HB0349

LRB101 00244 CPF 45248 b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB0349

by Rep. Kelly M. Cassidy

SYNOPSIS AS INTRODUCED:

New Act

Creates the Drug and Sharps Waste Stewardship Act. Directs the Environmental Protection Agency to administer a drug and sharps waste stewardship program. Provides that the State Board of Pharmacy is to guide and advise the Agency in its administration of the program. Requires covered entities to provide lists of covered and not covered products to the State Board and to implement stewardship plans. Requires stewardship plans to be submitted to the Agency for review and acceptance. Requires that all counties have at least one collection site for unused drugs and sharps per 50,000 people, and no fewer than 5 such collection sites. Requires counties that do not have the necessary number of collection sites to establish a mail-back program, or alternative collection program for covered products, or both. Imposes an administrative fee on covered entities. Provides penalties for covered entities that fail to comply with the provisions of the Act. Creates the Drug and Sharps Stewardship Fund and the Drug and Sharps Stewardship Penalty Account within the Fund. Directs the Agency to post lists of compliant covered entities on its website. Exempts stewardship programs already in existence under local ordinances at the time the Act takes effect from the Act's provisions, but provides that those entities with programs that are not within the Act's purview are not to receive any monetary support from the Drug and Sharps Stewardship Fund or the Drug and Sharps Stewardship Penalty Account. Exempts confidential proprietary information from public disclosure by the Agency.

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FISCAL NOTE ACT MAY APPLY

HOME RULE NOTE ACT MAY APPLY

A BILL FOR

AN ACT concerning safety.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Article 1. Short Title; Definitions

Section 1-1. Short title. This Act may be cited as the Drug and Sharps Waste Stewardship Act.

Section 1-5. Definitions. In this Act:

"Agency" means the Illinois Environmental Protection Agency.

"Authorized collection site" means a location where an authorized collector operates a secure collection receptacle for collecting covered products.

"Authorized collector" means a person or entity that has entered into an agreement with a program operator to collect covered drugs, including, but not limited to, any of the following:

(1) A person or entity that is registered with the United States Drug Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction.

(2) A law enforcement agency.

(3) A retail pharmacy that offers drug take-back services in compliance with subpart 205 of part 889 of title 35 of the Illinois Administrative Code.

"Controlled substance" means a substance listed under the Illinois Controlled Substances Act or Section 812 or 813 of Title 21 of the United States Code.

"Cosmetic" has the meaning provided in Section 2 of the Illinois Food, Drug and Cosmetic Act.

"Covered drug" means a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State of Illinois in any form, including, but not limited to, any of the following:

(1) Prescription and nonprescription drugs approved by the United States Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or Section 351 of the federal Public Health Service Act (42 U.S.C. 262).

(2) A drug marketed pursuant to an over-the-counter drug monograph.

(3) A drug in a medical device, or a combination product containing a drug and a medical device.

"Covered drug" does not include any of the following:

(1) Vitamins or supplements.

(2) Herbal-based remedies and homeopathic drugs, products, or remedies.

(3) Cosmetics, soap with or without germicidal agents,

laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or any other personal care product that is regulated as both a cosmetic and a nonprescription drug under the Federal Food, Drug, and Cosmetic Act.

(4) A drug for which a pharmaceutical product stewardship program or drug take-back program is provided in the State as part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy under 21 U.S.C. 355-1.

(5) Biological drug products, as defined by 42 U.S.C. 262(i)(1), including those products currently approved in the State under a new drug application that will be deemed to be licensed under Section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to Section 7002(e) of the federal Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148).

(6) A medical device, or a component part or accessory of a medical device, if it does not contain a covered drug.

(7) Drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals.

(8) Dialysate drugs or other saline solutions required to perform kidney dialysis.

"Covered entity" means:

(1) The manufacturer of covered products that are sold

in or into the State.

