

**SECTION 1. AUTHORITY, PURPOSE, AND INTENT**

- A. Pursuant to Chapter 70.05 RCW and Chapter 70.46 RCW, the Kitsap Public Health Board (Board) of the Kitsap Public Health District (Health District) adopts this Ordinance to protect and preserve the public health, safety and welfare of the residents of Kitsap County. Its provisions shall be liberally construed for the accomplishment of these purposes. This Ordinance 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 Ordinance to place the obligation of complying with its requirements upon drug producers and other persons designated by this Ordinance within its scope, and any provision of or term used in this Ordinance is not intended to impose any duty whatsoever upon the Health District or any of its officers or employees, for whom the implementation or enforcement of this Ordinance shall be discretionary and not mandatory.
- C. It is expressly the purpose of these regulations to provide for, and promote, the health of the general public and not to create or otherwise establish or designate any particular class or group of persons who will, or should, be especially protected or benefitted by the terms of these regulations.
- D. Nothing contained in these regulations is intended to create, nor shall be construed to create or form the basis for, any liability on the part of the Board or the Health District, or its officers, employees or agents, for any injury or damage resulting from the failure of any person subject to these rules and regulations to comply with these rules and regulations, or by reason or in consequence of any act or omission in connection with the implementation or enforcement of these rules and regulations on the part of the Health District.

**SECTION 2. ADMINISTRATION**

- A. The Health Officer and/or his or her designated representative shall administer and enforce these regulations under the authority of RCW 70.05.070.
- B. The Health Officer is authorized to take other such actions as he or she deems necessary to maintain public health and sanitation and to administer and enforce these regulations under the authority of RCW 70.05.070. Any additional policies or standards deemed necessary by the Health Officer shall be in writing and readily available for public inspection and viewing.
- C. The Board may charge fees for the administration of these regulations under the authority of RCW 70.05.060.
- D. The Health Officer may collect fees for the administration of these regulations under the authority of RCW 70.05.070.

### **SECTION 3. APPLICABILITY**

- A. These regulations shall apply to all persons and in all territory within the boundaries of Kitsap County.
- B. These regulations apply to residents of Kitsap 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 Health Officer.
- C. These regulations apply to all “producers” selling a covered drug in or into Kitsap County, as defined in Section 4 “Definitions”.

### **SECTION 4. DEFINITIONS**

The following definitions shall apply in the interpretation and enforcement of the ordinance:

- 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. For purposes of this Ordinance, “Authorized collector” shall also include law enforcement agencies.
- B. “Ordinance” means the Kitsap Public Health Board Ordinance 2016-02, Secure Medicine Return Regulations.
- C. "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. "Covered drug" does not include:
  - 1. Vitamins or supplements;
  - 2. Herbal-based remedies and homeopathic drugs, products or remedies;
  - 3. 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);
  - 4. 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);

5. Drugs that are biological products as defined by 21 CFR 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;
  6. 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; or
  7. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.
- D. "Covered entities" means residents of Kitsap 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 Health Officer. "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.
- E. "Health Officer" means the Health Officer of the Kitsap Public Health District or the Health Officer's duly authorized representative.
- F. "Drop-off site" means the location of an authorized collector where a secure drop box for all unwanted covered drugs is provided for residents of Kitsap 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.
- G. "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.
- H. "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. Pharmacopoeial 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.
- I. "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.
- J. "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 Ordinance, 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.
- K. "Mail-back services" means a collection method for the return of unwanted covered drugs from covered entities utilizing prepaid and preaddressed mailing envelopes.
- L. "Manufacture" means "manufacture" as defined in RCW 18.64.011, as amended. 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.
- M. "Manufacturer" means a person, corporation or other entity engaged in the manufacture of drugs or devices, as defined in RCW 18.64.011(as amended).
- N. "Nonprescription drug" means a drug that may be lawfully sold without a prescription.
- O. "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.
- P. "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(as amended), is conducted.
- Q. "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. For purposes of this Ordinance, "Potential authorized collector" shall also include law enforcement agencies.

