Board of Commissioners of Cook County

Legislation and Intergovernmental Relations Committee

PUBLIC HEARING

Wednesday, August 3, 2016 **1:00 PM** **Cook County Building, Board Room, Rm. 569**
118 North Clark Street, Chicago, Illinois

NOTICE AND AGENDA

There will be a meeting of the Committee or Subcommittee of the Board of Commissioners of Cook County at the date, time and location listed above to consider the following:

PUBLIC TESTIMONY

Authorization as a public speaker shall only be granted to those individuals who have submitted in writing, their name, address, subject matter, and organization (if any) to the Secretary 24 hours in advance of the meeting. Duly authorized public speakers shall be called upon to deliver testimony at a time specified in the meeting agenda. Authorized public speakers who are not present during the specified time for public testimony will forfeit their allotted time to speak at the meeting. Public testimony must be germane to a specific item(s) on the meeting agenda, and the testimony must not exceed three minutes; the Secretary will keep track of the time and advise when the time for public testimony has expired. Persons authorized to provide public testimony shall not use vulgar, abusive, or otherwise inappropriate language when addressing the Board; failure to act appropriately; failure to speak to an item that is germane to the meeting, or failure to adhere to the time requirements may result in expulsion from the meeting and/or disqualify the person from providing future testimony.

16-1983

Sponsored by: LARRY SUFFREDIN, LUIS ARROYO JR, RICHARD R. BOYKIN, JOHN P. DALEY, BRIDGET GAINER and PETER N. SILVESTRI, County Commissioners

PROPOSED ORDINANCE

AN ORDINANCE GOVERNING THE SAFE DISPOSAL OF PHARMACEUTICALS

WHEREAS, Cook County is a home rule unit of government pursuant to the 1970 Illinois Constitution, Article VII, Section 6(a); and

WHEREAS, pursuant to its home rule power, Cook County may exercise any power and perform any function relating to its government and affairs including the power to regulate for the protection of the public health, safety, morals, and welfare; and

WHEREAS, the health and welfare of the residents of Cook County, particularly children and the elderly, would be greatly improved and advanced by the proper disposal of unwanted, expired or unneeded prescription drugs; and

WHEREAS, there is a significant risk of poisoning, in particular to children and the elderly, due to the

improper or careless disposal of prescription drugs and the illegal re-sale of prescription drugs; and

WHEREAS, the groundwater and drinking water of Cook County is being contaminated by improperly disposed of prescription drugs passing through our wastewater and treatment centers; and

WHEREAS, the United States Supreme Court has held that waste disposal is traditionally a function of local government; and

WHEREAS, the first pharmaceutical disposal ordinance was enacted by Alameda County, California in 2012; and

WHEREAS, since Alameda County's enactment, other counties have enacted or introducing ordinances regulating the disposal of pharmaceuticals, including Los Angeles, Marin, Santa Barbara, Santa Clara, Santa Cruz, San Francisco, and San Mateo Counties in California and King County, Washington; and

WHEREAS, the Alameda County ordinance was upheld in the United States District Court for the Northern District of California in Pharmaceutical Research and Manufacturers of America, *et. al v. Alameda County, et. al.*, No. 3:12-cv-06203 (N.D. Cal., Aug. 28, 2013) and in the United States Court of Appeals for the Ninth Circuit in Pharmaceutical Research and Manufacturers of America, *et. al v. Alameda County, et. al.*, No. 3:12-cv-06203 (9th Circuit, September 30, 2014). The United States Supreme Court declined to hear the case; and

WHEREAS, in an opinion by Judge N.R. Smith, the Ninth Circuit held that the ordinance did not burden interstate commerce, given that the Ordinance did not affect the interstate flow of goods; and

WHEREAS, the ordinance was found to not discriminate in favor of in-County competitors, as in both on its face and in effect, it applied to all manufacturers that make their drugs available in Alameda County-without respect to the geographic location of the manufacturer; and

WHEREAS, the ordinance did not impose different requirements on Producers within California and Producers outside of California; and

WHEREAS, the ordinance did not act like a tariff and there was no evidence that the Ordinance will interrupt, or even decrease, the "flow of goods" into or out of Alameda County; and

WHEREAS, the ordinance had de minimis costs as compared with the health, safety and environmental benefits; and

NOW, THEREFORE, BE IT ORDAINED, the above recitals are expressly incorporated herein and made part hereof as though fully set forth herein.