(2) If no entity that meets the definition in paragraph (1) is located in the State, "covered entity" means the distributor of covered products that are sold in or into the State that is licensed as a wholesale drug distributor, as defined in the Wholesale Drug Distribution Licensing Act, but does not include a warehouse of a retail pharmacy chain that is licensed as a wholesale drug distributor if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

(3) If no entity that meets the definitions in paragraphs (1) or (2) is located in the State, "covered entity" means any person or entity who repackages, as defined in the Wholesale Drug Distribution Licensing Act, covered products that are sold in or into the State.

(4) If no entity that meets the definitions in paragraphs (1), (2), or (3) is located in the State, "covered entity" means the owner or licensee of a trademark or brand under which covered products are sold in or into the State, regardless of whether the trademark is registered.

(5) If no entity that meets the definitions in paragraphs (1), (2), (3), or (4) is located in the State, "covered entity" means the importer of the covered products that are sold in or into the State.

The Agency shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraphs (1) through (5).

"Covered product" means a covered drug or home-generated sharps waste.

"Distributor" means a wholesale drug distributor, as that term is defined in Wholesale Drug Distribution Licensing Act.

"Drug" means any of the following:

(1) An article recognized in the United States Pharmacopoeia or the National Formulary published by the United States Pharmacopoeia Convention, or the Homeopathic Pharmacopoeia of the United States published by the Homeopathic Pharmacopoeia Convention of the United States, or any supplement of the Formulary or those Pharmacopoeiae.

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

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

(4) A substance intended for use as a component of any substance specified in this subsection.

"Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance, characteristics, and intended use, though inactive ingredients

may vary.

"Home-generated sharps waste" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household. "Home-generated sharps waste" does not include either of the following:

(1) Components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports.

(2) A biological product, as defined in Section 262(i)(1) of Title 42 of the United States Code, including a combination product, as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

"Mail-back program" means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes.

"Medical waste generator" means any person whose act or process produces medical waste and includes, but is not limited to, a provider of health care. All of the following are examples of businesses that generate medical waste:

(1) Medical and dental offices, clinics, hospitals,

surgery centers, laboratories, research laboratories, unlicensed health facilities, those facilities required to be licensed, chronic dialysis clinics, and education and research facilities.

(2) Veterinary offices, veterinary clinics, and veterinary hospitals.

(3) Pet shops.

(4) Trauma scene waste management practitioners.

"Nonprescription drug" means any drug that may be lawfully sold without a prescription.

"Pharmacy" has the meaning provided in the Pharmacy Practice Act.

"Prescription drug" means a drug, including, but not limited to, a controlled substance, that is required under State or federal law to be dispensed with a prescription, or is restricted to use by practitioners only.

"Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this Act.

"Proprietary information" means information that is all of the following:

(1) Submitted under this Act.

(2) A trade secret, or commercial or financial information, that is privileged or confidential, and is identified as such by the entity providing the information

to the Agency.

(3) Not required to be disclosed under any other law or any regulation affecting a covered product or covered entity.

"Retail pharmacy" has the meaning provided for "pharmacy" in the Pharmacy Practice Act.

"Retail pharmacy chain" means a retail pharmacy with 5 or more stores in the State.

"Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

"State Board" means the Illinois State Board of Pharmacy.

"Stewardship organization" means an organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 that is established by a group of covered entities in accordance with this Act to develop, implement, and administer a stewardship program established under this Act.

"Stewardship plan," or "plan" means the plan that is developed by a covered entity or stewardship organization under this Act for collecting and properly managing covered products.

"Stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products.

"Ultimate user" means a State resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for his or her own use or for the use of a member of

his or her household. "Ultimate user" does not include a needle exchange program, or a medical waste generator as defined in this Act.

Article 5. Covered Entities and Stewardship Organizations

Section 5-1. Covered and noncovered products.

(a) No later than 90 days after the effective date of this Act, a covered entity shall provide to the State Board a list of covered products and a list and description of any drugs or sharps that are not covered products that it sells or offers for sale in the State.

A covered entity, or a stewardship organization on behalf of a group of covered entities, shall update the lists described in this subsection and provide the updated lists to the State Board on or before January 15 of each year or upon request by the Agency.

(b) No later than 90 days after the effective date of this Section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the State Board identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.

(c) The State Board shall verify the information received under subsections (a) and (b) and make it available to the Agency upon request.

