

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.