Title 11
HAZARDOUS MATERIALS MANAGEMENT
(Formerly HAZARDOUS CHEMICALS)
UPDATED: July 22, 2013

Chapters:

11.50 KING COUNTY BOARD OF HEALTH SECURE MEDICINE RETURN REGULATIONS

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11.50.010 Short title. This chapter may be cited and referred to, and shall be known as, the King County Board of Health Secure Medicine Return Regulations. (R&R 13-03 § 3, 2013).

11.50.020 Purpose and scope of chapter.
A. This chapter is enacted as an exercise of the Board of Health powers of King County to protect and preserve the public health, safety and welfare. Its provisions shall be liberally construed for the accomplishment of these purposes. This chapter governs the protection of human health and safety against the improper handling and disposal of leftover or expired medicines.
B. It is the intent of this chapter to place the obligation of complying with its requirements upon drug producers and other persons designated by this chapter within its scope, and any provision of or
term used in this chapter is not intended to impose any duty whatsoever upon King County or any of its officers or employees, for whom the implementation or enforcement of this chapter shall be discretionary and not mandatory. (R&R 13-03 § 4, 2013).

11.50.030 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

A. "Collector" means a person that gathers unwanted covered drugs from covered entities for the purpose of collection, transportation and disposal.

B.1. "Covered drug" means a drug sold in any form and used by covered entities, including prescription, nonprescription, brand name and generic drugs.

2. "Covered drug" does not include:
   a. vitamins or supplements;
   b. herbal-based remedies and homeopathic drugs, products or remedies;
   c. cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9);
   d. Drugs for which producers provide a pharmaceutical product stewardship or take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1);
   e. Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this rule if the producer already provides a pharmaceutical product stewardship or take-back program;
   f. Medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories; and
   g. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

C. "Covered entities" means residents of King County, including individuals living in single and multiple family residences and other residential settings, and including other nonbusiness sources of prescription and nonprescription drugs that are unused, unwanted, disposed of or abandoned by residents as identified by the director. "Covered entities" does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor's offices, veterinarian clinics, pharmacies, or airport security and law enforcement drug seizures.

D. "Director" means the director of the Seattle-King County Department of Public Health or the director's duly authorized representative.

E. "Drug wholesaler" means a corporation, individual or other entity that buys drugs or devices for resale and distribution to corporations, individuals or entities other than consumers.

F. "Drugs" means:
   1. Articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States or any supplement of the formulary or those pharmacopoeias as published by the U.S. Pharmacopeial Convention and the Homeopathic Pharmacopoeia Convention of the United States;
   2. Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
   3. Substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or
   4. Substances intended for use as a component of any substances specified in 1., 2. or 3. of this subsection, but not including medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories.

G. "Independent stewardship plan" means a plan other than the standard stewardship plan for the collection, transportation and disposal of unwanted covered drugs that:
   1. May be proposed by a producer or group of producers; and
   2. If approved, is financed, developed and implemented by the participating producer or group of producers, and operated by the participating producer or group of producers or a stewardship organization.

H. "Local hazardous waste management program" means the King County local hazardous waste management program identified in BOH 2.08.080.
I. "Manufacture" means "manufacture" as defined in RCW 18.64.011 that is the production, preparation, propagation, compounding or processing of a drug or other substance or device or the packaging or repackaging of the substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

J. "Manufacturer" means a person, corporation or other entity engaged in the manufacture of drugs or devices, as defined in RCW 18.64.011.

K. "Mail-back services" means a collection method for the return of unwanted covered drugs from covered entities utilizing prepaid and preaddressed mailing envelopes.

L. "Nonprescription drug" means a drug that may be lawfully sold without a prescription.

M. "Person" means a firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative or other entity of any kind or nature.

N. "Pharmacy" means a place licensed by the state of Washington board of pharmacy where the practice of pharmacy, as defined in RCW 18.64.011, is conducted.

O. "Prescription drug" means any drugs, including controlled substances, that are required by an applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.

P. "Producer" means a manufacturer that is engaged in the manufacture of a covered drug sold in or into King County, including a brand-name or generic drug. "Producer" does not include:
1. A retailer whose store label appears on a covered drug or the drug's packaging if the manufacturer from whom the retailer obtains the drug is identified under section 6.C. of this rule;
2. A pharmacist who compounds a prescribed individual drug product for a consumer; or
3. A wholesaler who is not also a manufacturer.

