

Board of Health Ordinance 12

An Ordinance repealing in its entirety
Clallam County Code, Chapter 41.11.220 through 41.11.380
Article II. Secure Medicine Return Regulations

BE IT ORDAINED BY THE CLALLAM COUNTY BOARD OF HEALTH:

Article II. Secure Medicine Return Regulations

Section 41.11.220, Authority, purpose and intent, is ~~amended to read as follows:~~

~~(1) Pursuant to Chapters 70.05 and 70.46 RCW, the Clallam County Board of Health adopts the ordinance codified in this article to protect and preserve the public health, safety and welfare of the residents of Clallam County. Its provisions shall be liberally construed for the accomplishment of these purposes. This article governs the protection of human health and safety against the improper handling and disposal of leftover or expired medicines.~~

~~— (2) It is the intent of this article to place the obligation of complying with its requirements upon drug producers and other persons or entities designated by this article to be within its scope, and any provision or term used in this article is not intended to impose any duty whatsoever upon the County or any of its officers or employees, for whom the implementation or enforcement of this article shall be discretionary and not mandatory.~~

~~— (3) 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 benefited by the terms of these regulations.~~

~~— (4) 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 of Health, 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 County.~~

~~Hereby repealed in its entirety~~

Section 41.11.230, Administration, is ~~amended to read as follows:~~

~~— (1) The Health Officer and/or his or her designated representatives shall administer and enforce these regulations under the authority of RCW 70.05.070.~~

~~— (2) 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.~~

~~— (3) The Board of Health may charge fees for the administration of these regulations under the authority of RCW 70.05.060.~~

~~— (4) The Health Officer may collect fees for the administration of these regulations under the authority of RCW 70.05.070.~~

~~Hereby repealed in its entirety~~

Section 41.11.240, Applicability, is ~~amended to read as follows:~~

~~(1) These regulations shall apply to all persons and in all territory within the boundaries of Clallam County except enrolled members of any federally recognized tribe or domestic dependent nation who may volunteer to participate in this program.~~

~~— (2) These regulations apply to residents of Clallam 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.~~

~~— (3) These regulations apply to all “producers” selling a covered drug in or into Clallam County, as defined in CCC 41.11.250, Definitions.~~

~~Hereby repealed in its entirety~~

Section 41.11.250, Definitions, is amended to read as follows:

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

~~— (1) “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 collection, transportation and disposal. For purposes of this article, “authorized collector” shall also include law enforcement agencies.~~

~~— (2) “Ordinance” means the Clallam County Board of Health Ordinance 6, Secure Medicine Return Regulations.~~

~~— (3) “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 prefilled injector products with a retractable or otherwise securely covered needle. “Covered drug” does not include:~~

~~— (a) Vitamins or supplements;~~

~~— (b) Herbal based remedies and homeopathic drugs, products or remedies;~~

~~— (c) Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9);~~

~~— (d) Drugs for which producers provide a pharmaceutical product stewardship or take back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (Title 21 U.S.C. Section 355-1);~~

~~— (e) Drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of the regulation codified in this article if the producer already provides a pharmaceutical product stewardship or take back program;~~

~~— (f) Injector products and medical devices or their component parts or accessories that contain no covered drug or no more than trace residual amounts of covered drug; or~~

~~— (g) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.~~

~~— (4) “Covered persons” means all those persons described in CCC 41.11.240(1), 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 persons” does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctors’ offices, veterinarian clinics, pharmacies, or airport security and law enforcement drug seizures.~~

~~— (5) “Health Officer” means the local Health Officer of Clallam County appointed pursuant to RCW 70.05.050 or the local Health Officer’s duly authorized representative(s).~~

~~— (6) “Drop off site” means the location of an authorized collector where a secure drop box for all unwanted covered drugs is provided for persons subject to this article, 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.

— (7) “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.

— (8) “Drug” includes:

— (a) Articles recognized in the official United States Pharmacopoeia and 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;

— (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 subsections (8)(a) through (c) of this section.

