



Board of Commissioners of Cook County

Legislation Details (With Text)

File #: 16-1983 Version: 3 Name: AN ORDINANCE GOVERNING THE SAFE

DISPOSAL OF PHARMACEUTICALS

Type: Ordinance Status: Approved

File created: 3/1/2016 In control: Legislation and Intergovernmental Relations

Committee

On agenda: 3/2/2016 Final action: 10/26/2016

Title: PROPOSED SUBSTITUTE ORDINANCE

AN ORDINANCE GOVERNING THE SAFE DISPOSAL OF PHARMACEUTICALS

NOW, THEREFORE, BE IT ORDAINED, by the Cook County Board of Commissioners that Chapter 46 Law Enforcement, Article II, Sheriff, Division 4, Pharmaceutical Disposal Program, Sections 46-101 - 46 119 is hereby enacted as follows:

Sec. 46-101 -Short Title.

This Division shall be known and may be cited as the Cook County Safe Disposal of Pharmaceuticals Ordinance.

Sec. 46-102 - Definitions.

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

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

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

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 sold, offered for sale or distribution in Cook County in pill, capsule, solid dosage, tablet, suppository, bolus, lozenge, implant, strip, powder and/or pellet 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 collection 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 collection or take-back

program;

- (6) medical devices or their component parts or accessories; and
- (7) Drugs that are in a cream, elixir, spirit, tincture, syrup, solution, lotion, emulsion, topical, transdermal, aerosol, propellant, valve, actuator, injectable, infusion, irrigation, ointment, suspension, liquid and/or paste form.

The definition of Covered Drug shall be inclusive and determined by guidelines issued by the Director with the advice of the Pharmaceutical Disposal Advisory Committee established in Section 46-115.

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 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. Pharmacopoeial 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.

Drug Wholesaler means a Person that sells or distributes Drugs and Covered Drugs for resale to an Entity other than a consumer.

Generic Drug 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.

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.

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.

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. Notwithstanding the previous sentence, Pharmacy does not

include a Pharmacy dispensing pharmaceuticals exclusively pursuant to an "Inpatient Drug Order" as defined by the Illinois Pharmacy Practice Act, 225 ILCS 85/3 (k).

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. 46-104(c) of this Division;
- (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Sec. 46-104(c) 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.

Registration is the informing of the Director of the distribution of Covered Drugs by a Producer in a manner set forth by the Director.

Registration Fee is a sum paid by a Producer to cover the cost of the Collection Plan for the protection of the public safety, health and environment.

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.

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

Sec. 46-103 - Implementation of this Division.

- (a) The Director shall:
- (1) Develop a Collection Plan that is in compliance with this Division, including determining whether a Drug is a Covered Drug as established in accordance with Section Sec. 46-102; and
- (2) Determine the method of collection of Unwanted Covered Drugs as specified under this Division; and
- (3) Determine the total cost of the collection of Unwanted Covered Drugs as specified under this Division.
- (b) Producers shall:
- (1) Within 90 days of the passage of this Division register with the Director, in a form mandated by the Director; and

(2) Pay all registration fees mandated by Section 32-1 of the Cook County Code.

Sec. 46-104 - Collection Plan - Participation.

- (a) Each Producer shall participate in the Collection Plan and pay a Registration Fee.
- (b) By three months after the effective date of this Division, or by three months after a Producer starts sale of a Covered Drug in the County, a Producer must register with the Director in writing of the Producer's intent to participate in the Collection Plan. Within 60 days of a Producer's Registration, the Director shall meet with the Producer in order to formulate a plan to ensure the Producer's compliance with this Division.
- (c) By three months after the effective date of this Division, or by three 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 three 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 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.
- (d) 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. 46-104.
- (e) The Director may audit the records of a Producer.

Sec. 46-105 - Collection Plan - Components.

The Director shall take all appropriate actions to design, oversee, manage and implement the Collection Plan. The Collection Plan shall include:

- (a) Contact information for all Producers participating in the Collection 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 Collection 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. 46-106, 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. 46-106 (b) 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 Collection Plan in accordance with Sec. 46-106 and Sec. 46-108 of this Division;
- (d) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Collection 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 Collection 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 description of a plan for the removal of any patient information on Drug packaging;
- (f) A description of the public education effort and promotion strategy required in Sec. 46-107 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 Collection Plan for collection amounts, education and promotion; and
- (h) A description of how the Collection 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. 46-106 - Collection Plan - Collection of Covered Drugs.