(d) The State Board may issue a letter of inquiry to any covered entity, requesting a list of all drugs and sharps it distributes in Illinois, regardless of whether the drugs or sharps are covered under this Act, the name of the manufacturer of such products, and any additional information necessary to carry out this Act. An entity that is issued a letter of inquiry under this subsection shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the Agency, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this Act, it shall submit all of the following to the State Board in response to the letter of inquiry:

(1) the basis for the claim that it is not a covered entity;

(2) a list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale within the State; and

(3) if applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified under paragraph (2).

(e) The State Board shall obtain and verify and, within 30 days of receipt or upon request by the Agency, submit to the Agency a list of drugs and sharps sold or offered for sale in the State excluded from the definition of covered drugs or from the definition of home-generated sharps waste.

(f) Notwithstanding Section 30-10, information submitted by the State Board to the Agency under this Act may include proprietary information.

(g) The State Board shall notify the Agency if any covered entity or stewardship organization is in violation of this Section for purposes of enforcement by the Agency.

Section 5-5. Implementation and administration.

(a) The Agency shall adopt regulations for the implementation of this Act with an effective date of no later than January 1, 2021.

(b) The State Board may adopt rules for the administration of the portions of this Act for which it has been given responsibility.

Section 5-10. Compliance.

(a) Except as specified in subsection (d) of Section 25-1, a covered entity is not in compliance with this Act and is subject to penalties under Article 25 if, commencing one year after the adoption of rules under Section 5-5, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the Agency under Section 10-1.

(b) In order to comply with the requirements of this Act, a

covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986.

Section 5-15. Education and outreach program.

(a) A program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:

(1) promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary;

(2) provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary;

(3) establish a website that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program;

(4) prepare and provide additional outreach materials not specified in this Section, as needed, to promote the collection and proper management of covered drugs and home-generated sharps waste; and

(5) encourage ultimate users to separate products that are not covered products from covered products, when

appropriate, before submitting the covered products to an authorized collection site or mail-back program.

(b) A program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program.

Article 10. Stewardship Plans

Section 10-1. Stewardship plan; submission; Agency review.

(a) Within 6 months after the adoption of regulations by the Agency under Section 5-5, a program operator shall submit to the Agency for approval a complete stewardship plan that meets the requirements of Section 10-5 for the establishment and implementation of a stewardship program, in a format determined by the Agency. The Agency shall approve a proposed stewardship program if the program operator submits a completed plan that meets the requirements of this Section.

(b) Before submitting a stewardship plan to the Agency under this Section, a program operator shall submit its proposed stewardship plan to the State Board for review, and to any other applicable State agencies with areas of authority relative to the stewardship plan. The duration of time that the State Board takes to review a stewardship plan under this subsection shall not count toward the time limit specified in subsection (a).

A State agency that receives a plan shall review the plan for compliance with State and federal laws and regulations related to that agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

A program operator may submit an updated proposed plan to a State agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the Agency.

If, 90 days after submitting a plan to an applicable State agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the Agency that the stewardship plan is consistent with all other applicable laws and regulations.

(c) The Agency shall determine if a stewardship plan is complete, including the determinations required under subsection (b), and notify the submitting program operator within 30 days of receipt.

If the Agency finds that the stewardship plan is complete, the Agency's 90-day review period for consideration of approval of the plan set forth in subsection (d) shall commence upon the original date of receipt.

If the Agency determines the stewardship plan is

incomplete, the Agency shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.

If the Agency determines upon resubmission that the stewardship plan is complete, the Agency's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

(d) The Agency shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan. The Agency may consult with, or submit a stewardship plan for review to, the State Board or another State agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the Agency takes to review a stewardship plan shall not count toward the 90-day time limit specified in this subsection.

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the Agency, and shall not implement the changes prior to that approval.

(f) If the Agency disapproves a submitted stewardship plan under subsection (d), the Agency shall explain, in writing within 30 days, how the plan does not comply with this Act, and the program operator shall resubmit a revised plan to the Agency.