— (9) “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.

— (10) “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 article, 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.

— (11) “Mail-back services” means a collection method for the return of unwanted covered drugs from covered persons utilizing prepaid and preaddressed mailing envelopes.

— (12) “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.

— (13) “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).

— (14) “Nonprescription drug” means a drug that may be lawfully sold without a prescription.

— (15) “Person” means an individual person, 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.

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

— (17) “Plan proponent” means the entity or person who submits a stewardship plan and is responsible for the submission and implementation of that plan.

— (18) “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 article, “potential authorized collector” shall also include law enforcement agencies.

— (19) “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.

— (20) “Producer” means a manufacturer that is engaged in the manufacture of a covered drug sold in or into Clallam 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 CCC 41.11.260(3);

— (b) A pharmacist who compounds a prescribed individual drug product for a consumer; or

— (c) A drug wholesaler who is not also a manufacturer.

— (21) “Regulation” means these “Secure Medicine Return Regulations” adopted by the Clallam County Board of Health.

— (22) “Retail pharmacy” means a pharmacy licensed by the Washington State Pharmacy Quality Assurance Commission for retail sale and dispensing of drugs.

— (23) “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 as the standard stewardship plan.

— (24) “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.

— (25) “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.

Hereby repealed in its entirety

Section 41.11.260, Stewardship plan - Participation, is ~~amended to read as follows~~:

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

— (2) The standard stewardship plan and any independent stewardship plan shall be approved by the Health Officer before collecting unwanted covered drugs. Once approved, stewardship plans must have prior written approval of the Health Officer for proposed changes as provided in CCC 41.11.350.

— (3) Within 60 days of the date of adoption of the regulation codified in this article, 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 Clallam County at the date of adoption of the regulation codified in this article, 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 Clallam County.

— (4) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall meet the following deadlines and standards:

— (a) Within four months of the date of adoption of the ordinance codified in this article:

~~_____ (i) 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~~

~~_____ (ii) Notify all potential authorized collectors in Clallam County of the opportunity to participate as a drop-off site in accordance with CCC 41.11.280. 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 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.~~

~~_____ (b) Within six months of the adoption date of the regulation codified in this article, submit a proposed stewardship plan as described in CCC 41.11.270 to the Health Officer for review.~~

~~_____ (c) Within three months of the Health Officer's approval of the stewardship plan:~~

~~_____ (i) 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~~

~~_____ (ii) Begin operating or participating in a stewardship plan in accordance with this article. Operating or participating in a stewardship plan means actually providing collection services within 90 days of the plan approval.~~

~~_____ (d) Annually notify any nonparticipating potential authorized collectors in Clallam 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 30 calendar days of the expression of such interest.~~

~~_____ (e) 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. Suggested changes to the plan must be submitted to the Health Officer within 10 business days of the date of the request for comments. 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 CCC 41.11.350 for changes made to the stewardship plans in the time between plan updates.~~

~~_____ (f) Pay all administrative and operational costs and fees associated with their stewardship plan as required under CCC 41.11.310 and 41.11.380.~~

~~_____ (5) A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan may:~~

~~_____ (a) 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.~~

~~_____ (b) Notify the Health Officer of any producer selling covered drugs in or into Clallam County that is failing to participate in a stewardship plan.~~

~~_____ (c) Perform any other functions necessary 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 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 number, 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 CCC 41.11.270 to the Health Officer for review.

— (7) 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.

— (8) The Health Officer may, upon request, provide consultation and technical assistance about the requirements of this article to assist a producer, group of producers or stewardship organization in developing its proposed plan.

Hereby repealed in its entirety

Section 41.11.270, Stewardship plan - Components, is amended to read as follows:

All stewardship plans shall include the following components:

— (1) Contact information for all drug producers participating in the stewardship plan including name, company, USPS mailing address, phone number, and email. The proponent of a stewardship plan shall have a continuing obligation to keep its contact information current and accurate.