- (a) This Section does not require any Person to serve as a Collector in the Collection 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 the Director. 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 under the Collection 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 150,000 County residents in each District, distributed to provide reasonably convenient and equitable access, but at no time shall there be less than five drop-off sites 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.
- (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 Collection 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) At the Director's discretion, make mail-back services available, free of charge, to disabled and homebound County residents upon request through the Collection Plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to Persons providing services to such County residents. If implemented by the Director, the toll-free telephone number and web site required by this subsection (b)(5) shall be in English, Spanish, Polish, Chinese, Korean, Arabic and Russian.

(c) 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 the Collection Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.

Sec. 46-107 - Collection Plan - Promotion.

- (a) The Director may coordinate with each Producer and develop a single system of promotion. The Director may coordinate with each Producer, or its representative, to secure its participation in the single system of promotion. The system of promotion shall:
- (1) Promote the Collection Plan 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) Coordinate with Producers to include promotion of the Collection Plan on the Producers' marketing and packaging materials and devices.
- (3) Work with Collectors participating in the Collection Plan to develop clear, standardized instructions for County residents on the use of collection bins and a readily-recognizable, consistent design of collection bins.
- (4) 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 Collection 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.
- (5) 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 Sec. 46-107 within 90 days of the end of the survey period. The privacy of all survey respondents shall be maintained.
- (6) Work with the Illinois Poison Center to advertise drop-off sites and other collection opportunities under the Collection Plan.
- (b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 16-107 shall be in English, Spanish, Polish, Chinese, Korean, Arabic and Russian.
- (1) The Director shall provide guidance on the development of a single system of promotion.

Sec. 46-108 - Collection Plan - Disposal of Covered Drugs.

(a) Covered Drugs collected under the Collection 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 and/or pursuant to a method permitted by the United States Drug Enforcement Administration under 21 C.F.R. part 1317.95.

- (b) The Director may grant approval under the Collection 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. 46-108 to be infeasible for the Plan based on cost, logistics or other considerations.
- (c) The Director may 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 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. 46-109 -Collection Plan - Administrative and Operational Costs and Fees.

A Producer participating in the Collection Plan shall pay to the Cook County Department of Revenue an annual registration fee as established under Section 32-1 of the Cook County Code. The Fee shall be set to recover, but not exceed, actual costs to the County of the registration and implementation of the Collection Plan at a rate duly approved by the Board. When setting the annual registration fee, the Board may consider the following:

- (1) Collection and transportation supplies for drop-off sites;
- (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. 46-108 of this Division:
- (8) Creation, promotion and advertisement of the Collection Program;
- (9) Creation, maintenance and operation of the single toll-free telephone number and single web site as established in Section 46-107.

No Person or Producer may charge a point-of-sale fee to consumers or increase the cost of a Covered Drug to recoup the costs of the Collection Plan, nor may they charge a specific point-of-collection fee at the time the Covered Drugs or increase the cost of a Covered Drug are collected. The Department of Revenue shall establish reasonable procedures for the collection of the annual registration fee, including procedures for appealing the amount of the fee and enforcement actions for nonpayment. All appeals and enforcement actions shall be conducted in accordance with Article IX - Administrative Hearings of the Cook County Code.

All Registration Fees shall be shall deposited into the Pharmaceutical Disposal Program Special Fund, pursuant to Section 46-110 of the Cook County Code.

Sec. 46-110 - Pharmaceutical Disposal Fund.

The Comptroller shall create a special fund to be known as the "Pharmaceutical Disposal Fund" which shall be subject to budget and appropriation for purposes related to the funding of the Collection Plan. The Department of Revenue shall collect, account for and transfer any remittals pursuant to Section 46-109 of the Cook County Code into such Fund. The Comptroller shall distribute monies from the Fund after appropriation by the Cook County Board of Commissioners for the purpose of funding the Collection Plan.

Sec. 46-111 - Collection Plan - Reporting Requirements.