BE IT FURTHUR ORDAINED, by the Cook County Board of Commissioners that Chapter 46 Law Enforcement, Article II, Sheriff, Division 5, Pharmaceutical Disposal Program, Sections 46-102 - 46-121 is hereby enacted as follows:

Sec. 46-102 - Definitions.

For the purposes of this Division, the following definitions apply:

Board means the Board of Commissioners of Cook County, Illinois.

County means Cook County, Illinois.

County residents mean human beings residing in the County.

Collector means a Person approved by the Director to gather Unwanted Covered Drugs from County residents for the purpose of collection, transportation, and disposal.

Covered Drug means a Drug in any form used by County residents, including prescription, nonprescription, brand name and generic drugs. Notwithstanding the previous sentence, "Covered Drug" does not include:

(1) vitamins or supplements;

(2) herbal-based remedies and homeopathic drugs, products, or remedies;

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

(4) Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration-managed risk evaluation and mitigation strategy (21 U.S.C. § 355-1);

(5) Drugs that are biological products as defined by 21 C.F.R. § 600.3(h) as it exists on the effective date of this Division if the Producer already provides a pharmaceutical product stewardship or take-back program; and (6) medical devices or their component parts or accessories.

Director means the Director of the Prescription Drug Take Back Program of the Cook County Sheriff's Office, or a duly authorized representative.

District means the districts of Cook County as defined in Article II, Section 22-34 of the Code of Ordinances of Cook County, Illinois.

Drug Wholesaler means a Person who buys Drugs for resale and distribution to corporations, individuals, or entities other than consumers.

Drug means:

(1) any article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States or any supplement of the formulary or those pharmacopoeias as published by the U.S. Pharmacopeial Convention and the Homeopathic Pharmacopoeia Convention of the United States;

(2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) any substance, other than food, intended to affect the structure or any function of the body of humans or other animals; or

(4) any substance intended for use as a component of any substance specified in (1), (2), or (3) of this definition.

Manufacture means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a Repackager or Drug Wholesaler, or practitioner who, distributes or dispenses such substance or device in the course of his or her professional practice or, prepares, compounds, packages, or labels such substance or device.

Manufacturer means a Person engaged in the Manufacture of Drugs.

Mail-back services means a collection method for the return of Unwanted Covered Drugs from County residents utilizing pre-paid and pre-addressed mailing envelopes.

Nonprescription Drug means a Drug that may be lawfully sold without a prescription.

Person means any individual, corporation, limited liability corporation, organization, government, governmental subdivision or agency, business trust, estate, trust, partnership, association and any other legal entity.

Pharmacy means a place licensed by the state of Illinois Department of Financial and Professional Regulation engaged in the practice of "Pharmacy," as defined by the Illinois Pharmacy Practice Act, 225 ILCS 85/1 *et. seq.* is conducted.

Prescription Drug means any Drug, including any controlled substance, that is required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.

Producer means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County, including a brand-name or generic Drug. Notwithstanding the previous sentence,

Producer does not include:

(1) a retailer whose store label appears on a Covered Drug or the drug's packaging if the Manufacturer from whom the retailer obtains the drug is identified under Sec. 46-103(d) of this Division;

(2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Sec. 46-103(d) of this Division;

(3) a pharmacist who compounds or repackages a prescribed individual drug product for a consumer; or

(4) a wholesaler who is not also the Manufacturer.

Repackager means a person who owns or operates an establishment that repacks and relabels a product or package for further sale, or for distribution without a further transaction.

Sheriff means the Office of the Cook County Sheriff.

Stewardship Plan means a plan for the collection, transportation and disposal of Unwanted Covered Drugs required under Sec. 46-104 of this Division that is:

(1) financed, developed, implemented and participated in by one or more Producers;

(2) operated by the participating Producers or a Stewardship Organization; and

(3) approved by the Director.

Stewardship Organization means an organization designated by a Producer or group of Producers to act as an agent on behalf of one or more Producers to develop and implement and operate a Stewardship Plan.