Q. "Retail pharmacy" means a pharmacy licensed by the state of Washington board of pharmacy for retail sale and dispensing of drugs.

R. "Standard stewardship plan" means the plan for the collection, transportation and disposal of unwanted covered drugs that is:
1. Financed, developed, implemented and participated in by producers;
2. Operated by the participating producers or a stewardship organization; and
3. Approved as the standard stewardship plan.

S. "Stewardship organization" means an organization designated by a producer or group of producers to act as an agent on behalf of each producer to develop and implement and operate the standard stewardship plan or an independent stewardship plan.

T. "Unincorporated community service area" means any of the areas established under King County Ordinances 17139 and 17415.

U. "Unwanted covered drug" means any covered drug no longer wanted by its owner, that:
1. Has been abandoned or discarded; or
2. Is intended to be discarded by its owner. (R&R 13-03 § 5, 2013).

11.50.040 Stewardship plans - participation.

A. Each producer shall participate in the standard stewardship plan approved by the director, except that a producer may individually, or with a group of producers, form and participate in an independent stewardship plan if approved by the director.

B. The standard stewardship plan and any independent stewardship plan shall be approved by the director before collecting unwanted covered drugs. Once approved, stewardship plans must have prior written approval of the director for proposed changes as described under BOH 11.50.130.

C. By six months after the date of adoption of this rule, or by six months after a producer initiates sale of a covered drug in or into King County, a producer shall notify the director in writing of the producer's intent to participate in the standard stewardship plan or to form and participate in an independent stewardship plan. A retailer whose store label appears on a covered drug or the drug's packaging must notify the director of intent to participate or provide written notification that the manufacturer from whom the retailer obtains the drug has provided its notice of intent to participate.

D. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall:
1. By nine months after this rule is adopted, identify in writing to the director a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the stewardship plan;

2.a. By nine months after this rule is adopted, notify all retail pharmacies and law enforcement agencies in the county of the opportunity to participate as a drop-off site in accordance with BOH 11.50.060.A. and E., and provide a process for forming an agreement between the plan and interested collectors; and

b. annually thereafter, make the same notification to any nonparticipating or new retail pharmacies or law enforcement agencies in the county;

3. By one year after this rule is adopted, submit a proposed stewardship plan as described in BOH 11.50.050 to the director for review;

4. Within three months after the director's approval of the stewardship plan, operate or participate in a stewardship plan in accordance with this chapter;

5. At least every four years after each plan initiates operations, submit an updated plan to the director explaining any substantive changes to components of the stewardship plan required in BOH 11.50.050, and accompanied by the review fee in accordance with BOH 11.50.160. The director shall review updated stewardship plans using the process described in BOH 11.50.120; and

6. Pay all administrative and operational costs and fees associated with their stewardship plan as required under BOH 11.50.090 and 11.50.160.

E. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may:

1. Enter into contracts and agreements with stewardship organizations, other service providers, or other entities as necessary, useful or convenient to provide all or portions of their stewardship plan;

2. Notify the director of any producer selling covered drugs in or into the county that is failing to participate in a stewardship plan; and

3. Perform any other functions as may be necessary or proper to provide the stewardship plan and to fulfill any or all of the purposes for which the plan is organized.

F. After the first full year of operation of the approved standard stewardship plan, a producer or group of producers participating in the standard stewardship plan may notify the director in writing of intent to form an independent stewardship plan, and identify a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the proposed independent stewardship plan. Within three months of such notification, the producer or group of producers may submit a proposed independent stewardship plan as described under BOH 11.50.050 to the director for review.

G. The director may approve in writing extensions to later dates for the submission dates and deadlines in this section.

H. After presenting official credentials and providing notice of an audit or inspection to determine compliance with this chapter or to investigate a complaint, the director may audit a producer's, group of producers' or stewardship organization's records related to a stewardship plan or request that the producer, group of producers or stewardship organization arrange for the director to inspect at reasonable times a stewardship plan's or a collector's facilities, vehicles and equipment used in carrying out the stewardship plan. (R&R 13-03 § 6, 2013).