- (a) Within six months after the end of the first 12-month period of operation and annually thereafter, the Director and the Pharmaceutical Disposal Advisory Committee established in Section 46-115 shall submit a report to the Board 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 Collection Plan;
- (2) The amount, by weight, of Covered Drugs collected, including the amount by weight from each collection method used;
- (3) the number and types of Pharmaceuticals being disposed of in the Collection Plan;
- (4) the total cost of the provision of services of the Collection Plan;
- (5) the total amount of fees collected from participating Producers;
- (6) a list of the number, site and type of collection sites established and to be established;
- (7) The number of mailers provided for disabled and/or home-bound County residents;
- (8) The locations where mailers were provided, if applicable;
- (9) The dates and locations of collection events held, if applicable;
- (10) The transporters used and the disposal facility or facilities used for all Covered drugs;
- (11) 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;
- (12) A description of the public education, outreach and evaluation activities implemented during the reporting period;
- (13) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- (14) A summary of the Collection 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
- (15) The total expenditures of the Collection Plan during the reporting period.

- (16) The report may also include 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.
- (b) The Director shall make reports submitted under this Section available to the public.
- (c) For the purposes of this Sec. 46-111, "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. 46-112- Change of Collection Plan

The Director may change the Collection Plan or substantively alter plan operations, including, but not limited to, changes to participating Manufacturers, collection methods, policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities. The Director must provide timely notice to all Producers before changing the Collection Plan.

Sec. 46-113 - Collection Plan - Enforcement and Penalties.

- (a) The Director shall administer the penalty provisions of this Division.
- (b) If the Director makes findings and determines that any Person has violated this Division or a regulation adopted pursuant to this Division, the Director shall send a written warning, as well as a copy of this Division and any regulations adopted pursuant to this Division, to the Person or Persons who violated it. The Person or Persons shall have 30 days after receipt of the warning to come into compliance and correct all violations.
- (c) If the Person or Persons fail to come into compliance or correct all violations, the Director may impose administrative fines for violations of this Division or of any regulation adopted pursuant to this Division.
- (1) Upon findings made under subsection (b), the Person or Persons shall be subject to an administrative fine as follows:
- a. A fine not exceeding one hundred dollars (\$100.00) for a first violation;
- b. A fine not exceeding two hundred dollars (\$200.00) for a second violation;
- c. A fine not exceeding five hundred dollars (\$500.00) for the third violation and each subsequent violation.
- (2) Each day a violation continues constitutes a separate violation.
- (3) Fine Procedures. Notice of the fine shall be served on the Person or Persons. The notice shall contain an advisement of the right to request a hearing in the Cook County Department of Administrative Hearings. Hearings on violations shall be conducted in accordance with Article IX. Administrative Hearings of the Cook County Code of Ordinances. Payments for fines shall be deposited into the Pharmaceutical Disposal Fund established pursuant to Section 46-110.
- (4) Failure to Pay Fine. If said fine is not paid within 30 days from the date appearing on the notice of the fine or of the notice of determination of the Director or his or her designee after the hearing, the Director may use any lawful means for collecting the fine, including instituting an action in any court of proper jurisdiction.
- (d) The Director may bring a civil action to enjoin violations of or compel compliance with any requirement of this Division or any rule or regulation adopted pursuant to this Division, as well as for

payment of civil penalties and any other appropriate remedy.

- (e) Any Person who knowingly and willfully violates the requirements of this Division or any rule or regulation adopted pursuant to this Division is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500) for each day per violation.
- (f) In determining the appropriate penalties, the court or the Director 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.
- (g) No civil or administrative action under this Sec. 46-113 may be brought more than four years after the date of the alleged violation.

Sec. 46-114 -Collection Plan - Rules and Performance Standards

- (a) The Director, may adopt rules and regulations as necessary to implement, administer, and enforce this Division.
- (b) The Director may work with the Producers and/or the Pharmaceutical Disposal Advisory Committee as established in Section 46-115 to define goals for collection amounts, education, and promotion of the Collection Plan.

