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SKAGIT COUNTY CODE

Proposed Chapter 20 in Title 12

Secure Medicine Return Ordinance

Chapter 20.

Secure Medicine Return Ordinance

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12.20.010 Authority, purpose and intent.

(1) The purpose of this Chapter is to protect the public health by providing prompt, safe, and effective disposal methods for expired or otherwise unwanted drugs and to prevent such substances from being obtained for unauthorized purposes or being disposed of in a manner that can adversely affect the environment.

(2) This Chapter has been enacted for the welfare of the public as a whole. Nothing contained in this Chapter is intended to be nor may be construed to create or form the basis of any liability on the part of the County, its officers, employees, or agents for any injury or damage resulting from the failure of anyone to comply with the provisions of this Chapter, or by reason or in consequence of the implementation or enforcement pursuant to this Chapter, or by reason of any action or inaction on the part of the County related in any manner to the enforcement of this Chapter by its officers, employees, or agents.

(3) This Chapter is adopted by the Skagit County Board of Health in accordance with the authority granted in Chapter 70.05 RCW.

12.20.020 Administration.

The Skagit County Health Officer and the Skagit County Board of Health shall administer this Chapter under the authority and requirements of Chapter 70.05 RCW. The Health Officer is authorized to take actions she or he deems necessary to maintain public health and sanitation and to administer and enforce this Chapter under the authority of RCW 70.05.070. Under RCW 70.05.060 and .070, fees may be charged and collected for this administration.

12.20.030 Effective date.

This ordinance shall be effective upon adoption by the Skagit County Board of Health.

12.20.040 Definitions.

As used in this Chapter, the following terms have the meanings indicated unless the context clearly indicates otherwise.

(1) "Authorized collector" means any person or entity 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 gather unwanted drugs, including controlled substances, from covered entities for the purpose of collection, transportation and disposal. For purposes of this Chapter, "authorized collector" shall also include law enforcement agencies.

(2) "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 inhaler devices and pre-filled injector devices with a retractable or otherwise securely covered needle. 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 CFR 600.3(h) as it exists on the effective date of this ordinance 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 have been emptied or contain no more than trace residual amounts of a covered drug; and
- (g) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other similar products.

(3) "Covered entities" means residents of Skagit County, including individuals living in single and multiple family residences and other residential settings, and including other non-business sources of prescription and nonprescription drugs that are unused, unwanted, disposed of or abandoned by residents as identified by Public Health. "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.

(4) "Drop-off site" means the location of an authorized collector where a secure drop box for the collection of unwanted 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.

(5) "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.

(6) "Drug" means:

- (a) Substances recognized in the official United States pharmacopoeia, 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. Pharmacopoeia Convention and the Homeopathic Pharmacopoeia Convention of the United States;
- (b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
- (c) Substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or
- (d) Substances intended for use as a component of any substances specified in (a), (b) or (c) of this subsection.

(7) "Health Officer" means the Skagit County Health Officer, as defined in RCW 70.05.010, or a duly authorized representative.

(8) "Independent stewardship plan" means a plan other than the standard stewardship plan for the collection, transportation and disposal of unwanted covered drugs that:

(a) May be proposed by a producer or group of producers; and

(b) 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.

(9) "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 1317.80 are in the lawful possession of the resident.

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

(11) "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 such 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.

(12) "Manufacturer" means a person, corporation or other entity engaged in the manufacture of drugs or devices.

(13) "Nonprescription drug" means a drug that may be lawfully sold without a prescription.

(14) "Ordinance" means the "Secure Medicine Return" ordinance adopted by the Skagit County Board of Health enacting Skagit County Code, Chapter 20 Title 12.

(15) "Person" means an individual, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative or other entity of any kind or nature.

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

(17) "Potential authorized collector" means any person or entity, 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. For purposes of this Chapter, "Potential authorized collector" shall also include law enforcement agencies.

(18) "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.

(19) "Producer" means a manufacturer that is engaged in the manufacture of a covered drug sold in or into Skagit County, including a brand-name or generic drug. Producer does not include:

- (a) 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 SCC 12.20.050;
- (b) A pharmacist who compounds a prescribed individual drug product for a consumer; or
- (c) A drug wholesaler who is not also the manufacturer.

(20) "Public Health" means the Skagit County Public Health Department.

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

(22) "Standard stewardship plan" means the plan for the collection, transportation and disposal of unwanted covered drugs that is:

- (a) Financed, developed, implemented and participated in by producers;
- (b) Operated by the participating producers or a stewardship organization; and
- (c) Approved by the Health Officer as the standard stewardship plan.

