1/7/09
Received from Kevin Eidson - Karen Alvin Clouse
delivered to Hill yesterday
Copy for Commissioner.
S

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
BUREAU OF HEALTH LICENSURE AND REGULATION
DIVISION OF HEALTH RELATED BOARDS
227 French Landing, Suite 300
Heritage Place MetroCenter
Nashville, TN 37243
tennessee.gov/health

MEMORANDUM

TO: Honorable Rusty Crowe
Chairman of the Senate General Welfare, Health & Human Resources Committee

Honorable Joe Armstrong
Chairman of the House Health and Human Resources Committee

FROM: Kevin K. Eidson, Pharm D
Board of Pharmacy

DATE: December 31, 2008

RE: Charitable Clinic Pharmacy Report

Please find enclosed the Charitable Clinic Pharmacy Report as required by Public Chapter 919, Public Acts of 2006.

KKE:ma

Attachments

Report to the General Assembly: Charitable Clinic Pharmacy Pilot Program

A Report to the 2009 106th Tennessee General Assembly

Tennessee Department of Health

Bureau of Health, Licensure and Regulation

Board of Pharmacy

December, 2008

BACKGROUND AND SUMMARY OF THE LAW:

Public Chapter 919 of the 2006 Public Acts of the 104th Tennessee General Assembly created the Nina Norman Prescription Drug Donation Act of 2006, which establishes a pilot program to redispense donated prescription drugs, other than controlled substances, to indigent patients who have a valid prescription order. "Indigent patients" are defined as persons with an income level that is below two hundred percent (200%) of the federal poverty level. The law provides that a donor patient may voluntarily donate any unused drugs for redispensing by the charitable clinic pharmacy through the institutional facility. A "donor patient" is defined as the patient to whom the drug was prescribed or the patient's representative, in the event that the patient is deceased or not competent; the donor patient is seeking or has sought treatment in an institutional facility. The "institutional facility" is defined as a hospital, nursing home, home care organization, HIV supportive living facility or hospice.

In the event that a donor patient elects to donate drugs through this program, the drugs would be physically transferred from the institutional facility to the charitable clinic pharmacy by a person authorized by the Board of Pharmacy ("Board") to pick up the drugs for the pharmacy. A charitable clinic must be a pharmacy licensed by the Board and must meet all of the requirements for licensure as any other retail pharmacy. Once the drugs are transferred to the pharmacy, the drugs would be dispensed by a pharmacist licensed to engage in the practice of pharmacy in Tennessee to the indigent patient. The institutional facility is required to have a contract with the charitable clinic pharmacy to ensure the safe transfer of the drugs. The pharmacists dispensing the drugs from the charitable clinic pharmacy shall not redispense adulterated, misbranded, and expired drugs; shall not accept drugs of which they cannot assure the integrity; shall not accept controlled substances; and shall only accept drugs in their dispensed, sealed, and tamper-evident packaging. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for determining the description of the drugs that will be included in the contract between the institutional facility and the pharmacy. The law also provides that any persons or entities who/that participate in this program shall not be subject to criminal prosecution, civil liability or disciplinary action; except, however, pharmacists could be subject to discipline by the Board if the pharmacist violates any applicable Board laws or rules or any rules promulgated by the Board specific to this program.

DEVELOPMENT AND IMPLEMENTATION:

When this law was enacted on or about June 20, 2006, the Board was administratively attached to the Department of Commerce and Insurance, and at that time, the law required the Board to work in cooperation with the Department of Health to develop, implement and monitor this pilot program and to make findings and recommendations to the Health Committees of the General Assembly in the form of reports submitted on or before March 1, 2007 and January 1, 2008. The law also required the Board to promulgate rules to develop donor consent forms, waiver forms, and specific requirements for a charitable clinic pharmacy to participate in the pilot program, and to approve the contract between the institutional facility and the charitable clinic pharmacy for the transfer of drugs.