Unwanted Covered Drug means any Covered Drug that the owner has discarded or intends to discard.

Sec. 46-103 - Stewardship Plans - Participation.

(a) Each Producer shall participate in a Stewardship Plan. Each Producer must:

(1) operate, individually or jointly with other Producers, a Stewardship Plan approved by the Director; or

(2) enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Stewardship Plan approved by the Director; or

(3) enter into an agreement with the Director to operate, on the Producer's behalf, a Stewardship Plan approved by the Director.

(b) Each Stewardship Plan must be approved by the Director before the entity administering the plan starts collecting Unwanted Covered Drugs. Once approved, each Stewardship Plan must have prior written approval of the Director for proposed changes as described under Sec. 46-102.

(c) By six months after the effective date of this Division, or by six months after a Produce starts sale of a Covered Drug in the County, a Producer must notify the Director in writing of the Producer's intent to participate in a Stewardship Plan, or to form a new Stewardship Plan.

(d) By six months after the effective date of this Division, or by six months after a retailer whose label appears on a Covered Drug or the Covered Drug's packaging starts selling the Covered Drug in the County, or by six months after a Covered Drug repackaged by Repackager is first sold in the County, and, thereafter, upon request from the Director, a retailer or Repackager whose label appears on a Covered Drug or the Covered Drug's packaging must provide:

(1) written notification as to whether the Manufacturer from whom the retailer or Repackager obtains the Covered Drug has provided its notice of intent to participate; and

(2) the contact information of the Manufacturer from whom the retailer or Repackager obtains the Covered Drug, including the telephone number, mailing address and email address of the retailer's or Repackager's point of contact at the Manufacturer.

(e) A Producer, either individually or jointly with other Producers, shall:

(1) By nine months after the effective date of this Division, or nine months after starting sale of a Covered Drug in the County, identify in writing to the Director a Stewardship Plan operator, including the operator's telephone, mailing address and email contact information, that is authorized to be the official point of contact for the Stewardship Plan;

(2) By nine months after the effective date of this Division, or nine months after starting sale of a Covered Drug in the County, notify all Pharmacies and law enforcement agencies in the County of the opportunity to participate as a drop-off site in accordance with Sec. 46-105 of this Division and provide a process for forming an agreement between the Stewardship Plan and interested Collectors; and annually thereafter, make the same notification to any nonparticipating or new Pharmacies in the County;

(3) By one year after the effective date of this Division, or one year after starting sale of a Covered Drug in the County, submit a proposed Stewardship Plan as described in Sec. 46-104 to the Director for review;

(4) Within three months after the Director's approval of the Stewardship Plan, operate or participate in the Stewardship Plan in accordance with this Division;

(5) At least every four years after the Stewardship Plan starts operations, submit an updated Stewardship Plan to the Director explaining any substantive changes to components of the Stewardship Plan required in Sec. 46-104. The updated Stewardship Plan shall be accompanied by the plan review fee in accordance with Section 46-115 of this Division. The Director shall review updated Stewardship Plans using the process described in Sec. 46-111 of this Division; and

(6) Pay all administrative and operational costs and fees associated with its Stewardship Plan.

(f) A Producer, either individually or jointly with other Producers, may:

(1) Enter into contracts and agreements with Stewardship Organizations, other service providers, or other entities as necessary, useful or convenient to carry out all or portion of their Stewardship Plan;

(2) Notify the Director of any Producer selling Covered Drugs Manufactured by that Producer or group of Producers in the County that is failing to participate in a Stewardship Plan; and

(3) Perform any other functions as may be necessary or proper to carry out the Stewardship Plan and to fulfill any or all of the purposes for which the plan is organized.

(g) After the first full year of participation in a Stewardship Plan, a Producer or group of Producers may notify the Director in writing of intent to form a new Stewardship Plan, and identify a plan operator, including the plan operator's telephone, mailing address, and email contact information, that is authorized to be the official point of contact for the proposed new Stewardship Plan. Within three months of such notification, the Producer or group of Producers shall submit a proposed Stewardship Plan as described under Sec. 46-104 to the Director for review.

