KING COUNTY
Signature Report
June 21, 2013
R&R BOH13-03

Proposed No. BOH13-03.1

Sponsors

A RULE AND REGULATION relating to providing safe
collection and disposal of unwanted drugs from residential
sources through producer provided and funded product
stewardship plans by amending R&R 66, Section 1 (part), as
amended, and BOH 2.08.085, adding a new chapter to BOH
Title 11, and prescribing penalties; enacted pursuant to RCW
70.05.060, including the latest amendments or revisions
thereto.

BE IT ADOPTED BY THE KING COUNTY BOARD OF HEALTH:

SECTION 1. Findings:

A. Residents of King County benefit from the authorized use of prescription and
nonprescription, or over-the-counter, medicines. However abuse, fatal overdoses and
poisonings from prescription and nonprescription medicines used in the home have
emerged as an epidemic in recent years.

B. More people die from prescription medicines than from heroin and cocaine
combined. Drug overdoses in King County have surpassed car crashes as a leading cause
of preventable deaths, with the majority of overdoses involving prescription opiates.

C. Prescription and nonprescription medicines used in the home are the leading
cause of poisonings reported to the Washington Poison Center, and preventable
poisonings from medicines have been rising rapidly, especially among children and seniors.

D. Unused, expired and leftover drugs that accumulate in homes increase risks of drug abuse, overdoses, and preventable poisonings. A system for the proper disposal of unneeded drugs is an element of a comprehensive strategy to prevent prescription drug abuse.

E. Flushing medicines down toilets and sinks is an inappropriate disposal practice because wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Trash disposal of medicines is an undesirable disposal option because trash cans are not secure and mixed pharmaceutical wastes are household hazardous wastes that should not be disposed of in the solid waste stream.

F. Medicine take-back programs provide secure collection and environmentally sound destruction of unwanted medicines to protect public health.

G. Voluntary medicine take-back programs in the county are insufficient to protect the public, so local action is warranted to reduce risks of abuse, overdoses and poisoning.

H. The Board of Health finds it in the interest of public health to establish a county-wide secure medicine return program providing equitable access for all of the county’s residents that is financed and operated by drug producers selling medicines in or into King County for residential use. Although producers may not charge a specific point-of-sale or point-of-collection fee, the board does not otherwise intend to preclude producers from recouping the costs of their program through other means, including allocating costs to the prices of their covered drugs in King County.
I. The Board of Health approved the Local Hazardous Waste Management Program's plan, on April 15, 2010, which states support for product stewardship approaches for waste pharmaceuticals from residential sources. The plan states that product stewardship provides a means "to shift from a system focused on government-funded and ratepayer-financed waste disposal and diversion, to one that relies on producer responsibility in order to reduce public costs, increase accessibility to services, attain higher environmental benefits, and drive improvements in product design that promotes environmental sustainability."

J. Drug producers are well-positioned to efficiently develop and operate the medicine take-back system, working with other stakeholders such as pharmacies and law enforcement, within standards prescribed by the board to ensure safety and security of the system, and in compliance with pertinent federal and state laws, regulations, and guidelines.

K. The Board of Health encourages pharmacies, health care providers, health professionals, government agencies responsible for solid waste management, wastewater treatment and health and community organizations in the county to inform residents through all their standard communication methods about safe storage of medicines and the use of collection services for unwanted medicines provided through the drug producers' stewardship program.

SECTION 2. Sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 of this rule should constitute a new chapter on secure medicine return in BOH Title 11.
NEW SECTION. SECTION 3. 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.

NEW SECTION. SECTION 4. 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.

NEW SECTION. SECTION 5. 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. 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.


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 section 15 of this rule.

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 section 8.A. and E. of this rule, 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 section 7 of this rule 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 section 7 of this rule, and accompanied by the review fee in accordance with section 18 of this rule. The director shall review updated stewardship plans using the process described in section 14 of this rule; and
6. Pay all administrative and operational costs and fees associated with their stewardship plan as required under sections 11 and 18 of this rule.

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 section 7 of this rule 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.

NEW SECTION. SECTION 7. Stewardship plans - components. The standard stewardship plan or any independent stewardship plan, which must be submitted and reviewed according to section 14 of this rule, 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 section 8 of this rule, 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 section 6.D.2. of this rule, 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 sections 8 and 10 of this rule;
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


NEW SECTION, SECTION 8. 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.