Effective July 1, 2007, the Board of Pharmacy was transferred from the Department of Commerce and Insurance to the Department of Health pursuant to Chapter 407 of the 2007 Public Acts; therefore, the report on the Charitable Clinic Pharmacy Program will be submitted from the Department of Health only.

When the Board was administratively attached to the Department of Commerce and Insurance, members of the Board staff (including the Board's interim director and legal counsel) met with representatives from the Department of Health and a representative from the Department of Mental Health and Developmental Disabilities to exchange ideas for the promulgation of rules for the functioning of the program. Details about the specific meetings that occurred between the Board and other State departments for the development and implementation of the program are contained in the March, 2007 report to the Health Committees of the General Assembly. In addition, a timeline for the development and promulgation of public necessity and permanent rules is also contained in the March, 2007 report. A copy of that report is attached hereto as **Exhibit "A"**.

At the time that the March, 2007 report was submitted to the Health Committees of the General Assembly, public necessity rules were effective, and a public rulemaking was held at a regularly scheduled Board of Pharmacy meeting on March 29, 2007 for the promulgation of permanent rules. The permanent rules became effective on September 2, 2007. A copy of the permanent rules is attached hereto as **Exhibit "B"**. Both the public necessity and the permanent rules established the following for the implementation of the program: the requirements for a charitable clinic pharmacy license; the duties and expectations of a pharmacist and pharmacist in charge working at a charitable clinic pharmacy; and the fees for licensure and renewal.

While the program was established through the promulgation of rules and development of forms necessary to donate drugs, there was no participation in the program as of the date of the December, 2007 report to the Health Committees of the General Assembly. The Board filed the December, 2007 report to comply with the mandate contained in Tenn. Code Ann. §63-10-504(c)(2). A copy of the December, 2007 report is attached hereto as **Exhibit "C".** At that time, because there was no participation in the program, yet some inquiries about the program and requests for charitable clinic pharmacy applications, the Board recommended that it make another report to the General Assembly no later than January 1, 2009 to determine the impact and efficacy of the program.

As of the date of this December 2008 report, there has still not been any participation in this program; no individual, entity or association has applied for a charitable clinic pharmacy license from the Board of Pharmacy and as such, there have not been any charitable clinic pharmacies established pursuant to the Board's licensure program. This program cannot function without the establishment of charitable clinic pharmacies from which the donated drugs will be redispensed.

FINDINGS AND RECOMMENDATIONS:

Because of the lack of participation in this program, the Board is unable to make any meaningful report to the General Assembly about the functioning and effectiveness of this program. Although the program is not currently functioning because of the lack participation, the Board office

periodically receives requests for charitable clinic pharmacy applications, indicating that there is some interest in the program. Accordingly, the Board recommends that it submit another report to the General Assembly no later than January 1, 2010. At that time, if there is still no participation, the Board may recommend termination of the program.

EXHIBIT "A"

Report to the General Assembly: Charitable Clinic Pharmacy Pilot Program

A Report to the 2007 105th Tennessee General Assembly

Tennessee Department of Commerce and Insurance

Leslie A. Newman, Commissioner
Meredith Sullivan, Assistant Commissioner for Regulatory Boards

March, 2007

BACKGROUND AND SUMMARY OF THE LAW:

Public Chapter 919 of the 2006 Public Acts of the 104th Tennessee General Assembly created the Nina Norman Prescription Drug Donation Act of 2006, which establishes a pilot program to redispense donated prescription drugs, other than controlled substances, to indigent patients who have a valid prescription order. "Indigent patients" are defined as persons with an income level that is below two hundred percent (200%) of the federal poverty level. The law provides that a donor patient may voluntarily donate any unused drugs for redispensing by the charitable clinic pharmacy through the institutional facility. A "donor patient" is defined as the patient to whom the drug was prescribed or the patient's representative, in the event that the patient is deceased or not competent; the donor patient is seeking or has sought treatment in an institutional facility. The "institutional facility" is defined as a hospital, nursing home, home care organization, HIV supportive living facility, or hospice.