(h) The Director may, on a case-by-case basis, approve in writing requests for extensions of time for the submission dates and deadlines in this Sec. 46-103.

(i) The Director may audit the records of a Producer, group of Producers, or Stewardship Organization related to a Stewardship Plan or request that the Producer, group of Producers, or Stewardship Organization arrange for the Director to inspect at reasonable times a Stewardship Plan's or a Collector's facilities, vehicles, and equipment used in carrying out the Stewardship Plan.

Sec. 46-104 - Stewardship Plans - Components.

Each Stewardship Plan, which must be submitted and reviewed according to Sec. 46-111, shall include:

(a) Contact information for all Producers participating in the Stewardship Plan, including each Drug Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Director may direct all inquiries regarding the Producer's participation in the Stewardship Plan;

(b) A description of the proposed collection system to provide convenient ongoing collection service for all Unwanted Covered Drugs from County residents in compliance with the provisions and requirements in Sec. 46-105, including a list of all collection methods and participating Collectors, a list of drop-off sites, a description of how any periodic collection events will be scheduled and located, a description of how any mail-back services will be provided and an example of the prepaid, preaddressed mailers the plan will use. The description of the collection service shall include a list of Retail Pharmacies and law enforcement agencies contacted by the plan under Sec. 46-103 (e)(2) of this Division, and a list of all Collectors who offered to participate;

(c) A description of the handling and disposal system, including identification of and contact information for Collectors, transporters and waste disposal facilities to be used by the Stewardship Plan in accordance with Sec. 46-105 and Sec. 46-107 of this Division;

(d) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Stewardship Plan, including a description of how all Collectors, transporters and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Drug Enforcement Administration, and how any Pharmacy collection site will operate under applicable rules and guidelines of the Safe Pharmaceutical Disposal Act of Illinois, 210 ILCS 150/1, *et. seq*.

(e) A certification that any patient information on Drug packaging will be promptly destroyed;

(f) A description of the public education effort and promotion strategy required in Sec. 46-106 of this Division, including a copy of standardized instructions for County residents, signage developed for Collectors, and required promotional materials;

(g) Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education and promotion; and

(h) A description of how the Stewardship Plan will consider:

(1) use of existing providers of waste pharmaceutical services;

(2) separating Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and

(3) recycling of Drug packaging to the extent feasible.

Sec. 46-105 - Stewardship Plans - Collection of Covered Drugs.

(a) This Section does not require any Person to serve as a Collector in a Stewardship Plan. A Person may offer to serve as a Collector voluntarily, or may agree to serve as a Collector in exchange for incentives or payment offered by a Producer, group of Producers or Stewardship Organization. Collectors may include law enforcement agencies, Pharmacies, mail-back services or other entities, operating in accordance with state and federal laws and regulations for the handling of Covered Drugs, including but

not limited to those of the United States Drug Enforcement Administration, and in compliance with this Division. A Pharmacy collection site shall operate under applicable rules and guidelines of the Safe Pharmaceutical Disposal Act of Illinois, 210 ILCS 150/1, *et. seq*.

(b) The collection system for each Stewardship Plan shall:

(1) Provide reasonably convenient and equitable access for County residents in all Districts through drop-off sites. The system of drop-off sites shall provide at least one drop-off site for every 20,000 County residents in each District, located in every city, town or unincorporated area, geographically distributed to provide reasonably convenient and equitable access, but at no time shall there be less than five drop-offsites per District. If the service convenience goal in this subsection (b)(1) cannot be achieved due to a lack of drop-off sites at pharmacies, law enforcement agencies, or other qualified Collectors in each District, then those areas shall be served through periodic collection events and/or or mail-back services. The system of drop-off sites shall provide in every city, town, or unincorporated community service area with a pharmacy or law enforcement facility, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents, geographically distributed to provide reasonably convenient and equitable access.

(2) Be safe and secure, including providing for the prompt destruction of patient information on Drug packaging.

(3) Give preference to having Retail Pharmacies and law enforcement agencies serve as drop-off sites.

