, those manufacturers must immediately join an existing approved drug take-back program.

(10) A covered manufacturer may change the approved drug take-back program it participates in but the covered manufacturer must maintain continuous participation in an established drug take-back program and may not leave an approved program until it transfers participation to an approved drug take-back program that has begun drug collection.

(11) The department shall make all proposals submitted under this section available to the public and shall provide an opportunity for written public comment on each proposal.

(12) (a) All program operators must collaborate to present a consistent statewide drug take-back system for residents to ensure that all state residents can easily identify, understand, and access services provided by any approved drug take-back program. The department may identify or clarify in rule additional requirements for coordination or performance amongst program operators, if necessary, to ensure consistent operation of the drug take-back program. Requirements may include, but are not limited to: Consistent drop box appearance and signage; consistent messaging in education and outreach; and consistent metrics included in operator annual reports as required in RCW 69.48.100 to ensure the department can accurately analyze the data.

(b) Failure to comply with these requirements may result in enforcement action against a program operator as authorized under RCW 69.48.110. [2021 c 155 § 3; 2018 c 196 § 5.]

Sunset Act application: See note following chapter digest.

Findings—Intent—2021 c 155: See note following RCW 69.48.010.