(23) "Stewardship organization" means an organization designated by a producer or group of producers to act as an agent on behalf of each participating producer to develop, implement and operate a stewardship plan.

(24) "Unwanted covered drug" means any covered drug no longer wanted by its owner, that:

- (a) Has been abandoned or discarded; or
- (b) Is intended to be discarded by its owner.

12.20.050 Stewardship plan participation.

- (1) Each producer shall participate in the standard stewardship plan approved by the Health Officer, except that a producer may individually, or with a group of producers, form and participate in an independent stewardship plan approved by the Health Officer.
- (2) The standard stewardship plan and any independent stewardship plan shall be approved by the Health Officer before collecting unwanted covered drugs. Once approved, stewardship plans must have prior written approval of the Health Officer for proposed changes as described in SCC 12.20.140.
- (3) Within sixty (60) days after the date of adoption of this ordinance:
 - (a) A producer shall notify Public Health in writing of the producer's intent to participate in the standard stewardship plan or to form and participate in an independent stewardship plan; and
 - (b) A retailer whose store label appears on a covered drug or the drug's packaging shall notify Public Health of the intent to participate in a stewardship plan 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 Skagit County at the date of adoption of this ordinance, 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 one hundred and eighty (180) days from the date of initiating sales of the covered drug in or into the county to make this notification to Public Health.

- (4) A producer or a group of producers participating in the standard stewardship plan or an independent stewardship plan shall:
 - (a) Within one hundred and twenty (120) days after this ordinance is adopted identify in writing to Public Health 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;
 - (b) Within one hundred and twenty (120) days 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 SCC 12.20.070 (1) and (4), and provide a process for forming an agreement between the plan and interested potential authorized collectors, including providing a sample collector agreement; and

- (i) Annually thereafter, make the same notification to any nonparticipating potential authorized collectors in the county; and
 - (ii) 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.
 - (c) Within one hundred and eighty (180) days after this ordinance is adopted, submit a proposed stewardship plan as described in SCC 12.20.060 to Public Health for review and approval;
 - (d) Within ninety (90) days after the Health Officer's approval of the stewardship plan:
 - (i) Provide written documentation to Public Health confirming 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
 - (ii) Begin operation of the approved stewardship plan, including providing the collection system for unwanted covered drugs in accordance with the requirements of SCC 12.20.070.
 - (e) At least every four (4) years after each plan initiates operations, submit an updated plan to Public Health explaining any substantive changes to components of the stewardship plan required in SCC 12.20.060, and accompanied by the review fee in accordance with SCC 12.20.180. Public Health shall review updated stewardship plans using the process described in SCC 12.20.130.
 - (f) Pay all administrative and operational costs and fees associated with the stewardship plan as required under SCC 12.20.100 and 12.20.180.
- (5) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may:
- (a) 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.
 - (b) Notify Public Health of any producer selling covered drugs in or into the county that is failing to participate in a stewardship plan; or

- (c) 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.
- (6) 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 Public Health in writing of the intent to form an independent stewardship plan. The notification shall 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 ninety (90) days of such notification, the producer or group of producers may submit a proposed independent stewardship plan as described under SCC 12.20.060 to Public Health for review and approval.
- (7) The Health Officer may approve in writing extensions to later dates for the submission dates and deadlines in this section.
- (8) When requested, Public Health may 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.

12.20.060 Stewardship plan components.

The standard stewardship plan or any independent stewardship plan, which must be submitted and reviewed according to SCC 12.20.130, shall include:

- (1) Contact information for all drug producers participating in the stewardship plan.
- (2) 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 SCC 12.20.070, including:
 - (a) A list of all collection methods and participating potential authorized collectors;
 - (b) A list of drop-off sites with addresses;
 - (c) A list of potential authorized collectors contacted by the plan under SCC 12.20.050 (4)(b), a list of all potential authorized collectors who offered to participate, and if applicable an explanation of the reason any potential authorized collector who offered to participate was not included in the plan;
 - (d) A sample of the collector agreement that the plan operator provides to a potential authorized collector to arrange for services at a drop-off site;
 - (e) A description of how periodic collection events will be scheduled and located, if applicable;

