DRAFT ORDINANCE

AN ORDINANCE OF THE CITY COUNCIL OF THE CITY OF CAPITOLA ADDING CHAPTER 8.40 TO TITLE 8 OF THE CAPITOLA MUNICIPAL CODE REQUIRING THE SAFE DISPOSAL OF DRUGS AND SHARPS

The City Council of the City of Capitola hereby finds and declares the following:

WHEREAS, drugs and sharps are necessary medical technologies which allow us to live longer, healthier and more productive lives and reduce suffering at the end of life; and

WHEREAS, the public, particularly children, the elderly and public employees, are at significant and unnecessary risk of poisoning and injury due to improper or careless disposal of drugs and sharps; and

WHEREAS, our groundwater and drinking water are being contaminated by unwanted, leftover or expired drugs passing through our wastewater treatment centers; and

WHEREAS, there is no mandatory statewide stewardship program for unwanted drugs or sharps in California, and manufacturers, retailers and producers have not offered any support for a permanent collection program to date; and

WHEREAS, although state law (California Health and Safety Code Section 118286) requires that home-generated sharps be transported to a collection center in sharps containers or other containers authorized by the local enforcement agency, and prohibits the loose disposal of home-generated sharps waste in trash or recycling containers, many people continue to dispose of contaminated sharps in a manner that increases the risk that others will come into contact with them; and

WHEREAS, the lack of sufficient safe, convenient disposal locations for leftover, expired, and/or unwanted drugs creates significant risks to human health and to the environment. As a result, leftover, expired, and/or unwanted drugs are often left in homes where they can be accidentally ingested or abused by children, adults, and the elderly, increasing the risk of poisoning, addiction, and death; and

WHEREAS, unwanted drugs are also often flushed down toilets or sinks. However, municipal wastewater treatment plants are not designed to remove the complex compounds in the drugs that end up in the sewer system. As a result, drugs can pass through wastewater treatment systems and contaminate receiving waters; and

WHEREAS, an Environmental Protection Agency report on drinking water released in December 2013 tested effluent samples from 50 large wastewater treatment plants nationwide for active pharmaceutical ingredients and metabolites. Out of the 63 total compounds tested for, 43 were detected in at least one of the samples and all samples were found to contain at least one pharmaceutical compound. The presence of pharmaceuticals in surface water is well documented to have ecological impacts, including negative effects on fish and other aquatic life; and

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WHEREAS, establishing a safe, convenient collection and disposal system for leftover, expired, and unwanted drugs will reduce unintentional poisonings and drug overdose deaths by making drugs less accessible to persons who might accidentally ingest or abuse them; and

WHEREAS, establishing a safe, convenient collection and disposal system for leftover, expired, and unwanted drugs will also reduce the quantity of pharmaceutical compounds that are discharged into the Monterey Bay National Marine Sanctuary and other environmentally sensitive waters throughout the City; and

WHEREAS, Extended Producer Responsibility (EPR) laws, sometimes referred to as

Product Stewardship laws, place responsibility for end-of-life management of consumer products on the manufacturers and producers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle; and

WHEREAS, many local and national governmental bodies support EPR, including CalRecycle (formerly the California Integrated Waste Management Board), the National Association of Counties, and the National League of Cities; and

WHEREAS, California has passed four significant products stewardship laws for mercury thermostats (AB 2347, enacted as Chapter 572 of the statutes of 2008), carpet (AB 2398, enacted as Chapter 681 of the statutes of 2010), paint (AB 1343, enacted as Chapter 420 of the statutes of 2010) and mattresses (SB 254, enacted as Chapter 388 of the statues of 2013). All four laws require producers to establish and fund product stewardship programs for their waste streams; and

WHEREAS, in 2010, Congress passed the "Secure and Responsible Drug Disposal Act of 2010," Public Law No. 111-273, which authorized the Attorney General to expand the methods through which pharmaceuticals classified as controlled substances may be collected, including through collection at pharmacies. The goal of the bill was to increase opportunities for drug collection in order to reduce substance abuse, accidental poisoning, and the release of harmful substances into the environment. On October 9, 2014, the Drug Enforcement Agency promulgated regulations implementing that Act. These regulations, among other things, authorize retail pharmacies to maintain secure collection bins for controlled substances; and

WHEREAS, Mexico, a number of Canadian provinces, much of Europe and several other countries already have active, well-established EPR drug disposal programs in place. Many of the same drug companies that participate in these programs manufacture drugs sold in the United States; and