If the Agency finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this Act and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this Act until the program operator submits a plan that the Agency approves.

(g) A program operator shall fully implement an approved stewardship program no later than 270 days after approval by the Agency of the stewardship plan.

(h) If a stewardship plan is revoked under subsection (a) of Section 25-10 or terminated by the program operator that submitted the plan, a covered entity no longer subject to that plan may, without being subject to penalties under Article 25, sell or offer for sale covered products in the State for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved stewardship plan to which the covered entity was subject.

(i) The Agency shall make all stewardship plans submitted under this Section available to the public, except proprietary information in the plans protected under Section 30-10.

Section 10-5. Stewardship plan requirements.

(a) To be complete, a stewardship plan for covered drugs

shall do all of the following:

(1) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.

(2) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.

(3) Include any determinations provided by a State agency under subsection (b) of Section 10-1. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(4) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(5) Provide for a handling, transport, and disposal system that complies with applicable State and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

(6) Provide for a collection system that complies with the requirements of this Act and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented:

(A) Provides for a minimum of 5 authorized

collection sites or one authorized collection site per 50,000 people, whichever is greater.

(B) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.

(C) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

(7) Require a program operator to do all of the following:

(A) Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subsection (c), that would render the covered drug inert. A program operator shall accept that request through a website and toll-free telephone number that it shall maintain to comply with the requests.

(B) Provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under applicable State and federal law, including, but

not limited to, United States Drug Enforcement Administration regulations.

(C) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner. A receipt or collection manifest shall be left with the authorized collection site to support verification of the service. The authorized collection site shall maintain and make available to the Agency this documentation. An authorized collector shall comply with applicable State and federal laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.

(8) Provide the policies and procedures for the safe and secure collection, transportation, and disposal of the covered drug, describe how and where records will be maintained, describe how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

(b) At least 120 days before submitting a stewardship plan

to the Agency, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

A retail pharmacy shall make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. If the minimum threshold described in subparagraph (A) of paragraph (6) of subsection (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

A program operator shall include as an authorized collector under its stewardship program any entity that meets the definition of an authorized collector and offers to participate in the stewardship program, in writing and without compensation, even if the minimum threshold described in subparagraph (A) of paragraph (6) of subsection (a) has been achieved. The program operator shall include the offering entity as an authorized collector in the program within 90 days of receiving the written offer to participate. A program

operator shall not be required to respond to offers under this subsection until the program operator's stewardship plan has been approved by the Agency.

(c) After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by the Agency, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control, by establishing one or both of the following:

(1) A mail-back program. The mail-back program may include providing information on where and how to receive mail-back materials or providing the locations at which it distributes prepaid, preaddressed mailing envelopes. The program operator shall propose the locations of those envelope distribution locations as part of the stewardship plan. Prepaid mailing envelopes may be mailed to an ultimate user upon request.

(2) An alternative form of collection and disposal of covered drugs that complies with applicable State and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(d) To be complete, a stewardship plan for home-generated sharps waste shall do all of the following:

(1) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered

product sold or offered for sale by each participating covered entity.

(2) Include any determinations provided by a State agency under subsection (b) of Section 10-1. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(3) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(4) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable State and federal laws.

(5) Maintain a website and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.

(6) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this Act and that meets all the following requirements:

(A) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back

materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period. Containers and mail-back materials shall include:

(i) for any sharps, on the packaging, inserts, instructions, or separate information provided to the ultimate user, information on proper sharps waste disposal;

(ii) on a label affixed to the container or packaging or on a separate insert included in the container or packaging, the program operator's website and toll-free telephone number; and

(iii) prepaid postage affixed to the container or to the mail-back packaging.

(B) Upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility.

(i) A local agency shall not knowingly request reimbursement for disposal expenses under this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.

(ii) Reimbursement costs shall be limited to

the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.

(iii) A request for reimbursement under this subparagraph shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this Section.

(iv) A cost is eligible for reimbursement under this subparagraph if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan under Section 30-5, in the event a jurisdiction repeals its local stewardship program ordinance.

(f) A stewardship plan shall include educational and outreach provisions to meet the requirements under Section 5-15.