11.50.050 Stewardship plans - components. The standard stewardship plan or any independent stewardship plan, which must be submitted and reviewed according to BOH 11.50.120, shall include:

A. Contact information for all drug producers participating in the stewardship plan;

B. A description of the proposed collection system to provide convenient ongoing collection service for all unwanted covered drugs from covered entities in compliance with the provisions and requirements in BOH 11.50.060, including a list of all collection methods and participating collectors, a list of drop-off locations, a description of how periodic collection events will be scheduled and located if applicable, a description of how mail-back services will be provided and an example of the prepaid, preaddressed mailers to be utilized. The description shall include a list of retail pharmacies and law enforcement agencies contacted by the plan under BOH 11.50.040.D.2., and a list of all collectors who offered to participate;
C. A description of the handling and disposal system, including identification of and contact information for collectors, transporters and waste disposal facilities to be used by the stewardship plan in accordance with BOH 11.50.060 and 11.50.080;

D. A description of the policies and procedures to be followed by persons handling unwanted covered drugs collected under the stewardship plan, including a description of how all collectors, transporters and waste disposal facilities utilized will ensure the collected, unwanted covered drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the stewardship plan will operate under all applicable federal and state laws, rules and guidelines, including those of the United States Drug Enforcement Administration, and how any pharmacy collection site will operate under applicable rules and guidelines of the state of Washington Board of Pharmacy;

E. A description of how patient information on drug packaging will be kept secure during: collection; transportation; and recycling or disposal;

F. A description of the public education effort and promotion strategy required in section 9 of this rule, including a copy of standardized instructions for residents, signage developed for collectors and required promotional materials;

G. A proposal on the short-term and long-term goals of the stewardship plan for collection amounts, education and promotion; and

H. A description of how the stewardship plan will consider:

1. Use of existing providers of waste pharmaceutical services;

2. Separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and


11.50.060 Stewardship plans - collection of covered drugs.

A. This chapter does not require any person to serve as a collector in a stewardship plan. A person may offer to serve as a collector voluntarily, or may agree to serve as a collector in exchange for incentives or payment offered by a producer, group of producers or stewardship organization. Collectors may include law enforcement, pharmacies, mail-back services or other entities, operating in accordance with state and federal laws and regulations for the handling of covered drugs, including those of the United States Drug Enforcement Administration, and in compliance with this chapter. A pharmacy collection site shall operate under applicable rules and guidelines of the state of Washington Board of Pharmacy.

B. The collection system shall be convenient on an ongoing, year-round basis to adequately serve the needs of covered entities and shall be designed in consideration of equitable opportunities for all King County residents for the safe and convenient return of unwanted covered drugs, in accordance with this section.

C. The collection system for all unwanted covered drugs shall be safe and secure, including protection of patient information on drug packaging.

D.1. The service convenience goal for the standard stewardship plan and any independent stewardship plan is a system of drop-off sites distributed to provide reasonably convenient and equitable access for all residents in incorporated and unincorporated areas of the county.

2. In establishing and operating a stewardship plan, a producer, group of producers or stewardship organization shall give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites. A stewardship plan shall include, as collectors, any retail pharmacy or any law enforcement agency willing voluntarily to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter within three months of their offer to participate, unless the collector requests a longer time frame. A producer or group of producers establishing and operating a stewardship plan may also accept other collectors willing to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter.

3. The system of drop-off sites shall provide in every city, town, or unincorporated community service area with a pharmacy or law enforcement facility, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents, geographically distributed to provide reasonably convenient and equitable access.

4. If the service convenience goal in 3. of this subsection cannot be achieved by the standard stewardship plan or any independent stewardship plan due to a lack of drop-off sites at pharmacies, law enforcement agencies or other qualified collectors in specific areas of the county, then those areas shall
be served through periodic collection events or mail-back services, or a combination of these collection methods.

E. Drop-off sites shall accept covered drugs from covered entities during all hours that the retail pharmacy, law enforcement agency, or other collector is normally open for business with the public. Drop-off sites shall utilize secure drop boxes in compliance with all applicable requirements of the United States Drug Enforcement Administration and the state of Washington Board of Pharmacy.

F. Mail-back services shall be free of charge, and shall be made available to differentially-abled and home bound residents upon request through the stewardship plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to persons providing services to such residents, and may also be utilized as a collection method according to subsection D.4. of this section.