WHEREAS, in 2012, Alameda County became the first local government in the United States to pass legislation requiring pharmaceutical companies to design, fund, and operate a program to safely collect and dispose of unwanted drugs, similar to the take-back programs in Canada's pharmacies. On September 30, 2014, the Ninth Circuit Court of Appeal rejected a legal challenge to Alameda County's Ordinance brought by pharmaceutical trade associations. Pharm. Research & lvlfrs. Of Am. v. Cty. of Alameda, 13~16833, 768 F.3d1037 (9th Cir. 2014). The U.S. Supreme Court subsequently declined to hear an appeal of this ruling; and

WHEREAS, King County, Washington as well as the City and County of San Francisco and the Counties of Santa Cruz, San Mateo, Santa Clara, San Luis Obispo and Marin have

enacted similar ordinances requiring drug manufacturers to design, fund, and operate programs to safely collect and dispose of local residents' unwanted drugs and/or sharps; and

WHEREAS, beginning in 2008, the County of Santa Cruz has operated a voluntary County-funded collection program, pursuant to which the County of Santa Cruz and the City have been working together with the cities of Watsonville, Santa Cruz and Scotts Valley to provide a convenient and permanent system to collect unwanted pharmaceuticals. As of October 2015, this program consists of 46 locations at pharmacies, police departments, and sheriff’s stations, which collect both controlled and non-controlled substances, as well as city and county household hazardous waste disposal sites. Participation in collection and disposal of unwanted drugs is still voluntary, resulting in a patchwork of businesses participating in one or both programs, leading to confusion among consumers and sometimes improper disposal in the wrong containers; and

WHEREAS, on December 8, 2015, the Santa Cruz County Board of Supervisors passed

an Ordinance (Ordinance No. 5214, effective the 31st day after the date of final passage) requiring the safe disposal of drugs and sharps and establishing a Product Stewardship Program to safely collect and dispose of unused/unwanted pharmaceutical and sharps waste from county residents. This City Ordinance is intended to compliment and be consistent with Santa Cruz County's Safe Disposal of Drugs and Sharps Ordinance (Santa Cruz County Code Chapter 7.95); and

WHEREAS, a manufacturer and/or producer-funded collection and disposal program in the City for unwanted drugs and sharps would significantly increase convenient disposal options for City residents' unwanted drugs and sharps, enabling collection of larger quantities of unwanted drugs and sharps and reducing risks to public safety, health, and the environment.

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF CAPITOLA AS FOLLOWS:

SECTION I

The Capitola Municipal Code is hereby amended by adding Chapter 8.40 to read as follows:

Chapter 8.40 CAPITOLA SAFE DRUG AND SHARPS DISPOSAL

Sections:

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8.40.010 Purpose and Intent

The purpose of this chapter is to protect the health, safety and welfare of the public and of the environment by providing for the safe and orderly collection and disposal of drug and sharps waste and by placing responsibility for end-of-life management of drug and sharps products on the manufacturers and/or producers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle. This chapter is intended to be consistent with the Santa Cruz County Safe Drug and Sharps Disposal Ordinance.

8.40.020 Title

This chapter may be cited as the "Capitola Safe Drug and Sharps Disposal Ordinance."

8.40.030 Definitions

For the purposes of this chapter, the following terms have the meanings given below.

A. "City Council" refers to the City Council of the City of Capitola.

B. "City" means the City of Capitola, California.

C. "Consumer Generators" means residents of single and multiple family residences or other locations who possess, dispose of and/or abandon household Covered Drugs or Sharps. "Consumer Generators" does not include airport security, drug seizures by law

enforcement, pharmacy waste, business waste, or any other source identified by the Department as a non-consumer source.
D. “Controlled Substance” for purposes of this section shall mean any substance listed under California Health and Safety Code Sections 11053 through 11058 and/or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.
E. “Cosmetics” means (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (ii) articles intended for use as a component of any such articles.
F. “Covered Drug” means all brand name and Generic Prescription Drugs. Notwithstanding the foregoing sentence, “Covered Drug” does not include: (i) vitamins or supplements; (ii) herbal-based remedies and homeopathic drugs, products, or remedies; (iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as Cosmetics under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Section 301 et seq. (2002)); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Section 355-1); (v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this chapter if the Producer already provides