— (2) A description of the proposed collection system to provide convenient ongoing collection service for all unwanted covered drugs from covered persons in compliance with the provisions and requirements in CCC 41.11.280. The collection system description shall include the following:

— (a) A list of all collection methods and participating potential authorized collectors and the collection methods used by the participating potential authorized collectors;

— (b) A list of drop-off sites with addresses;

— (c) A description of how periodic collection events will be scheduled and located if applicable;

— (d) A description of how mail-back services will be provided and an example of the prepaid, preaddressed mailers to be utilized;

— (e) A list of potential authorized collectors contacted by the plan under CCC 41.11.260(4)(a); and

— (f) 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.

— (3) A description of the handling and disposal system including the following:

— (a) Identification of and contact information for potential authorized collectors, transporters and waste disposal facilities to be used by the stewardship plan in accordance with CCC 41.11.280 and 41.11.300.

— (b) A description of the policies and procedures to be followed by persons handling unwanted covered drugs collected under the stewardship plan, including the following:

— (i) 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;

— (ii) 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;

— (iii) A description of how any pharmacy drop-off site will operate under applicable regulations and guidance of the Washington State Pharmacy Quality Assurance Commission; and

— (iv) A description of how patient information on drug packaging will be kept private and secure during collection, transportation, and recycling or disposal.

— (4) A description of the public education effort and promotion strategy required by CCC 41.11.290, including a copy of standardized instructions for residents, signage developed for authorized collectors; and required promotional materials.

~~— (5) A proposal stating the short-term (one-year) and long-term (five-year) goals of the stewardship plan for collection amounts (by weight) and public awareness.~~

~~— (6) A description of how the stewardship plan will consider:~~

~~— (a) Use of existing providers of waste pharmaceutical services;~~

~~— (b) Separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and~~

~~— (c) Recycling of drug packaging to the extent feasible.~~

~~— (7) Proof that the proponent of the plan has obtained and shall maintain in full force during the term of this plan public liability and property damage insurance with companies or through sources approved by the State Insurance Commissioner pursuant to RCW Title 48, as now or hereafter amended. The County, its appointed and elected officials, agents and employees, shall be specifically named as additional insureds in a policy with the same company which insures the contractor or by endorsement to an existing policy or with a separate carrier approved pursuant to RCW Title 48, as now or hereafter amended, and the following coverages shall be provided:~~

~~— (a) Commercial general liability for bodily injury, including death, with coverage in the amount of not less than \$2,000,000 per occurrence and \$4,000,000 aggregate.~~

~~— (b) Property damage with coverage in the amount of not less than \$500,000 per occurrence and \$1,000,000 aggregate.~~

~~— (c) Errors and omissions or professional liability (with an extended reporting period endorsement of two years) with coverage in the amount of not less than \$2,000,000 per occurrence. The County acknowledges that it will not be possible for the County to obtain “additional insured” status with respect to this coverage.~~

~~— (d) Business automobile liability with coverage including “uninsured motorist” coverage with coverage in the amount of not less than \$500,000 per occurrence, \$1,000,000 aggregate. The County acknowledges that it will not be possible for the County to obtain “additional insured” status with respect to this coverage.~~

~~— (e) Workers’ compensation providing an amount of coverage not less than that which is required by statute.~~

~~— (f) Any such policy of insurance the plan proponent is required to obtain and maintain pursuant to this plan shall be primary over any third party liability coverage provided to Clallam County by and through its membership in the Washington Counties Risk Pool, or WCRP. The third party liability coverage provided by the WCRP to Clallam County shall be noncontributory with respect to any policy of insurance the plan proponent is required to obtain and maintain pursuant to this plan. The County shall have no obligation to report occurrences unless a claim or lawsuit is filed with it and the County has no obligation to pay any insurance premiums.~~

~~— (g) Evidence of the insurance coverage listed in subsections (7)(a) through (f) of this section shall be submitted by the plan proponent with the submission to the Health Officer for approval of the plan.~~

