

Proposed Snohomish Secure Medicine Return Regulation

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A REGULATION relating to providing safe collection and disposal of unwanted drugs from residential sources through producer provided and funded product stewardship plans by adding a new chapter to Snohomish Health District Sanitary Code (SHDSC), and prescribing penalties; enacted pursuant to RCW 70.05.060, including the latest amendments or revisions thereto.

BE IT ADOPTED BY THE BOARD OF HEALTH OF THE SNOHOMISH HEALTH DISTRICT:

SECTION 1. Findings:

A. Residents of Snohomish 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. Drug overdoses in Snohomish County have surpassed car crashes as the leading cause of unintentional injury deaths, with the majority of overdoses involving prescription opiates. People who are addicted to heroin often first abused prescription opiate medicines.

C. Home medicine cabinets are the most common source of prescription drugs that are diverted and misused. Studies find about 70% of those who abuse prescription medicines obtain the drugs from family members or friends, usually for free. About two-thirds of teens says it is easy to obtain prescription opioids and prescription stimulants.

D. Prescription and nonprescription medicines are a leading cause of poisonings in the home, with children and seniors especially at risk.

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

F. 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 county's solid waste stream. Pharmaceutical wastes including expired, unused or contaminated drugs and vaccines are expressly prohibited from being disposed of at Snohomish County Solid Waste Disposal sites pursuant to the Snohomish County Code (SCC) 7.41.050(7), and the contents of all garbage containers in the county are required to be disposed at county owned and operated sites pursuant to Snohomish County Code (SCC) 7.35.125(3).

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

H. 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. The Snohomish County Partnership for Secure Medicine Disposal has collected and safely destroyed more than 34,000 pounds of household medicines since 2010 through secure drop boxes at law enforcement facilities. However, limited and unstable public resources are insufficient to sustain this program or to expand drop box sites to more convenient locations such as pharmacies, as now allowed under the United States Drug Enforcement Administration's Final Rule for Disposal of Controlled Substances [21 CFR Part 1317].

I. The Snohomish Health District Board of Health finds it in the interest of public health to establish a county-wide secure medicine return program providing convenient and equitable access for all of the county's residents that is financed and operated by drug producers selling medicines in or into Snohomish 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 Snohomish County.

J. Drug producers are well-positioned to efficiently develop and operate the pharmaceutical stewardship program, working with other stakeholders such as pharmacies, health care facilities, 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. Since 2012, a growing number of local governments have enacted ordinances requiring drug producers to design, fund, and operate secure and convenient programs to safely collect and dispose of residents' unwanted pharmaceuticals.

L. The Snohomish Health District 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. Codification instruction. Sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, and 21 of this regulation constitute the substantive regulations to be memorialized as a new chapter of the Snohomish Health District Sanitary Code (SHDSC) on secure medicine return for Snohomish County.

NEW SECTION. SECTION 3. Short title. The full title of this Chapter is the "Secure Medicine Regulations in Snohomish County" which has been adopted by the Snohomish Health District Board of Health and is codified as Chapter ____ of the SHDSC and it shall also be known as the "Secure Medicine Return Regulation".

NEW SECTION. SECTION 4. Authority, Purpose and Scope.

A. Pursuant to Chapter 70.05 RCW and Chapter 70.46 RCW, the Board of Health of the Snohomish Health District adopts this Chapter to protect and preserve the public health, safety and welfare of the residents of Snohomish County. 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 the Snohomish Health District or any of its officers or employees, for whom the implementation or enforcement of this chapter shall be discretionary and not mandatory. Nothing contained in these regulations is intended to be nor shall be construed to create or form the basis of any liability on the part of the Snohomish Health District or its officers, employees or agents for any injury or damages by reason of any act or omission with the implementation or enforcement of this chapter.

