



AGENDA

WASHINGTON COUNTY BOARD OF COMMISSIONERS SITTING AS THE LOCAL PUBLIC HEALTH AUTHORITY FOR WASHINGTON COUNTY

Agenda Category: Public Hearing – Health and Human Services (ALL CPOs)

Agenda Title: CONDUCT THIRD READING, SECOND PUBLIC HEARING OF ORDINANCE NO. 848 – DRUG TAKEBACK ORDINANCE

Presented by: Marni Kuyl, Director of HHS and Brad Anderson, Sr. Assistant County Counsel

SUMMARY:

The proposed ordinance would require drug manufacturers that sell their products in Washington County to provide and fund a safe and convenient way to dispose of unused medications. This would decrease the amount of unused medications available for misuse, diversion and accidental ingestion. It will also protect the environment. Because the Board is considering this Ordinance sitting as the Local Public Health Authority for Washington County, the ordinance would apply to all of Washington County.

The proposed ordinance uses an Extended Producer Responsibility (EPR) model that follows similar initiatives to address old and unused paint, eliminate amalgam from the dental waste stream, and recover electronic equipment from the waste stream. The model reduces the negative impacts to public health and the environment over the life-cycle of products.

The Board moved to amend the ordinance on April 23, 2019 at the second reading, first public hearing of the proposed ordinance. Therefore, the proposed language before the Board is the A-Engrossed ordinance.

Clerk's Desk Item: A-Engrossed Ordinance and Exhibit A ([click to access electronic copy](#))

DEPARTMENT'S REQUESTED ACTION:

Conduct third reading of the ordinance and hold second public hearing. Approve A-Engrossed Ordinance.

COUNTY ADMINISTRATOR'S RECOMMENDATION:

I concur with the requested action.

ADOPTED

Agenda Item No.	<u>5.b.</u>
Date:	05/07/19

MAY 0 1 2019

Washington County
County Clerk

IN THE BOARD OF COUNTY COMMISSIONERS
FOR WASHINGTON COUNTY, OREGON
SITTING AS THE LOCAL PUBLIC HEALTH AUTHORITY
OF WASHINGTON COUNTY

A-ENGROSSED
ORDINANCE No. 848

**An Ordinance Requiring Drug Manufacturers
to Takeback Unwanted Drugs**

The Board of County Commissioners of Washington County, Oregon, sitting as the Local Public Health Authority of Washington County (“Board”), ordains that in order to protect the public health, prompt safe and effective disposal methods for expired or otherwise unwanted drugs is necessary.

SECTION 1.

A. The Board finds that prompt safe and effective disposal methods for expired or otherwise unwanted drugs is necessary to prevent such substances from being obtained for unauthorized purposes or being disposed of in a manner that can adversely affect the environment.

B. The Board finds that an extended producer responsibility model is the most effective and proven method to address the proper disposal of expired or otherwise unwanted drugs.

C. The Board further finds that to protect the public health and safety of the people of Washington County and to make the model work most effectively, this ordinance applies to all of Washington County under the Board of Commissioners authority as the Local Public Health Authority of Washington County.

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1 SECTION 2.

2 The Board finds and takes public notice that it is in receipt of all information necessary to
3 consider this Ordinance in an adequate manner, and that this Ordinance complies with the ORS
4 Chapter 431.

5 SECTION 3.

6 The attached Exhibit A is hereby adopted and incorporated herein at Chapter 1 of the
7 Washington County Local Public Health Authority Code.

8 SECTION 4.

9 A. Nothing herein is intended, nor shall it be construed, as amending, replacing or
10 otherwise being in conflict with any other ordinances of Washington County unless expressly so
11 stated.

12 B. If any section, clause, phrase, or word of this Ordinance, including the exhibit, shall
13 for any reason be held invalid, unconstitutional, or unenforceable by a body of competent
14 jurisdiction, the remainder of this Ordinance or its application and all portions not so stricken shall
15 not be affected thereby and shall remain in full force and effect.

16 C. The Office of County Counsel is authorized to codify this Ordinance and to make
17 any technical changes, not affecting its substance, as are reasonably necessary to accomplish
18 codification.

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1 SECTION 5.

2 This Ordinance shall take effect thirty (30) days after adoption.

3 ENACTED this 7th day of May, 2019, being the 3rd reading
4 and 2nd public hearing before the Board of County Commissioners of Washington County,
5 Oregon, sitting as the Local Public Health Authority of Washington County.