Article 15. Budgets, Reports, and Records

Section 15-1. Stewardship plan program budget. With the submission of a stewardship plan, a program operator shall submit to the Agency an initial stewardship program budget for the first 5 calendar years of operation of its stewardship

program that includes both of the following:

(a) the total anticipated revenues and costs of implementing the stewardship program; and

(b) a total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period.

Section 15-5. Program operator reports.

(a) On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the Agency both of the following:

(1) a written report describing the stewardship program activities during the previous reporting period of one calendar year; and

(2) a written program budget for stewardship program implementation for the upcoming calendar year.

(b) An annual report submitted under paragraph (1) of subsection (a) shall include, at a minimum, all of the following for the prior year:

(1) A list of covered entities participating in the stewardship organization.

(2) The updated and reverified list provided under subsection (a) of Section 5-1 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.

(3) The amount, by weight, of covered products

collected from ultimate users at each authorized collection site that is part of the stewardship program.

(4) For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.

(5) For a stewardship plan for home-generated sharps waste, information on the mail-back program.

(6) Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.

(7) Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) How the program operator complied with all elements in its stewardship plan.

(9) Any other information the Agency reasonably requires.

(c) An annual program budget submitted under paragraph (2) of subsection (a) shall include, at a minimum, both of the following for the upcoming calendar year:

(1) an independent financial audit of the stewardship

program, as required under subsection (b) of Section 15-10, funded by the stewardship organization from the charge paid from its member covered entities under Section 20-1 or by a covered entity if it operates its own stewardship program; and

(2) anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner.

(d) The Agency shall determine if a submitted annual report and program budget are complete and notify the submitting stewardship organization or covered entity within 30 days.

If the Agency finds that an annual report and program budget are complete, the Agency's 90-day review period for consideration of approval of the annual report and program budget, set forth in subsection (e), shall commence upon the original date of receipt.

If the Agency determines either an annual report or a program budget is incomplete, the Agency shall identify for the program operator within 30 days the required additional information, and the program operator shall submit a revised annual report or program budget, as applicable, within 30 days.

If the Agency determines upon resubmission that the annual report or program budget is complete, the Agency's 90-day

review period for consideration of approval of the annual report or program budget shall commence upon the date of receipt of the resubmitted report or program budget.

(e) The Agency shall review the annual report and program budget required under subsection (a) and within 90 days of receipt shall approve, disapprove, or conditionally approve the annual report and program budget.

If the Agency conditionally approves an annual report or program budget, the Agency shall identify the deficiencies in the annual report or program budget and the program operator shall comply with the conditions of the conditional approval within 60 days of the notice date, unless the Director of the Agency determines that additional time is needed.

If the Agency conditionally approves an annual report or program budget and the conditions are not met within 60 days of the notice date, unless additional time is granted under this subsection, the Agency shall disapprove the annual report or program budget.

If the Agency disapproves an annual report or program budget, the Agency shall identify the deficiencies in the annual report or program budget and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

Section 15-10. Keeping minutes, books, and records;

audits.

(a) A program operator shall keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program.

(b) The minutes, books, and records of a program operator shall be audited at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year.

A program operator shall arrange for the independent certified public accountant audit to be delivered to the Agency, along with the annual report and program budget submitted under subsection (a) of Section 15-5.

The Agency may conduct its own audit of a program operator. The Agency shall review the independent certified public accountant audit for compliance with this Act and consistency with the program operator's stewardship plan, annual report, and program budget submitted under this Act. The Agency shall notify the program operator of any conduct or practice that does not comply with this Act or of any inconsistencies identified in the Agency's audit. The program operator may obtain copies of the Agency's audit, including proprietary information contained in the Agency's audit, upon request. The Agency shall not disclose any confidential proprietary information protected under Section 30-10 that is included in the Agency's audit.

Section 15-15. Local jurisdiction reimbursement; requirements. For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal under Section 10-5, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time, upon request by the covered entity or program operator.

Section 15-20. Adequate access report. As part of the administration of this Act, within 12 months of a program operator's submission of 3 consecutive complete annual reports submitted under Section 15-5, the Agency shall develop, and post on its website, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, to the ultimate user.