NEW SECTION. SECTION 5. Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

A. "Authorized Collector" means any person authorized as a collector by the United States Drug Enforcement Administration pursuant to 21 CFR 1317, such as manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, or narcotic treatment programs, that gathers unwanted drugs, including controlled substances, 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 and nonprescription drugs, brand name and generic drugs, drugs for veterinary use, and drugs in medical devices and combination products, including pre-filled injector products with a retractable or otherwise securely covered needle.

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 regulation if the producer already provides a pharmaceutical product stewardship or take-back program;
- f. Injector products and medical devices or their component parts or accessories that contain no covered drug or no more than trace residual amounts of covered drug; and
- g. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

C. "Covered entities" means residents of Snohomish 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 Health Officer of the Snohomish Health District or the director's duly authorized representative.

E. "Drop-off site" means the location of an authorized collector or a law enforcement agency where a secure drop box for all covered drugs is provided for residents of the county, or the location of a long-term care facility at which a hospital/clinic or retail pharmacy is authorized by the United States Drug Enforcement Administration to maintain a secure drop box for unwanted covered drugs from residents of the long-term care facility.

F. "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.

G. "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.

H. "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.

I. "Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients and, for the purposes of this chapter, a facility where covered drugs that may be disposed in a secure drop box pursuant to 21 CFR Part 1317.80 are in the lawful possession of the resident.

J. "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.

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

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

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

N. "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.

O. "Pharmacy" means a place licensed by the state of Washington State Pharmacy Quality Assurance Commission where the practice of pharmacy, as defined in RCW 18.64.011, is conducted.

P. "Potential Authorized Collector" means any person, such as manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, or narcotic treatment programs, that may modify their registration with the United States Drug Enforcement Administration to be authorized for collection of drugs, including controlled substances.

Q. "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.

R. "Producer" means a manufacturer that is engaged in the manufacture of a covered drug sold in or into Snohomish 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 regulation;
2. A pharmacist who compounds a prescribed individual drug product for a consumer; or
3. A wholesaler who is not also a manufacturer.

S. "Regulation" means the "Secure Medicine Return Regulation" adopted by the Board of Health of the Snohomish Health District.

T. "Retail pharmacy" means a pharmacy licensed by the state of Washington State Pharmacy Quality Assurance Commission for retail sale and dispensing of drugs.

U. "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.

V. "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.

W. "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.

NEW SECTION. SECTION 6. 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 section 15 of this regulation.

C. By two months after the date of adoption of this regulation 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. For a covered drug not sold in or into Snohomish County at the date of adoption of this regulation, the producer of the covered drug, and, if applicable, the retailer whose store label appears on a covered drug or the drug's packaging, shall have six (6) months from the date of initiating sales of the covered drug in or into the county to make this notification to the director.

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

1. By four months after this regulation 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 four months after this regulation is adopted, notify all potential authorized collectors in the county of the opportunity to participate as a drop-off site in accordance with section 8.A., E., and F. of this regulation, and provide a process for forming an agreement between the plan and interested potential authorized collectors;

b. annually thereafter, make the same notification to any nonparticipating potential authorized collectors in the county; and

c. commence good faith negotiations with each potential authorized collector expressing an interest in participating as a drop-off site within thirty (30) calendar days of the expression of such interest.

3. By six months after this regulation is adopted, submit a proposed stewardship plan as described in section 7 of this regulation to the director for review;

4. Within three months after the director's approval of the stewardship plan:

a. provide documentation to the director that all potential authorized collectors participating in the approved stewardship plan, not including law enforcement, have amended their registrations with the United States Drug Enforcement Administration; and

b. 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 regulation, and accompanied by the review fee in accordance with section 18 of this regulation. The director shall review updated stewardship plans using the process described in section 14 of this regulation; and

6. Pay all administrative and operational costs and fees associated with their stewardship plan as required under sections 11 and 18 of this regulation.

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, 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 regulation 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. 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.