- (f) A description of how mail-back services will be provided and an example of the prepaid, preaddressed mailers to be utilized; and
 - (g) A description of proposed alternative collection methods for any covered drugs that may not be acceptable for return in secure drop boxes, during collection events or in mailers.
- (3) A description of the handling and disposal system, including identification of and contact information for transporters and waste disposal facilities to be used by the stewardship plan in accordance with SCC 12.20.070 and 12.20.090.
 - (4) 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 guidance of the Washington State Pharmacy Quality Assurance Commission.
 - (5) A description of how patient information on drug packaging will be kept secure during: collection; transportation; and recycling or disposal.
 - (6) A description of the public education effort and promotion strategy required in SCC 12.20.080, including a copy of standardized instructions for covered entities, signage developed for authorized collectors and required promotional materials.
 - (7) A proposal on the short-term and long-term goals of the stewardship plan for collection amounts and public awareness.
 - (8) A description of how the stewardship plan will consider:
 - (a) Use of existing providers of waste pharmaceutical services;
 - (b) Separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and
 - (c) Recycling of drug packaging to the extent feasible.

12.20.070 Collection of covered drugs.

- (1) 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. Retail pharmacies, hospitals/clinics with an on-site pharmacy, law enforcement agencies, and any other entities participating as authorized collectors in a stewardship plan, shall operate in accordance with state and federal laws and regulations for the handling of unwanted covered drugs, including those of the United States Drug Enforcement Administration, and in compliance with this Chapter. A pharmacy drop-off site shall operate under applicable regulations and guidance of the Washington State Pharmacy Quality Assurance Commission.

- (2) The collection system shall be convenient, operated on an ongoing, year-round basis that adequately serves the needs of covered entities, and provide equitable and convenient access for all Skagit County residents to return unwanted covered drugs, in accordance with this section.
- (3) The collection system for all unwanted covered drugs shall be safe and secure and include provisions for protecting patient information on drug packaging.
- (4) Operation, Locations, and Minimum Number of Drop-off Sites. 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.
 - (a) 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, within ninety (90) days of their offer to participate, any retail pharmacy, any 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, unless the potential authorized collector requests a longer time frame. A producer, or group of producers establishing and operating a stewardship plan may also include any potential authorized collector, narcotic treatment program 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.
 - (b) Drop-off sites shall accept all covered drugs from covered entities during all hours that the authorized collector is normally open for business with the public. However, drop-off sites at long-term care facilities shall only accept covered drugs from individuals who reside, or have resided, at the facility pursuant to 21 CFR 1317.80.
 - (c) 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. A producer, group of producers, or stewardship organization shall

provide a service schedule that meets the needs of each drop-off site to ensure that each secure drop box is serviced as often as necessary to avoid reaching capacity, and that collected covered drugs are transported to final disposal in a timely manner, including a process for additional prompt, on-call collection upon notification from the drop-off site. 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.

(d) Locations and Minimum Number of Drop-off Sites.

- (i) At least two drop-off sites shall be provided in each city in Skagit County. Should any city's population increase to greater than 40,000 residents, then at least one additional drop-off site for each additional 20,000 residents shall be provided in that city.
- (ii) At least one drop-off site shall be provided in each town in Skagit County.
- (iii) Drop-off sites shall be geographically distributed to provide reasonably convenient and equitable access to residents of each city and town and in the unincorporated county.
- (iv) Drop-off sites located at a long-term care facility or narcotic treatment program shall not count towards the minimum drop-off sites required in each city or town under this subsection.
- (v) If the minimum number of drop-off sites in this subsection cannot be achieved in specific areas of the county, then the stewardship plan shall include collection of covered drugs by periodic collection events, held at least once annually, in those cities and towns in which the minimum required drop-off sites cannot be achieved. The stewardship plan must also notify municipal buildings, fire stations, and public libraries serving those areas in which the minimum required drop-off sites cannot be achieved of the opportunity to distribute prepaid and preaddressed mailers, and provide an adequate and ongoing supply of mailers to those that agree to participate as a mailer distribution location.

(5) Mail-back Service and Collection Events.

- (a) Mail-back services shall be free of charge, and shall be made available to any resident of the county, including differentially-abled and home bound residents. An adequate and ongoing supply of prepaid and preaddressed envelopes shall be provided:

- (i) to county residents upon request through the stewardship plan's toll-free telephone number and web site;
 - (ii) upon request to persons providing home care services to residents, including hospice services; and
 - (iii) at municipal buildings, fire stations, public libraries, and other publicly accessible entities in the county that request to serve as a mailer distribution location.
- (b) Periodic collection events, if utilized as a collection method, shall 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.
- (6) Alternative collection methods shall be provided for any covered drugs that cannot be accepted or comingled with other covered drugs in secure drop boxes, in mailers, or at collection events. Such collection methods shall be reviewed and approved by Public Health and shall operate in compliance with applicable local, state and federal regulations.
- (7) In determining the collection services required under this section, the annual population estimate provided by the Washington State Office of Financial Management shall be utilized to define the population of cities, towns and unincorporated areas of Skagit County.