a take-back program; and (vi) pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.
G. “County” means the County of Santa Cruz, California.
H. “Department” means the City of Capitola City’s Manager’s Department.
I. “City Manager” means the City of Capitola City Manager or his or her designee.
J. “Drug Wholesaler” means a Person that sells or distributes Covered Drugs for resale to an Entity other than a consumer.
K. “Drugs” means: (i) articles recognized in the official United States Pharmacopoeia, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and (iv) articles intended for use as a component of any article specified in clause (i), (ii), or (iii) of this definition. Notwithstanding the foregoing sentence, “Drugs” does not include or mean medical devices, their component parts or accessories.
L. “Entity” means a Person other than an individual.
M. “Generic” means a Drug that is chemically identical or bioequivalent to a brand name Drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.
N. “Hazardous Waste” means a “hazardous waste” as defined in the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 USCA § 6901 et seq.) and the implementing regulations (40 C.F.R. §§239 through 282), as amended. This waste includes, but is not limited to, bulk chemotherapy drugs, P-listed waste, U-listed waste and characteristic hazardous waste.
O. “Manufacture” means the production, preparation, propagation, compounding, or processing of Covered Drugs or Sharps but does not include the activities of a

Repackager, Drug Wholesaler or medical practitioner who distributes or dispenses such substances or devices in the ordinary course of his or her professional practice or prepares, compounds, packages or labels such substances or devices.
P. “Manufacturer” means a Person engaged in the Manufacture of Covered Drugs or Sharps.
Q. “Mail-back Program” means a system whereby Consumer Generators of Unwanted Products obtain prepaid and preaddressed mailing envelopes in which to place Unwanted Products for shipment to an Entity that will dispose of them safely and legally.
R. “Medical Waste” means “Medical waste” as defined in Section 117690 of the California Health and Safety Code, as amended.

S. “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, however organized.
T. “Pharmacy” means a place licensed by the State of California Board of Pharmacy where the practice of pharmacy is conducted.
U. “Plan” or “Product Stewardship Plan” means a product stewardship plan required under this chapter that describes the manner in which a Product Stewardship Program will be provided.
V. “Plan Operator” means the Person that develops, implements and operates a Product Stewardship Plan, including but not limited to a Producer or Stewardship Organization.
W. “Prescription Drug” means any Drug, including, but not limited to, any Controlled Substance, that is required by federal or state law, rule or regulation to be dispensed by prescription only or is restricted to use by practitioners only.
X. “Producer” shall be determined, with regard to Covered Drugs and Sharps that are sold, offered for sale, or distributed in the City as meaning one of the following:
1. The Person who Manufactures Covered Drugs or Sharps and who sells, offers for sale, or distributes Covered Drugs or Sharps in the City under that Person's own name or brand.
2. If there is no Person who sells, offers for sale, or distributes Covered Drugs or Sharps in the City under the Person's own name or brand, the Producer of Covered Drugs or Sharps is the owner or licensee of a trademark or brand under which the Covered Drugs or Sharps are sold or distributed in the City, whether or not the trademark is registered.
3. If there is no Person who is a Producer of Covered Drugs or Sharps for purposes of paragraphs (1) and (2), the Producer of Covered Drugs or Sharps is the Person who brings the Covered Drug into the City for sale or distribution.
Notwithstanding the foregoing, “Producer” does not include: (i) a Retailer or Repackager that only puts its label on a Covered Drug or Sharps; (ii) a pharmacist who dispenses Prescription Drugs to, or repackages or compounds a prescribed individual Drug product for a consumer; or (iii) a Drug Wholesaler who is not also a Manufacturer.
Y. “Product Stewardship Program" or "Program" means a program financed, developed, implemented, and operated by Producers to collect, transport, and dispose of Unwanted Products.
Z. “Provider” means any Person that sells or otherwise furnishes Covered Drugs or Sharps to consumers at a medical or veterinary office, clinic, hospital or approved needleexchange program located in the City.
AA. “Public Hearing” means any hearing held by the Department or the City which is open to the public for the purposes of collecting public comment. It does not necessarily refer to

meetings of the City Council.