G. Periodic collection events, if utilized as a collection method according to subsection D.4. of this section, must be arranged with law enforcement personnel through voluntary agreements, and shall be conducted in compliance with United States Drug Enforcement Administration protocols, any additional requirements of participating law enforcement agencies, and in compliance with this chapter. (R&R 13-03 § 8, 2013).

11.50.070 Stewardship plans - promotion.

A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall:

1. Promote the use of their stewardship plan so that collection options for covered drugs are widely understood by residents, pharmacists, retailers of covered drugs and health care practitioners including doctors and other prescribers, and promote the safe storage of covered drugs by residents before secure disposal through their stewardship plan;

2. Work with collectors participating in their stewardship plan to develop clear, standardized instructions for residents on the use of drop boxes and a readily recognizable, consistent design of drop boxes. The local hazardous waste management program may provide guidance to producers and collectors on the development of the instructions and design;

3. Establish a toll-free telephone number and web site where collection options and current locations of drop-off sites will be publicized and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return unwanted covered drugs to the stewardship plan. These materials must be provided to pharmacies, health care facilities and other interested parties for dissemination to residents. Plain language and explanatory images should be utilized to make use of medicine collection services readily understandable by all residents, including individuals with limited English proficiency. A producer or group of producers participating in the standard stewardship plan or any independent stewardship plan shall coordinate these promotional activities to ensure that residents can easily identify, understand and access the collection services provided by any stewardship plan;

4. Annually evaluate the effectiveness of its outreach and stewardship plan activities; and

5. Conduct a survey of residents of King County and a survey of pharmacists and health professionals in the county who interact with patients on use of medicines after the first full year of operation of the plan, and again after five and nine years of operation. Survey questions shall measure percent awareness of the stewardship plan, assess to what extent drop-off sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Draft survey questions shall be submitted to the director for review and comment at least thirty days prior to initiation of the survey. Results of the survey shall be reported to the director and made available to the public on the stewardship plan’s website.

B. The local hazardous waste management program shall:

1. Promote the use of stewardship plans and the plans' toll-free telephone numbers and web sites through their standard educational methods;

2. Provide sample educational materials for use by pharmacies, law enforcement agencies, health care providers and local government agencies in the county;

3. Conduct educational outreach to targeted populations and groups as informed by survey results and other research indicators; and

4. Assume the costs of developing and providing promotional and educational materials under this subsection. (R&R 13-03 § 9, 2013).
11.50.080 Stewardship plans - disposal of covered drugs.

A. Covered drugs collected under a stewardship plan must be disposed of at a permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 264 and 265.

B. The director may grant approval for a producer or group of producers participating in the standard stewardship plan or an independent stewardship plan to dispose of some or all collected covered drugs at a permitted large municipal waste combustor, as defined by the United States environmental protection agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility described under subsection A. of this section is deemed not feasible for the stewardship plan based on cost, logistics or other considerations.

C. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may petition the director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections A. and B. of this section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:
   1. Monitoring of any emissions or waste;
   2. Worker health and safety;
   3. Air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

11.50.090 Stewardship plans - administrative and operational costs and fees.

A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall pay all administrative and operational costs related to their stewardship plan, except as provided under this section. Administrative and operational costs related to the stewardship plan include:
   1. Collection and transportation supplies for each drop-off site;
   2. Purchase of all secure drop boxes for drop-off sites in any independent stewardship plan;
   3. Purchase of additional secure drop boxes needed for drop-off sites in the standard stewardship plan beyond the four hundred provided under subsection B. of this section;
   4. Ongoing maintenance or replacement of secure drop boxes, as requested by collectors;
   5. Prepaid, preaddressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized;
   6. Operating periodic collection events if utilized, including costs of law enforcement staff time if necessary;
   7. Transportation of all collected pharmaceuticals to final disposal, including costs of law enforcement escort if necessary;
   8. Environmentally sound disposal of all collected pharmaceuticals under BOH 11.50.080; and

B. The local hazardous waste management program shall ensure the provision of up to four hundred secure drop boxes for retail pharmacies and law enforcement agencies willing to participate as drop-off sites for the standard stewardship plan. Collectors who leave the standard stewardship plan for any reason are encouraged to donate the secure drop box to the standard stewardship plan. Producers participating in the standard stewardship plan shall retrieve drop boxes from collectors as requested.