I. 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 an authorized 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 regulation, 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 regulation, including a list of all collection methods and participating potential authorized collectors, a list of drop-off sites with addresses, 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 potential authorized collectors contacted by the plan under section 6.D.2. of this regulation, and a list of all potential authorized collectors who offered to participate, and, if any potential authorized collector who offered to participate was not included in the plan, an explanation for the reasons for such decision;

C. A description of the handling and disposal system, including identification of and contact information for potential authorized collectors, transporters and waste disposal facilities to be used by the stewardship plan in accordance with sections 8 and 10 of this regulation;

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 authorized 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, regulations and guidelines, including those of the United States Drug Enforcement Administration, and how any pharmacy drop-off site will operate under applicable regulations and guidances of the state of Washington State Pharmacy Quality Assurance Commission;

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 regulation, including a copy of standardized instructions for residents, signage developed for authorized collectors and required promotional materials;

G. A proposal on the short-term and long-term goals of the stewardship plan for collection amounts and public awareness; 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
3. Recycling of drug packaging to the extent feasible.

NEW SECTION. SECTION 8. Stewardship plans - collection of covered drugs.

A. This chapter does not require any person to serve as an authorized collector in a stewardship plan. A person may offer to participate as an authorized collector voluntarily, or may agree to participate as an authorized collector in exchange for compensation offered by a producer, group of producers or stewardship organization. Collectors may include any potential authorized collectors, law enforcement, appropriate long-term care facilities, and mail-back services, 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 regulations and guidances of the state of Washington State Pharmacy Quality Assurance Commission.

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 Snohomish 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, and meeting the requirements of this subsection.

2. In establishing and operating a stewardship plan, a producer, group of producers or stewardship organization shall give preference to having drop-off sites located at retail pharmacies, hospitals/clinics with an on-site pharmacy, and law enforcement agencies. A stewardship plan shall include, as collectors, any retail pharmacy, hospital/clinic with an on-site pharmacy or any law enforcement agency willing voluntarily to participate 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 any potential authorized collector or long-term care facility willing to participate 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 and town with a potential authorized collector or law enforcement agency, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents at the locations of potential authorized collectors or law enforcement, geographically distributed to provide reasonably convenient and equitable access.

4. If the minimum number of drop-off sites in 3. of this subsection cannot be achieved by the standard stewardship plan or any independent stewardship plan due to a lack of potential drop-off sites in specific areas of the county, then service to those areas shall be supplemented by periodic collection events or mail-back services, or a combination of these collection methods.

E. Drop-off sites shall accept all covered drugs from covered entities during all hours that the authorized collector or law enforcement agency is normally open for business with the public. Drop-off sites at long-term care facilities shall only accept covered drugs from individuals who reside, or have resided, at the long-term care facility, pursuant to 21 CFR 1317.80.

F. Drop-off sites shall utilize secure drop boxes in compliance with all applicable federal and state laws, including requirements of the United States Drug Enforcement Administration. Secure drop boxes shall be emptied and serviced as often as necessary to avoid reaching capacity. Secure drop box signage shall include a prominently displayed twenty-four (24) hour,

toll-free telephone number and website for the stewardship plan, by which any person can provide feedback on collection activities, including but not limited to the need to empty the receptacle.

G. 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.

H. 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.

NEW SECTION. SECTION 9. Stewardship plans - promotion.

A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan must develop and provide a system of promotion, education, and public outreach about safe storage and secure collection of covered drugs. Each stewardship plan shall:

1. Promote the use of their stewardship plan so that where and how to return covered drugs to drop-off sites and how to use other collection options for covered drugs are widely understood by residents, pharmacists, retailers of covered drugs, health care practitioners including doctors, dentists, and other prescribers, veterinarians, and veterinary hospitals;

2. Discourage the disposal of covered drugs in the garbage and state that pharmaceutical wastes, including expired, unused or contaminated drugs and vaccines, are not accepted at Snohomish County Solid Waste Disposal sites under Snohomish County Code (SCC) 7.41.050(7);

3. Promote the safe storage of prescription and nonprescription medicines by residents before secure disposal through their stewardship plan;

4. 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 Snohomish Health District may provide guidance to producers and collectors on the development of the instructions and design;

5. 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, county agencies, 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. The web site and all materials shall include notices that unused, expired, or contaminated pharmaceutical wastes should not be disposed in the garbage system in Snohomish County, pursuant to Snohomish County Code (SCC) 7.41.050(7).