BB. “Repackager” means a Person who owns or operates an establishment that repacks, repackages, and/or re-labels a product or package (including a Covered Drug and/or Sharps) for further sale or for distribution without a further transaction.
CC. “Retailer” means any Person that sells Covered Drugs or Sharps directly to consumers at a business located in the City.
DD. “Santa Cruz County Safe Drug and Sharps Disposal Ordinance” refers to Chapter 7.95 of the Santa Cruz County Municipal Code, entitled “, Santa Cruz County Safe Drug and Sharps Disposal”, as such may be amended.
EE. “Sharps” means one or more hypodermic needles, pen needles, intravenous needles, lancets and other devices used to penetrate the skin for drawing blood, or for the delivery of medications or Drugs.
FF. “Stewardship Organization” means an organization designated by a group of Producers to act as an agent on behalf of each Producers to operate a Product Stewardship Program.
GG. “Unwanted Products” means Covered Drugs or Sharps no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

8.40.040 Product Stewardship Program

A. Requirement for Sale. This chapter shall apply only to Producers whose Covered Drugs and/or Sharps are sold and/or distributed in the City and to Retailers who sell Covered Drugs and/or Sharps in the City. This chapter shall apply only to areas within the City limits. This chapter shall be administered and implemented by the City of Capitola City Manager’s Department. Each Producer shall participate in a Stewardship Program. Each Producer must:
1. Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the Department; or
2. Enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Product Stewardship Program approved by the Department.
B. Product Stewardship Program Costs.
1. A Producer, group of Producers, or Stewardship Organization must pay all administrative and operational fees and costs associated with their Product Stewardship Program and related Product Stewardship Plan, including, but not limited to, the cost of collecting, transporting, and disposing of Unwanted Products collected from Consumer Generators and the recycling and/or disposal of packaging collected with the Unwanted Product.
2. No Person or Producer may charge a specific point-of-sale fee to consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Consumer Generators or delivered for disposal.

3. A Producer, group of Producers, or Stewardship Organization must pay all costs and expenses incurred by the City, including but not limited to the Department, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the City shall only recover its actual costs of

administration and enforcement under this chapter and shall not charge any amounts under this chapter in excess of its actual administrative and enforcement costs.
4. A Producer, group of Producers, or Stewardship Organization must pay all collection and disposal costs and expenses as of the date that the ordinance codified in this chapter becomes effective. If the City incurs any costs or expenses due to delays in establishment of an approved Stewardship Plan, the Producer, group of Producers, or Stewardship Organization must reimburse the City in full for such costs.

8.40.050 Product Stewardship Plan

A. Plan Content. Each Product Stewardship Program shall have a Product Stewardship Plan (which must be submitted, reviewed and approved in accordance with Section 8.40.050(B) below) that contains each of the following:
1. Certification that the Product Stewardship Program will accept all Unwanted Products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the Plan;
2. Contact information (including the name, physical and mailing address, telephone number, and email address) for the individual and the Entity submitting the Plan, the Plan Operator, and each of the Producers participating in the Product Stewardship Program;
3. A description of the methods by which Unwanted Products from Consumer Generators will be collected and handled at all retail sale facilities of Sharps and Covered Drugs in the City, including without limitation a description of bins to be used and collection methods;
4. A description of the methods by which Unwanted Products from Consumer Generators will be collected and handled at all public health facilities in the City, as well as at such other locations as designated by the Department, including without limitation a description of bins to be used and collection methods;
5. The location of each collection site and locations where envelopes for a Mailback Program are available (if applicable);
6. A list containing the name, location, permit status, and record of any penalties, violations, and/or regulatory orders received in the previous five years by each Person that will be involved in collecting and/or transporting Unwanted Products and each Medical Waste or Hazardous Waste disposal facility proposed to participate in the Product Stewardship Program;

7. A description of how the Unwanted Products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;
8. A description of the public education and outreach activities required under this chapter and how their effectiveness will be evaluated;
9. A description of how the scope and extent of the Product Stewardship Program are reasonably related to the amount of Covered Drugs and Sharps that are sold in the City, by the Producer or group of Producers;
10. A starting date when collection of Unwanted Products will begin;
11. A description of how support will be provided to any law enforcement agencies within the City that have, or later agree to have, a collection program for Controlled Substances, including, without limitation: (i) the provision of a

collection kiosk with appropriate accessories and signage, (ii) an ability to accept Controlled Substances and other Covered Drugs, and (iii) technical support up to and including an appropriate Person to provide on-site assistance with the sorting and separation of Controlled Substances at no cost to a participating law enforcement agency;

12. If more than one Producer will be involved in a proposed Product Stewardship Program, then the Product Stewardship Plan for that Program must include a fair and reasonable manner for allocating the costs of the Program among the participants in that Program, such that the portion of costs paid by each Producer is reasonably related to the amount of Covered Drugs and Sharps that Producer sells in the City.

