AMENDED

April 28, 2010

**H. 4559**

Introduced by Reps. Barfield, Huggins, Crawford, Jefferson, Williams, H.B. Brown, Viers, Govan, Chalk, G.M. Smith, Weeks, Bowen, Clemmons, Gunn, Hardwick, Harrison, Hart, Hearn, Long, V.S. Moss, J.H. Neal, Ott, J.E. Smith, Toole, Vick, White, Willis, Whipper, R.L. Brown and Neilson

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Read the first time February 17, 2010.

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING ARTICLE 16 TO CHAPTER 53, TITLE 44 TO ENACT THE “UTILIZATION OF UNUSED PRESCRIPTION DRUGS ACT” SO AS TO PROVIDE THAT THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, IN CONSULTATION WITH THE BOARD OF PHARMACY, SHALL DEVELOP A VOLUNTARY PROGRAM WHEREBY HEALTH CARE FACILITIES CAN DONATE UNUSED PRESCRIPTION DRUGS OF PATIENTS WHO NO LONGER NEED THEM AND WHO HAVE VOLUNTARILY AGREED TO DONATE THEIR PRESCRIPTION DRUGS TO CHARITABLE CLINICS PROVIDING SERVICES TO MEDICALLY INDIGENT PERSONS; TO PROVIDE THAT CERTAIN PROGRAM PROCEDURES AND REQUIREMENTS MUST BE PROMULGATED IN REGULATION BY THE DEPARTMENT AND BY THE BOARD OF PHARMACY, INDIVIDUALLY, TO CARRY OUT THE PROVISIONS OF THIS ARTICLE; AND TO CREATE AN ADVISORY COUNCIL TO OVERSEE AND ADVISE THE DEPARTMENT IN ESTABLISHING THIS PROGRAM AND IN CARRYING OUT THE RESPONSIBILITIES UNDER THIS ARTICLE; BY ADDING SECTION 44‑53‑60 SO AS TO PROVIDE THAT THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, IN CONJUNCTION WITH THE BOARD OF PHARMACY, SHALL DEVELOP A PROGRAM TO RECEIVE AND DISPOSE OF UNUSED MEDICATIONS FROM THE PUBLIC AND SHALL DEVELOP GUIDELINES FOR THE SAFE AND PROPER DISPOSAL OF MEDICATIONS WHICH MUST BE AVAILABLE AND DISTRIBUTED TO THE PUBLIC.

Amend Title To Conform

Whereas, the General Assembly has:

(1) determined that the high cost of prescription drugs is a burden on the uninsured and medically indigent who may forego the drugs they need or take only partial doses which can ultimately increase health costs;

(2) determined that many health care facilities destroy quantities of unused but viable prescription medications when residents pass away or when medications otherwise are no longer needed by the resident; and

Whereas, in an effort to improve the quality, efficiency, and utilization of the state’s health care system, the General Assembly hereby establishes a voluntary statewide program allowing health care facilities and other health care related facilities licensed by the Department of Health and Environmental Control to transfer from their facilities unused prescription drugs to authorized participating pharmacies for distribution to medically indigent South Carolina residents. Now, therefore,

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This act may be cited as the “Utilization of Unused Prescription Drugs Act”.

SECTION 2. Chapter 53, Title 44 of the 1976 Code is amended by adding:

“Article 16

Utilization of Unused Prescription Drugs

Section 44‑53‑1810. As used in this article:

(1) ‘Charitable clinic’ means an ambulatory care facility organized as a nonprofit corporation that has a licensed out‑patient pharmacy located at the facility or that has a contract with a retail pharmacy to participate in the program established pursuant to this article.

(2) ‘Department’ means the Department of Health and Environmental Control.

(3) ‘Health care facility’ means acute care hospitals, psychiatric hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, and the Department of Disabilities and Special Needs.

(4) ‘Medically indigent’ means a person eligible to receive Medicaid or Medicare benefits or a person who has no prescription drug coverage and who otherwise lacks reasonable means to purchase prescribed drugs.

(5) ‘Pharmacy’ means a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy-related services are provided by a pharmacist.

(6) ‘Prescription drug’ means a drug that may be dispensed only upon prescription by a licensed health care professional with prescriptive authority, as provided for in law. This term does not include controlled substances, as defined in Section 44‑53‑110, or a drug that can only be dispensed to a patient registered with the drug’s manufacturer in accordance with federal Food and Drug Administration requirements.

Section 44‑53‑1820. (A) The Department of Health and Environmental Control, in consultation and cooperation with the Board of Pharmacy, shall develop and implement a voluntary program consistent with public health and safety through which unused prescription drugs may be transferred from health care facilities to charitable clinics for the purpose of redispensing the medication to residents who are medically indigent.