Article 20. Financial Provisions

Section 20-1. Administrative and operational costs. In order to further the objective that covered entities establish and implement stewardship programs that comply with the requirements of this Act, each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which

it participates, including the cost of collecting, transporting, and disposing of covered products.

Section 20-5. Administrative fee.

(a) On or before the end of State Fiscal Year 2023, and once every 3 months thereafter, a program operator shall pay to the Agency an administrative fee. The Agency shall set the fee at an amount that, when paid by every covered entity, is adequate to cover the Agency's and any other State agency's full costs of administering and enforcing this Act. The total amount of fees collected shall not exceed the State's actual and reasonable regulatory costs to implement and enforce this Act. These costs may include the actual and reasonable costs associated with regulatory activities under this Act before submission of stewardship plans under Section 10-1.

For a stewardship organization, the administrative fee paid under this subsection shall be funded by the covered entities that make up the stewardship organization. This administrative fee shall be in addition to the charge paid under Section 20-1. A stewardship organization may require its participating covered entities to pay the administrative fee and the charge paid under Section 20-1 at the same time.

(b) The fees received by the Agency under this Section shall be deposited into the Drug and Sharps Stewardship Fund, which is hereby created as a special fund in the State treasury. Upon appropriation by the General Assembly, moneys in

the fund may be expended by the Agency, the State Board, and any other agency that assists in the regulatory activities of administering and enforcing this Act. Upon appropriation by the General Assembly, moneys in the fund may be used for those regulatory activities and to reimburse any outstanding loans made from other funds used to finance the startup costs of the Agency's activities under this Act. Moneys in the fund shall not be expended for any purpose not enumerated in this Act.

(c) The penalties received by the Agency under Section 25-5 shall be deposited into the Pharmaceutical and Sharps Stewardship Penalty Account, which is hereby created as an account within the Pharmaceutical and Sharps Stewardship Fund. Upon appropriation by the General Assembly, moneys in the account may be expended by the Agency on activities including, but not limited to, the promotion of safe handling and disposal of covered products, grants for related purposes, and the administration and enforcement this Act.

Section 20-10. Audits.

(a) A stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization under Sections 20-1 and 20-5 to verify that the administrative fees and charges paid are proper and accurate. A stewardship organization may conduct an audit of authorized collectors to verify the charges submitted are proper and accurate.

The purpose of the audits described in this subsection is to ensure parties required by this Act to pay or collect an administrative fee or charge are paying or collecting the proper amount to implement the program.

(b) If a stewardship organization conducts an audit under subsection (a), it shall do each of the following:

(1) conduct the audit in accordance with generally accepted auditing practices;

(2) limit the scope of the audit of covered entities to confirming whether a charge or administrative fee has been properly paid by the covered entities;

(3) hire an independent third-party auditor to conduct the audit; and

(4) provide a copy of the audit to the Agency.

Article 25. Enforcement

Section 25-1. Posting listed stewardship organizations.

(a) On or before June 30, 2022, and at least annually thereafter, the Agency shall post on its website a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this Act.

The State Board shall coordinate with the Agency to verify that the list posted under this subsection is consistent with

the information submitted to each agency under Section 5-1.

(b) A covered entity or stewardship organization that is not listed on the Agency's website under subsection (a), but demonstrates compliance with this Act before the Agency is required to post the following year's list under subsection (a), may request a certification letter from the Agency stating that the covered entity or stewardship organization is in compliance with this Act. A covered entity or stewardship organization that receives a certification letter shall be deemed to be in compliance with this Act.

(c) A distributor or wholesale drug distributor of covered products, and a pharmacy or other retailer that sells or offers for sale a covered product, shall monitor the Agency's website to determine which covered entities and stewardship organizations are in compliance with this Act. The distributor or wholesale drug distributor and the pharmacy or other retailer shall notify the Agency if it determines that a covered product that it sells or offers for sale is from a covered entity that is not listed on the Agency's website.

(d) The sale, distribution, or offering for sale of any inventory that was in stock before the commencement of a stewardship program is exempt from this Act and not required to be subject to a stewardship plan.