In the event that a donor patient elects to donate drugs through this program, the drugs would be physically transferred from the institutional facility to the charitable clinic pharmacy by a person authorized by the Board to pick up the drugs for the pharmacy. A charitable clinic must be a pharmacy licensed by the Board and must meet all of the requirements for licensure as any other retail pharmacy. Once the drugs are transferred to the pharmacy, the drugs would be dispensed by a pharmacist licensed to engage in the practice of pharmacy in Tennessee to the indigent patient. The institutional facility is required to have a contract with the charitable clinic pharmacy to ensure the safe transfer of the drugs. The pharmacists dispensing the drugs from the charitable clinic pharmacy shall not redispense adulterated, misbranded, and expired drugs; shall not accept drugs of which they cannot assure the integrity; shall not accept controlled substances; and shall only accept drugs in their dispensed, sealed, and tamper-evident packaging. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for determining the description of the drugs that will be included in the contract between the institutional facility and the pharmacy. The law also provides that any persons or entities who/that participate in this program shall not be subject to criminal prosecution, civil liability or disciplinary action; except, however, pharmacists could be subject to discipline by the Board if the pharmacist violates any applicable Board laws or rules or any rules promulgated by the Board specific to this program.

In developing and implementing this pilot program, the law mandates the following from the Board, which is administratively attached to the Tennessee Department of Commerce and Insurance ("Department"):

- To develop and implement this pilot program in cooperation with the Department of Health;
- To promulgate rules to develop donor consent forms, waiver forms, and specific requirements for a charitable clinic pharmacy to participate in the pilot program;
- To approve the contract between the institutional facility and the charitable clinic pharmacy for the transfer of drugs; and
- To monitor the pilot program in cooperation with the Department of Health by submitting two (2) reports along with any recommendations and findings to the health committees of the general assembly; the first report must be submitted on or before March 1, 2007 and the second report must be submitted on or before January 1, 2008.

DEVELOPMENT AND IMPLEMENTATION:

In order to comply with the legislative mandate of developing and implementing this pilot program in cooperation with the Department of Health, on July 31, 2006 representatives from the Board and the Department (Terry Grinder, Interim Director for the Board of Pharmacy; Alison Cleaves, Chief Counsel for Regulatory Boards; Sara Luna, Administrative Assistant to Assistant Commissioner Sullivan) met with representatives from the Department of Health (Kevin Eidson, Director of Pharmacy and Robbie Bell, Director of the Division of Health Related Boards); and from the Department of Mental Health and Developmental Disabilities (Jason Carter, Chief of Pharmacy). At that meeting, the participants developed ideas about the pharmacist's and pharmacist-in-charge's responsibilities to the indigent patients in this program, the safe transfer of the drugs from the institutional facility to the pharmacy, and who would be eligible to donate to the program. All the meeting participants wanted the rules to ensure that the indigent patients were given competent patient care. In meeting this goal, the participants indicated that the rules should address how the drugs would be transferred from the institution to the pharmacy, while ensuring the integrity of the drugs that would be dispensed to indigent patients and how the pharmacist in charge would record the drugs received and the drugs destroyed by the pharmacist because the drugs were adulterated, expired, misbranded, recalled, deteriorated, or not kept under proper conditions.

Understanding the goal that the rules must achieve, the Department through Board staff and Legal staff conducted research to determine which other states had established a drug donation program similar to the one created by the General Assembly. Other state counterparts were contacted to inquire about the function of their drug donation programs and the Department obtained other states' laws and rules, which included California, Connecticut, Colorado, Delaware, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Ohio, Oklahoma, and Rhode Island. Legal staff embarked on a comparative study to determine which states' programs were most similar to Tennessee's and what rules promulgated by other state boards could be used as models for Tennessee's rules. Once a thorough review of those laws and rules were completed, legal staff drafted rules for this pilot program.

