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Effective Date: 8/29/18

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Tennessee Board of Pharmacy
Division:	
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Revision Type (check all that apply):

___ Amendment
_X_ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1140-17	Drug Donation Repository Program
Rule Number	**Rule Title**
1140-17-.01	Definitions
1140-17-.02	Purpose
1140-17-.03	Eligibility Criteria for Program Participation as a Repository by Medical Facilities and Pharmacies
1140-17-.04	Standards and Procedures for Accepting Donated Prescription Drugs and Supplies
1140-17-.05	Standards and Procedures for Inspecting and Storing Donated Prescription Drugs and Supplies
1140-17-.06	Standards and Procedures for Dispensing Donated Prescription Drugs and Supplies
1140-17-.07	Eligibility Criteria for Individuals to Receive Donated Prescription Drugs and Supplies
1140-17-.08	Forms and Record Keeping
1140-17-.09	Handling Fee
1140-17-.10	List of Drugs and Supplies Program Will Accept.
1140-17-.11	Exemption From Disciplinary Action, Civil Liability and Criminal Prosecution.
1140-17-.12	Long-term Care Facilities

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

New Rule Chapter 1140-17
Drug Donation Repository Program

Rule 1140-17-.01 Definitions.

In addition to the definitions contained in T.C.A. § 63-10-501, the following definitions are applicable to this chapter:

(1) "Cancer Drug" means a prescription drug that is used to treat any of the following:

(a) Cancer or the side effects of cancer; or

(b) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(2) "Controlled Substance" means the same as defined in T.C.A. § 39-17-402.

(3) "Department" means the Tennessee Department of Health.

(4) "Donor" means a person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy, who donates prescription drugs to a repository program approved pursuant to these rules.

(5) "Eligible individual" means an indigent person or an uninsured person who meets all other criteria established by these rules.

(6) "Indigent" means a person with an income that is below 200 percent (200%) of the federal poverty level (FPL) as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

(7) "Medical facility" means any of the following:

(a) A physician's office;

(b) A hospital;

(c) A health clinic;

(d) A nonprofit health clinic, including a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(e) A free clinic as defined in T.C.A. § 63-6-703;

(f) A charitable organization as defined in T.C.A. § 48-101-501; or

(g) A nursing home as defined in T.C.A. § 68-11-201.

(8) "Legend Drug" means the same as defined in T.C.A. § 53-10-101.

(9) "NDC #" means the unique national drug code number that identifies a specific approved drug, its manufacturer and its package presentation.

(10) "Nurse practitioner" means an advanced practice nurse as defined in T.C.A. § 63-7-126.

(11) "Pharmacist" means a pharmacist as defined in T.C.A. § 63-10-204.

(12) "Pharmacy" means a pharmacy as defined in T.C.A. § 63-10-204.

(13) "Physician" means an individual licensed under T.C.A. § 63-6-201 or § 63-9-104.

(14) "Physician's Assistant" means an individual licensed under T.C.A. § 63-19-105.

(15) "Prescription drug" means the same as defined in T.C.A. § 63-10-204 except the drug is only tablet or capsule form, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances and drugs covered by the risk evaluation and mitigation strategy program of the federal food and drug administration

(16) "Repository" means a pharmacy or medical facility that meets the eligibility requirements of Rule 1140-17-.03.

(17) "Reverse Distributor" means an establishment that dispositions or otherwise processes saleable or nonsaleable legend drugs and controlled substances received from a pharmacy such that the legend drugs and controlled substances may be processed for credit to the purchaser, Manufacturer, or seller and disposed of for no further distribution.

(18) "Supplies" means the supplies necessary to administer the prescription drugs donated.

(19) "USP" means United States Pharmacopoeia.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

1140-17-.02 Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with Tenn. Code Ann. §§ 63-10-501 et seq. relative to the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies;

(2) Additional eligibility criteria for indigent or uninsured persons;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

1140-17-.03 Eligibility Criteria for Program Participation as a Repository by Medical Facilities and Pharmacies.

(1) To be eligible for participation in the prescription drug donation repository program, a medical facility or pharmacy shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, unencumbered, state-issued licenses or registrations in good standing. In the case of a physician's office, the physician(s) and other medical staff shall be duly licensed.

(2) A medical facility or pharmacy which intends to operate as a repository within the prescription drug donation repository program shall receive a determination of exemption from the United States internal revenue service pursuant to 26 U.S.C. § 501(c)(3) prior to making application to the Board to act as a repository. The medical facility or pharmacy shall present the exemption along with the form prescribed by the department and available on the program's web page as outlined in Tenn. Comp. R. & Regs 1140-17-.03(4).