12.20.080 Promotion.

- (1) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall develop and provide a system of promotion, education, and public outreach about safe storage and secure collection of covered drugs. Each stewardship plan shall include and have a plan to:
- (a) Promote the use of their stewardship plan so that where and how to return unwanted covered drugs to drop-off sites and how to use other collection options for unwanted covered drugs are widely understood by residents, pharmacists, retailers of covered drugs, and health care practitioners and other prescribers, including doctors, dentists, veterinarians, and veterinary hospitals;
 - (b) Discourage the disposal of unwanted covered drugs in the garbage, municipal sewer, or on-site septic systems as required per SCC 12.16.210(5)(a);
 - (c) Promote the safe storage of prescription and nonprescription drugs by residents before secure disposal through their stewardship plan;

- (d) Work with participating authorized collectors to develop clear, standardized instructions for residents on the use of drop boxes and a readily recognizable, consistent design of drop boxes. Public Health may provide guidance to producers and authorized collectors on the development of the instructions and design;
- (e) 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 prescription and nonprescription drugs and describing where and how to return unwanted covered drugs to the stewardship plan. The educational and outreach materials must be provided free of charge 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 drug collection services readily understandable by all residents, including individuals with limited English proficiency. The web site and all materials shall discourage disposal of unused, expired or contaminated pharmaceutical wastes in the solid waste system or the sewer system in Skagit County;
- (f) Conduct surveys of residents and of pharmacists, health professionals, and veterinarians in the county who interact with residents on use of prescription and nonprescription drugs to assess the effectiveness of the stewardship plan as follows:
 - (i) A survey shall be conducted prior to the start of operation of an approved plan; after the first twelve (12) months of plan operation, after twenty-four (24) months of plan operation, and biennially thereafter until such time as Public Health designates a less frequent schedule;
 - (ii) Survey questions shall measure awareness of the stewardship plan, assess awareness of the drop-off sites and other collection methods, assess the convenience and ease of use of drop-off sites and other collection methods, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription drugs used in the home. The survey conducted prior to the start of operation of an approved plan shall measure awareness of existing drop-off sites and other collection methods, and assess knowledge and attitudes about risk of abuse, poisoning and overdoses from prescription and nonprescription drugs; and
 - (iii) Draft survey questions shall be submitted to Public Health for review and comment at least thirty (30) days prior to initiation of the survey. All survey data and results shall be reported to Public Health and made available to the public on the stewardship plan's website within ninety (90) days of the end of the survey period;

- (g) Annually evaluate the effectiveness of its promotion, outreach, and public education, and include this evaluation in its annual report; and
 - (h) Provide educational and outreach materials and surveys in English, Spanish, Russian, Tagalog, Chinese and Korean. Additional languages may be designated by Public Health on an annual basis.
- (2) 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 each stewardship plan, including providing residents with a single toll-free telephone number and single web site to access information about collection services for each approved plan.
- (3) Pharmacies and other entities selling prescription and nonprescription drugs in or into Skagit County:
- (a) Are encouraged to promote secure disposal of covered drugs by residents through the use of an approved stewardship plan or plans; and
 - (b) Shall provide materials explaining the use of approved stewardship plans to customers upon request. Such materials must be provided to pharmacies by the program operator upon request and at no cost to the pharmacy.
- (4) Public Health and government agencies throughout the county responsible for health, solid waste management, and wastewater treatment are encouraged to use their standard educational methods to promote:
- (a) safe storage of prescription and nonprescription medicines by residents,
 - (b) secure disposal of covered drugs by residents through the use of the stewardship plans, and
 - (c) the toll-free telephone number and web site for approved stewardship plans.

12.20.090 Disposal of covered drugs.

- (1) Covered drugs collected under a stewardship plan must be disposed of at a permitted hazardous waste facility as defined by the United States Environmental Protection Agency under 40 CFR parts 264 and 265.
- (2) The Health Officer 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 CFR parts 60 and 62, if use of a permitted hazardous waste disposal facility required under subsection (1) is deemed not feasible for the stewardship plan based on cost, logistics or other considerations.
- (3) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may petition the Health Officer for approval to use alternative

final disposal technologies that provide superior environmental and human health protection for environmental and human health protection than provided by the disposal technologies in subsections (1) and (2), or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:

- (a) Monitoring of any emissions or waste;
- (b) Worker health and safety;
- (c) Air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
- (d) Overall impact to the environment and human health.