(4) Include, as Collectors, any Pharmacy or any law enforcement agency willing to serve voluntarily as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Division within three months of their offer to participate, unless the Collector requests a longer time frame. A Stewardship Plan may also accept other Collectors willing to serve as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Division; and

(5) Make mail-back services available, free of charge, to disabled and homebound County residents upon request through the Stewardship Plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to Persons providing services to such County residents. The toll-free telephone number and web site required by this subsection (b)(5) shall be in English, Spanish, Polish, Chinese, Korean, and Russian.

(c) In addition to the collection system described in subsection (b)(1), all stewardships plans shall jointly operate a drop-off site within each County-owned pharmacy.

(d) Drop-off sites shall accept all Covered Drugs from County residents during all hours that the Pharmacy, law enforcement agency, or other Collector is normally open for business with the public. Drop-off sites not operated by a law enforcement agency shall utilize secure collection bins in compliance with all applicable requirements, including but not limited to those of the United States Drug Enforcement Administration and the Safe Pharmaceutical Disposal Act of Illinois, 210 ILCS 150/1, *et. seq*. In the event that more than one Stewardship Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.

Sec. 46-106 - Stewardship Plans - Promotion.

(a) All Stewardship Plans shall coordinate with each other and develop a single system of promotion that shall:

(1) Promote the Stewardship Plans so that collection options for Covered Drugs are widely understood by County residents, pharmacists, retailers of Covered Drugs and health care practitioners including

doctors and other prescribers, veterinarians and veterinary hospitals, and promote the safe storage of Covered Drugs by County residents;

(2) Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions for County residents on the use of collection bins and a readily-recognizable, consistent design of collection bins;

(2) Establish a single toll-free telephone number and single web site where collection options and current locations of drop-off sites will be publicized, and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drugs to the Stewardship Plan. These materials must be provided to Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County residents. Plain language and explanatory images should be used to make use of medicine collection services readily understandable by all County residents, including individuals with limited English proficiency;

(4) Conduct a biennial survey of County residents and a survey of pharmacists, veterinarians, and health professionals in the County who interact with patients on use of medicines after the first full year of operation of the plans. Survey questions shall measure percent awareness of the Stewardship Plans, assess to what extent drop-off sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Draft survey questions shall be submitted to the Director for review and comment at least 30 days prior to initiation of the survey. Results of the survey shall be reported to the Director and made available to the public on the website required in this Sec. 46-106 within 90 days of the end of the survey period. The privacy of all survey respondents shall be maintained.

(b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 16-106 shall be in English, Spanish, Polish, Chinese, Korean, and Russian.

(c) The Director shall provide guidance on the development of a single system of promotion.

Sec. 46-107 - Stewardship Plans - Disposal of Covered Drugs.

(a) Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 264 and 265.

(b) The Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if the Director deems the use of a hazardous waste disposal facility described under subsection (a) of this Sec. 46-107 to be infeasible for the Stewardship Plan based on cost, ogistics or other considerations.

(c) A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections (a) and (b) of this Section 6 or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each 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.

Sec. 46-108 - Stewardship Plans - Administrative and Operational Costs and Fees.

(a) A Producer or group of Producers participating in a Stewardship Plan shall pay all administrative and operational costs related to their Stewardship Plan, except as provided under this Sec. 46-108. Administrative and operational costs related to the Stewardship Plan include but are not limited to the following:

(1) Collection and transportation supplies for each drop-off site;

(2) Acquisition of all secure collection bins for drop-off sites;

(3) Ongoing maintenance or replacement of secure collection bins, as requested by Collectors;

(4) Prepaid, preaddressed mailers provided to disabled and/or home-bound County residents;

(5) Operation of periodic collection events, including costs of law enforcement staff time if necessary;

(6) Transportation of all collected Covered Drugs to final disposal, including costs of law enforcement escort if necessary;

(7) Environmentally sound disposal of all collected Covered Drugs under Sec. 46-107 of this Division;

(8) Program promotion under Sec. 46-106 of this Division; and

(b) No Person or Producer may charge a 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.

(c) Producers are not required to pay for costs of staff time at drop-off sites provided by Collectors volunteering to participate in a Stewardship Plan.

Sec. 46-109 - Stewardship Plans - Reporting Requirements.