Sec. 46-115- Pharmaceutical Disposal Advisory Committee

- (a) There shall be created a Pharmaceutical Disposal Advisory Committee made up of the President of the Cook County Board of Commissioners or his or her designee and five other members appointed by the President. Members of the Advisory Committee shall include:
- (1) The President, or his or her designee; and
- (2) One member of the Cook County Board of Commissioners; and
- (3) The Sheriff, or his or her designee; and
- (4) The Director of the Cook County Department of Environmental Control, or his or her designee; and
- (5) The Chief Operating Officer of the Cook County Department of Public Health, or his or her designee; and
- (6) A member of the Board of Commissioners of the Metropolitan Water Reclamation District of Greater Chicago, to be appointed by the President of the Board of Commissioners of the Metropolitan Water Reclamation District of Great Chicago.
- (b) The Sheriff, or his or her designee, shall serve as the Chairman of the Advisory Committee. The Director shall serve as an ex officio member. The members of the Committee shall serve without pay.
- (c)The purpose of the Advisory Committee is to oversee, advise and assist with the promotion and implementation of this Division. The Advisory Committee may formulate recommendations to bring about improvement in this regard.
- (d)The members of the Advisory Committee shall meet quarterly or as designated by the Chairman.
- (e)The Advisory Committee with the assistance of the Director shall prepare an annual report describing the work undertaken by the program pursuant to Section 46-111. The report shall include minutes of meetings of the Advisory Committee over the past year, a description of the types of

programs that have been implemented or outsourced and the total cost of the Stewardship Program.

Sec. 46-116 - Undertaking For the General Welfare.

In adopting and implementing this Division, the County is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any Person who claims that such breach proximately caused injury.

Sec. 46-117- No Conflict with Federal or State Law.

This Division shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. Nothing in this Division shall authorize any County agency or department to impose any duties or obligations in conflict with limitations on authority established by State or federal law at the time such agency or department action is taken. The County shall suspend enforcement of this Division to the extent that said enforcement would conflict with any preemptive State or federal legislation subsequently adopted. Nothing in this Division is intended or shall be construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair competition laws of the State of Illinois or the Unites States.

Sec. 46-118 - Severability.

If any of the provisions of this Division 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 Division are severable.

Sec. 46-119 - Applicability.

Without limitation, this section applies to areas of unincorporated Cook County, to areas owned or operated by Special Districts within unincorporated Cook County, and to areas within municipalities within the County which have not adopted ordinances governing the operation of pharmaceutical stewardship plans within the said municipalities. To the extent a municipality has adopted an ordinance addressing pharmaceutical stewardship plans, or to the extent a municipality adopts an ordinance electing not to be bound by this pharmaceutical stewardship plans, the ordinance of the municipality shall apply, and this section shall not apply, to any areas within the jurisdiction of the municipality.

Effective date: Sections 46-101 through 46-112 and 46-114 through 46-119 shall be in effect January 1, 2017. Section 46-113 shall be in effect January 1, 2018.

NOW, THEREFORE, BE IT FURTHER ORDAINED, by the Cook County Board of Commissioners that Chapter 32 - Fees, Section 32-1 is hereby amended as follows:

Sec. 32-1. - Fee schedule.

The fees or charges provided for or required by the below-listed sections shall be as shown below:

. . .

Code Section Description Fees, Rates, Charges (in dollars)

CHAPTER 46, Law Enforcement

46-3(2) Jail cost reimbursement for each conviction or orders of supervision for a criminal violation other than a petty or business offense 10.00

46-31(a) Merit system application and examination fee 25.00

46-36(b) Fee for participation in the Youthful Offender Alcohol and Other Drug Education

Program 5.00

46-109 Pharmaceutical Collection Registration Fee 250.00

. . .

Effective date: This ordinance shall be in effect January 1, 2018.

...end

Sponsors: LARRY SUFFREDIN, LUIS ARROYO JR, RICHARD R. BOYKIN, JOHN P. DALEY, BRIDGET

GAINER, PETER N. SILVESTRI, JERRY BUTLER, JOHN A. FRITCHEY, JESÚS G. GARCÍA, GREGG GOSLIN, EDWARD M. MOODY, STANLEY MOORE, SEAN M. MORRISON, TIMOTHY O.