~~— (8) Execution in the presence of a notary public by the plan proponent, or an authorized employee, representative or agent of the plan proponent of a “Defense and Indemnity Agreement” containing the following text, said “Defense and Indemnity Agreement” to be included in the initial submission to the Health Officer seeking approval of a plan:~~

~~— (1) The Plan proponent agrees to hold harmless, indemnify and defend the County, its officers, officials, employees and agents, from and against any and all claims, actions, suits, liability, loss, expenses, damages and judgments of any nature whatsoever, including reasonable costs and attorneys’ fees in defense thereof, for injury, sickness, disability or death to persons or damage to property (including loss of use thereof) or business (including economic loss), caused by or arising out of the Plan proponent’s acts, errors or omissions in the performance of the Plan. Provided, however, that the Plan proponent’s obligation under this provision will not extend to injury,~~

sickness, disability, death or damage caused by or arising out of the sole negligence of the County, its officers, officials, employees or agents.

————— (2) With regard to any claim against the County, its officers, officials, employees and agents by any employee of the Plan proponent, subcontractor, anyone directly or indirectly employed by any of them, or anyone for whose acts any of them may be liable, the indemnification obligation under this Section will not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for the Plan proponent or subcontractor under workers' compensation acts, disability benefit acts or other employee benefit acts. It is clearly agreed and understood by the parties to the Plan that the Plan proponent expressly waives any immunity the Plan proponent might have had under such laws. By seeking approval of this Plan, the Plan proponent acknowledges that the foregoing waiver has been mutually negotiated by the parties as is required by RCW 4.24.115, and that the provisions of this Section will be incorporated, as relevant, into any contract the Plan proponent makes with any subcontractor or agent performing work under the Contract.

————— (3) The Plan proponent's obligations under these provisions include, but are not limited to, investigating, adjusting, and defending all claims alleging loss from action, error or omission, or breach of any common law, statutory or other delegated duty by the Plan proponent, the Plan proponent's employees, agents or subcontractors.

Hereby repealed in its entirety

Section 41.11.280, Stewardship plan – Collection of drugs, is ~~amended to read as follows:~~

~~(1) This article 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 article 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.~~

~~————— (2) 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 Clallam County residents for the safe and convenient return of unwanted covered drugs, in accordance with this section.~~

~~————— (3) The collection system for all unwanted covered drugs shall be safe and secure, and include the protection of patient information on drug packaging.~~

~~————— (4) 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 Clallam County, and meeting the requirements of this subsection. To do so, collection systems shall meet the following standards:~~

~~————— (a) There must be at least one drop-off site within the geographical boundaries of all three cities in Clallam County. 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.~~

~~————— (b) 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. Distribution of mail-back packets/supplies is to be made available at all North Olympic Library System (NOLS) branches in Clallam County.~~

~~————— (c) 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 collectors or long-term care facilities for drop-off sites.~~

~~————— (d) Any retail pharmacy, hospital or clinic with an on-site pharmacy or any law enforcement agency that meets the requirements of this article and requests to be added as a drop-off site shall be added as a drop-off site within 90 days of the stewardship plan receiving the request unless the requestor asks for additional time.~~

~~————— (e) 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 article may request to 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.~~

~~———— (5) Drop-off sites shall accept all covered drugs from covered persons 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.~~

~~———— (6) 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 is necessary on a schedule that meets the need of each location to avoid reaching capacity. Secure drop box signage shall include a prominently displayed 24-hour, toll-free telephone number and website for the stewardship plan. Covered persons 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.~~

~~———— (7) 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 Officer 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.~~

~~———— (8) Mail-back services shall be free of charge and made available to differently abled and homebound residents upon request through the stewardship plan's toll-free telephone number and website. Prepaid, preaddressed mailers shall be distributed to persons providing services to differently abled and homebound residents, and may also be utilized as a collection method.~~

