By Senator Fasano

11-00340A-09 20092650__

A bill to be entitled

An act relating to pharmaceutical take-back programs; creating s. 499.0295, F.S.; requiring drug manufacturers who sell drugs in this state to establish a take-back program that accepts and disposes of pharmaceuticals turned in by consumers by a certain date; provides program requirements; requires the manufacturer to submit a program plan to the Department of Health, which must review and approve or reject the plan; requiring retail pharmacies to post a sign informing consumers about the take-back program; requiring a manufacturer to pay a fee to the department designed to cover the department's administrative costs for the program; authorizing the department to impose administrative fines for violations; establishing an advisory committee to advise the department on issues relating to take-back programs; providing for member appointment, terms, selection of a chairperson, number of meetings, and reimbursement for expenses; authorizing the department to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.0295, Florida Statutes, is created to read:

499.0295 Pharmaceutical take-back program.—

(1) Effective July 1, 2011, a manufacturer of a drug may

not sell the drug or allow the drug to be sold in this state unless the manufacturer operates a pharmaceutical take-back program approved by the department. The take-back program must:

(a) Accept prescription and proprietary drugs presented to the program by consumers, including residents of long-term care facilities and persons enrolled in hospice and home health programs;

(b) Accept all prescription and proprietary drugs sold in this state regardless of manufacturer;

(c) Offer pharmaceutical take-back services at no cost to the consumer at the time of sale of the drug or at the time of collection of the drug;

(d) Be convenient and adequate to serve consumers in urban and rural areas;

(e) Dispose of collected drugs by incineration or hazardous waste disposal;

(f) Include an education and outreach program to inform consumers, retail pharmacies, health practitioners, county health departments, hospitals, hospice care providers, and long-term care facilities of the availability of the program; and

(g) Include a method for evaluation and improvement of the program.

(2) A manufacturer may operate its pharmaceutical take-back program individually or collectively with other manufacturers.

(3) A manufacturer that sells drugs in this state shall submit a plan describing the manufacturer's proposed pharmaceutical take-back program to the department for approval. The plan must:

(a) Describe how the program meets the requirements of

subsection (1);

(b) Include recovery goals for the first 3 years of the program, expressed as pounds per capita, and a plan for action if the recovery goals are not met;

(c) Describe the proposed method for disposal of the collected drugs;

(d) Describe how the manufacturer will coordinate with other manufacturers to minimize consumer confusion about different pharmaceutical take-back programs;

(e) Meet other requirements established by rule of the department; and

(f) Be accompanied by a fee determined by the department under subsection (9).

(4) Within 60 days after a manufacturer submits a plan under subsection (3), the department shall approve or reject the plan. If the plan is rejected, the department shall provide the manufacturer with a written statement of the reasons for the rejection, and the manufacturer may submit a revised plan within 60 days after the date of the written statement of rejection. The department shall approve or reject the revised plan within 60 days after its submission.

(5) Following department approval, the manufacturer shall submit an updated plan to the department annually, on or before the anniversary of the approval of the original plan. The department shall review the disposal proposal in the updated plan, and shall approve or reject the updated plan as provided in subsection (4).

(6) If at the time the plan is due for submission to the department there is no legal method for a manufacturer to accept

all prescription and proprietary drugs through the pharmaceutical take-back program, a manufacturer may apply to the department for an extension of the time to submit the plan. The department may grant an extension for up to 1 year.

(7) The department may withdraw approval of a plan if a manufacturer does not operate the manufacturer's pharmaceutical take-back program in accordance with the approved plan.

(8) Retail pharmacies must post a sign informing consumers of the availability of pharmaceutical take-back programs. The department shall make an example of the sign available on the department's website.

(9) The department shall adopt rules establishing the application fee for submission of a pharmaceutical take-back program plan. The application fee may not exceed the costs incurred by the department in regulating pharmaceutical take-back programs, including the cost of any full-time employees necessary to administer the program.

(10) The department may impose administrative penalties for violations of this section as established by rule which may not exceed $500 per violation.

(11) Moneys received under subsections (9) and (10) shall be used to support the program.

(12) There is created the Advisory Committee on Pharmaceutical Take-Back Programs, consisting of seven members appointed by the State Health Officer who shall serve at the pleasure of the officer. The advisory committee shall advise the department on issues relating to pharmaceutical take-back programs.

(a) The term of office of each member is 3 years except

that some members of the first council may serve shorter terms in order to establish staggered terms. A member is eligible for reappointment for one additional term.

(b) The advisory committee shall elect one of its members to serve as chairperson.

(c) The advisory committee shall meet at least four times per year, at times and places specified by the call of the chairperson or of a majority of the members of the advisory committee.

(d) A member of the committee shall serve without compensation, but is entitled to reimbursement for per diem and travel expenses incurred in the performance of duties related to the committee in accordance with s. 112.061.

(e) All state agencies are directed to assist the advisory committee in the performance of its duties and to furnish such information and advice as the members of the advisory committee consider necessary to perform their duties.

(13) The department may adopt rules to administer this section.

Section 2. This act shall take effect July 1, 2009.