B. Existing County-Approved Product Stewardship Plan. If a Producer, group of Producers, or Stewardship Organization is/are operating a Product Stewardship Program within the County under an existing Product Stewardship Plan that has been approved by the County of Santa Cruz in accordance with Chapter 7.95 of the Santa Cruz County Code ("County-Approved Plan"), such Producer, group of Producers, or Stewardship Organization may comply with Section 8.40.050(A) above, by supplementing such County-Approved Plan to cover the City and include all items listed in Section 8.40.050(A) above. The Product Stewardship Plan, as supplemented, must be submitted to the Department for review and approval of the provisions relating to and/or applicable to the City in accordance with Section 8.40.050(D) below.

C. Department Review and Approval; Updates.

1. No Producer, group of Producers, or Stewardship Organization within the City may begin collecting Unwanted Products to comply with this chapter until it has received written approval of its Product Stewardship Plan from the Department. The City may (in its discretion) continue collection on an interim basis if there is any delay in establishing a Stewardship Program as required under this chapter. Once approved by the Department, each Product Stewardship Plan must receive prior written approval from the Department for any proposed changes to the Plan.

2. All Product Stewardship Plans must be submitted to the Department for approval. Each Producer, group of Producers, or Stewardship Organization operating a Product Stewardship Program shall submit its initial Product Stewardship Plan (conforming to the above requirements) to the Department for review within sixty (60) days after the effective date of this chapter, or at a later date as approved in writing by the Department.

3. Within sixty (60) days after the Department's receipt and review of a Product Stewardship Plan, the Department will determine whether the Plan complies with the requirements of this chapter and of any regulations adopted pursuant to this chapter. The Department may at its sole discretion conduct a noticed Public Hearing as part of this process.

a. As part of its approval, the Department may set reasonable performance goals for the Program.

b. If the Department approves a Plan, it shall notify the applicant of its approval in writing.

c. If the Department rejects a Plan, it shall notify the applicant in writing of its reasons for rejecting the Plan. The Department may reject a Plan without conducting a Public Hearing.

d. An applicant whose Plan has been rejected by the Department must submit a revised Plan to the Department within thirty (30) days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, at its sole discretion, the Department may (without any obligation to do so) develop, approve and impose upon the applicant the Department's own Product Stewardship Plan or an approved Plan submitted by other Producer(s) pursuant to this chapter. The imposed Plan will be presented at a Public Hearing. The Department is not required, and nothing in this chapter shall be interpreted as requiring, the Department to create or impose a Product Stewardship Plan.
e. If the Department rejects a revised Product Stewardship Plan or any other subsequently revised Plan, the City Manager may deem the Producer(s) at issue to be out of compliance with this chapter and subject to the enforcement provisions contained in this chapter.
4. At least every three (3) years, a Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall update its Product Stewardship Plan, explaining any substantive changes to components of the Plan, and submit the updated Plan to the Department for review and approval.
5. A Producer who begins to offer a Covered Drug or Sharps for sale in the City after the effective date of this chapter, must submit a Product Stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within sixty (60) days following the Producer's initial offer for sale of a Covered Drug or Sharp in the City.

6. Any proposed changes to a Product Stewardship Plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change. Notwithstanding the foregoing, for County-Approved Plans, only those changes relating to and/or applicable to the City must be submitted in writing to the Department for review and approval before implementation.
7. Required Plan Amendment. Within 60 days of the final promulgation of rules by the California Board of Pharmacy regarding collection of controlled substances by retail pharmacies in conformity with the U.S. Drug Enforcement Agency regulations implementing the Secure and Responsible Drug Disposal Act of 2010, each Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall submit to the Department for review and approval an update to its Product Stewardship Plan that describes how the Plan will, within 120 days, comply with and conform to the requirements of such final rules of the California Board of Pharmacy.
8. The Department may audit the records of a Producer, group of Producers, or Stewardship Organization related to a Product Stewardship Plan and/or Product Stewardship Program, or request that the Producer, group of Producers, or Stewardship Organization arrange for the Department to inspect at reasonable times the facilities, vehicles, and equipment used in carrying out the Product Stewardship Plan.