6 BOARD OF COUNTY COMMISSIONERS
7 FOR WASHINGTON COUNTY, OREGON

8
9 **ADOPTED**

8 [Signature] 05/07/19
9 CHAIR

10 Barbara Hejzmanek
11 RECORDING SECRETARY

12 READING

12 PUBLIC HEARING

13 First April 2, 2019
14 Second April 23, 2019
15 Third May 7, 2019
16 Fourth _____
17 Fifth _____

13 First April 23, 2019
14 Second May 7, 2019
15 Third _____
16 Fourth _____
17 Fifth _____

16 VOTE: Aye: Harrington, Rogers,
17 Schouten, Treece, Willey

Nay: _____

17 Recording Secretary: Barbara Hejzmanek Date: May 7, 2019

Chapter 1. Drug Takeback Ordinance

Sections:

- 1.010: Authority, purpose and intent.
- 1.020: Administration.
- 1.030: Reserved.
- 1.040: Definitions.
- 1.050: Stewardship plan participation.
- 1.060: Stewardship plan components.
- 1.070: Collection of covered drugs.
- 1.080: Promotion.
- 1.090: Disposal of covered drugs.
- 1.100: Administrative and operational costs and fees.
- 1.110: Reporting requirements.
- 1.120: Identification of producers of covered drugs.
- 1.130: Review of proposed plans.
- 1.140: Notice and approval process for modifications to an approved stewardship plan.
- 1.150: Enforcement.
- 1.160: Reserved.
- 1.170: Regulations and performance standards.
- 1.180: Plan review and annual operating fees.
- 1.190: Other powers reserved – Alternative remedies and emergency orders.
- 1.200: Reserved.

1.010 Authority, purpose and intent.

(1) The purpose of this Ordinance 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 Ordinance has been enacted for the welfare of the public as a whole. Nothing contained in this Ordinance 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 Ordinance, or by reason or in consequence of the implementation or enforcement pursuant to this Ordinance, or by reason of any action or inaction on the part of the County related in any manner to the enforcement of this Ordinance by its officers, employees, or agents.

(3) This Ordinance is adopted by the Washington County Board of Commissioners sitting as the Local Public Health Authority in accordance with the authority granted in ORS 431.415.

1.020 Administration.

The Washington County Department of Health and Human Services, Public Health Division shall administer this Ordinance under the authority and requirements of ORS Chapter 431. Public Health is authorized to take actions deemed necessary to maintain public health and sanitation and to administer and enforce this Ordinance. Fees may be charged and collected for this administration.

1.030 Reserved.

1.040 Definitions.

As used in this Ordinance, 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 Residents for the purpose of collection, transportation and disposal. For purposes of this Ordinance, "authorized collector" shall also include law enforcement agencies.

(2) "Covered drug" means a drug sold in any form and used by Residents, 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. Ordinance 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;

- (g) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other similar products;
 - (h) Drugs used exclusively for food-producing animals; and
 - (i) Dialysate drugs and supplies required to perform home peritoneal kidney dialysis.
- (3) "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.
- (4) "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.
- (5) "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. Pharmacopeia 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.
- (6) "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.
- (7) "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.

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

(9) "Manufacture" means 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.

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

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

(12) "Ordinance" means this "Drug Takeback Ordinance" adopted by the Washington County Board of Commissioners as the Local Public Health Authority.

(13) "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.

(14) "Pharmacy" means a place licensed by the State Board of Pharmacy where the practice of pharmacy, as defined in ORS 689.005, is conducted.

(15) "Plan operator" means any person or entity that a producer uses to enact an approved independent or standard stewardship plan. A "stewardship organization" may be a plan operator.

(16) "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 Ordinance, "Potential authorized collector" shall also include law enforcement agencies.

(17) "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.

(18) "Producer" means a manufacturer that is engaged in the manufacture of a covered drug sold

in or into Washington 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 Section 1.050;
- (b) A pharmacist who compounds a prescribed individual drug product for a consumer; or
- (c) A drug wholesaler who is not also the manufacturer.

(19) "Public Health" means Washington County Department of Health and Human Services, Public Health Division.

(20) "Residents" means all individuals living in Washington 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. "Residents" 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.

(21) "Retail pharmacy" means a pharmacy registered by the State Board of Pharmacy 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 Public Health 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.

1.050 Stewardship plan participation.

(1) Each producer shall participate in the standard stewardship plan approved by Public Health, except that a producer may individually, or with a group of producers, form and

participate in an independent stewardship plan approved by Public Health.