6. Conduct a survey of residents of Snohomish County and a survey of pharmacists, health professionals, and veterinarians in the county who interact with residents on use of medicines after the first full year of operation of the plan, and again biennially thereafter. 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 within ninety (90) days of the end of the survey period; and

7. Annually evaluate the effectiveness of its promotion, outreach, and public education, and include this evaluation in its annual report.

B. If more than one stewardship plan is approved then all approved stewardship plans shall coordinate their promotional activities to ensure that all residents can easily identify, understand and access the collection services provided by any stewardship plan, including providing residents with a single toll-free telephone number and single web site to access information about collection services for every approved plan.

C. Pharmacies and other entities selling medicines in or into Snohomish County are encouraged to promote secure disposal of covered drugs by residents through the use of the stewardship plan. Pharmacies must provide materials explaining the use of the stewardship plan to customers upon request.

D. The Snohomish Health District and government agencies throughout the county responsible for health, solid waste management, and wastewater treatment shall promote safe storage of prescription and nonprescription medicines by residents, secure disposal of covered drugs by residents through the use of the stewardship plans, and the plans' toll-free telephone numbers and web sites through their standard educational methods.

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 secure drop boxes for each drop-off site;
3. Ongoing maintenance or replacement of secure drop boxes, as requested by collectors;
4. Prepaid, preaddressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized;
5. Operating periodic collection events if utilized, including costs of law enforcement staff time if necessary;
6. Transportation of all collected pharmaceuticals to final disposal;
7. Environmentally sound disposal of all collected pharmaceuticals under section 10 of this regulation; and

8. Program promotion under section 9 of this regulation, including costs of providing materials to pharmacies to fulfill customer requests.

B. 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.

C. Producers are not required to pay for costs of staff time at drop-off sites provided by authorized collectors volunteering for a stewardship plan, but may offer compensation to authorized collectors for their participation.

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 sites with addresses, 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 for collection amounts and public awareness, 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.

NEW SECTION. SECTION 13. Stewardship plans - identification of producers of covered drugs.

A. Within sixty (60) days of a request from the director, any drug wholesaler that sells any covered drug in or into the county must provide a list of producers of covered drugs to the Snohomish Health District in a form agreed upon with the director. Wholesalers must update the list, no more than annually, if requested by the director.

B. Any person receiving a letter of inquiry from the director regarding whether or not it is a producer under this chapter must respond in writing within sixty (60) days. If such person does not believe it is a producer under this chapter, it must state the basis for such belief and provide a list of any covered drugs it sells, distributes, repackages, or otherwise offers for sale within the county, and identify the name and contact information of the manufacturer of the covered drug.

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

A. By six months after the date of adoption of this regulation, a producer, group of producers or stewardship organization shall submit its proposed stewardship plan to the director for review, accompanied by the plan review fee in accordance with section 18 of this regulation and indicating whether the plan is proposed as the standard stewardship plan or an independent stewardship plan. If multiple proposals are submitted for the standard stewardship plan, the director shall designate the standard stewardship plan at time of plan approval.

B. The director shall review each proposed stewardship plan and determine whether the proposed plan meets the requirements of section 7 of this regulation and other applicable sections of this regulation. 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 (90) 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 (60) 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 may deem the producer or group of producers out of compliance with this chapter and subject to the enforcement provisions in this chapter.

2. If a revised proposal for the 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 and shall provide an opportunity for written public comment on each plan as described in subsection B.

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 an approved 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 (30) days before the change is scheduled to occur and accompanied by the review fee in accordance with section 18 of this regulation.