TIMELINE FOR RULE IMPLEMENTATION:

August 29, 30, 2006- A public necessity notice of rulemaking draft was presented to the Board at the August 29-30, 2006 Board meeting with the comments from the Department of Health. The Board of Pharmacy approved the draft with some changes that were circulated back to the Department of Health and to Assistant Commissioner Sullivan who reviewed the draft for its impact on the Department.

November 7, 8, 2006 – A revised draft was presented to the Board with suggested changes from the Department of Health and Assistant Commissioner Sullivan. The Board absorbed those changes, yet had some questions for the Department of Health about whether the destruction of

medications by the pharmacist would violate any Department of Health rules or whether those drugs should be returned back to the institutional facility. At this meeting, the Board also determined that the rules did not violate Executive Order 38 in that the rules would not adversely affect small businesses. All pharmacies whether they are large or small businesses can participate in this program as a charitable clinic pharmacy as long as the business is licensed as a pharmacy by the Board and the pharmacy complies with all applicable laws and rules.

November 9, 2006- Received correspondence from the Department of Health indicating that the pharmacists at the charitable clinic pharmacy can destroy a medication that they receive that cannot be redispensed for whatever reason the rules indicate that the drug cannot be used. The Department of Health suggested that the rules have some language that would address recordkeeping of the drugs destroyed by the pharmacist.

December 14, 2006- The Board convened by teleconference to consider Department of Health's suggestion. The Board voted to promulgate the public necessity rules with Health's suggestion for the implementation of the charitable clinic pharmacy pilot program.

December 21, 2006- The public necessity rules were then sent to the Attorney General's Office for review.

February 14, 2007 – The public necessity rules were received by Legal staff from the Attorney General's office as having been approved.

February 16, 2007- The public necessity rules were filed with the Secretary of State's Office. The rules became effective on that date and will remain in effect until July 31, 2007. A copy of the public necessity rules are attached hereto.

February 22, 2007- The public necessity rules along with a donor consent form, waiver form and pharmacy license application were placed on the Board of Pharmacy website with a description of the pilot program and notification that the Board was accepting pharmacy license applications for participation in this program.

March 29, 2007- A public rulemaking hearing will be held before the Board to hear and respond to public comments about the rules before the Board votes to promulgate them as permanent rules.

FINDINGS AND RECOMMENDATIONS:

The Board, in cooperation with the Department of Health, is unable to make any findings or recommendations relative to the implementation or functioning of this program because the Board's rules specific to this program have just recently become effective and therefore, there are not any charitable clinic pharmacies established. The Board with the Department of Health will be in a better position to comment about the program when they report to the Health Committees of the General Assembly on or before January 1, 2008.

EXHIBIT "B"

Rulemaking Hearing Rules
of
the Department of Commerce and Insurance
Division of Regulatory Boards
Tennessee State Board of Pharmacy

Chapter 1140-12
Charitable Clinic Pharmacies

New Rules

Table of Contents

1140-12-.01 Purpose.

The rules in this chapter implement the Nina Norman Prescription Drug Donation Act of 2006, T.C.A. § 63-10-501, et seq., which has been enacted into law to develop a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines to indigent patients that would otherwise be destroyed.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. § 63-10-501through § 63-10-505.

1140-12-.02 Definitions.

In addition to the definitions contained in T.C.A. § 63-10-503, the following definitions are applicable to this chapter:

(1) "Board" means the Tennessee Board of Pharmacy;

(2) "Dispense" shall have the same meaning as set forth in T.C.A. § 63-10-204(11);

(3) "Distribute" shall have the same meaning as set forth in T.C.A. § 63-10-204 (12);

(4) "Manifest" means a list of drugs being transferred or destroyed and shall include at a minimum, the drug name, strength, quantity, and expiration date;

(5) "Person" means any individual, partnership, association, or corporation;

(6) "Pharmacist" shall have the same meaning as set forth in T.C.A. § 63-10-204(26);