8.40.060 Disposal of Unwanted Products

A. Compliance with Applicable Law. Each Product Stewardship Program must comply with

all local, state, and federal laws and regulations applicable to its operations, including, but not limited to, laws, rules, and regulations governing the treatment and disposal of Unwanted Products.
B. Treatment and Disposal. Each Product Stewardship Program must treat Sharps waste by high heat sterilization and dispose of all unwanted Covered Drugs by incineration at a Medical Waste or Hazardous Waste facility authorized to accept such waste. Each treatment and/or disposal facility utilized must be in possession of all required regulatory permits and licenses.
C. New Technologies. Producers with Product Stewardship Programs may petition the Department for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current Medical Waste or Hazardous Waste disposal technologies for Sharps and Covered Drugs if and when those technologies are proven and available. The proposed technology, at a minimum, must provide equivalent protection in each, and superior protection in one or more, of the following areas:
1. Monitoring of any emissions or waste;
2. Worker health and safety;
3. Reduction or elimination of air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
4. Overall impact on the environment and human health.

D. Packaging Separation. Each Product Stewardship Program shall encourage Consumer Generators to separate Unwanted Products from their original containers and packaging, when appropriate, prior to collection or disposal.

8.40.070 Product Stewardship Program Promotion and Outreach

A. A Product Stewardship Program must promote the Program to Consumer Generators, pharmacists, Retailers of Covered Drugs and/or Sharps, and health care practitioners (including, but not limited to, doctors and other prescribers, veterinarians and veterinary hospitals) as to the proper and safe method to storage and dispose of Unwanted Products.
B. A Product Stewardship Program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials for use by Retailers of Covered Drugs and/or Sharps. These materials may include, but are not limited to, two or more of the following:
1. Signage that is prominently displayed and easily visible to the consumer.
2. Written materials and templates of materials for reproduction by Retailers to be provided to the consumer at the time of purchase or delivery, or both.
3. Advertising and/or other promotional materials related to the Product Stewardship Program.
C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in the City and disseminate the materials to health care facilities, Pharmacies, and other interested parties. The Program also must establish a website publicizing collection locations and Program operations and a toll-free telephone number that Consumer Generators can call to find nearby collection locations and understand how the Program works.

8.40.080 Retailer and Provider participation

A. Every Retailer and every Provider of Covered Drugs and Sharps in the City shall establish a system consistent with the requirements of this chapter for the collection of

consumer-generated Covered Drugs and Sharps waste for proper disposal during the Retailer's or Provider's normal hours of operation, except that:
1. A Retailer or Provider who does not sell or provide Sharps to consumers is not required to establish a collection system for Sharps waste; and
2. A Retailer or Provider who does not sell or provide Covered Drugs to consumers is not required to establish a collection system for Covered Drugs waste.
B. Each system established by a Retailer or Provider for the collection and disposal of consumer generated Covered Drugs and Sharps waste shall include, at a minimum, the following elements:
1. Subject to the limitations contained in subsection (A) of this Section above and subsection (E) of this Section below, each Retailer or Provider shall provide one of the following:

a. On-site collection system. Receptacles for the collection of consumergenerated Covered Drugs and Sharps waste within the Retailer or Provider establishment. The receptacle shall meet applicable state and federal standards for safe disposal of Covered Drugs and/or Sharps. The Retailer or Provider shall provide for the management and disposal of all consumer-generated Covered Drugs and/or Sharps waste that is collected at the Retailer or Provider establishment in a safe manner consistent with all state and federal laws and regulations; or
b. Mail-back collection system. Prepaid and preaddressed mail-back envelopes in sufficient capacity for safe disposal of the Covered Drugs and/or Sharps sold or provided to a consumer and meeting applicable state and federal standards for safe disposal of Covered Drugs and/or Sharps.
2. Signage prominently displayed within five feet of every public entrance to the Retailer or Provider establishment and easily visible to the consumer, indicating that the Retailer or Provider establishment collects consumer-generated Covered Drugs and/or Sharps waste from consumers.
C. A Retailer or Provider of Sharps must provide at no additional cost to the consumer an approved Sharps disposal container or containers sufficient to dispose of all Sharps purchased. A Retailer or Provider of Sharps may refuse to accept from a consumer Sharps waste that is not properly contained in an approved container. In the event of a refusal to accept Sharps waste, the Retailer or Provider shall provide the consumer with an appropriate container for proper disposal of said Sharps waste.
D. Sharps disposal containers shall be either a rigid puncture-resistant container with a sealable lid approved by the U.S. Food and Drug Administration for the purpose of transporting Sharps for disposal or a pre-paid mail-back container approved by the U.S. Food and Drug Administration for the purpose of transporting Sharps for disposal.
E. All costs of participation by Retailers and Providers shall be paid or reimbursed by the Producer, group of Producers, or Stewardship Organization as part of its Program as provided in this chapter. Retailers and Providers shall not be expected to incur any costs for participation in a Product Stewardship Program.