(3) Participation in the prescription drug donation repository program is voluntary.

(4) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the program's web page, written notification to the department of all of the following:

(a) The name, street address, and telephone number of the pharmacy or medical facility, and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency;

(b) The name and telephone number of the responsible pharmacist, physician, physician's assistant or nurse practitioner who is employed by or under contract with the pharmacy or medical facility; and

(c) A statement, signed and dated by the responsible pharmacist, physician, physician's assistant or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

(5) Withdrawal from participation: A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the department on a form prescribed by the department and available on the program's web page.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.04 Standards and Procedures for Accepting Donated Prescription Drugs and Supplies.

(1) A person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy may donate drugs or supplies to the repository program. Any individual may donate legally obtained prescription drugs or supplies to a repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a repository.

(2) No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall be donated or accepted as part of the prescription drug donation repository program. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

(3) Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

(4) A repository may accept a prescription drug only if all of the following requirements are met:

(a) The drug is in its original sealed and tamper-evident packaging, which includes unit dose packaging created by a licensed pharmacy. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed;

(b) The drug has been stored according to manufacturer or USP storage requirements;

(c) The packaging contains the expiration date of the drug.

(d) The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

(e) The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

(f) All drugs shall be inventoried at the repository. The inventory shall include the name of the drug, strength of the drug, NDC number, quantity of the drug, expiration date of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

For purposes of this subparagraph a health care professional is any person licensed in accordance with the provisions of Title 63 by any health related board of the Tennessee Department of Health to perform any profession of the healing arts.

(5) A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

(a) The supplies are in their original, unopened, sealed packaging or unit dose packaging created by a licensed pharmacy;

(b) The supplies are not adulterated or misbranded; and

(c) All supplies shall be inventoried at the repository. The inventory shall include a description of the supplies, expiration date of the supplies, and the date of donation. Such inventory shall be recorded on a form provided by the department.

(6) Drugs and supplies may be donated on the premises of a repository to a person designated by the repository. Donations of prescription drugs and supplies may be made by mail, which includes the use of any common carrier. A drop box may not be used to deliver or accept donations.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.05 Standards and Procedures for Inspecting and Storing Donated Prescription Drugs and Supplies.

(1) A licensed pharmacist employed by or under contract with a repository shall inspect donated prescription drugs and supplies, prior to dispensing, to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs.

(2) A repository shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with non-donated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program, returned, or destroyed.

(3) Repositories shall return or destroy donated non-controlled substances that are not suitable for dispensing and make a record of such return or destruction which shall include, at a minimum, the drug name, strength, quantity, method of destruction, and date of destruction. A reverse distributor may be used for destruction.

(4) Controlled substances shall not be accepted for donation. Controlled substances submitted for donation shall be disposed of pursuant to DEA regulations. Destruction shall be accomplished by either the use of

a reverse distributor or by following current DEA regulations regarding destruction of controlled substances.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.06 Standards and Procedures for Dispensing Donated Prescription Drugs and Supplies.

(1) Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist, physician, physician's assistant or nurse practitioner. A Tennessee licensed pharmacist shall inspect the prescription drugs and supplies to determine the prescription drugs and supplies are not adulterated or misbranded prior to dispensing.

(2) A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

(a) First, to an indigent individual; and

(b) Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed.

(3) A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling. A medical facility or pharmacy may not dispense a prescription drug after the expiration date of the drug.

(4) The repository shall remove the original donor's identification and the name of the donor's dispensing pharmacy from the package prior to dispensing the drugs or supplies.

(5) If a donor receives official notice of a recall of a prescription drug donated pursuant to these rules, the donor shall make every effort to notify the repository to whom the drugs were donated of the recall.

(6) If an organization who is administering a drug repository program receives official notice of a recall of a prescription drug donated pursuant to these rules, the organization shall make every effort to notify the pharmacy, medical facility, or patient, if known, to whom such donated drugs were dispensed, of the recall. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a recall.

(7) Any donor or drug repository program who receives notice of a recall shall dispose of all recalled prescription drugs pursuant to the Tennessee Board of Pharmacy rules. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a recall.

(8) Prescription drugs or supplies donated under this program shall not be resold.

(9) Repositories may distribute drugs and supplies donated under this program to other repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form containing the inventory information on file in accordance with Rule 1140-17-.04(4)(f).