(7) "Pharmacy" means a charitable clinic pharmacy as set forth in T.C.A. § 63-10-503(2);

(8) "Pharmacy practice site" shall have the same meaning as set forth in Tenn. Comp. R. & Regs. Rule 1140-1-.01(23);

(9) "Pharmacist in charge" shall have the same meaning as set forth in T.C.A. § 63-10-204(27);

(10) "Program" means the drug donation program established by the Nina Norman Prescription Drug Donation Act of 2006 established in T.C.A. § 63-10-501, et seq.;

(11) "Single Unit Dose" means sealed, tamper-evident packaging of medication from a manufacturer, repackager licensed by the Food and Drug Administration, or from a pharmacy when packaged in individual dosage units in United States Pharmacopeia Class B packaging and labeled with the appropriate product information including full product name, dosage form, strength, lot number, and expiration date.

Authority: Chapter 919 of the Public Acts of 2006, §1 and T.C.A. § 63-10-505(g).

1140-12-.03 Application and Renewal Requirements.

(1) Any person who desires to obtain a charitable clinic pharmacy license shall submit an application to the board, along with the required license fee, and comply with the pharmacy practice site licensure requirements established in Rule 1140-1-.08(3)(a).

(2) Applications for licensure are available upon request from the board.

(3) All charitable clinic pharmacy licenses shall be renewed on a biennial basis from the date that the license was initially granted. All licenses shall be renewed on or before the last day of the two (2) year license cycle.

(4) An applicant may renew the charitable clinic pharmacy license within six (6) months from the license expiration date with payment of the renewal fee and late renewal penalty fee.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. §§ 63-10-502(2) and 63-10-505(g)(4)(A).

1140-12-.04 Fees.

(1) Initial license fee.....$168.00

(2) Renewal fee.....$168.00

(3) The late renewal penalty fee is ten dollars ($10.00) per month for each month or fraction of a month that renewal is late.

Authority: .Chapter 919 of the Public Acts of 2006, § 1 T.C.A. §§ 63-10-502(2) and 63-10-505(g)(4)(A).

1140-12-.05 Pharmacist Responsibilities.

(1) Medication Transfers.

(a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the following criteria are satisfied upon receiving medications from the institutional facility:

1. the only drugs that are accepted by the pharmacy to be dispensed are those drugs that are in their dispensed, sealed and tamper-evident packaging which includes, but is not limited to, single-unit doses or blister packs with the outside packaging opened if the single unit dose packaging remains intact;

2. the donor patient or donor patient's representative executed a drug donation form for the drugs transferred from the institutional facility to the pharmacy. In the event that the pharmacist does not receive a copy of the donor form with the transferred drugs, then the pharmacist shall not dispense the drugs;

3. the donor patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the institutional facility. In the event that the identifying patient information is not removed when received by the charitable clinic pharmacist from the institutional facility, then the pharmacist shall remove or redact this information;

4. the drug name, strength, lot number, and expiration date is on the drug package or label. In the event that the identifying drug information is not on the package or label when received from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them;

5. drug(s) that are being transferred are accompanied by a manifest from the institutional facility;

6. drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions shall not be dispensed from the pharmacy if they are transferred from the institutional facility. In the event that the pharmacist receives drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them after creating the documentation required in Rule 1140-12-.05(3)(a);

7. controlled substances are not accepted or dispensed from the pharmacy if they are transferred. In the event that institutional facility transfers controlled substances, the pharmacist shall send the controlled substances back to the institutional facility;

8. the donated drugs may be transferred from one (1) pharmacy to another by an individual designated by the pharmacist in charge or through any other means by which the donated drugs may be tracked and delivery confirmed; and

9. the donated drugs are physically transferred from the institutional facility to the pharmacy by an individual designated by the pharmacist in charge of the pharmacy or through any other means by which the donated drugs may be tracked and delivery confirmed.