8.40.090 Lists of Producers and Manufacturers of Covered Drugs and Sharps

A. Within sixty (60) days after the effective date of this chapter (or at a later date as approved in writing by the Department), each Drug Wholesaler that sells any Covered Drugs and/or Sharps in the City must provide a list of the Producers of those Covered

Drugs and/or Sharps to the Department in a form prescribed by the Department. Drug Wholesalers must update and submit to the Department such list of Producers of Covered Drugs and/or Sharps by January 15th of each calendar year.
B. Within six (6) months after the effective date of this chapter, or within six (6) months after a Retailer whose label appears on a Covered Drug or Sharps or on the Covered Drug's or Sharps' packaging starts selling the Covered Drug or Sharps in the City (or at a later date as approved in writing by the Department), and, thereafter, upon request from the

Department, a Retailer whose label appears on a Covered Drug or Sharps or on the Covered Drug's or Sharps' packaging must provide the contact information of the Manufacturer from whom the Retailer obtains the Covered Drug or Sharps, including the mailing address, physical address, telephone number, and email address of the Retailer's point of contact at the Manufacturer.
C. Within six (6) months after the effective date of this chapter, or within six (6) months after a Covered Drug or Sharps repackaged by a Repackager is first sold in the City (or at a later date as approved in writing by the Department), and, thereafter, upon request from the Department, a Repackager whose label appears on a Covered Drug or Sharps or on the Covered Drug's or Sharps' packaging must provide the contact information of the Manufacturer from whom the Repackager obtains the Covered Drug or Sharps, including the mailing address, physical address, telephone number, and email address of the Repackager's point of contact at the Manufacturer.

8.40.100 Reporting

A. On or before July 1, 2017 (or at a later date as approved in writing by the Department) and in each subsequent year, every Producer, group of Producers, or Stewardship Organization operating a Product Stewardship Program in the City must prepare and submit to the Department an annual written report describing the Program activities during the previous reporting period. The report must include, at minimum, the following:
1. A list of Producers participating in the Product Stewardship Program;
2. A list of Retailers and/or Providers participating in the collection of consumergenerated Covered Drugs and/or Sharps waste;
3. The amount, by type and by weight, of Unwanted Products collected from Consumer Generators collected at each drop-off site and in the entire City and, if applicable, the total amount by type and by weight collected by a Mail-back Program;
4. A description of the collection system, including, without limitation, the location of each collection site and if applicable, locations where envelopes for a Mail-back Program are provided;
5. The name and location of disposal facilities at which Unwanted Products were disposed of and the weight by type of Unwanted Products collected from Consumer Generators disposed of at each facility;
6. Whether policies and procedures for collecting, handling, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;
7. Whether any safety or security problems occurred during collection, handling, transportation, or disposal of Unwanted Products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;

8. A description of public education and outreach activities implemented during the reporting period and their effectiveness, including, without limitation, the methodology used to evaluate the outreach and Program activities;
9. How the Product Stewardship Program complied with all other elements in the Product Stewardship Plan approved by the Department, including, without limitation, its degree of success in meeting any performance goals set by the Department as part of its approval of the Program; and
10. Any other information that the Department may reasonably require.
B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

8.40.110 Program Assessment and Collection of Data

A. At least once per year, at a time to be determined by the Department, each Product Stewardship Program will conduct a detailed characterization study of Unwanted Products collected at specified locations to help assess effectiveness of the Product Stewardship Program
B. Assessments shall be conducted in a secure location with proper supervision, in full compliance with federal and state laws, rules, and regulations, and in accordance with guidelines issued by the Department.
C. Data collected from Program assessments shall be shared with the Department and other relevant agencies in a timely manner.
D. The Department may require additional assessments as needed to address problems or to help determine Program needs.