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.07 Eligibility Criteria for Individuals to Receive Donated Prescription Drugs and Supplies.

(1) An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Tennessee and meets one or both of the following criteria:

(a) Is indigent.

(b) Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

(2) A repository shall collect from each individual recipient a signed intake collection form provided by the department.

(a) The intake collection form shall attest that:

1. The individual is a resident of the state of Tennessee;

2. The individual's income is below 200 percent of the FPL;

3. The individual is uninsured and has no prescription coverage for the prescribed drugs;

4. The individual acknowledges that the drugs may have been donated; and

5. The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act (16 C.F.R. §§ 1700-1702).

(b) The intake collection form will include an identification card to be given to the recipient for continued use for one year.

(3) The identification card given to the recipient is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.08 Forms and Record Keeping.

(1) The following forms developed for the administration of this program shall be utilized by participants of the program and are available on the program's web page:

(a) Prescription drug donation repository program notice of participation or withdrawal.

(b) Prescription drug donation repository program donation, transfer, inventory or destruction record.

(c) A record of medications dispensed.

(d) Intake collection form. A repository is authorized to make available to a recipient a blank intake collection form.

(2) The identification card shall be given to the recipient by the repository, and the completed intake collection form shall be collected from the recipient by the repository.

(3) Record-keeping requirements.

(a) All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five (5) years by participating pharmacies and medical facilities.

(b) Other records required as part of this program shall be maintained pursuant to all current applicable practice acts.

(c) Data collected by the prescription drug donation repository program from all repositories shall be submitted quarterly or upon request to the department. The data will consist of the information collected in accordance with (1) above.

(d) A repository shall submit reports to the department yearly and upon request of the department. Such reports shall include the following data:

1. Number of donors during the reporting year;

2. Number of donations during the reporting year;

3. List of prescription drugs and supplies donated during the reporting year;

4. Number of people who received donations of prescription drugs or supplies during the reporting year;

5. Total number of prescription drugs and supplies dispensed during the reporting year; and

6. Total cost to eligible individuals who received donations during the reporting year.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.09 Handling Fee. A repository may charge the recipient of a donated prescription drug a handling fee, not to exceed a maximum of 200 percent of the applicable tiered reimbursement rate as produced by the Bureau of TennCare, to cover stocking and dispensing costs. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.10 List of Drugs and Supplies Program Will Accept. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these rules may be accepted for donation under the prescription drug donation repository program.

Any compounded drug which is made into tablet or capsule form, regardless of packaging, shall not be accepted by the prescription drug donation repository program

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.11 Exemption From Disciplinary Action, Civil Liability and Criminal Prosecution.

(1) Except for gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(2) Except as provided in subsection (4), a medical facility or another person who is not a drug manufacturer subject to subsection (1) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own gross negligence, willful misconduct, or bad faith. The medical facility or other person who is not a drug manufacturer subject to subsection (1) is also exempt from disciplinary action related to the facility's or person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(3) Except for gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy shall not be civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(4) The immunity and exemption provided in subsections (2) and (3) do not extend to the following:

(a) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(b) Acts or omissions outside the scope of the program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

1140-17-.12 Long-Term Care Facilities. A long term-care facility licensed under title 68 may donate prescription drugs to the repository program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Debra Wilson, D.Ph	X				
Rissa H. Pryse D.Ph	X				
Katy Wright, D.Ph.	X				
Lisa Tittle	X				
Adams Rodgers, D.Ph.	X				
Kevin K. Eidson, Pharm. D.		X			
R. Michael Dickenson, D.Ph.	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Board of Pharmacy (board/commission/ other authority) on 01/30/2018 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *11/28/17 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *01/30/2018 (mm/dd/yy)*

Date: April 4, 2018

Signature:

Name of Officer: Matthew Gibbs

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: 4-4-2018

Notary Public Signature:

My commission expires on: My Commission Expires January 26, 2021

SUZANNE MECHKOWSKI
STATE OF TENNESSEE NOTARY PUBLIC
SUMNER COUNTY

Agency/Board/Commission: Tennessee Board of Pharmacy

Rule Chapter Number(s): 1140-17

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

5/23/2018
Date

Department of State Use Only

Filed with the Department of State on: 5/31/18

Effective on: 8/29/18

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

January 30, 2018
Tennessee Board of Pharmacy Rulemaking Hearing
Public Hearing Comments

The Tennessee Department of Health ("TDH") received seventeen written comments regarding the proposed rule chapter. On the day of the rulemaking hearing, Dr. Phil Baker, CEO and founder of Good Shepherd Pharmacy, a co-signer to the written comments, presented the written comments, orally, to the Tennessee Board of Pharmacy ("BOP"). The comments were also signed by Dr. George Wang, co-founder and director of SIRUM.

