RECALLED

April 22, 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 and Willis

S. Printed 4/22/10--H.

Read the first time February 17, 2010.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

ESTIMATED FISCAL IMPACT ON GENERAL FUND EXPENDITURES:

A Cost to the General Fund (See Below)

ESTIMATED FISCAL IMPACT ON FEDERAL & OTHER FUND EXPENDITURES:

$0 (No additional expenditures or savings are expected)

**EXPLANATION OF IMPACT:**

Department of Health & Environmental Control

The department estimates that the bill would require 5 pharmacists and 2 Administrative Coordinators to implement this program. First year costs are estimated at $1,203,754 which includes recurring costs of $578,754 for salaries and fringe benefits plus $250,000 for operating expenses associated with 20 to 25 regional sites, and $375,000 in one-time costs (to up-fit 890 licensed sites with security, technical and electronic systems; equipment for program staff; printed forms; and training).

Department of Labor, Licensing and Regulation

The department reports that enactment of this bill would have no fiscal impact on the state general fund. Any costs associated with the additional responsibilities of the Board of Pharmacy will be covered by license fee revenues.

**SPECIAL NOTES:**

Section 44-53-1860 of the bill may conflict with Section 44-53-1820(D). The committee may wish to clarify which agency has primary responsibility for promulgating regulations.

*Approved By:*

Harry Bell

Office of State Budget

**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.

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) ‘Community residential care facility’ means a facility which offers room and board and provides a degree of personal assistance for two or more persons eighteen years old or older.

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

(4) ‘Health care facility’ means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, methadone treatment facilities, tuberculosis hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, habilitation centers for mentally retarded persons or persons with related conditions, and any other facility for which Certificate of Need review is required by federal law.

(5) ‘Medically indigent’ means a person eligible to receive Medicaid or Medicare or a person who has no health insurance and who otherwise lacks reasonable means to purchase prescribed drugs.

(6) ‘Other health care related facility’ means a community residential care facility or any other facility licensed by the Department of Health and Environmental Control pursuant to Article 2, Chapter 7, Title 44.

(7) ‘Prescription drug’ means a drug that may be dispensed only upon prescription by a 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.

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, and other health care related 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, other health care related facilities, charitable clinics, pharmacies, and prescription drug manufacturers is voluntary. Nothing in this article requires any resident of any health care facility, other health care related 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 and other health care related facilities to post a sign clearly and conspicuously in each facility to notify its residents of the program.

(D) The department shall promulgate regulations and establish procedures necessary to implement the program established pursuant to this article, including, but not limited to:

(1) program eligibility requirements for health care facilities and other health care related facilities;

(2) resident voluntary consent documents and procedures;

(3) a system for matching health care facilities or other health care related facilities donating prescription drugs with charitable clinics.

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 and other health care related 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 redispensing to medically indigent persons.

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

(3) Expired or beyond use date prescription drugs may not be accepted.

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

(5) No controlled substances may be accepted.

Section 44‑53‑1840. (A) A pharmacy operating in conjunction with a charitable clinic may redispense 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 redispensing the prescription drugs to determine that the drugs are not adulterated; and

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

(C) Prescription drugs donated pursuant to this article must not be resold.

Section 44‑53‑1850. (A) For matters related only to the lawful donation, acceptance, or redispensing 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 health care professional with prescriptive authority, as provided for in law, or a pharmacy that accepts or redispenses 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, the Department of Mental Health, and the Department of Disabilities and Special Needs;

(4) the Board of Pharmacy;

(5) a charitable clinic, prescription drug manufacturer, governmental entity, health care facility, or other health care related facility that participates in this program that donates or reuses, or both, 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 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 promulgate regulations 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 a formulary 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 destruction of controlled substances that are donated;

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

(7) establishment of standards for acceptance of unused prescription medications from facilities.

Section 44‑53‑1870. (A) There is established an advisory council on the utilization of prescription drugs to oversee and provide advice and expertise on the development and implementation of the program for the utilization of unused prescription drugs as established pursuant to this article.

(B) The advisory council is comprised of:

(1) the director of the Department of Health and Environmental Control, or a designee;

(2) the chairman of the Board of Pharmacy, or a designee;

(3) two representatives of the nursing home industry;

(4) one representative of a health care related facility;

(5) two pharmacists licensed and practicing in this State.

Members designated in items (3), (4), and (5) must be appointed by the Governor.

(C) Members shall serve terms of four years and until their successors are appointed and qualify, and vacancies must be filled in the manner of the original appointment for the unexpired portion of the term. Members of the council shall receive mileage as provided in law for members of boards, committees, and commissions but may not receive subsistence or per diem.”

SECTION 3. Article 1, Chapter 53 of the 1976 Code is amended by adding:

“Section 44‑53‑60. (A) The department, in conjunction with the Board of Pharmacy, shall develop and implement a program to receive unused prescription and nonprescription drugs from the public for disposal and shall publicize this program to the public, health care professionals, and health care facilities.

(B)The department shall develop guidelines for the safe and proper disposal of unused prescription and nonprescription drugs and shall publish this information which must be available to and distributed to the public, health care professionals, and facilities licensed by the department pursuant to Article 1, Chapter 7.”

SECTION 4. Of the initial members appointed pursuant to items (3), (4), and (5) of Section 44‑53‑1870(B) of the 1976 Code, as added by Section 2 of this act, two must be appointed for four years, two must be appointed for three years, and one must be appointed for two years.

SECTION 5. This act takes effect upon approval by the Governor.

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