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.

NEW SECTION. SECTION 10. 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 CFR 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

4. Overall impact to the environment and human health.

NEW SECTION. SECTION 11. 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 section 10 of this rule; and

9. Program promotion under section 9 of this rule.

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.

NEW SECTION. SECTION 12. **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.
467 C. For the purposes of this section, "reporting period" means the period from
468 January 1 through December 31 of the same calendar year, unless otherwise specified to
469 the plan operator by the director.

470 NEW SECTION. SECTION 13. Stewardship plans - lists of producers of
471 covered drugs. Beginning sixty days after the date of adoption of this rule, each drug
472 wholesaler that sells any covered drug in or into the county must provide a list of
473 producers of covered drugs to the local hazardous waste management program in a form
474 agreed upon with the director. Wholesalers must update the list by January 15 each year.

475 NEW SECTION. SECTION 14. Stewardship plans - review of proposed
476 plans.

477 A. By one year after the date of adoption of this rule, a producer, group of
478 producers or stewardship organization participating in the standard stewardship plan or
479 any independent stewardship plan shall submit its proposed stewardship plan to the
480 director for review, accompanied by the plan review fee in accordance with section 18 of
481 this rule. The director may upon request provide consultation and technical assistance
482 about the requirements of this chapter to assist a producer, group of producers or
483 stewardship organization in developing its proposed plan.

484 B. The director shall review the proposed stewardship plan and determine
485 whether the proposed plan meets the requirements of section 7 of this rule and other
486 applicable sections of this rule. In reviewing a proposed stewardship plan, the director
487 shall provide opportunity for written public comment and consider any comments
488 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.

3. 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.

NEW SECTION. SECTION 15. 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 section 18 of this rule.

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 preaddressed mailers, that do not substantively alter achievement of the service
convenience goal under section 8.D. of this rule, or other changes that do not
substantively alter plan operations under subsection A. of this section.


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 section 14 of this rule, 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 section 13 of this rule.

NEW SECTION. SECTION 17. **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.

NEW SECTION. SECTION 18. 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 section 6.D.5. of this rule; or
5. Review of any petition for approval to use alternative final disposal technologies under section 10.C. of this rule.

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.

SECTION 19. R&R 66, Section 1 (part), as amended, and BOH 2.08.085 are
each hereby amended to read as follows:

Powers of the committee.

A.1. The committee shall be responsible for accepting and recommending a
management plan and budget for:

a. the reduction of moderate risk waste generation, its entry into the solid waste
stream, entry into the liquid waste (sewage) stream, into storm drainage or surface waters
and evaporation into the air; and

b. the protection and enhancement of the public health and environmental
quality in King County by the reduction of the threat posed by the production, use,
storage and disposal of hazardous materials.

2. The management coordination committee (will) shall develop an annual
plan and budget and reach agreement on it through consensus of the entire committee.

Lacking a consensus, a majority and a minority report will be forwarded to the King
County Board of Health.

B. The committee shall recommend contracts with the city of Seattle, suburban
cities, sewer districts(,) or other governments or entities located entirely or partially
within King County, and King County, to implement portions of the management plan, in
consideration of sums collected under BOH 2.08.090.

C. The committee shall develop an annual plan and budget for implementation of
BOH chapter 11. (the chapter established under section 2 of this rule) and reach
agreement on it through consensus of the entire committee. Lacking a consensus, a
majority and a minority report shall be forwarded to the King County Board of Health.
The committee shall recommend contracts or interagency agreements to implement
portions of the plan.

SECTION 20. Severability. If any provision of this rule or its application to any
person or circumstance is held invalid, the remainder of the rule or the application of the
provision to other persons or circumstances is not affected.

R&R BOH13-03 was introduced on and passed by the Board of Health on 6/20/2013, by the following vote:

Yes: 11 - Ms. Frisinger, Mr. Conlin, Ms. Patterson, Ms. Lambert, Mr. Licata, Dr. Baker, Dr. Danielson and Mr. McDermott
No: 0
Excused: 2 - Ms. Clark and Dr. Nicola

BOARD OF HEALTH
KING COUNTY, WASHINGTON

Joe McDermott, Chair

ATTEST:

Anne Noris, Clerk of the Board

Attachments: None