~~———— (9) 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 article.~~

~~———— (10) 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 mailer, or at collection events. Such collection methods shall be reviewed and approved by Health and Human Services Environmental Health and shall operate in compliance with applicable regulations.~~

~~Hereby repealed in its entirety~~

Section 41.11.290, Stewardship plan – Promotion, is ~~amended to read as follows~~:

~~(1) A producer or group of producers participating in a stewardship plan must develop and provide a system of promotion, education, and public outreach about safe storage and secure collection of covered drugs.~~

~~— (2) The education and public outreach strategy shall include the following:~~

~~— (a) A toll-free telephone number and website available for use by the public.~~

~~— (b) 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 Clallam County, pursuant to this article.~~

~~— (c) 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 website 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 Clallam County, pursuant to this article.~~

~~— (d) Annual reports evaluating the effectiveness of the promotion, outreach and public education shall be submitted to the Board of Health.~~

~~— (e) A biennial survey shall be conducted of covered entities and pharmacists, health professionals, and veterinarians in Clallam 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 nonprescription drugs used in the home. Draft survey questions shall be submitted to the Health Officer for review and comment at least 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 90 days of the end of the survey period.~~

~~— (3) All approved stewardship plans operating in Clallam 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 a single website to access information about collection services for all stewardship plans operating in Clallam County.~~

~~— (4) Pharmacies and other entities selling medicines in or into Clallam County are encouraged to promote secure disposal of unwanted covered drugs by covered entities by using approved stewardship plans. Pharmacies must provide materials explaining the use of approved stewardship plans to customers upon request.~~

~~— (5) The Board of Health and Clallam 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 by using the stewardship plans, the toll-free telephone number and the website for approved stewardship plans through the agencies' standard educational methods.~~

Hereby repealed in its entirety

Section 41.11.300, Stewardship plan – Disposal of covered drugs, is ~~amended to read as follows:~~

~~(1) 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.~~

~~— (2) 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.~~

~~— (3) 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 than permitted hazardous waste disposal facilities or municipal waste combustors 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.~~

~~Hereby repealed in its entirety~~

Section 41.11.310, Stewardship plan – Administrative and operational costs, is ~~amended to read as follows:~~

~~(1) 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:~~

~~— (a) Collection and transportation supplies for each drop-off site;~~

~~— (b) Purchase of secure drop boxes for each drop-off site;~~

~~— (c) Ongoing maintenance or replacement of secure drop boxes, as requested by authorized collectors;~~

~~— (d) Prepaid, preaddressed mailers provided to differently abled and homebound residents, and to specific areas of Clallam County, if utilized;~~

~~— (e) Operating periodic collection events if utilized, including costs of law enforcement staff time, if necessary;~~

~~— (f) Transportation of all collected pharmaceuticals to final disposal;~~

~~— (g) Environmentally sound disposal of all collected pharmaceuticals under CCC 41.11.300; and~~

~~— (h) Program promotion under CCC 41.11.290, including costs of providing materials to pharmacies to fulfill customer requests.~~

~~(2) No person or producer may charge a specific point-of-sale fee to consumers to recoup the costs of their stewardship plan, nor may they charge a specific point-of-collection fee at the time the covered drugs are collected from covered persons.~~

~~(3) 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.~~

~~Hereby repealed in its entirety~~

Section 41.11.320, Stewardship plan – Reporting requirements, is ~~amended to read as follows:~~

~~(1) At the following intervals: three, six, nine, and 12 months of the start of operations of the plan, and semiannually 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 article. The report must 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, the number of mailers provided for differently abled and homebound 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;~~
- ~~———— (d) 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;~~
- ~~———— (e) A description of the public education, outreach and evaluation activities implemented during the reporting period;~~
- ~~———— (f) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;~~
- ~~———— (g) 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~~
- ~~———— (h) The total expenditure of the stewardship plan during the reporting period.~~