- R. "Prescription drug" means any drugs, including controlled substances, which 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.
- S. "Producer" means a manufacturer that is engaged in the manufacture of a covered drug sold in or into Kitsap 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 5.C. of this regulation;
  2. A pharmacist who compounds a prescribed individual drug product for a consumer; or
  3. A drug wholesaler who is not also a manufacturer.
- T. "Regulation" means the "Secure Medicine Return Regulations" adopted by the Kitsap Public Health Board.
- U. "Retail pharmacy" means a pharmacy licensed by the Washington State Pharmacy Quality Assurance Commission for retail sale and dispensing of drugs.
- V. "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.
- W. "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.
- X. "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.

## **SECTION 5. STEWARDSHIP PLAN – PARTICIPATION**

- A. 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 if approved by the Health Officer.
- B. 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 provided in section 14 of this regulation.
- C. Within sixty (60) days of the date of adoption of this regulation a producer shall notify the Health Officer 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 Health Officer 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 Kitsap 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 notify the Health Officer within six months of the date of initiating sales of the covered drug in or into Kitsap County.
- D. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall meet the following deadlines and standards.
  - 1. Within four months of the date of adoption of this Ordinance:
    - a) Identify a plan operator who is authorized to be the official point of contact for the stewardship plan and provide in writing the name and contact information, including the mailing address, telephone number, and email of the plan operator to the Health Officer; and
    - b) Notify all potential authorized collectors in Kitsap County of the opportunity to participate as a drop-off site in accordance with section 7 of this ordinance. The notification shall include a process for forming an agreement between the plan and interested potential authorized collectors. If a potential authorized collector expresses an interest in participating as a drop-off site in response to the notification, within thirty (30) calendar days of the expression of such interest the producer or group of producers shall commence good faith negotiations with the nonparticipating potential authorized collector.
  - 2. Within six months of the adoption date of this regulation, submit a proposed stewardship plan as described in section 6 of this ordinance to the Health Officer for review.

3. Within three months of the Health Officer's approval of the stewardship plan:
    - a) Provide documentation to the Health Officer 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) Begin operating or participating in a stewardship plan in accordance with this Ordinance.
  4. Annually notify any nonparticipating potential authorized collectors in Kitsap County of the opportunity to participate in a stewardship plan. If a potential authorized collector expresses an interest in participating, the producer or group of producers shall commence good faith negotiations with the nonparticipating potential authorized collector within thirty (30) calendar days of the expression of such interest.
  5. Every four years review and update the stewardship plan, as needed. Any substantive changes to the required components of the stewardship plan shall be explained in writing and be submitted with the updated stewardship plan and review fee to the Health Officer. An updated plan will not be reviewed until the explanation of changes and review fee are submitted. If the producer or group of producers determines that no changes to the stewardship plan are necessary, the producer or group of producers shall notify the Health Officer in writing that no changes are being made to the stewardship plan and no updated plan will be submitted. This section does not exempt producers or groups of producers from compliance with section 14 of this regulation for changes made to the stewardship plans in the time between plan updates.
  6. Pay all administrative and operational costs and fees associated with their stewardship plan as required under sections 10 and 17 of this ordinance.
- E. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may:
1. Enter into contracts or agreements with stewardship organizations, service providers, or other entities to design, coordinate, or implement all of or a portion of their stewardship plan.
  2. Notify the Health Officer of any producer selling covered drugs in or into Kitsap County that is failing to participate in a stewardship plan.
  3. Perform any other functions necessary 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 Health

Officer in writing of intent to form an independent stewardship plan. The notification must 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 6 of this regulation to the Health Officer for review.

- G. If requested by a producer or group of producers, the Health Officer may approve extensions of the submission dates and deadlines in this section. Extension requests and approvals must be in writing.
- H. The Health Officer may, upon request, provide consultation and technical assistance about the requirements of this Ordinance to assist a producer, group of producers or stewardship organization in developing its proposed plan.