SCHNEIDER, DEBORAH SIMS, ROBERT STEELE, JEFFREY R. TOBOLSKI

Indexes:

Code sections:

Attachments:

| Date | Ver. | Action By | Action | Result |
|------------|------|---|---------------------------------------|--------|
| 10/26/2016 | 2 | Board of Commissioners | approve as substituted | Pass |
| 10/25/2016 | 1 | Legislation and Intergovernmental Relations Committee | recommend for approval as substituted | Pass |
| 10/25/2016 | 1 | Legislation and Intergovernmental Relations Committee | accept as substituted | Pass |
| 10/5/2016 | 1 | Legislation and Intergovernmental Relations Committee | accept as substituted | Pass |
| 10/5/2016 | 1 | Legislation and Intergovernmental Relations Committee | recommend for deferral | Pass |
| 8/3/2016 | 1 | Legislation and Intergovernmental Relations Committee | no action taken | |
| 3/2/2016 | 1 | Board of Commissioners | refer | Pass |

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

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

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

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 sold, offered for sale or distribution in Cook County in pill, capsule, solid dosage, tablet, suppository, bolus, lozenge, implant, strip, powder and/or pellet 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 collection 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 collection or take-back program;
- (6) medical devices or their component parts or accessories; and
- (7) Drugs that are in a cream, elixir, spirit, tincture, syrup, solution, lotion, emulsion, topical, transdermal, aerosol, propellant, valve, actuator, injectable, infusion, irrigation, ointment, suspension, liquid and/or paste form.

The definition of *Covered Drug* shall be inclusive and determined by guidelines issued by the Director with the advice of the Pharmaceutical Disposal Advisory Committee established in Section 46-115.

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 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.

Drug Wholesaler means a Person that sells or distributes Drugs and Covered Drugs for resale to an Entity other than a consumer.

Generic Drug 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.

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.

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.

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. Notwithstanding the previous sentence, Pharmacy does not include a Pharmacy dispensing pharmaceuticals exclusively pursuant to an "Inpatient Drug Order" as defined by the Illinois Pharmacy Practice Act, 225 ILCS 85/3 (k).

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. 46-104(c) of this Division;
- (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Sec. 46-104(c) 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.

Registration is the informing of the Director of the distribution of Covered Drugs by a Producer in a manner set forth by the Director.

Registration Fee is a sum paid by a Producer.

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.

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

Sec. 46-103 - Implementation of this Division.

- (a) The Director shall:
 - (1) Develop a Collection Plan that is in compliance with this Division, including determining whether a Drug is a Covered Drug as established in accordance with Section Sec. 46-102; and
 - (2) Determine the method of collection of Unwanted Covered Drugs as specified under this Division; and
 - (3) Determine the total cost of the collection of Unwanted Covered Drugs as specified under this Division.
- (b) Producers shall:
 - (1) Within 90 days of the passage of this Division register with the Director, in a form mandated by the Director; and
 - (2) Pay all registration fees mandated by Section 32-1 of the Cook County Code.

Sec. 46-104 - Collection Plan - Participation.

- (a) Each Producer shall participate in the Collection Plan and pay a Registration Fee.
- (b) By three months after the effective date of this Division, or by three months after a Producer starts sale of a Covered Drug in the County, a Producer must register with the Director in writing. Within 60 days of a Producer's Registration, the Director shall meet with the Producer. The written registration form for Producers shall be limited to the following:
 - a) The name of the Producer; and
 - b) An address of the Producer: and
 - c) The name of the Registered Agent or other designee of the Producer for purposes of communicating with the Director; and
 - d) Contact information, including telephone number and email address, for the Registered Agent or other designee of the Producer; and
- (c) By three months after the effective date of this Division, or by three 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 three 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 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.
- (d) 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. 46-104.

Sec. 46-105 - Collection Plan - Components.

The Director shall take all appropriate actions to design, oversee, manage and implement the Collection Plan. The Collection Plan shall include:

- (a) Contact information as specified in the Registration form outlined in Section 46-104;
- (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. 46-106, 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. 46-106 (b) 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 Collection Plan in accordance with Sec. 46-106 and Sec. 46-108 of this Division;
- (d) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Collection 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 Collection 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 description of a plan for the removal of any patient information on Drug packaging;
- (f) A description of the public education effort and promotion strategy required in Sec. 46-107 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 Collection Plan for collection amounts, education and promotion; and
- (h) A description of how the Collection 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. 46-106 - Collection Plan - Collection of Covered Drugs.