- (2) The standard stewardship plan and any independent stewardship plan shall be approved by Public Health before collection of unwanted covered drugs begins. Once approved, stewardship plans must have prior written approval of Public Health for proposed changes as described in Section 1.140.
- (3) Within sixty (60) days after the effective date 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 Washington County at the effective date 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 the effective date of this ordinance, 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 the effective date of this ordinance, notify all potential authorized collectors in the county of the opportunity to participate as a drop-off site in accordance with Section 1.070 (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 the effective date of this ordinance, submit a proposed stewardship plan as described in Section 1.060 to Public Health for review and approval;
 - (d) Within ninety (90) days after Public Health'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 Section 1.070.
 - (e) At least every four (4) years after each plan begins, submit an updated plan to Public Health explaining any substantive changes to components of the stewardship plan required in Section 1.060, and accompanied by the review fee in accordance with Section 1.180. Public Health shall review updated stewardship plans using the process described in Section 1.130.
 - (f) Pay all administrative and operational costs and fees associated with the stewardship plan as required under Sections 1.100 and 1.180.
- (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 Section 1.060 to Public Health for review and approval.

- (7) Public Health 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 Ordinance to assist a producer, group of producers or stewardship organization in developing its proposed plan.

1.060 Stewardship plan components.

The standard stewardship plan or any independent stewardship plan, which must be submitted and reviewed according to Section 1.130, 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 Residents in compliance with the provisions and requirements in Section 1.070, 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 Section 1.050 (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 Sections 1.070 and 1.090.

- (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 State Board of Pharmacy.
- (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 Section 1.080, including a copy of standardized instructions for Residents, 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 pharmaceutical waste 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.

1.070 Collection of covered drugs.

- (1) 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. 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 Ordinance. A pharmacy drop-off site shall operate under applicable regulations and guidance of the State Board of Pharmacy.
- (2) The collection system shall be convenient, operated on an ongoing, year-round basis that adequately serves the needs of Residents, and provide equitable and convenient access for all Washington 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 voluntarily willing to participate as a drop-off site for unwanted covered drugs and able to meet the requirements of this Ordinance, 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 Ordinance.
 - (b) Drop-off sites shall accept all covered drugs from Residents 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 one drop-off site shall be provided in each city with a population under 10,000 if a drop-off site is available. Otherwise a drop off site must be located within five miles of the city limits, and mail-in options shall be available and part of the plan promotion, education and public outreach. At least two drop-off

sites shall be provided in each city in Washington County with a population between 10,000 and 40,000. In any city with a population over 40,000, there shall be in addition to the two drop-off sites at least one additional drop-off site for each additional 20,000 residents in that city.

- (ii) At least two drop-off sites shall be provided in both unincorporated Aloha and Bethany.
- (iii) Drop-off sites shall be geographically distributed to provide reasonably convenient and equitable access to Residents of each city 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 the owners of 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 homebound 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 website;
 - (ii) Upon request to persons providing home care services to Residents, including hospice services; and
 - (iii) To the owners of municipal buildings, fire stations, public libraries, and other publicly owned buildings 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 Ordinance.

- (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 produced by the Portland State University Population Research Center shall be utilized to define the population of cities and unincorporated areas of Washington County.

1.080 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 Section 1.210(5)(a);
 - (c) Promote the safe storage of prescription and nonprescription drugs by Residents before secure disposal through the 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 website 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 website and all materials shall discourage disposal of unused, expired or contaminated pharmaceutical wastes in the solid waste system or the sewer system in Washington 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, Chinese (both Mandarin and Cantonese) 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 website to access information about collection services for each approved plan.
- (3) Pharmacies and other entities selling prescription and nonprescription drugs in or into Washington 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 website for approved stewardship plans.

1.090 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) Public Health 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 Public Health 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.

1.100 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 Section 1.070;
 - (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 Section 1.090; and
 - (h) Program promotion, surveys, and evaluation under Section 1.080, 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 Residents.
- (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.

1.110 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. The report must include 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 activities during the previous twelve (12) month reporting period to comply with this Ordinance. 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 returned by 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.

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

1.120 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 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 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 the county, and identify the name and contact information of the manufacturer of the covered drug.