(2) Prohibited Activities.

(a) Any pharmacist working at a charitable clinic pharmacy shall not purchase, possess, trade, distribute or dispense any controlled substances from the charitable clinic pharmacy.

(3) Recordkeeping.

(a) Any pharmacist working at a charitable clinic pharmacy shall create and maintain a manifest of the prescription drugs transferred from the institutional facility to the pharmacy that were not dispensed because the drugs were expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as provided in Rule 1140-12-.05(4). Pharmacists shall maintain this manifest at the pharmacy for two (2) years from the date of destruction.

(b) The pharmacists working at the charitable clinic pharmacy shall maintain a manifest of all prescription drugs transferred from the institutional facility to the pharmacy and dispensed from the pharmacy for two (2) years from the date of receipt.

(c) The pharmacists working at the pharmacy shall maintain a manifest of all prescription drugs transferred from one (1) pharmacy to another for two (2) years from the date of transfer.

(4) Labeling.

(a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the donor patient's identifying information is redacted from the donated drugs prior to redispensing.

(b) Any pharmacist working at a charitable clinic pharmacy shall redispense the donated drugs to an indigent patient and place a label on the drugs with the indigent patient's identifying information, dosage instructions, auxiliary labels, and drug expiration date.

(5) All pharmacists working at a charitable clinic pharmacy shall comply with all other applicable Board rules.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. § 63-10-505 (c)(1) and (g)(4)(A).

1140-12-.06 Pharmacist-In-Charge Responsibilities.

(1) The pharmacist in charge at the charitable clinic pharmacy shall ensure that the following occurs at the pharmacy:

(a) donated drugs dispensed from pharmacy are properly labeled;

(b) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are not redispensed to indigent patients;

(c) donated drugs are inspected prior to redispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

(d) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are destroyed;

(e) manifests for donated drugs that are dispensed or destroyed are created or maintained at the pharmacy in accordance with Rule 1140-12-.05;

(f) that the institutional facility transferring the drugs has a contract with the pharmacy about the transfer of drugs that is approved by the Board of Pharmacy in cooperation with the Department of Health in accordance with T.C.A. § 63-10-505; and

(g) that the contract between the institutional facility and the pharmacy will contain a description of the drugs that will be included in the contract. The pharmacist in charge is responsible for determining the description of the drugs.

Authority: Chapter 919 of the Public Acts of 2006, § 1, T.C.A. §§ 63-10-505(g)(4)(A) and 63-10-505(b)(3).

1140-12-.07 Donor Patient Form.

(1) The donor patient form shall include, at a minimum, the following:

(a) name of the patient to whom the medication was originally dispensed;

(b) name of the institutional facility authorized to deliver the unused prescription medication;

(c) name of drug, quantity, prescription number, date of prescription and name of pharmacy where it was originally dispensed;

(d) name of the charitable clinic pharmacy;

(e) date the drug was donated;

(f) authorization to donate the drug voluntarily for use in the program;

(g) a signature line for the donor patient or for the donor patient's representative in the event that patient is deceased or not competent; and

(h) a statement that the donor patient's participation in the pilot program shall not be used as an independent basis for a civil, criminal, or disciplinary action against the donor patient's, donor patient's estate, health care provider, charitable clinic, department of health, board, or the charitable clinic pharmacy, pharmacists and pharmacy technicians as long as they abide by board rules.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. §§ 63-10-505(g)(2) and 63-10-505(c)(5)(A).

1140-12-.08 Waiver Form.

(1) The waiver form shall include, at a minimum, the following:

(a) name of indigent patient;

(b) name of drug, quantity, prescription number, date of prescription, name of charitable clinic pharmacy dispensing the drug;

(c) a signature line for the indigent patient; and

(d) waiver releasing the institutional facility, donor patient, and donor patient's estate from liability.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. §§ 63-10-505(g)(3) and 63-10-505(f).

1140-12-.09 Civil Penalties.