## **SECTION 6. STEWARDSHIP PLANS - COMPONENTS**

All stewardship plans shall include the following components:

- A. Contact information for all drug producers participating in the stewardship plan including name, company, mailing address, phone, and email.
- 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 7 of this regulation. The collection system description shall include the following:
  - 1. A list of all collection methods and participating potential authorized collectors and the collection methods used by the participating potential authorized collectors;
  - 2. A list of drop-off sites with addresses;
  - 3. A description of how periodic collection events will be scheduled and located if applicable;
  - 4. A description of how mail-back services will be provided and an example of the prepaid, preaddressed mailers to be utilized;
  - 5. A list of potential authorized collectors contacted by the plan under section 5.D.1 of this regulation; and
  - 6. 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 the following:
1. 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 7 and 9 of this regulation.
  2. A description of the policies and procedures to be followed by persons handling unwanted covered drugs collected under the stewardship plan, including the following:
    - a. A description of how all authorized collectors, transporters and waste disposal facilities utilized in the stewardship plan will safely and securely track the covered drugs from initial collection to final disposal;
    - b. A description of 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
    - c. A description of how any pharmacy drop-off site will operate under applicable regulations and guidance of the Washington State Pharmacy Quality Assurance Commission.
    - d. A description of how patient information on drug packaging will be kept private and secure during collection, transportation, and recycling or disposal.
- D. A description of the public education effort and promotion strategy required by section 8 of this regulation, including a copy of standardized instructions for residents, signage developed for authorized collectors and required promotional materials.
- E. A proposal stating the short-term (1 year) and long-term (5 year) goals of the stewardship plan for collection amounts (by weight) and public awareness.
- F. 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.

## **SECTION 7. STEWARDSHIP PLANS – COLLECTION OF DRUGS**

- A. This Ordinance 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. Any entities participating as authorized collectors including, but not limited to, retail pharmacies, hospitals and clinics with an on-site pharmacy, and law enforcement agencies shall operate in accordance with this Ordinance as well as state and federal laws and regulations for the handling of unwanted covered drugs, including those of the United States Drug Enforcement Administration. A pharmacy drop-off site shall also operate under applicable regulations and guidance of the 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 Kitsap 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, and include the protection of patient information on drug packaging.
- D. 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 Kitsap County, and meeting the requirements of this subsection. To do so, collection systems shall meet the following standards:
  - 1. There must be at least one drop-off site within the geographical boundaries of every city in Kitsap County. In addition, for any city with a population over thirty thousand residents, there must be at least one additional drop-off site for every additional 30,000 in population. In cities with more than one drop-off site, the drop-off sites must be geographically separated to provide reasonably convenient and equitable access from different locations within and outside the city boundaries.
  - 2. If there is no potential authorized collector within the geographic boundaries of a city, service to those geographic areas shall be supplemented with periodic collection events, mail-back services or a combination of periodic collection events and mail-back services.
  - 3. All collection systems shall prioritize locating drop-off sites at retail pharmacies, hospitals and clinics with on-site pharmacies and law enforcement agencies. If retail pharmacies, hospitals and clinics with on-site pharmacies and law enforcement agencies are unavailable or unable to provide a drop-off site in a particular geographic area, collection plans may consider alternative authorized collectors, potential authorized or long-term care facilities collectors for drop-off sites.
  - 4. Any retail pharmacy, hospital or clinic with an on-site pharmacy or any law enforcement agency that is able to meet the requirements of this Ordinance and requests to be added as a drop-off site shall be added as a drop-off site within ninety (90) days of the stewardship

plan receiving the request unless the requestor asks for additional time.