12.20.100 Administrative and operational costs and fees.

(1) 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:

- (a) Collection and transportation supplies for each drop-off site;
- (b) Purchase and installation of secure drop boxes for each drop-off site;
- (c) Ongoing maintenance or replacement of secure drop boxes, as requested by authorized collectors;
- (d) Providing mail-back services and providing prepaid, preaddressed mailers to residents and to mailer distribution locations under SCC 12.20.070;
- (e) Operating periodic collection events, if utilized, including costs of law enforcement staff time if necessary;
- (f) Transportation of all collected drugs to final disposal;
- (g) Environmentally sound disposal of all collected drugs under SCC 12.20.090; and
- (h) Program promotion, surveys, and evaluation under SCC 12.20.080, including costs of providing materials to pharmacies and other entities for distribution to residents, and ongoing management of a website and toll-free number.

(2) 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.

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

12.20.110 Reporting requirements.

- (1) Quarterly Reports. Within thirty (30) days after each ninety (90) day period of operation, the plan operator of the standard stewardship plan and any independent stewardship plan shall submit a quarterly report to Public Health on behalf of participating producers that states the total amount, by weight, of unwanted covered drugs collected during the previous ninety (90) day period by each collection method used. After the first two (2) years of operation of an approved stewardship plan, Public Health may determine that quarterly reporting of the collection amount is no longer required and shall notify the plan operator of any change in the reporting schedule.
- (2) Annual Reports. Within ninety (90) days after the end of the first twelve (12) month period of operation, and annually thereafter, the plan operator of the standard stewardship plan and of any independent stewardship plan shall submit an annual report to Public Health on behalf of participating producers describing their plan's activities during the previous twelve (12) month reporting period to comply with this Chapter. The annual report shall include:
- (a) A list of producers participating in the stewardship plan;
 - (b) The amount, by weight, of unwanted covered drugs collected, including the amount by weight from each collection method used;
 - (c) A list of drop-off sites with addresses and the amount by weight of unwanted covered drugs collected from each drop-off site during each ninety (90) day period of the annual reporting period;
 - (d) The number of mailers provided:
 - (i) Directly to residents in response to a request through the toll-free telephone number or website;
 - (ii) To each home care service provider; and
 - (iii) To each municipal facility, fire station, public library, and other mailer distribution location.
 - (e) The number of mailers received from county residents by the plan during each ninety (90) day period of the annual reporting period;

- (f) A list of dates and locations of any collection events held and the amount by weight of unwanted covered drugs collected at each event;
- (g) A list of transporters and the disposal facility or facilities used;
- (h) Whether any safety or security problems occurred during collection, transportation or disposal of unwanted covered drugs during the annual reporting period and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to avoid similar problems and to improve safety and security in the future;
- (i) A description of the public education, outreach and evaluation activities implemented during the annual reporting period and an evaluation of the effectiveness of these promotion, outreach, and public education activities;
- (j) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- (k) A summary of the stewardship plan's goals for collection amounts and public awareness, the degree of success in meeting those goals during the annual reporting period and, if any goals have not been met, what effort will be made to achieve the goals in the next twelve (12) month period; and
- (l) The total expenditure of the stewardship plan during the reporting period.

(2) Public Health shall make reports submitted under this section available to the public.

12.20.120 Identification of producers of covered drugs.

- (1) Within sixty (60) days of a request from Public Health, any drug wholesaler that sells any covered drug in or into the county shall provide a list of producers of covered drugs to Public Health in a form agreed upon with Public Health. Wholesalers shall update the list, no more than annually, if requested by Public Health.
- (2) Any person receiving a letter of inquiry from Public Health 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.

12.20.130 Review of proposed plans.

- (1) Within one hundred and eighty (180) days after the date of adoption of this ordinance, a producer, group of producers or stewardship organization shall submit its proposed stewardship plan to Public Health for review. The proposed plan shall be accompanied by the plan review fee in accordance with SCC 12.20.180. A producer, group of producers or

stewardship organization shall indicate 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, Public Health shall designate the standard stewardship plan at the time of plan approval.