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

~~(3) For the purposes of this section, "reporting period" means the period from January 1st through December 31st of the same calendar year, unless otherwise specified to the plan operator by the Health Officer.~~

Hereby repealed in its entirety

Section 41.11.330, Stewardship plan – Identification of producers of covered drugs, is ~~amended to read as follows:~~

~~(1) Within 60 days of a request from the Health Officer, any drug wholesaler that sells any covered drug in or into Clallam 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.~~

~~(2) Any person receiving a letter of inquiry from the Health Officer regarding whether or not it is a producer under this article must respond in writing within 60 days. If such person does not believe it is a producer under this article, 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 Clallam County, and identify the name and contact information of the manufacturer of the covered drug.~~

Hereby repealed in its entirety

Section 41.11.340, Stewardship plan – Review of proposed plans, is ~~amended to read as follows:~~

~~(1) Within six months of the date of adoption of the regulation codified in this article, 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 CCC 41.11.380. 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.~~

~~— (2) The Health Officer shall review each proposed stewardship plan to determine compliance with this article. In reviewing a proposed stewardship plan, the Health Officer shall provide opportunity for written public comment and consider any comments received.~~

~~— (3) Within 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.~~

~~— (4) 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 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 (2) and (3) of this section. Any suggested changes to the plan proposal must be submitted to the Health Officer within 10 business days of the date of the open comment period.~~

~~— (5) 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 article and subject to the enforcement provisions in this article.~~

~~— (a) 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 components 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 article.~~

~~— (b) 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 article if the producer participates in and complies with the standard stewardship plan.~~

~~— (6) In approving a proposed stewardship plan, the Health Officer may exercise reasonable discretion to waive strict compliance with the requirements of this article to achieve the objectives of this article.~~

~~— (7) The Health Officer shall make all stewardship plans submitted under this section available to the public both before and after they are approved.~~

~~Hereby repealed in its entirety~~

Section 41.11.350, Stewardship plan – Prior approval for change, is ~~amended to read as follows:~~

~~(1) 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.~~

~~— (2) Any proposed changes shall be submitted to the Health Officer in writing at least 30 days before the change is scheduled to occur and accompanied by the review fee in accordance with CCC 41.11.380.~~

~~— (3) The plan operator of an approved stewardship plan shall notify the Health Officer at least 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 (1) of this section.~~

~~— (4) 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 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 30 days of such change.~~

~~Hereby repealed in its entirety~~

Section 41.11.360, Stewardship plan – Administration and enforcement, is ~~amended to read as follows:~~

~~(1) The Health Officer is authorized to administer and enforce these regulations.~~

~~— (2) 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 noncompliance with these regulations.~~

~~— (3) After presenting official credentials and providing notice of an audit or inspection to determine compliance with this article 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 or an authorized collector's facilities, vehicles and equipment used in carrying out the stewardship plan.~~

~~— (4) Right of Entry and Inspection.~~

~~— (a) 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 been 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.~~

~~— (b) 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.~~

~~— (c) 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.~~

~~— (5) Notice and Order to Correct Violation.~~

~~— (a) 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 article.~~

~~— (b) Content. The notice and order to correct violation shall contain:~~

~~— (i) A statement that participation in a stewardship plan is required and a reference to this article;~~

~~— (ii) 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;~~

~~— (iii) 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~~

~~_____ (iv) 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.~~

~~_____ (c) 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.~~

~~_____ (d) Time to Correct Violation.~~

~~_____ (i) 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 Clallam County 60 days after receiving a written Health Officer's Notice and Order to Correct Violation may be assessed a penalty under subsection (6) of this section.~~

~~_____ (ii) If the Health Officer determines that a stewardship plan is not in compliance with this article or its plan approved under CCC 41.11.350, 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 be out of compliance with this article, or its plan approved under CCC 41.11.350, has 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 30 days, the Health Officer may assess a penalty under subsection (6) 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 article or an approved plan creates a condition that, in the Health Officer's judgment, constitutes an immediate hazard. If a plan is suspended, the proponent of that plan shall take all reasonable steps to inform the citizens of available alternate methods for secure return of covered drugs.~~