Comment #1
Dr. Baker requested the word "original" as it pertains to "original sealed and tamper evidence packaging," as indicated in Rule 1140-17-.04(4)(a), does not exclusively mean a manufacturer's original packaging. From time to time, according to Dr. Baker, a pharmacy may package a drug. Dr. Baker wished to ensure a pharmacy-created package would be accepted by the repository program.

Response
The BOP accepted this change and added the phrase "[including] unit dose packaging created by a licensed pharmacy" to Rule 1140-17-.04(4)(a) and Rule 1140-17-.04(5).

Comment #2
Dr. Baker indicated the current rule provisions regarding recalls are burdensome, especially as it relates to donors notifying the drug repository program of recalled, donated drugs. Furthermore, Dr. Baker requested for the rules to be amended to account for the varying degrees of recalls.

Response
The Board is precluded from changing the donor-notification system as outlined in Rule 1140-17-.06(5) because T.C.A. § 63-10-503(c)(1) indicates that the donor "shall make every effort, as required by rule, to notify the repository program to whom the drugs were donated of the recall." The same statutory section applies to recall notifications received by the drug repository program. The BOP determined it could not change the donor-notification system due to statutory direction.

Comment #3 and #11
Dr. Baker asked the BOP to remove the requirement of visible lot numbers on the packaging of donated drugs. The removal of this requirement would allow for an increase in the number of drugs that could be donated to the drug repository program.

Also, a request was made to add additional recall rules to indicate that all drugs dispensed without a lot number would be subject to recall in the event it is impossible to differentiate between drugs that have and have not been recalled due to the lack of a lot number.

Response
The BOP voted to remove the requirement that a repository shall only accept drugs with visible lot numbers and voted to add a requirement that drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number as indicated in Rules 1140-17-.04(4)(c) and (f) and Rules 1140-17-.06(6) and (7). Both the removal of the lot number requirement and addition of the recall requirement were based upon the suggestions of Dr. Baker. The Board determined that in event of a recall, the public would be protected if all drugs (without corresponding lot numbers) were recalled. However, if a drug does have a visible lot number, that particular drug may survive recall as a batch that was not impacted by the recall notification.

Comment #4
Dr. Baker suggested that a pharmacist be allowed to inspect donated drugs before the drugs are dispensed, but not immediately after the drugs are received by the drug repository program via donation. This distinction would allow the pharmacist's staff to "pre-sort" donated drugs and free the pharmacist to perform other tasks.

Response

Consistent with statutory direction, the BOP voted to add the phrase "prior to dispensing" to Rule 1140-17-.05(1) which speaks to standards and procedures for inspecting and storing donated drugs.

Comment #5
Dr. Baker asked the BOP to allow "underinsured persons" (e.g. individuals with a prescription drug benefit, but the prescription drug benefit may still allow for unaffordable prescription drug coverage) to be added to the classes of individuals who may receive donated drugs. With the addition of underinsured persons, presumably, the drug repository program would be available to serve a larger segment of the population.

Response
Pursuant to T.C.A. § 63-10-501(7), an eligible individual, as defined, is someone with an income that is below two hundred percent of the federal poverty level (i.e. indigent person) or an individual who does not have insurance (i.e. uninsured person). In addition, the BOP was given rule-making authority to establish additional eligibility criteria for only indigent or uninsured persons. Given this statutory direction, the BOP voted to deny the request to allow underinsured persons to be eligible to receive donated drugs from the drug repository program.

Comment #6
Dr. Baker indicated that current draft rules allowed the maximum handling fee a repository may charge for dispensing donated drugs to be tied directly to the Medicaid dispensing fee. Due to the confusing and cumbersome nature of the Medicaid dispensing fee, Dr. Baker suggested each individual drug repository be allowed to set their own handling fee so long as the fee does not exceed the costs incurred by the drug repository in dispensing the drug.

Response
While the BOP did not adopt Dr. Baker's suggestion in total, the BOP voted to change the handling fee in order to add clarity to the handling fee rule provision as found in Rule 1140-17-.09. The BOP voted to allow a repository to charge no more than two hundred percent of the applicable tiered reimbursement rate as produced by the Bureau of TennCare.

