

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

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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.