~~_____ (iii) Extension. 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.~~

~~_____ (iv) 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 regulations.~~

~~_____ (6) Enforcement.~~

~~_____ (a) The Health Officer, after issuance of a written Health Officer's Notice and Order to Correct Violation ("NOCV") and the failure of the producer, group of producers, drug wholesaler or covered person to remedy or cure the violation to the satisfaction of the Health Officer, may enforce the requirements and restrictions of this article through any procedure or action authorized by CCC Title 20.~~

~~_____ (b) For purposes of implementing the terms and conditions of CCC Title 20, all violations of this article shall be considered a commercial violation subject to the monetary penalties listed in CCC 20.28.010(2), as that section is currently enacted or as it may hereafter be amended.~~

~~_____ (7) Interpreting CCC Title 20 for Purposes of This Article.~~

~~_____ (a) Should the text of this article conflict with the text of CCC Title 20, as currently enacted or hereafter amended, then the text of this article shall be deemed controlling.~~

~~_____ (b) For the purposes of CCC 20.08.010(5), and any other location in CCC Title 20 where the term "Director" is used, that term for purposes of this article is defined to mean the Health Officer.~~

~~———— (e) For the purposes of CCC 20.28.010(2), the monetary fine that may be imposed by the Health Officer for a commercial violation shall be not less than \$500 per day per violation and not more than \$2,000 per day per violation.~~

~~———— (d) Chapter 20.36 CCC, Liens, shall not be applicable to violations of this article.~~

~~———— (8) Appeals of Written Orders by the Health Officer. All appeals of a written order issued by the Health Officer, whether the Hearing Examiner's order was issued pursuant to this article or CCC Title 20, shall be subject to the appeal process described in CCC 41.11.160.~~

~~———— (9) Other Remedies Remain Available. The Health Officer or designee may, with respect to any alleged violation of this article or any alleged failure of a drug wholesaler, producer, group of producers or covered person to comply with the terms and conditions of their plan, invoke, implement or utilize any civil cause of action, including, but not limited to, injunctive or declaratory relief, in order to enforce this article and/or any NOCV or other written order issued by the Health Officer. Any civil action will be filed in the name of the Clallam County Board of Health and may include recovering attorney's fees and legal costs from the violating party or parties.~~

~~Hereby repealed in its entirety~~

Section 41.11.370, Stewardship plan – Regulations, performance standards, and ~~report is amended to read as follows:~~

~~(1) The Health Officer may adopt regulations necessary to implement, administer and enforce this article.~~

~~———— (2) The Health Officer may work with the plan operator to define goals for collection amounts and public awareness for a stewardship plan.~~

~~———— (3) 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 article. 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.~~

~~Hereby repealed in its entirety~~

Section 41.11.380, Stewardship plan – Plan review and annual operating fees ~~is amended to read as follows:~~

~~(1) 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 (4) of this section for:~~

~~———— (a) Review of a proposed stewardship plan;~~

~~———— (b) Resubmittal 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 years under CCC 41.11.260(4)(e); and~~

~~———— (e) Review of any petition for approval to use alternative final disposal technologies under CCC 41.11.300(3).~~

~~———— (2) 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 (4) of this section.~~

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

~~(4) 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 article. All fees collected under the provision of this article shall be payable to the Clallam County Board of Health. Hereby repealed in its entirety~~

ADOPTED this 15th of February 2022

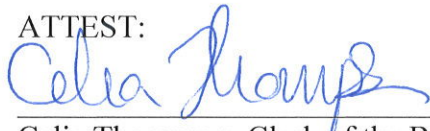
CLALLAM COUNTY BOARD OF HEALTH

excused absence

Don Lawley, Chair


Allison Berry, M.D., MPH, Health Officer

ATTEST:



Celia Thompson, Clerk of the Board