Comment #7 and #14
Dr. Baker stated the current definition of "donor" was ambiguous and, potentially, could deter out-of-state entities (e.g. out-of-state drug repositories, non-Tennessee licensed healthcare facilities, or non-Tennessee licensed pharmacies) from donating to the Tennessee-based drug repository program.

Contrasted to the request for out-of-state entities to be able to donate to the Tennessee-based drug repository program is a request from Dr. Baker to allow the repository program to donate drugs to out-of-state repositories. From time-to-time, out-of-state repositories may experience a shortage of popular drugs and could benefit from a transfer of drugs donated to the Tennessee-based drug repository program which the Tennessee-based drug repository does not need for local patients.

Response
In draft rule form, the definition for "donor" mirrors the statutory definition for "donor" in T.C.A. § 63-10-501(6).

The BOP determined that any Tennessee-licensed pharmacy, wholesaler, or manufacturer, regardless of physical location, may donate to the Tennessee-based drug repository program. The BOP wished to conduct more research, by way of advisory counsel, to determine if non-Tennessee licensed medical facilities may be a "donor" according to the definition.

Currently, there are no restrictions in Tennessee statutory law or BOP regulations prohibiting the transfer of drugs out-of-state by a Tennessee-licensed pharmacy or health care facility. However, the transferring entity must be cognizant of the transferee's state law and federal law regarding drug transfers.

Comment #8, #13, and #17
Dr. Baker suggested, in Comment #8, the paperwork burden for the drug repository program may negatively impact participation (to be a drug repository) because the drug repository program will be maintained by a non-profit entity. Dr. Baker asked if individual drug repository programs can generate in-house forms. Dr. Baker requested edits to rules regarding (forms for) the inventory of drugs and supplies, the inspection record, and forms developed by the TDH.

In Comment #13, Dr. Baker asked the BOP for clarity regarding the requirements for destruction records. Specifically, Dr. Baker asked the BOP to include, within this rule chapter, the drug name, strength, and quantity in the destruction record for non-controlled donated drugs that are destroyed by the repository program.

For Comment #17, Dr. Baker indicated that participation by eligible persons could be diminished by requiring the drug repository program to submit information contained in the intake collection form to the TDH, as indicated in the draft rule. The intake collection form contains personal information regarding the donee's residence, income level, insurance coverage, acknowledgement that the drugs dispensed may be donated, and a waiver of "child-proof"-packaged drugs. Ultimately, Dr. Baker asked the BOP to remove the requirement for the drug repository program to submit information contained in the intake collection form.

Response
T.C.A. § 63-10-503(e)(3) instructs the TDH to adopt rules to establish necessary forms for administration of the drug repository program, "including forms for use by individuals who donate, accept, distribute, or dispense... drugs or supplies under the program[.]" Comment #8 was rejected by the BOP based upon the forgoing statutory grounds.

The BOP accepted Comment #13 and added the following to Rule 1140-17-.05(3), "which shall include, at a minimum, the drug name, strength, quantity, method of destruction, and date of destruction" regarding the destruction record of non-controlled donated drugs.

The BOP accepted Comment #17 and removed the requirement for the repository program to submit the intake collection form to the TDH.

Comment #9 and #10
Comment #9, as written, indicated that some drugs will be excluded from donation because the drugs require storage temperatures beyond normal room temperature. Drs. Baker and Wang asked the BOP, via the written comment, to adopt a suggestion that would allow for donation of temperature-controlled drugs.

Within Comment #10, Dr. Baker verbally asked for the unambiguous inclusion of non-tablet or capsule drugs which meet the drug repository program's standards for donated drugs. Dr. Baker stated that many of the most needed drugs are inhalers, patches, injectables, and or solutions.

Response
The statutory definition of prescription drug indicates the drug must be in tablet or capsule form. T.C.A. § 63-10-501(11). The BOP indicated the aforementioned statutory language precluded the BOP from allowing non-tablet or non-capsule drugs to be accepted by the drug repository program by way of edits to the draft rule language.

Comment #12
Dr. Baker stated the current draft rules could be interpreted to indicate the United States Parcel Services is the only entity that may be used when donations are made by "mail." Rule 1140-17-.04(6). Dr. Baker requested inclusion of the phrase "or any common carrier" to the forgoing rule.

Response
The BOP adopted this suggestion and added the phrase "which includes the use of any common carrier" to Rule 1140-17-.04(6).