(B) Participation in the program by individual residents, health care facilities, charitable clinics, pharmacies, and prescription drug manufacturers is voluntary. Nothing in this article requires a resident of any health care facility, charitable clinic, pharmacy, pharmacist, or prescription drug manufacturer to participate in the program.

(C) The department shall provide written notification to all eligible health care facilities to post a sign clearly and conspicuously in each facility to notify its residents of the program.

Section 44‑53‑1830. The following criteria must be used in soliciting and accepting unused prescription drugs for use pursuant to this article:

(1) Health care facilities that have entered into an agreement to participate with a charitable clinic shall document each resident’s participation in the program with a written statement that the resident’s excess and otherwise eligible unused prescription drugs may be donated to a charitable clinic for the purpose of dispensing to medically indigent persons.

(2) Only prescription drugs in their original manufacturer’s sealed multi‑dose blister packages, unit dose containers, or perforated blister packages may be accepted and dispensed.

(3) Prescription drugs may not be accepted with less than a ninety-day expiration or beyond use date.

(4) A prescription drug must not be accepted or dispensed if the pharmacist accepting or dispensing the drug, in his or her judgment, has reason to believe that the drug is adulterated, misbranded, or has been improperly stored.

(5) No controlled substances or a drug that can only be dispensed to a patient registered with the drug’s manufacturer in accordance with federal Food and Drug Administration requirements may be accepted.

Section 44‑53‑1840. (A) A pharmacy operating in conjunction with a charitable clinic may dispense prescription drugs donated pursuant to this article to persons who are medically indigent residents.

(B) A pharmacy operating in conjunction with a charitable clinic wherein both meet the eligibility requirements established and authorized pursuant to this article and that accepts donated prescription drugs shall:

(1) comply with all applicable federal and state laws relating to the storage, distribution, and dispensing of prescription drugs;

(2) inspect all prescription drugs prior to dispensing the prescription drugs to determine that the drugs are not adulterated or misbranded; and

(3) dispense prescription drugs only pursuant to a valid prescription issued by a licensed health care professional with prescriptive authority, as provided for in law.

(C) Prescription drugs donated pursuant to this article must not be sold or billed to a third party payor.

Section 44‑53‑1850. (A) For matters related only to the lawful donation, acceptance, or dispensing of prescription drugs under this article, the following persons and entities participating in this program, in compliance with criteria provided for in this article, in the absence of bad faith, are immune from criminal or civil liability for injury, death, or loss to person or property and are not subject to professional disciplinary action:

(1) a charitable clinic, a licensed health care professional with prescriptive authority, as provided for in law, or a pharmacy that accepts or dispenses prescription drugs pursuant to this article;

(2) a resident of a facility, or the resident’s next of kin or legal guardian or estate, who agrees to donate unused prescription drugs;

(3) the Department of Health and Environmental Control and other governmental entities;

(4) the Board of Pharmacy;

(5) a prescription drug manufacturer, governmental entity, or health care facility that participates in this program that donates prescription drugs pursuant to this article;

(6) a prescription drug manufacturer or its representative that directly donates prescription drugs in professional samples to a charitable clinic or a pharmacy participating in this program;

(7) a pharmacy or pharmacist operating in conjunction with a charitable clinic or a pharmacy that employs a licensed health care professional who accepts or can legally dispense prescription drugs.

(B) For matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by a prescription drug manufacturer that is donated by an entity pursuant to this article, a prescription drug manufacturer is, in the absence of bad faith, immune from criminal or civil liability for injury, death, or loss to person or property including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

Section 44‑53‑1860. The Board of Pharmacy, in consultation with the Department of Health and Environmental Control, shall develop policies to implement the provisions of this article pertaining to:

(1) eligibility criteria for pharmacies and charitable clinics authorized to receive and dispense donated prescription drugs pursuant to this article;

(2) establishment of drug eligibility criteria that includes all prescription drugs approved by the federal Food and Drug Administration;

(3) standards and procedures for transfer, acceptance, safe storage, security, and dispensing of donated prescription drugs;

(4) standards and procedures for inspecting donated prescription drugs to ensure that the drugs are in compliance with the provisions of this article and to ensure that, in the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity;

(5) procedures for verifying whether pharmacies and pharmacists participating in the program are licensed and in good standing with the Board of Pharmacy; and

(6) establishment of standards for acceptance of unused prescription medications from health care facilities.”

SECTION 3. This act takes effect upon approval by the Governor and upon development of policies by the Board of Pharmacy in consultation with the Department of Health and Environmental Control.

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