- (2) The Health Officer shall review each proposed stewardship plan and determine whether the proposed plan meets the requirements of SCC 12.20.060 and other applicable sections of this ordinance. In reviewing a proposed stewardship plan, Public Health shall provide opportunity for written public comment and consider any comments received.
- (3) After the review and within ninety (90) days after receipt of the proposed stewardship plan, the Health Officer shall either approve, approve subject to conditions, or reject the proposed stewardship plan in writing to a producer, group of producers or stewardship organization. If the proposed plan is approved subject to conditions or rejected, the Health Officer will provide reasons for the decision.
- (4) Plan Rejection. If the proposed stewardship plan is rejected, the producer, group of producers or stewardship organization shall submit a revised stewardship plan to Public Health within the timeframe specified by the Health Officer in the written notice of the rejection, which shall not be less than thirty (30) days. Public Health shall review and approve or reject a revised stewardship plan as provided under subsections (2) and (3) of this section.
- (5) Conditional Plan Approval. If the proposed stewardship plan is approved subject to conditions, the Health Officer shall provide a written notice to the plan operator that lists the conditions that must be addressed by the producer or group of producers participating in the stewardship plan or their stewardship organization. The Health Officer shall define the timeframe, which shall not be less than thirty (30) days, of each action that must be taken or each revision to the stewardship plan that shall be made by the producer, group of producers or stewardship organization. The Health Officer will identify any conditions that must be addressed prior to operation of the stewardship plan as required in SCC 12.20.050 (4) (d).
- (6) Revised Plan Rejection. If the Health Officer rejects a revised stewardship plan, or any subsequently revised plan, the Health Officer may deem the producer or group of producers out of compliance with this Chapter and subject to the enforcement provisions in this Chapter.
 - (a) If a revised proposal for the standard stewardship plan is rejected, the Health Officer may require the submission of a further revised stewardship plan as provided under subsection (4) of this section or develop and impose changes to some or all components of a rejected plan.
 - (b) If a revised independent stewardship plan is rejected, the producer or group of producers submitting the independent stewardship plan shall participate in an

approved stewardship plan and are not eligible to propose an independent stewardship plan for one hundred and eighty (180) days after the rejection. The Health Officer 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 an approved stewardship plan.

- (7) In approving a proposed stewardship plan, the Health Officer 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.
- (8) Public Health shall provide an opportunity for written public comment on each proposed stewardship plan.

12.20.140 Notice and approval process for modifications to an approved stewardship plan.

- (1) Proposed changes to an approved stewardship plan that substantively alter plan operations, including, but not limited to, changes to participating producers, collection methods, achievement of the service convenience goal, policies and procedures for handling covered drugs, education and promotion methods or disposal facilities, shall be submitted to Public Health at least thirty (30) days before the change is scheduled to occur and must be approved in writing by Public Health before the change is made. The request for proposed changes must be accompanied by the review fee in accordance with SCC 12.20.180.
- (2) The plan operator of an approved stewardship plan shall notify Public Health at least fifteen (15) days before a proposed change is scheduled to occur that does not substantively alter plan operations. Non-substantive changes may include: changes to drop-off site locations; methods for scheduling and locating periodic collection events, methods for distributing prepaid, preaddressed mailers; and changes to agreements with authorized collectors for services at drop-off sites provided that the proposed changes do not substantively alter achievement of the service convenience goal under SCC 12.20.070, and do not substantively alter plan operations under subsection (1) of this section.
- (3) The producer or group of producers participating in an approved stewardship plan shall notify Public Health of any changes to the plan operator for the stewardship plan within fifteen (15) days of the change.
- (4) The plan operator shall notify Public Health of any changes in ownership or contact information for participating producers within thirty (30) days of such change.

12.20.150 Enforcement.

- (1) The Health Officer is authorized to administer and enforce this Chapter. Enforcement may include, but is not limited to, issuance of notices that a person is in violation of a requirement under this Chapter and issuance of enforcement orders.

(2) Upon presentation of official credentials and providing notice of an audit or inspection to determine compliance with this Chapter or to investigate a complaint, the person shall allow a Public Health employee designated by the Health Officer to audit a producer's, group of producers' or stewardship organization's records that are related to a stewardship plan or to inspect at reasonable times a stewardship plan's or an authorized collector's facilities, vehicles and equipment used to carry out the stewardship plan.

(3) Violations. All violations of the requirements and restrictions in this Chapter are hereby declared to be detrimental to the public health, safety and welfare and are hereby declared to be public nuisances.

(a) Each violation of this Chapter shall be a separate and distinct offense and, in the case of a continuing violation, each day's continuance shall be a separate and distinct violation.

(b) A notice of violation may be issued to advise a producer, group of producers participating in a stewardship plan, or drug wholesaler of a violation and to encourage compliance.