1.130 Review of proposed plans.

- (1) Within one hundred and eighty (180) days after the effective date 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 Section 1.180. 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) Public Health shall review each proposed stewardship plan and determine whether the proposed plan meets the requirements of Section 1.060 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, Public Health shall: 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, Public Health 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 Public Health 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, Public Health 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. Public Health 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. Public Health will identify any conditions that must be addressed prior to operation of the stewardship plan as required in Section 1.050 (4) (d).
- (6) **Revised Plan Rejection.** If Public Health rejects a revised stewardship plan, or any subsequently revised plan, Public Health may deem the producer or group of producers out of compliance with this Ordinance and subject to the enforcement provisions in this Ordinance.
- (a) If a revised proposal for the standard stewardship plan is rejected, Public Health 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. Public Health will not deem a producer out of compliance with this Ordinance when the revised independent stewardship plan is rejected by Public Health, if the producer thereafter participates in and complies with an approved stewardship plan.
- (7) In approving a proposed stewardship plan, Public Health may exercise reasonable discretion to waive strict compliance with the requirements of this Ordinance that apply to producers in order to achieve the objectives of this Ordinance.

1.140 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 Section 1.180.

- (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 Section 1.070, and do not substantively alter plan operations under subsection (1) of this section. Public Health may determine that the proposed change is a substantive change. If Public Health determines that the proposed change is substantive, then the process described in Section 1.140(1) shall be followed.
- (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.

1.150 Enforcement.

- (1) Public Health is authorized to administer and enforce this Ordinance. Enforcement may include, but is not limited to, issuance of a civil infraction, notices of noncompliance with a requirement under this Ordinance and issuance of enforcement orders.
- (2) Public Health may audit or inspect records and facilities upon providing notice of an audit or inspection to determine compliance with this Ordinance or to investigate a complaint. Producer, group of producers or stewardship organization shall allow Public Health or its agent to audit 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) Civil Infraction. The failure to comply with the requirements and restrictions in this Ordinance, including the failure to comply with an order issued by Public Health under this Ordinance, and further including but not limited to the list of acts of noncompliance detailed below, is a continuing offense and shall be punishable by the issuance of a civil infraction against a producer or group of producers or drug wholesaler for each violation, and may include all costs incurred for enforcement of the noncompliance. Civil infractions shall be issued in accordance with Washington County Code Chapter 1.12. Any noncompliance with this ordinance is a Class A Civil Infraction. Administrative enforcement of a civil infraction shall be under Washington County Code Chapter 1.12.
- (4) 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 civil infraction, may be subject to any and all remedies allowed under law including by not limited to, equitable relief, injunctive relief and damages.

- (5) Failure to begin operation of an approved stewardship plan and provide the collection system for unwanted covered drugs required under this Ordinance within ninety (90) days of Public Health's approval of the stewardship plan may result in a civil infraction. Each day of delayed implementation of the stewardship plan will constitute a new and separate civil infraction.
- (6) Failure to provide access to the records required pursuant to Section 1.150(2) shall result in a civil infraction.
- (7) If Public Health determines that a stewardship plan is not in compliance with this Ordinance or its plan approved under Section 1.130, Public Health may send the producer or group of producers participating in the plan a notice of noncompliance stating the plan is in noncompliance, providing notice of compliance requirements, and warning of the potential issuance of a civil infraction. The producer or group of producers has thirty (30) days after receipt of the notice to achieve compliance. This subsection does not preclude Public Health from suspending an approved plan, in addition to other available remedies, if noncompliance with this Ordinance or an approved plan creates a condition that, in Public Health's judgment, constitutes a threat to the public health, safety and welfare.

1.160 Reserved.

1.170 Regulations and performance standards.

- (1) The County may adopt rules necessary to implement, administer and enforce this Ordinance.
- (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 Washington County Residents as required under Section 1.070.
 - (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 Washington County Residents and healthcare providers about how to use collection options for unwanted covered drugs as required under Section 1.080.

1.180 Plan review and annual operating fees.

- (1) Fees required of producers for the review of stewardship plans and other actions related to this Ordinance shall be adopted by the Board of Commissioners in the Washington County Fee Schedule 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

Washington County Fee Schedule.

- (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 Section 1.050;
 - (e) Review of any petition for approval to use alternative final disposal technologies under Section 1.090; and
 - (f) Oversight of annual plan operations.
- (3) A plan operator or a stewardship organization may remit the fee on behalf of participating producers.

1.190 Other powers reserved – Alternative remedies and emergency orders.

Nothing in this Ordinance shall limit the authority of Washington County Public Health to act under any other legal authority. The powers conferred by this Ordinance shall be in addition to and supplemental to the powers conferred by any other law. If Public Health 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.

1.200 Reserved.