(a) Within six months after the end of the first 12-month period of operation, and annually thereafter, the plan operator of a Stewardship Plan shall submit a report to the Director on behalf of participating Producers describing their plan’s activities during the previous reporting period. The report must include:

(1) A list of Producers participating in the Stewardship Plan;

(2) The amount, by weight, of Covered Drugs collected, including the amount by weight from each collection method used;

(3) A list of drop-off sites;

(4) The number of mailers provided for disabled and/or home-bound County residents;

(5) The locations where mailers were provided, if applicable;

(6) The dates and locations of collection events held, if applicable;

(7) The transporters used and the disposal facility or facilities used for all Covered drugs;

(8) Whether any safety or security problems 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 alleviate the problem and to improve safety and security in the future;

(9) A description of the public education, outreach and evaluation activities implemented during the reporting period;

(10) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;

(11) A summary of the Stewardship Plan's goals, 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

(12) The total expenditures of the Stewardship Plan during the reporting period.

(b) The Director shall make reports submitted under this Section available to the public.

(c) For the purposes of this Sec. 46-109, "reporting period" means the period from January 1 through December 31 of the same calendar year, unless otherwise specified to the plan operator by the Director.

Sec. 46-110 - Stewardship Plans - List Of Producers of Covered Drugs.

Beginning 60 days after the effective date of this Division, each Drug Wholesaler that sells any Covered Drug in the County must provide a list of the Producers of those Covered Drugs to the Director in a form prescribed by the Director. Wholesalers must update and resubmit the list by January 15 each year.

Sec. 46-111 - Stewardship Plans - Review Of Proposed Plans.

(a) By one year after the effective date of this Division, or one year after starting sale of a Covered Drug in the County, each Producer, group of Producers or Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review, accompanied by the plan review fee in accordance with Sec. 46-115 of this Division. The Director may upon request provide information, counseling, and technical assistance about the requirements of this Division to assist with the development of a proposed Stewardship Plan.

(b) The Director shall review the proposed Stewardship Plan and determine whether it meets the requirements of this Division. In reviewing a proposed Stewardship Plan, the Director shall provide an opportunity for written public comment on the proposed Stewardship Plan and consider any comments received.

(c) After the review under subsection (b) of this Sec. 46-111 and within 90 days after receipt of the proposed Stewardship Plan, the Director shall either approve or reject the proposed Stewardship Plan in writing and, if rejected, provide reasons for the rejection.

(d) If the Director rejects a proposed Stewardship Plan, a Producer, group of Producers, or Stewardship Organization must submit a revised Stewardship Plan to the Director within 60 days after receiving written notice of the rejection. The Director shall review and approve or reject a revised Stewardship Plan

as provided under subsections (b) and (c) of this Sec. 46-111.

(e) If the Director rejects a revised Stewardship Plan, or any subsequently revised plan, the Director may deem the Producer or group of Producers out of compliance with this Division and subject to the enforcement provisions in this Division.

(f) In approving a proposed Stewardship Plan, the Director may exercise reasonable discretion to waive strict compliance with the requirements of this Division that apply to Producers in order to achieve the objectives of this Division.

(g) The Director shall make all Stewardship Plans and proposed plans submitted under this Section 46-111 available to the public.

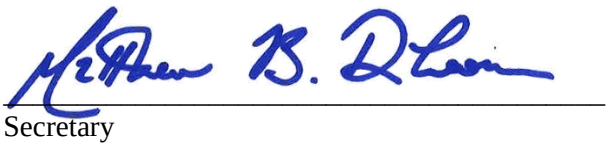
Sec. 46-112 - Stewardship Plans - Prior Approval for Change.

(a) Proposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to, changes to participating Manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities, must be approved in writing by the Director before the changes are implemented.

(b) A Producer or group of Producers or Stewardship Organization participating in an approved Stewardship Plan shall submit proposed changes to an approved Stewardship Plan within six months upon notice from the Director of a change to the population of a District as described in Sec. 46-105 (b)(1).

(c) A Producer or group of Producers or Stewardship Organization participating in a Stewardship Plan shall submit to the Director any proposed change to a Stewardship

Legislative History: 3/2/16 Board of Commissioners referred to the Legislation and Intergovernmental Relations Committee



Secretary

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Members:	Committee of the Whole