- (a) This Section does not require any Person to serve as a Collector in the Collection 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 the Director. 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 under the Collection 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 150,000 County residents in each District, distributed to provide reasonably convenient and equitable access, but at no time shall there be less than five drop-off sites 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.
- (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 Collection 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) At the Director's discretion, make mail-back services available, free of charge, to disabled and homebound County residents upon request through the Collection Plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to Persons providing services to such County residents. If implemented by the Director, the toll-free telephone number and web site required by this subsection (b)(5) shall be in English, Spanish, Polish, Chinese, Korean, Arabic and Russian.
- (c) 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 the Collection Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.

Sec. 46-107 - Collection Plan - Promotion.

- (a) The Director may coordinate with each Producer and develop a single system of promotion. The Director may coordinate with each Producer, or its representative, to secure its participation in the single system of promotion. The system of promotion shall:
 - (1) Promote the Collection Plan 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) Coordinate with Producers to include promotion of the Collection Plan on the Producers' marketing and packaging materials and devices.
 - (3) Work with Collectors participating in the Collection Plan to develop clear, standardized instructions for County residents on the use of collection bins and a readily-recognizable, consistent design of collection bins.
 - (4) 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 Collection 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.

- (5) 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 Sec. 46-107 within 90 days of the end of the survey period. The privacy of all survey respondents shall be maintained.
- (6) Work with the Illinois Poison Center to advertise drop-off sites and other collection opportunities under the Collection Plan.
- (b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 16-107 shall be in English, Spanish, Polish, Chinese, Korean, Arabic and Russian.
- (c) The Director shall provide guidance on the development of a single system of promotion.

Sec. 46-108 - Collection Plan - Disposal of Covered Drugs.

- (a) Covered Drugs collected under the Collection 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 and/or pursuant to a method permitted by the United States Drug Enforcement Administration under 21 C.F.R. part 1317.95.
- (b) The Director may grant approval under the Collection 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. 46-108 to be infeasible for the Plan based on cost, logistics or other considerations.
- (c) The Director may 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 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. 46-109 -Collection Plan - Administrative and Operational Costs and Fees.

A Producer participating in the Collection Plan may pay to the Cook County Department of Revenue an annual registration fee as established under Section 32-1 of the Cook County Code. The Fee shall be set to recover, but not exceed, actual costs to the County of the registration and implementation of the Collection Plan at a rate duly approved by the Board. The Board must provide sixty (60) day notice to all Producers before setting the annual registration fee. When setting the annual registration fee, the Board may consider the following:

- (1) Collection and transportation supplies for drop-off sites;
- (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. 46-108 of this Division;
- (8) Creation, promotion and advertisement of the Collection Program;
- (9) Creation, maintenance and operation of the single toll-free telephone number and single web site as established in Section 46-107.
- (10) A Producer may receive a reduction in the amount of the annual registration fee assessed to the Producer for any amounts spent by the Producer in support of the creation, promotion and/or advertisement of the Collection Program as set forth in Section 46-109 (8).

No Person or Producer may charge a point-of-sale fee to consumers or increase the cost of a Covered Drug to recoup the costs of the Collection Plan, nor may they charge a specific point-of-collection fee at the time the Covered Drugs or increase the cost of a Covered Drug are collected.

The Department of Revenue shall establish reasonable procedures for the collection of the annual registration fee, including procedures for appealing the amount of the fee and enforcement actions for nonpayment. All appeals and enforcement actions shall be conducted in accordance with Article IX - Administrative Hearings of the Cook County Code.

All Registration Fees shall be shall deposited into the Pharmaceutical Disposal Program Special Fund, pursuant to Section 46-110 of the Cook County Code.

Sec. 46-110 - Pharmaceutical Disposal Fund.

The Comptroller shall create a special fund to be known as the "Pharmaceutical Disposal Fund" which shall be subject to budget and appropriation for purposes related to the funding of the Collection Plan. The Department of Revenue shall collect, account for and transfer any remittals pursuant to Section 46-109 of the Cook County Code into such Fund. The Comptroller shall distribute monies from the Fund after appropriation by the Cook County Board of Commissioners for the purpose of funding the Collection Plan.