(c) A notice of violation or order shall advise a producer, group of producers participating in a stewardship plan, drug wholesaler, or other person or persons of the violation:

(i) Identify the person subject to the notice or order;

(ii) Provide a brief description of the violation with reference to the applicable section of this Chapter;

(iii) State the action or actions necessary to remediate the violation and a date or time by which remediation shall be completed;

(iv) State that each violation of this ordinance is a separate and distinct offense and in the case of a continuing violation, that each day's continuance is a separate and distinct violation;

(v) Explain that failure to correct the violation or otherwise comply with the order by the remediation date will, if applicable, result in the issuance of civil penalties, including all costs incurred for enforcement of the notice or order, or other legal action.

(vi) Advise the person subject to the order of the right to appeal.

(d) A notice of violation or order shall be served on the producer, group of producers participating in a stewardship plan, drug wholesaler, or other person or persons responsible for the violation either personally or by mailing via certified mail, return

receipt requested, to the last known address of the violator. Service by certified mail is effective upon receipt or five (5) days after the date of mailing, whichever occurs first.

- (e) Upon written request received prior to the remediation date imposed in an order, the Health Officer may extend the remediation for good cause. The Health Officer may consider substantial completion of the necessary correction or unforeseeable circumstances that render completion impossible by the date established as a good cause.
 - (f) The Health Officer may at any time add to, rescind in part, or otherwise modify a notice of violation or order. The supplemental notice or order shall be governed by the same procedures applicable to notices and order.
 - (g) If a person or entity fails to remediate a violation by the remediation date in an order, the Health Officer may request the Prosecuting Attorney to bring a civil action against a violator.
 - (h) This subsection does not preclude the Health Officer from suspending an approved plan and issuing an enforcement order, if a violation of this Chapter creates a condition that, in the Health Officer's judgment, constitutes an immediate hazard.
- (4) Noncompliance. The failure to comply with the requirements and restrictions in this Chapter, including the failure to comply with a Health Officer order issued under this Chapter, and further including but not limited to the list of violations detailed below, is a continuing offense and shall be punishable by a civil penalty that may be assessed against a producer or group of producers or drug wholesaler for each violation, and all costs incurred for enforcement of the violation. Civil penalties, when imposed, and all costs incurred for enforcement shall be in accordance with the "Schedule of Charges: Skagit County Public Health Department."
- (a) 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 violation may be assessed a penalty.
 - (b) Failure to begin operation of an approved stewardship plan and provide the collection system for unwanted covered drugs required under this Chapter within ninety (90) days of the Health Officer's approval of the stewardship plan may result in a fine. Each day of delayed implementation of the stewardship plan will constitute a new and separate offense.
 - (c) Failure to provide reasonable access to the records required pursuant to 12.20.150 (2).
 - (d) If Public Health determines that a stewardship plan is not in compliance with this Chapter or its plan approved under SCC 12.20.130 of this regulation, the Health Officer

may send the producer or group of producers participating in the plan a notice of violation stating the plan is in noncompliance, providing notice of compliance requirements, and warning of penalties for noncompliance, including all costs incurred for enforcement of that violation. The producer or group of producers has thirty (30) days after receipt of the notice to achieve compliance. This subsection does not preclude the Health Officer 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 Health Officer's judgment, constitutes an immediate hazard.

12.20.160 Requests for reconsideration and appeals.

(1) Requests for Reconsideration.

- (a) Persons named in a notice of violation, aggrieved by an enforcement order, other Health Officer order, rejection of a stewardship plan after a second review, or conditions imposed on a stewardship plan shall request reconsideration of the action by filing a request for reconsideration, on a form provided by Public Health and accompanied by the required filing fee, to Public Health within ten (10) business days of service of the action.
- (b) Requests for reconsideration shall identify alleged errors in the notice of violation, order, or other action and be supported by evidence, including statements and photographs as applicable, and by a written explanation including citation to applicable law and regulations. The Health Officer may rule on the request for reconsideration without a hearing; however, an aggrieved person may request a meeting with the Health Officer, which may be granted at the Health Officer's discretion.
- (c) The Health Officer shall issue a written decision within thirty (30) days of receipt of the request for reconsideration unless additional time is justified by good cause. Service of the decision shall be effective upon personal service on the person(s) requesting the reconsideration, or five (5) days after mailing the decision, via certified mail return receipt requested, to the address provided in the request for reconsideration.

(2) Appeals of Health Officer's Decision on a Request for Reconsideration.

- (a) Persons aggrieved by the Health Officer's decision on a request for reconsideration may appeal by filing a notice of appeal, on a form provided by Public Health, accompanied by the required filing fee, to Public Health within ten (10) business days of service of the Health Officer's decision.
- (b) Appeals of the Health Officer's decision shall be heard as an open record appeal by the Skagit County Board of Health.