Comment #15 and #16
In Comment #15, Dr. Baker asked the BOP to consider removing the requirement of using a reverse distributor to destroy controlled substances unintentionally donated to the drug repository program. Dr. Baker indicated it is cost prohibitive for a non-profit entity to utilize the services a reverse distributor.

In Comment #16, Dr. Baker requested the BOP to amend the rules to allow a return option for non-controlled medications donated to the drug repository program. Dr. Baker indicated, from time to time, a repository could receive a pallet of drugs which contain a rapidly-approaching expiration date. Dr. Baker stated it would be burdensome for the drug repository program to be saddled with the cost of destruction for this specific type of donation.

Response
The BOP voted to amend Rule 1140-17-.05(4) to indicate that destruction of controlled substances shall be accomplished by either using the services of a reverse distributor or by following current United States Drug Enforcement Agency regulations regarding destruction of controlled substances.

The BOP voted to amend Rules 1140-17-.05(2) and (3) to include a return option for donated drugs.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(1) The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

This new rule does not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

This new rule is established with clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

This new rule establishes new compliance and reporting requirements for businesses choosing to participate in the repository program. These compliance and reporting requirements are as flexible as other reporting requirements for pharmacies.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

This new rule establishes new schedules for businesses choosing to participate in the repository program, but these schedules are as flexible as other reporting requirements for pharmacies.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

The requirements for this new rule cannot be consolidated or simplified. The requirements are necessary for businesses involved in health emergencies.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These new rules do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

These new rules do not create unnecessary barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board of Pharmacy

Rulemaking hearing date: January 30, 2018

1. **Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

   These rules are necessary to comply with 2017 Public Chapter 392, which was signed by the Governor on May 18, 2017, and which allows persons, pharmacies, and medical facilities, including long-term care facilities, as well as drug manufacturers or wholesalers licensed by the Tennessee Board of Pharmacy to donate drugs or supplies to indigent and/or uninsured Tennessee residents. Indigent and uninsured Tennessee residents and health care facilities in Tennessee will bear the benefit of these rules. Manufacturers and distributors operating in Tennessee will bear the burden of these rules.

2. **Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

   These rules may increase costs for reporting, recordkeeping and administrative functions for those businesses choosing to participate in the repository program; however, any such increase should be minimal.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   While small businesses choosing to participate in the repository program may face a slight increase in operating costs, any such costs should be offset by the reduction in medication waste. Additionally, these rules will provide indigent and uninsured Tennessee residents with access to medications they otherwise could not afford.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of these rules.

5. **Comparison of the proposed rule with any federal or state counterparts:**

   Federal: None.

   State: None.

6. **Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

   These rules do not provide any exemptions for small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://publications.tnsosfiles.com/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The Tennessee Board of Pharmacy proposes a new rule chapter [Drug Donation Repository Program] to comply with 2017 Public Chapter 392, which was signed by the Governor on May 18, 2017.

This Rule Chapter allows participation in the repository program for resident(s) who are indigent or uninsured and attest to the following: 1) being a Tennessee resident, 2) having an income not exceeding 200 percent, 3) being uninsured, 4) acknowledging that the drugs may have been donated, and 5) consenting to a waiver of the requirement for child resistant packaging.

Additionally, this Rule Chapter encompasses other administrative rules required by 2017 Public Chapter 392, including: 1) requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, 2) additional eligibility criteria for indigent or uninsured persons, 3) necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program, 4) a means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility, 5) the maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program, and 6) a list of prescription drugs that the prescription drug donation repository program will accept.

Lastly, this Rule Chapter contains exemptions from disciplinary action, civil penalties and criminal prosecution for participants in the repository program and restricts the donation of controlled substances.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

2017 Public Chapter 392, which was signed by the Governor on May 18, 2017.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules will benefit indigent and uninsured Tennessee residents by providing a program by which persons and facilities can donate unused prescription medications to these residents in need. These rules will also affect health care facilities in Tennessee by reducing the heavy costs associated with medication. Manufacturers and distributors operating in Tennessee will bear the burden of these rules. Those who appeared at the rulemaking hearing supported the rule chapter, while requesting changes included in the comments section above. There were no comments urging rejection of this new rule chapter.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

These rules should not directly affect state or local governments.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Matthew Gibbs, Assistant General Counsel, Department of Health.

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Matthew Gibbs, Assistant General Counsel, Department of Health.

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Matthew.Gibbs@tn.gov.

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.