Sec. 46-111 - Collection Plan - Reporting Requirements.

- (a) Within six months after the end of the first 12-month period of operation and annually thereafter, the Director and the Pharmaceutical Disposal Advisory Committee established in Section 46-115 shall submit a report to the Board on behalf of participating Producers describing their plan's activities during the previous reporting period. The report must include:
 - (1) A list of Producers registered under Section 46-104;
 - (2) The amount, by weight, of Covered Drugs collected, including the amount by weight from each collection method used;
 - (3) the total cost of the provision of services of the Collection Plan;
 - (4) the total amount of fees collected from participating Producers;
 - (5) a list of the number, site and type of collection sites established and to be established;
 - (6) The number of mailers provided for disabled and/or home-bound County residents;
 - (7) The locations where mailers were provided, if applicable;
 - (8) The dates and locations of collection events held, if applicable;
 - (9) The transporters used and the disposal facility or facilities used for all Covered drugs;
 - (10) 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:
 - (11) A description of the public education, outreach and evaluation activities implemented during the reporting period;
 - (12) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
 - (13) A summary of the Collection 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
 - (14) The total expenditures of the Collection Plan during the reporting period.
 - (15) The report may also include 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.
 - (b) The Director shall make reports submitted under this Section available to the public.
 - (c) For the purposes of this Sec. 46-111, "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. 46-112- Change of Collection Plan

The Director may change the Collection Plan or substantively alter plan operations, including, but not limited to, changes to participating Manufacturers, collection methods, policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities. The Director must provide sixty (60) day notice to all Producers before changing the Collection Plan.

Sec. 46-113 - Collection Plan - Enforcement and Penalties.

- (a) The Director shall administer the penalty provisions of this Division.
- (b) If the Director makes findings and determines that any Person has violated this Division or a regulation adopted pursuant to this Division, the Director shall send a written warning, as well as a copy of this Division and any regulations adopted pursuant to this Division, to the Person or Persons who violated it. The Person or Persons shall have 30 days after receipt of the warning to come into compliance and correct all violations.
- (c) If the Person or Persons fail to come into compliance or correct all violations, the Director may impose administrative fines for violations of this Division or of any regulation adopted pursuant to this Division.
 - (1) Upon findings made under subsection (b), the Person or Persons shall be subject to an administrative fine as follows:
 - a. A fine not exceeding one hundred dollars (\$100.00) for a first violation;
 - b. A fine not exceeding two hundred dollars (\$200.00) for a second violation;
 - c. A fine not exceeding five hundred dollars (\$500.00) for the third violation and each subsequent violation.
 - (2) Each day a violation continues constitutes a separate violation.
 - (3) Fine Procedures. Notice of the fine shall be served on the Person or Persons. The notice shall contain an advisement of the right to request a hearing in the Cook County Department of Administrative Hearings. Hearings on violations shall be conducted in accordance with Article IX. Administrative Hearings of the Cook County Code of Ordinances. Payments for fines shall be deposited into the Pharmaceutical Disposal Fund established pursuant to Section 46-110.
 - (4) Failure to Pay Fine. If said fine is not paid within 30 days from the date appearing on the notice of the fine or of the notice of determination of the Director or his or her designee after the hearing, the Director may use any lawful means for collecting the fine, including instituting an action in any court of proper jurisdiction.
- (d) The Director may bring a civil action to enjoin violations of or compel compliance with any requirement of this Division or any rule or regulation adopted pursuant to this Division, as well as for payment of civil penalties and any other appropriate remedy.
- (e) Any Person who knowingly and willfully violates the requirements of this Division or any rule or regulation adopted pursuant to this Division is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500) for each day per violation.
- (f) In determining the appropriate penalties, the court or the Director 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.

(g) No civil or administrative action under this Sec. 46-113 may be brought more than four years after the date of the alleged violation.

Sec. 46-114 -Collection Plan - Rules and Performance Standards

- (a) The Director, may adopt rules and regulations as necessary to implement, administer, and enforce this Division.
- (b) The Director may work with the Producers and/or the Pharmaceutical Disposal Advisory Committee as established in Section 46-115 to define goals for collection amounts, education, and promotion of the Collection Plan.