5. Any potential authorized collector, not including retail pharmacies, hospitals and clinics with on-site pharmacies, law enforcement agencies or long-term care facilities able to meet the requirements of this Ordinance may request be added as a drop-off site. If such a request is received by a stewardship plan, the stewardship plan may add the requestor to their collection system.
- E. Drop-off sites shall accept all covered drugs from covered entities during the authorized collector's normal business hours. 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 the United States Drug Enforcement Administration regulations. 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. Covered entities or collection authorities must be able to utilize the toll-free telephone number or website to provide feedback on collection activities, including but not limited to the need to empty the secure drop box.
- G. In partnership with participating authorized collectors, a producer or group of producers participating in a stewardship plan shall develop clear, standardized instructions for the use of drop boxes and a readily recognizable, consistent design of drop boxes located at drop-off sites. The Health District may provide guidance on the development of the instructions and design. The instructions shall be available on the stewardship plan's website and posted at drop-off site locations.
- H. Mail-back services shall be free of charge and made available to differentially-abled and home bound residents upon request through the stewardship plan's toll-free telephone number and website. Prepaid, preaddressed mailers may be distributed to persons providing services to differentially-abled and home bound residents, and may also be utilized as a collection method.
- I. If utilized as a collection method, periodic collection events must be arranged with law enforcement personnel and shall be conducted in compliance with United States Drug Enforcement Administration protocols, participating law enforcement agency protocols and with this Ordinance.

## **SECTION 8. STEWARDSHIP PLANS – PROMOTION**

- A. A producer or group of producers participating a stewardship plan must develop and provide a system of promotion, education, and public outreach about safe storage and secure

collection of covered drugs.

B. The education and public outreach strategy shall include the following:

1. A toll-free telephone number and website available for use by the public.
2. Promotion of the locations, hours, and use of the drop-off sites. Included in the promotion materials shall be information on how to return unwanted covered drugs to drop-off sites and how to use other collection options for unwanted covered drugs. The promotion materials shall be published on the stewardship plan's website and distributed to covered entities; pharmacists; retailers of covered drugs; health care practitioners including doctors, dentists, and other prescribers; veterinarians and veterinary hospitals. All promotional materials shall include notices that unused, expired or contaminated pharmaceutical wastes are prohibited from disposal in the garbage system in Kitsap County, pursuant to Kitsap County Board of Health Ordinance 2010-1, Solid Waste Regulations.
3. Educational and outreach resources and materials for covered entities on the legal disposal of and safe storage of covered drugs. Plain language and explanatory images should be utilized to make use of medicine collection services readily understandable by all covered entities, including individuals with limited English proficiency. The educational and outreach materials shall be both published on the website and distributed to pharmacies, health care facilities, county agencies and other interested parties for dissemination to covered entities. The web site and all educational and outreach materials shall include notices that unused, expired or contaminated pharmaceutical wastes should not be disposed in the garbage system in Kitsap County, pursuant to Kitsap County Board of Health Ordinance 2010-1, Solid Waste Regulations.
4. Annual reports evaluating the effectiveness of the promotion, outreach and public education shall be submitted to the Health District.
5. A biennial survey shall be conducted of covered entities and pharmacists, health professionals, and veterinarians in Kitsap County who interact with covered entities. The first survey shall be conducted within 60 days after the first year of operating the stewardship plan. The goal of the survey is to measure the percentage of covered entities, pharmacists, health professionals and veterinarians who are aware of the stewardship plan; to assess the convenience and ease of use of the drop-off sites and other collection methods for covered entities; and to assess knowledge and attitudes of covered entities, pharmacists, health professionals, and veterinarians regarding the risks of abuse, poisoning and overdose from prescription and non-prescription drugs used in the home. Draft survey questions shall be submitted to the Health Officer for review and comment at least thirty (30) days prior to initiation of the survey. Results of the survey shall be reported to the Health Officer and made available to the public on the stewardship plan's website within ninety (90) days of the end of the survey period.

- C. All approved stewardship plans operating in Kitsap County shall coordinate their promotional activities to ensure that all covered entities can easily identify, understand and access the collection services provided by any stewardship plan. Coordination between stewardship plans shall include providing covered entities with a single toll-free telephone number and single website to access information about collection services for all stewardship plans operating in Kitsap County.
- D. Pharmacies and other entities selling medicines in or into Kitsap County are encouraged to promote secure disposal of unwanted covered drugs by covered entities through the use of approved stewardship plans. Pharmacies must provide materials explaining the use of approved stewardship plans to customers upon request.
- E. The Health District and Kitsap County government agencies responsible for health, solid waste management, and wastewater treatment shall promote safe storage and secure disposal of unwanted covered drugs by covered entities through the use of the stewardship plans, the toll-free telephone number and the website for approved stewardship plans through the agencies' standard educational methods.