8.40.120 List of Producers

The Department shall provide on its website a list of all Producers participating in Product Stewardship Programs approved by the Department and a list of all Producers the Department has identified as noncompliant with this chapter or any regulations adopted pursuant to this chapter.

8.40.130 Regulations and fees

A. The City Manager may, after a noticed Public Hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this chapter.
B. The City Council authorizes the City Manager to charge Producers or a group of Producers participating in a Product Stewardship Program for any costs the City incurs in administering and enforcing this chapter. The amount charged shall not exceed actual costs to the City.

8.40.140 Enforcement

A. The Department shall administer the penalty provisions of this chapter.

B. It shall be unlawful for any person to violate any provision or fail to comply with any of the requirements of this chapter.
C. Any Person, Producer, Plan Operator or Product Stewardship Organization that violates or continues to violate the provisions of this chapter shall be subject to the penalties, remedies, and criminal, civil and/or administrative enforcement actions set forth in Title 4 of the Capitola Municipal Code. Each and every day a violation of this chapter exists constitutes a separate and distinct offense for which enforcement action may be taken.
D. In determining the appropriate penalties, the Department shall consider the extent of

harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.
E. Whenever the City finds that a Person has violated a provision or failed to meet a requirement of this chapter, the City may order compliance by written notice of violation to the responsible Person pursuant to Chapter 4.10 of the Capitola Municipal Code.
F. The Department may establish appropriate administrative rules for implementing this chapter, conducting hearings, and rendering decisions pursuant to this section.
G. Upon the failure of any Person to comply with any requirement of this chapter and any rule or regulation adopted pursuant to this chapter, the City Attorney's office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including, without limitation, restraining such Person or Entity from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not permit the City or any court of competent jurisdiction to restrain the sale of any Covered Drug or Sharps in the City.
H. Any Person who knowingly and willfully violates the requirements of this chapter or any rule or regulation adopted pursuant to this chapter is guilty of a misdemeanor. A conviction for a misdemeanor violation under this chapter is punishable by a fine of not less than fifty dollars ($50.00) and not more than five hundred ($500.00) for each day per violation, or by imprisonment for a period not to exceed six (6) months, or by both such fine and imprisonment.
I. The remedies provided by this chapter are cumulative and in addition to any other remedies available at law or in equity.

8.40.150 Additional provisions

A. Disclaimer. In adopting and implementing this chapter, the City is assuming an undertaking only to promote the general welfare. The City is not assuming or imposing on its officers and/or employees an obligation by which they could be liable in money damages to any Person or Entity who claims that a breach proximately caused injury.
B. Conflict with State or Federal Law. This chapter shall be construed so as not to conflict with applicable federal, State, and/or Santa Cruz County laws, rules or regulations. Nothing in this chapter shall authorize any City agency or Department to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such agency or Department action is taken. The City shall

suspend enforcement of this chapter to the extent that said enforcement would conflict with any preemptive State or federal legislation subsequently adopted.
C. Severability. If any of the provisions of this chapter or the application thereof to any Person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to Persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this chapter are severable.
D. Nothing in this chapter, or the Product Stewardship Program in which Producers of Sharps and Covered Drug products who sell Sharps and/or Covered Drugs in the are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this chapter be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of California or of the United States.
E. This chapter shall be construed in accordance with California state law, including but not

limited to the Medical Waste Management Act set forth at California Health and Safety Code Section 117600, et seq., and shall not be construed in a way that would result in conflict with, or preemption by, any such state law.

F. Environmental Findings. This chapter is entitled to a categorical exemption of the California Environmental Quality Act ("CEQA") pursuant to 14 California Code of Regulations sections 15307, which exempts "actions taken by regulatory agencies, as authorized by state or local ordinance, to assure the maintenance, restoration, enhancement, or protection of the environment where the regulatory process involves procedures for protection."

G. This chapter shall be in effect for a period of ten (10) years following enactment.

SECTION II

This Ordinance shall take effect on the 31st day after the date of final passage.

This ordinance was introduced on the 25th day of August, 2016, and was passed and adopted by the City Council of the City of Capitola on the _____ day of _____, 2016, by the following vote:

AYES:
NOES:
ABSENT:
ABSTAIN:

APPROVED: _____
Ed Bottorff, Mayor

Attest:
_____, CMC
Susan Sneddon, City Clerk

10.C