C. The plan operator of an approved stewardship plan shall notify the director at least fifteen (15) 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 section 8.D. of this regulation, or other changes that do not substantively alter plan operations under subsection A. of this section.

D. The producer or group of producers participating in an approved stewardship plan shall notify the director of any changes to the plan operator who is the official point of contact for the stewardship plan within fifteen (15) days of the change. The plan operator shall notify the director of any changes in ownership or contact information for participating producers within thirty (30) days of such change.

NEW SECTION. SECTION 16. Stewardship plans - enforcement - penalties.

A. The director shall send a written Health Officer's order and a copy of this chapter and any regulations 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 Health Officer's Order shall state that participation in a plan is required and warn of penalties for noncompliance, including all costs incurred for enforcement of that Health Officer's Order, as provided in Chapter 1.3 of the SHDSC.

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 (60) days after receiving a written Health Officer's Order from the director may be assessed a penalty under subsections D., E. and F. 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 regulation, the director may send the producer or group of producers participating in the plan a written Health Officer's Order stating the plan is in noncompliance, providing notice of the compliance requirements and warning of penalties for noncompliance, including all costs incurred for enforcement of that Health Officer's Order, as provided in Chapter 1.3 of the SHDSC. The producer or group of producers has thirty (30) days after receipt of the notice to achieve compliance. If the stewardship plan is not in compliance after thirty (30) 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, in addition to other penalties, if a violation of this chapter or an approved plan creates a condition that, in the director's judgment, constitutes an immediate hazard.

D. The Snohomish Health District is authorized to enforce the restrictions or requirements of this Chapter against any person or entity, whether it be a producer, group of producers, or wholesaler who is not in compliance; assess all costs of enforcement against the person or entity, whether it be a producer, group of producers or wholesaler, who is in noncompliance in accordance with Chapter 1.3 of the SHDSC; and otherwise pursue compliance with this Chapter.

E. The Health Officer or designee may enforce the requirements and restrictions of this Chapter by one or a combination of the following by the issuance of a written Health Officer's Order:

1. Assessing all costs of enforcement in accordance with Chapter 1.3 of the SHDSC;
2. Requiring an informal administrative conference;
3. Prohibiting certain conduct or directing certain conduct;

4. Imposing a civil penalty of up to two thousand dollars that may be assessed against a producer or group of producers or wholesalers. 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.

F. The Health Officer or designee is authorized to pursue civil fines and costs including attorney fees by commencement of civil action in the name of the Snohomish Health District independent of and/or as a means of enforcing written orders of the Health Officer referenced above.

NEW SECTION. SECTION 17. Stewardship plans - regulations, performance standards and report.

A. The director may adopt regulations necessary to implement, administer and enforce this chapter.

B. The director may work with the plan operator to define goals for collection amounts and public awareness for a stewardship plan.

C. The director shall report annually to the Snohomish Health District 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 regulation; or
5. Review of any petition for approval to use alternative final disposal technologies under section 10.C. of this regulation.

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. Fees shall be set initially by the Snohomish Health District Board of Health and shall be subject to revision commensurate with the costs of delivering the service and to administering and enforcing this chapter. All fees collected under the provision of this chapter shall be payable to the Snohomish Health District.

SECTION 19. Severability. If any provision of this regulation or its application to any person or circumstance is held invalid, the remainder of the regulation or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. SECTION 20. Void Condition. This chapter shall be void when a state or federal law, or a combination of laws, takes effect that establishes a Washington State or national program for the convenient collection and environmentally sound disposal of covered drugs from residents that meets or exceeds the intent of this chapter for secure medicine return services. The Snohomish Health District Board of Health shall confirm that the state-wide or federal legislation meets or exceeds the intent of this chapter. Such confirmation will trigger the preemption provisions of this section.

SECTION 21. Effective date. This regulation shall take effect and be in force 30 days after its passage.