#### **SECTION 9. 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 Health Officer may grant approval for a producer or group of producers participating in a stewardship plan to dispose of some or all of the 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 hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.
- C. A producer or group of producers participating in a stewardship plan may petition the Health Officer for approval to use alternative final disposal technologies that provide superior, or equivalent protection at a lower cost, environmental and human health protection than permitted hazardous waste disposal facilities or municipal waste combustors 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, bio-accumulative, and toxic pollution; and
  - 4. Overall impact to the environment and human health.

**SECTION 10. STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS**

- A. A producer or group of producers participating in a 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, but are not necessarily limited to:
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 authorized collectors;
  4. Prepaid, preaddressed mailers provided to differentially-abled and home bound residents, and to specific areas of Kitsap 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 9 of this regulation; and
  8. Program promotion under section 8 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.

**SECTION 11. 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 Health Officer on behalf of participating producers describing their plan's activities during the previous reporting period to comply

with this Ordinance. 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. Any safety or security problems that 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 remedy 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 Health Officer 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 Health Officer.

## **SECTION 12. STEWARDSHIP PLANS – IDENTIFICATION OF PRODUCERS OF COVERED DRUGS**

- A. Within sixty (60) days of a request from the Health Officer, any drug wholesaler that sells any covered drug in or into Kitsap County must provide a list of producers of covered drugs to the Health District in a form agreed upon with the Health Officer. Wholesalers must update the list, no more than annually, if requested by the Health Officer.
- B. Any person receiving a letter of inquiry from the Health Officer regarding whether or not it is a producer under this Ordinance must respond in writing within sixty (60) days. If such

person does not believe it is a producer under this Ordinance, 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 Kitsap County, and identify the name and contact information of the manufacturer of the covered drug.

### **SECTION 13. STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS**

- A. Within six months of the date of adoption of this regulation, a producer, group of producers or stewardship organization shall submit its proposed stewardship plan to the Health Officer for review, accompanied by the plan review fee in accordance with section 17 of this regulation. The proposed plan should 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, the Health Officer shall designate the standard stewardship plan at time of plan approval.
- B. The Health Officer shall review each proposed stewardship plan to determine compliance with this Ordinance. In reviewing a proposed stewardship plan, the Health Officer shall provide opportunity for written public comment and consider any comments received.
- C. Within ninety (90) days after receipt of the proposed stewardship plan, the Health Officer 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 the 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 Health Officer within sixty (60) days after receiving written notice of the rejection. The Health Officer shall review and approve or reject a revised stewardship plan as provided under subsections B. and C. of this section.
- E. 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 Ordinance and subject to the enforcement provisions in this Ordinance.
  - 1. If a revised proposal for the standard stewardship plan is rejected, the Health Officer may, in the Health Officer'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 stewardship plan. If the Health Officer imposes some or all of the approved plan, the Health Officer may not deem the producers participating in and complying with the approved standard stewardship plan out of compliance with this Ordinance.
  - 2. 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 Health Officer may not deem a producer whose revised independent

stewardship plan is rejected out of compliance with this Ordinance if the producer participates in and complies with the standard stewardship plan.

- F. In approving a proposed stewardship plan, the Health Officer may exercise reasonable discretion to waive strict compliance with the requirements of this Ordinance in order to achieve the objectives of this Ordinance.
- G. The Health Officer shall make all stewardship plans submitted under this section available to the public both before and after they are approved.

#### **SECTION 14. 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 producers, collection methods, convenience and equity of collection methods for covered entities, policies and procedures for handling covered drugs, education and promotion methods or disposal facilities must have prior written approval of the Health Officer.
- B. Any proposed changes shall be submitted to the Health Officer in writing at least thirty (30) days before the change is scheduled to occur and accompanied by the review fee in accordance with section 17 of this regulation.
- C. The plan operator of an approved stewardship plan shall notify the Health Officer 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 the convenience and equity for covered entities; 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 Health Officer 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 Health Officer of any changes in ownership or contact information for participating producers within thirty (30) days of such change.