(c) A notice of appeal will not be considered filed unless the appeal fee is paid within ten (10) business days. The notice of appeal or an attached statement shall:

- (i) Identify the decision being appealed;
- (ii) Identify the appellant's name, address and interest in the matter;
- (iii) Provide a short statement identifying each error made by Public Health;
- (iv) Explain, including citations to the Skagit County Code, state law or regulation, or judicial decision, how the decision under appeal is erroneous; and
- (v) State the desired outcome of changes to the decision.

(3) Procedure for Open Record Appeals before the Skagit County Board of Health.

(a) At least seven (7) days prior to the date set for an open record hearing, Public Health shall file a copy of the records pertaining to the decision being appealed and a staff report explaining the decision being appealed or responding to the statements in the notice of appeal. A copy of the records and staff report shall also be mailed or otherwise served on the appellant seven (7) days prior to the date set for the hearing at the address provided in the appellant's notice of appeal.

(b) Hearings shall be conducted generally in the following order:

- (i) Appellant presentation;
- (ii) Staff responsive presentation;
- (iii) Appellant's rebuttal presentation; and
- (iv) Deliberations by the Board.

(c) The Board shall examine the record, the decision or recommendation, and the evidence and arguments presented in the open record hearing and select one of the following courses of action:

- (i) Remand the matter for further consideration by the Health Officer;
- (ii) Deny the appeal and affirm the decision under appeal; or
- (iii) If the Board determines the decision under appeal is clearly erroneous, the Board may adopt its own findings, conclusions and decision.

(4) The appellant bears the burden of proving that the decision under appeal was clearly erroneous.

(5) Unless a hearing is continued for good cause, the hearing shall be held and a decision rendered within ninety (90) days of the receipt of the notice of appeal. Service of the decision shall be effective upon personal service on the appellant or five (5) days after mailing the decision, via certified mail return receipt requested, to the address provided in the notice of appeal.

(7) An appeal of the Skagit County Board of Health's decision shall be by writ of review to the Superior Court. Appellants shall be responsible for the costs of preparing a record for appeal.

12.20.170 Regulations and performance standards.

- (1) The Skagit County Board of Health may adopt rules necessary to implement, administer and enforce this Chapter.
- (2) Public Health may work with the plan operator to define goals for collection amounts and public awareness for a stewardship plan.
 - (a) Upon review of collection amounts in annual reports, Public Health may direct a producer or group of producers participating in an approved stewardship plan to change the frequency of collection events or the provision of mail-back services to improve the plan's performance in providing adequate and reasonably convenient service to all Skagit County residents as required under SCC 12.20.070.
 - (b) Upon review of annual reports or results of public awareness surveys, Public Health may direct a producer or group of producers participating in an approved stewardship program to modify the plan's promotion and outreach activities to better achieve widespread awareness and understanding among Skagit County residents and healthcare providers about how to use collection options for unwanted covered drugs as required under SCC 12.20.080.

12.20.180 Plan review and annual operating fees.

- (1) Fees required of producers for the review of stewardship plans and other actions related to this Chapter shall be adopted by resolution of the Skagit County Board of Health and shall be commensurate with the costs of delivering the service and to administering and enforcing this ordinance. Public Health shall charge fees to a producer or group of producers participating in a stewardship plan according to the most current "Schedule of Charges: Skagit County Public Health Department."
- (2) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall pay fees to Public Health for:
 - a) Review of a proposed stewardship plan;

- b) Re-submittal of a proposed stewardship plan;
- c) Review of changes to an approved stewardship plan;
- d) Submittal of an updated stewardship plan at least every four (4) years under SCC 12.20.050;
- e) Review of any petition for approval to use alternative final disposal technologies under SCC 12.20.090; and
- f) Oversight of annual plan operations.

(3) A plan operator or a stewardship organization may remit the fee on behalf of participating producers.

12.20.190 Other powers reserved – Alternative remedies and emergency orders.

Nothing in this chapter shall limit the authority for Skagit County Public Health or Skagit County Health Officer to act under any other legal authority. The powers conferred by this Chapter shall be in addition to and supplemental to the powers conferred by any other law. If the Health Officer determines immediate action is necessary to protect the public health and safety or the environment, such action may be taken or be ordered to be taken and any person to whom such an order is directed shall comply immediately.

12.20.200 Severability.

If any provision of this Chapter or its application to any person or circumstances is held invalid, the remainder of this Chapter, or the application of the provisions to other persons or circumstances, shall not be affected.