(e) If the Act determines a covered entity or stewardship organization is not in compliance with this Act, the Agency shall remove the entity from the list maintained on the

Agency's website under subsection (a).

Section 25-5. Administrative penalties.

(a) The Agency may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this Act.

The amount of the administrative penalty imposed under this subsection shall not exceed $10,000 per day per violation unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed $50,000 per day per violation.

(b) The Agency shall not impose a penalty on a program operator under this Section for failure to comply with this Act if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.

Section 25-10. Additional penalties. Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this Act, in addition to any other penalties authorized under this Act, the Agency may take one or both of the following actions to ensure compliance with the requirements of this Act, after affording the covered entity,

stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:

(a) Revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this Act that was not met.

Section 25-15. Agency access and records; keeping records.

(a) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following:

(1) Upon request, provide the Agency with reasonable and timely access, as determined by the Agency, to its facilities and operations, as necessary to determine compliance with this Act.

(2) Upon request, provide the Agency with relevant records necessary to determine compliance with this Act.

(b) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall maintain and keep accessible all records required to be kept or submitted under this Section for a minimum of 3 years.

(c) All reports and records provided to the Agency under this Section shall be provided under penalty of perjury.

(d) The Agency may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails

to provide the Agency with the access to information required under this Section, including one or both of the following:

(1) Imposing an administrative penalty under Section 25-5.

(2) Posting a notice on the Agency's website, in association with the list that the Agency maintains under subsection (a) of Section 25-1, that the covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this Act.

(e) The Agency shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

Section 25-20. Handling, transport, and disposal. All handling, transport, and disposal undertaken as part of a stewardship program under this Act shall comply with applicable State and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

Article 30. Miscellaneous Provisions

Section 30-1. Violation exceptions.

(a) Except as provided in subsection (c), an action specified in subsection (b) that is taken by a stewardship

organization or a covered entity under this Act is not a violation of the Illinois Antitrust Act.

(b) Subsection (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

(1) The creation, implementation, or management of a stewardship plan approved by the Agency under Article 10 and the determination of the types or quantities of covered products collected or otherwise managed under a stewardship plan.

(2) The determination of the cost and structure of an approved stewardship plan.

(3) The establishment, administration, collection, or disbursement of the charge or administrative fee imposed under Section 20-1 or 20-5.

(c) Subsection (a) shall not apply to an agreement that does any of the following:

(1) Fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the Agency and otherwise in accordance with this Act.

(2) Fixes the output of production of covered products.

(3) Restricts the geographic area in which, or customers to whom, covered products are sold.

Section 30-5. Ordinances affected; local stewardship

programs.

(a) This Act does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program under an ordinance that took effect before January 1, 2020. If that ordinance is repealed, the drug or sharp program shall be subject to this Act in that jurisdiction within 270 days after the date on which the ordinance is repealed.

(b) This Act shall preempt a local stewardship program for drugs or sharps enacted by an ordinance with an effective date on or after January 1, 2020. The regulation of the collection, transportation, and disposal of drugs and sharps as described in this Act is an exclusive power and function of the State. A home rule unit may not regulate the collection, transportation, and disposal of drugs and sharps. This Section is a denial and limitation of home rule powers and functions under subsection (h) of Section 6 of Article VII of the Illinois Constitution.

(c) A local stewardship program for covered products enacted by an ordinance that has an effective date before January 1, 2020, may continue in operation, but the program and its participants shall not receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account, including, but not limited to, for administrative or enforcement costs. Participants of a local stewardship program for covered products enacted by an ordinance that has an effective date before January 1, 2020, shall be eligible to

participate in a stewardship program under this Act and thereby become eligible to receive funds from the Drug and Sharps Stewardship Fund or the Drug and Sharps Stewardship Penalty Account only if the local stewardship program is dissolved.

Section 30-10. Confidential proprietary information. Proprietary information submitted to the Agency under this Act shall be protected by all parties as confidential and shall be exempt from public disclosure under the State Records Act and the Freedom of Information Act. The Agency and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.