C. No person or producer may charge a specific point-of-sale fee to consumers to recoup the costs of their stewardship plan, nor may they charge a specific point-of-collection fee at the time the covered drugs are collected from covered entities.

D. Producers are not required to pay for costs of staff time at drop-off sites provided by collectors volunteering for a stewardship plan. (R&R 13-03 § 11, 2013).

11.50.100 Stewardship plans - reporting requirements.

A. Within six months after the end of the first twelve-month period of operation, and annually thereafter, the plan operator of the standard stewardship plan and of any independent stewardship plan shall submit a report to the director on behalf of participating producers describing their plan's activities during the previous reporting period to comply with this chapter. The report must include:
   1. A list of producers participating in the stewardship plan;
2. The amount, by weight, of unwanted covered drugs collected, including the amount by weight from each collection method used;
3. A list of drop-off locations, the number of mailers provided for differentially-abled and home bound residents, locations where mailers were provided, if applicable, dates and locations of collection events held, if applicable, transporters used and the disposal facility or facilities used;
4. Whether any safety or security problems occurred during collection, transportation or disposal of unwanted covered drugs during the reporting period and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and to improve safety and security in the future;
5. A description of the public education, outreach and evaluation activities implemented during the reporting period;
6. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
7. A summary of the stewardship plan's goals, the degree of success in meeting those goals in the past year and, if any goals have not been met, what effort will be made to achieve the goals in the next year; and
8. The total expenditure of the stewardship plan during the reporting period.

B. The director shall make reports submitted under this section available to the public.

C. For the purposes of this section, "reporting period" means the period from January 1 through December 31 of the same calendar year, unless otherwise specified to the plan operator by the director. (R&R 13-03 § 12, 2013).

11.50.110 Stewardship plans - lists of producers of covered drugs. Beginning sixty days after the date of adoption of this rule, each drug wholesaler that sells any covered drug in or into the county must provide a list of producers of covered drugs to the local hazardous waste management program in a form agreed upon with the director. Wholesalers must update the list by January 15 each year. (R&R 13-03 § 13, 2013).

11.50.120 Stewardship plans - review of proposed plans.
A. By one year June 20, 2013, a producer, group of producers or stewardship organization participating in the standard stewardship plan or any independent stewardship plan shall submit its proposed stewardship plan to the director for review, accompanied by the plan review fee in accordance with BOH 11.50.160. The director may upon request provide consultation and technical assistance about the requirements of this chapter to assist a producer, group of producers or stewardship organization in developing its proposed plan.
B. The director shall review the proposed stewardship plan and determine whether the proposed plan meets the requirements of BOH 11.50.050 and other applicable sections of this rule. In reviewing a proposed stewardship plan, the director shall provide opportunity for written public comment and consider any comments received.
C. After the review under subsection B. of this section and within ninety days after receipt of the proposed stewardship plan, the director shall either approve or reject the proposed stewardship plan in writing to a producer, group of producers or stewardship organization and, if rejected, provide reasons for rejection.
D. If the proposed stewardship plan is rejected, a producer, group of producers or stewardship organization must submit a revised stewardship plan to the director within sixty days after receiving written notice of the rejection. The director shall review and approve or reject a revised stewardship plan as provided under subsections B. and C. of this section.
E.1. If the director rejects a revised stewardship plan, or any subsequently revised plan, the director shall deem the producer or group of producers out of compliance with this chapter and subject to the enforcement provisions in this chapter.
2. If the revised standard stewardship plan is rejected, the director may, in the director's discretion, require the submission of a further revised standard stewardship plan or develop and impose changes to some or all components of the rejected plan to constitute an approved standard stewardship plan. If the director imposes some or all of the approved plan, the director may not deem the producers participating in and complying with the approved standard stewardship plan in accordance with this chapter out of compliance with this chapter.
If a revised independent stewardship plan is rejected, the producer or group of producers submitting the independent stewardship plan shall participate in the standard stewardship plan and are not eligible to propose an independent stewardship plan for six months after the rejection. The director may not deem out of compliance with this chapter a producer whose revised independent stewardship plan is rejected if the producer participates in and complies with the standard stewardship plan.

F. In approving a proposed stewardship plan, the director may exercise reasonable discretion to waive strict compliance with the requirements of this chapter that apply to producers in order to achieve the objectives of this chapter.