Sec. 46-115- Pharmaceutical Disposal Advisory Committee

- (a) There shall be created a Pharmaceutical Disposal Advisory Committee made up of the President of the Cook County Board of Commissioners or his or her designee and five other members appointed by the President. Members of the Advisory Committee shall include:
 - (1) The President, or his or her designee; and
 - (2) One member of the Cook County Board of Commissioners; and
 - (3) The Sheriff, or his or her designee; and
 - (4) The Director of the Cook County Department of Environmental Control, or his or her designee; and
 - (5) The Chief Operating Officer of the Cook County Department of Public Health, or his or her designee; and
 - (6) A member of the Board of Commissioners of the Metropolitan Water Reclamation District of Greater Chicago, to be appointed by the President of the Board of Commissioners of the Metropolitan Water Reclamation District of Great Chicago; and
 - (7) A member or a representative on behalf of the Producer community who is participating in the Collection Plan.; and
 - (8) A member of the general public on behalf of an environmental or public health organization with members and programs in Cook County.
- (b) The Sheriff, or his or her designee, shall serve as the Chairman of the Advisory Committee. The Director shall serve as an ex officio member. The members of the Committee shall serve without pay.
- (c)The purpose of the Advisory Committee is to oversee, advise and assist with the promotion and implementation of this Division. The Advisory Committee may formulate recommendations to bring about improvement in this regard.
- (d) The members of the Advisory Committee shall meet quarterly or as designated by the Chairman.
- (e)The Advisory Committee with the assistance of the Director shall prepare an annual report describing the work undertaken by the program pursuant to Section 46-111. The report shall include minutes of meetings of the Advisory Committee over the past year, a description of the types of programs that have been implemented or

outsourced and the total cost of the Stewardship Program.

Sec. 46-116 - Undertaking For the General Welfare.

In adopting and implementing this Division, the County is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any Person who claims that such breach proximately caused injury.

Sec. 46-117- No Conflict with Federal or State Law.

This Division shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. Nothing in this Division shall authorize any County agency or department to impose any duties or obligations in conflict with limitations on authority established by State or federal law at the time such agency or department action is taken. The County shall suspend enforcement of this Division to the extent that said enforcement would conflict with any preemptive State or federal legislation subsequently adopted. Nothing in this Division is intended or shall be construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair competition laws of the State of Illinois or the Unites States.

Sec. 46-118 - Severability.

If any of the provisions of this Division 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 Division are severable.

Sec. 46-119 - Applicability.

Without limitation, this section applies to areas of unincorporated Cook County, to areas owned or operated by Special Districts within unincorporated Cook County, and to areas within municipalities within the County which have not adopted ordinances governing the operation of pharmaceutical stewardship plans within the said municipalities. To the extent a municipality has adopted an ordinance addressing pharmaceutical stewardship plans, or to the extent a municipality adopts an ordinance electing not to be bound by this pharmaceutical stewardship plans, the ordinance of the municipality shall apply, and this section shall not apply, to any areas within the jurisdiction of the municipality.

Effective date: Sections 46-101 through 46-112 and 46-114 through 46-119 shall be in effect January 1, 2017. Section 46-113 shall be in effect July 1, 2018.

NOW, THEREFORE, BE IT FURTHER ORDAINED, by the Cook County Board of Commissioners that Chapter 32 - Fees, Section 32-1 is hereby amended as follows:

Sec. 32-1. - Fee schedule.

The fees or charges provided for or required by the below-listed sections shall be as shown below:

• • •

| Code | Description | Fees, Rates, |
|---------|-------------|--------------|
| Section | - | Charges (in |
| | | dollars) |

| CHAPTER 46, Law Enforcement | | | | | |
|--------------------------------|--|-------|--|--|--|
| 46-3(2) | Jail cost reimbursement for each conviction or orders of supervision for a criminal violation other than a petty or business offense | 10.00 | | | |
| 46-31(a) | Merit system application and examination fee | 25.00 | | | |
| 46-36(b) | Fee for participation in the Youthful Offender Alcohol and Other Drug Education Program | 5.00 | | | |
| 46-109 | Pharmaceutical Collection Registration Fee | 0.00 | | | |

Effective date: This ordinance shall be in effect July 1, 2018.