#### **SECTION 15. STEWARDSHIP PLANS – ADMINISTRATION AND ENFORCEMENT**

- A. The Health Officer is authorized to administer and enforce these regulations.
- B. The Health Officer is authorized to adopt additional rules or policies consistent with the provisions of these regulations for the purpose of enforcing and carrying out its provisions. Nothing in these rules and regulations is intended to abridge or alter the rights of action by the state or by persons, which exist in equity, common law or other statutes to abate non-

compliance with these regulations.

- C. After presenting official credentials and providing notice of an audit or inspection to determine compliance with this Ordinance or to investigate a complaint, the Health Officer 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 Health Officer 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.

D. Right of Entry and Inspection

1. Whenever necessary to make an inspection to enforce or determine compliance with the provisions of these regulations, and other relevant laws and regulations, or whenever the Health Officer has cause to believe that a violation of these regulations has or is being committed, the Health Officer or his/her duly authorized inspector may, in accordance with federal and state law, seek entry of any building, structure, property or portion thereof at reasonable times to inspect the same.
2. If such building, structure, property or portion thereof is occupied, the inspector shall present identification credentials, state the reason for the inspection, and request entry.
3. If consent to enter said building, structure, property, or portion thereof is not provided by the owner, occupier, or other persons having apparent control of the premises, the Health Officer may enter said premises only to the extent permitted by federal and state law.

E. Notice and Order to Correct Violation

1. Issuance. Whenever the Health Officer determines that violation of these regulations has occurred or is occurring, he/she, or his/her designee may attempt to secure voluntary correction by sending a Notice and Order to Correct Violation to a producer, group of producers, plan operator, drug wholesaler, or drug manufacturer in violation of this Ordinance.
2. Content. The Notice and Order to Correct Violation shall contain:
  - a) A statement that participation in a stewardship plan is required and a reference to this Ordinance;
  - b) A statement of the action required to be taken to correct the violation and a date or time by which correction is to be completed;
  - c) A statement that each violation of this regulation 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; and

- d) A statement that failure to obey the notice may result in the issuance of civil penalties, including all costs incurred for enforcement of the Notice and Order to Correct Violation, or other legal action to encourage compliance.
3. Service of Order. The Notice and Order to Correct Violation shall be served upon the producer or group of producers to whom it is directed, either personally or by mailing a copy of the order to correct violations by regular and/or certified mail, postage prepaid, return receipt requested, to the last known address of the violator. Proof of service shall be made at the time of service by a written declaration under penalty of perjury executed by the persons affecting the service, declaring the time and date of service and the manner by which service was made.
4. Time to Correct Violation.
- 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 Kitsap County sixty (60) days after receiving a written Health Officer's Notice and Order to Correct Violation may be assessed a penalty under subsection F. of this section.
- b) If the Health Officer determines that a stewardship plan is not in compliance with this Ordinance or its plan approved under Section 14 of this regulation, the Health Officer may send the producer or group of producers participating in the plan a written Notice and Order to Correct Violation stating the plan is in noncompliance. A producer or group of producers whose stewardship plan has been determined by the Health Officer to not be in compliance with this Ordinance, or its plan approved under Section 14 of this regulation has thirty (30) days after receiving a written Health Officer's Notice and Order to Correct Violation to achieve compliance. If the stewardship plan is not in compliance after thirty (30) days, the Health Officer may assess a penalty under subsection F. of this section. This subsection does not preclude the Health Officer from suspending an approved plan, in addition to other penalties, if a violation of this Ordinance or an approved plan creates a condition that, in the Health Officer's judgment, constitutes an immediate hazard. Extension.
- c) Upon written request received prior to the correction date or time, the Health Officer may extend the date set for corrections 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.
- d) Supplemental Order to Correct Violation. The Health Officer may at any time add to, rescind in part, or otherwise modify a Notice and Order to Correct Violation. The supplemental order shall be governed by the same procedures applicable to all Notice and Order to Correct Violations procedures contained in

these this regulations.