G. The director shall make all stewardship plans submitted under this section available to the public. (R&R 13-03 § 14, 2013).

11.50.130 Stewardship plans - prior approval for change.
A. Proposed changes to an approved stewardship plan that substantively alter plan operations, including, but not limited to, changes to participating manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling covered drugs, education and promotion methods or disposal facilities, must have prior written approval of the director.

B. A producer or group of producers participating in the standard stewardship plan or any independent stewardship plan shall submit to the director any proposed change to a stewardship plan as described under subsection A. of this section in writing at least thirty days before the change is scheduled to occur and accompanied by the review fee in accordance with BOH 11.50.160.

C. The plan operator of an approved stewardship plan shall notify the director at least fifteen days before implementing any changes to drop-off site locations, methods for scheduling and locating periodic collection events or methods for distributing prepaid, preaddressed mailers, that do not substantively alter achievement of the service convenience goal under BOH 11.50.060.D., or other changes that do not substantively alter plan operations under subsection A. of this section. (R&R 13-03 § 15, 2013).

11.50.140 Stewardship plans - enforcement - penalties.
A. The director shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer who is not participating in the standard stewardship plan or an independent stewardship plan as required under this chapter. The warning shall state that participation in a plan is required and warn of penalties for noncompliance.

B. A producer not participating in the standard stewardship plan or an independent stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty under subsections D. and E. of this section.

C. If the director determines that a stewardship plan is not in compliance with this chapter or its plan approved under BOH 11.50.120, the director may send the producer or group of producers participating in the plan a written warning stating the plan is in noncompliance, providing notice of the compliance requirements and warning of penalties for noncompliance. The producer or group of producers has thirty days after receipt of the notice to achieve compliance. If the stewardship plan is not in compliance after thirty days, the director may assess a penalty under subsections D. and E. of this section. This subsection does not preclude the director from suspending an approved plan if a violation of this chapter or an approved plan creates a condition that, in the director’s judgment, constitutes an immediate hazard.

D. A violation of this chapter is subject to a civil penalty of up to two thousand dollars and may be assessed against a producer or group of producers. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate penalty, the director shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, the financial burden to the violator and the size of the violator’s business.

E. The director may utilize BOH chapter 1.08 to assess civil penalties provided in this section. A producer or group of producers may appeal assessments imposed under this section as provided in BOH chapter 1.08. In addition to or as an alternative to utilizing the procedures in BOH chapter 1.08, the director may assess or recover penalties accruing under this section by legal action filed in King County superior court.

F. The director may utilize BOH chapter 1.08 to assess civil penalties as provided in that chapter against a wholesaler who is in violation of BOH 11.50.110. (R&R 13-03 § 16, 2013).
11.50.150 Stewardship plans - rules, performance standards and report.
A. The director may adopt rules necessary to implement, administer and enforce this chapter.
B. The director may work with the plan operator to define goals for collection amounts, education, and promotion for a stewardship plan.
C. The director shall report annually to the King County Board of Health concerning the status of the standard and independent stewardship plans and recommendations for changes to this chapter. The annual report shall include an evaluation of the secure medicine return system, a summary of available data on indicators and trends of abuse, poisonings and overdoses from prescription and nonprescription drugs and a review of comprehensive prevention strategies to reduce risks of drug abuse, overdoses and preventable poisonings. (R&R 13-03 § 17, 2013).

11.50.160 Plan review and annual operating fees.
A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall pay to the director plan review fees to be established under subsection D. of this section for:
   1. Review of a proposed stewardship plan;
   2. Resubmittal of a proposed stewardship plan;
   3. Review of changes to an approved stewardship plan;
   4. Submittal of an updated stewardship plan at least every four years under BOH 11.50.040.D.5.; or
   5. Review of any petition for approval to use alternative final disposal technologies under BOH 11.50.080.C.
B. In addition to plan review fees, a producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall pay to the director annual operating fees to be established under subsection D. of this section.
C. A plan operator or a stewardship organization may remit the fee on behalf of participating producers.
D. As soon as practicable, the director shall propose to the Board of Health a schedule of fees to be adopted by rule and charged to a producer or group of producers to cover costs of administering and enforcing this chapter. Fees shall be calculated to recover actual costs. (R&R 13-03 § 18, 2013).