(1) The board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of any other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the board in accordance with the following schedule:

Violation	Penalty
T.C.A. Section 63-10-505(b)(B)(3)	$0-$1,000
T.C.A. Section 63-10-505(c)(2)	$0-$1,000
T.C.A. Section 63-10-505(c)(3)	$0-$1,000
Rule 1140-12-.03	$0-$1,000
Rule 1140-12-.05	$0-$1,000
Rule 1140-12-.06	$0-$1,000

(2) Each day of continued violation may constitute a separate violation.

(3) In determining the amount of any penalty to be assessed pursuant to this rule, the board may consider such factors as the following:

(a) Willingness of the violation;

(b) Repetitions of the violation; and

(c) Magnitude of the risk of harm cased by the violation.

(4) Each violation of any statute, rule or order enforceable by the board shall constitute a separate and distinct offense and render the person committing the offense subject to a separate civil penalty for each violation.

Authority: Chapter 919 of the Public Acts of 2006, § 1 and T.C.A. §§ 56-1-308, 63-10-505(g)(4)(A).

Legal contact and/or party who will approve final copy for publication: _____

Alison G. Cleaves
Chief Counsel for Regulatory Boards
Department of Commerce and Insurance
Office of Legal Counsel
500 James Robertson Parkway
Davy Crockett Tower, 12th Floor
Nashville, Tennessee 37243
(615) 741-3072

Contact for disk acquisition: _____

Alison G. Cleaves
Chief Counsel for Regulatory Boards
Department of Commerce and Insurance
Office of Legal Counsel
500 James Robertson Parkway
Davy Crockett Tower, 12th Floor
Nashville, Tennessee 37243
(615) 741-3072

Signature of the agency officer directly responsible for proposing and/or drafting these rules:

_____

Alison G. Cleaves
Chief Counsel for Regulatory Boards

The roll-call vote by the Board of Pharmacy on these rulemaking hearing rules was as follows:

	Aye	No	Abstain
Sheila Mitchell, President	X		
James Robert Mitchell, Jr., Vice President	X		
David Todd Bess	X		
Monica Franklin	X		
Albert Larry Hill	X		
Julie Frazier	X		

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy on the 29th day of March, 2007.

Further, I certify that the provisions of Tenn. Code Ann. §4-5-222 have been fully complied with, that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the 31st day of January, 2007 and such notice of rulemaking hearing having been published in the February, 2007 issue of the Tennessee Administrative Register, and such rulemaking hearing having been conducted pursuant thereto on the 29th day of March, 2007.

Alison G. Cleaves
Chief Counsel for Regulatory Boards
Department of Commerce and Insurance

Subscribed and sworn to before me this the 17th day of May 2007.

W. C. Henderson
Notary Public

W. C. HENDERSON
STATE OF TENNESSEE NOTARY PUBLIC
WILSON COUNTY

My Commission expires on the 8th day of September, 2009.

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.

Robert E. Cooper, Jr.
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 19 day of June, 2007 and will become effective on the 2 day of Sept., 2007.

Riley C. Darnell
Secretary of State

By:

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2007 JUN 19 AM 8:40
SECRETARY OF STATE
PUBLICATIONS

EXHIBIT "C"

Report to the General Assembly: Charitable Clinic Pharmacy Pilot Program

A Report to the 2007 105th Tennessee General Assembly

Tennessee Department of Health

Susan R. Cooper, MSN, RN, Commissioner
Christy A. Allen, Assistant Commissioner for the Bureau of Health, Licensure and Regulation

December, 2007

BACKGROUND AND SUMMARY OF THE LAW:

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In the event that a donor patient elects to donate drugs through this program, the drugs would be physically transferred from the institutional facility to the charitable clinic pharmacy by a person authorized by the Board of Pharmacy ("Board") to pick up the drugs for the pharmacy. A charitable clinic must be a pharmacy licensed by the Board and must meet all of the requirements for licensure as any other retail pharmacy. Once the drugs are transferred to the pharmacy, the drugs would be dispensed by a pharmacist licensed to engage in the practice of pharmacy in Tennessee to the indigent patient. The institutional facility is required to have a contract with the charitable clinic pharmacy to ensure the safe transfer of the drugs. The pharmacists dispensing the drugs from the charitable clinic pharmacy shall not redispense adulterated, misbranded, and expired drugs; shall not accept drugs of which they cannot assure the integrity; shall not accept controlled substances; and shall only accept drugs in their dispensed, sealed, and tamper-evident packaging. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for determining the description of the drugs that will be included in the contract between the institutional facility and the pharmacy. The law also provides that any persons or entities who/that participate in this program shall not be subject to criminal prosecution, civil liability or disciplinary action; except, however, pharmacists could be subject to discipline by the Board if the pharmacist violates any applicable Board laws or rules or any rules promulgated by the Board specific to this program.

DEVELOPMENT AND IMPLEMENTATION:

When this law was enacted on or about June 20, 2006, the Board was administratively attached to the Department of Commerce and Insurance, and at that time, the law required to Board to work in cooperation with the Department of Health to develop, implement and monitor this pilot program and to make findings and recommendations to the Health Committees of the General Assembly in the form of reports submitted on or before March 1, 2007 and January 1, 2008. The law also required the Board to promulgate rules to develop donor consent forms, waiver forms, and specific requirements for a charitable clinic pharmacy to participate in the pilot program, and to approve the contract between the institutional facility and the charitable clinic pharmacy for the transfer of drugs.

Effective July 1, 2007, the Board of Pharmacy was transferred from the Department of Commerce and Insurance to the Department of Health pursuant to Chapter 407 of the 2007 Public Acts; therefore, the report on the Charitable Clinic Pharmacy Program will be submitted from the Department of Health only.

When the Board was administratively attached to the Department of Commerce and Insurance, members of the Board staff (including the Board's interim director and legal counsel) met with representatives from the Department of Health and a representative from the Department of Mental Health and Developmental Disabilities to exchange ideas for the promulgation of rules for the functioning of the program. Details about the specific meetings that occurred between the Board and other State departments for the development and implementation of the program are contained in the March, 2007 report to the Health Committees of the General Assembly. In addition, a timeline for the development and promulgation of public necessity and permanent rules is also contained in the March, 2007 report. A copy of that report is attached hereto as **Exhibit "A"**.

At the time that the March, 2007 report was submitted to the Health Committees of the General Assembly, public necessity rules were effective, and a public rulemaking was held at a regularly scheduled Board of Pharmacy meeting on March 29, 2007 for the promulgation of permanent rules. The permanent rules became effective on September 2, 2007. A copy of the permanent rules is attached hereto as **Exhibit "B"**. Both the public necessity and the permanent rules established the following for the implementation of the program: the requirements for a charitable clinic pharmacy license; the duties and expectations of a pharmacist and pharmacist in charge working at a charitable clinic pharmacy; and the fees for licensure and renewal.

As of the date of this report, there has not been any participation in this program; no individual, entity or association has applied for a charitable clinic pharmacy license from the Board of Pharmacy and as such, there have not been any charitable clinic pharmacies established pursuant to the Board's licensure program. This program cannot function without the establishment of charitable clinic pharmacies from which the donated drugs will be redispensed.

FINDINGS AND RECOMMENDATIONS:

Although the program is not currently functioning because of the lack participation, the Board office recently received a request for a pharmacy application, which was sent from the Board office to the requestor but has not yet been returned to the Board office. The law and the program are still relatively new, and the Department has not had ample opportunity to determine the impact or the efficacy of the program. Accordingly, the Department recommends that the General Assembly grant it additional time to evaluate this program from the perspective of determining whether charitable clinic pharmacies are established and if, how frequently and efficiently they are utilized. The Department recommends that it make another report to the General Assembly no later than January 1, 2009.