F. Enforcement

1. The Health Officer or designee may enforce the requirements and restrictions of this Ordinance by one or a combination of the following after issuance of a written Health Officer's Notice and Order to Correct Violation:

- a) Assessing all costs of enforcement against the producer or group of producers;
- b) Prohibiting certain conduct or directing certain conduct;
- c) Imposing a civil penalty of up to two thousand dollars that may be assessed against a producer or group of producers or drug wholesalers. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate penalty, the Health Officer 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.

G. 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 Kitsap Public Health District independent of and/or as a means of enforcing written orders of the Health Officer referenced above.

H. The Health District is authorized to enforce the restrictions or requirements of this Ordinance against any person or entity, whether it be a producer, group of producers, or drug wholesaler who is not in compliance; assess all costs of enforcement, including attorney fees, against the person or entity, whether it be a producer, group of producers or drug wholesaler, who is in noncompliance; and otherwise pursue compliance with this Ordinance by commencement of a civil action in the name of the Kitsap Public Health District.

G. Appeal of Public Health Action – Health Officer Administrative Hearing.

1. Any person aggrieved by the contents of a Notice and Order to Correct Violation issued under this regulation, or enforcement action conducted by the Health District, may request a hearing before the Health Officer or his or her designee. The appellant shall submit the request in writing, through completion of an "Application for Administrative Meeting or Appeal Hearing" form with the appropriate fee, and shall include the specific statements of the reason why error is assigned to the decision of Health District. Such request shall be presented to the Health Officer within ten (10) business days of the action appealed. Upon receipt of such request together with the hearing fee, the Health Officer shall notify the person of the time, date, and place of such hearing, which shall be set at a mutually convenient time not more than fifteen (15) business days from the date the request was received. Upon completion of the hearing, the Health Officer shall

provide a decision in writing to the appellant within fifteen (15) business days from the date of the hearing.

H. Appeal of Administrative Hearing/Decision.

1. Any person aggrieved by the findings or required actions of an administrative hearing, or of an administrative decision by the Health Officer regarding the rebuttal of the presumptively reasonable distance, shall have the right to appeal the matter by requesting a hearing before the Public Health Board. Such notice of appeal shall be in writing through completion of an “Application for Administrative Meeting or Appeal Hearing” form and presented, with the appropriate hearing fee as established in the current Health District fee schedule, to the Health Officer within five (5) business days of service of the findings and actions from the administrative hearing. All requests shall contain a description of the action, decision or policy for which the hearing is requested, and the basis on which it is being contested. The appellant and the Health Officer may submit additional information to the Public Health Board for review.
2. The Notice and Order to Correct Violation shall remain in effect during the appeal. Any person affected by the Notice and Order to Correct Violation may make a written request for a stay of the decision to the Health Officer within five (5) business days of the Health Officer’s decision. The Health Officer will grant or deny the request within five (5) business days.
3. Upon receipt of an appeal pursuant to this section together with the hearing fee, the Health Officer shall set a time, date, and place for the requested hearing before the Public Health Board and shall give the appellant written notice thereof. The hearing shall be set at a mutually convenient time not more than thirty (30) business days from the date the appeal was received by the Health Officer.

**SECTION 16. STEWARDSHIP PLANS – REGULATIONS, PERFORMANCE STANDARDS, AND REPORT**

- A. The Health Officer may adopt regulations necessary to implement, administer and enforce this Ordinance.
- B. The Health Officer may work with the plan operator to define goals for collection amounts and public awareness for a stewardship plan.
- C. The Health Officer shall report annually to the Board concerning the status of the standard and independent stewardship plans and recommendations for changes to this Ordinance. 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.

**SECTION 17. STEWARDSHIP PLANS – 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 Health Officer 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 5.D.5. of this regulation; and
  5. Review of any petition for approval to use alternative final disposal technologies under section 9.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 Health Officer 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 Board and shall be subject to revision commensurate with the costs of delivering the service and to administering and enforcing this Ordinance. All fees collected under the provision of this Ordinance shall be payable to the Health District.

**SECTION 18. 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.

**SECTION 19. EFFECTIVE DATE**

This regulation shall be effective immediately upon adoption by the Board.

**SECTION 20. REPEALER**

Reserved.