A bill to be entitled

An act relating to the pharmaceutical take-back program pilot project; creating s. 499.0295, F.S.; providing that a manufacturer of a drug may not sell the drug or allow the drug to be sold in the pilot project area unless the manufacturer operates a pharmaceutical take-back program approved by the Department of Health; providing requirements for such programs; providing requirements for submission of such a plan and its review by the department; requiring retail pharmacies to post a sign to inform consumers of the availability of pharmaceutical take-back programs; requiring the department to adopt a sample sign and post it on the Internet; providing civil penalties for violations; providing for an application fee; authorizing rulemaking; creating the Advisory Committee on Pharmaceutical Take-Back Programs; providing for membership; providing for duties; providing for reimbursement of member travel and other expenses; requiring reports; providing for termination of the pilot project and repeal of provisions; providing for the terms of initial committee members; providing that the requirement to have a plan registered with the department applies to manufacturers whose drugs are sold in the pilot project area on or after a specified date; 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 pilot project.--

(1) PROGRAM REQUIREMENTS.--

(a) The department shall develop a pilot project in Pasco and Hernando counties under which a manufacturer of a drug may not sell the drug or allow the drug to be sold in those counties unless the manufacturer operates in each county a pharmaceutical take-back program approved by the department. The pharmaceutical take-back program must do the following:

1. Accept all drugs presented to the program by consumers, including residents of long-term care facilities and persons enrolled in hospice, palliative care, and home health programs.

2. Accept all drugs sold regardless of the manufacturer.

3. Offer pharmaceutical take-back services at no cost to the consumer, either at the time of sale of the drug or at the time of collection of the drug.

4. Be convenient and adequate to serve consumers in urban and rural areas.

5. Dispose of collected drugs by incineration or hazardous waste disposal.

6. 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.

7. Include a method for evaluation and improvement of the program.

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

(2) PLAN APPROVAL.--

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

1. Describe how the program meets the requirements of subsection (1).

2. Include recovery goals for the first, second, and third years of the program, expressed as pounds of drugs recovered per capita, and a plan for action if the recovery goals are not met.

3. Describe the proposed method for disposal of the collected drugs.

4. Describe how the manufacturer will coordinate with other manufacturers to minimize consumer confusion about different pharmaceutical take-back programs.

5. Meet other requirements established by rule by the department.

6. Be accompanied by a fee determined by the department under subsection (5).

(b) The department shall review the disposal proposal in the plan in consultation with the Department of Environmental Protection.

(c) Within 60 days after a manufacturer submits a plan under paragraph (a), the department must 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 must approve or reject the revised plan within 60 days after its submission.

(d) A 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, in consultation with the Department of Environmental Protection, and shall approve or reject the updated plan as provided in paragraph (c).

(e) 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 nonprescription 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 not to exceed 1 year.

(f) The department may withdraw approval of a plan if a manufacturer does not operate the pharmaceutical take-back program in accordance with the approved plan. The department shall comply with chapter 120 in withdrawing approval of a plan.

(3) SIGNS.--The department shall require retail pharmacies to post a sign to inform consumers of the availability of pharmaceutical take-back programs. The department shall adopt an example of such a sign and post the example on the Internet.

(4) PENALTIES.--In addition to any other liability or penalty provided by law, the department may impose a civil penalty on a person for violation of this section or of the

rules adopted to implement this section of up to $250 for each violation. Civil penalties under this section shall be imposed as provided in s. 499.066.

(5) FEES.--The department shall set an application fee for submission of a pharmaceutical take-back program plan under subsection (2) not to exceed $100. The application fee must be designed to recover the cost to the department of regulating pharmaceutical take-back programs.

(6) RULEMAKING.--The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section.

(7) ADVISORY COMMITTEE.--

(a) There is created the Advisory Committee on Pharmaceutical Take-Back Programs, consisting of 11 members appointed by the State Surgeon General. The term of office of each member is 3 years, but a member serves at the pleasure of the State Surgeon General. Before the expiration of the term of a member, the State Surgeon General shall appoint a successor whose term begins immediately upon the expiration of the term of the current member. A member is eligible for reappointment for one additional term. If there is a vacancy for any cause, the director shall make an appointment to become effective immediately.

(b) The advisory committee shall advise the department on issues relating to pharmaceutical take-back programs.

(c) A majority of the members of the advisory committee constitutes a quorum for the transaction of business. Official action by the advisory committee requires the approval of a majority of the members of the advisory committee. The advisory

committee shall elect one of its members to serve as chairperson.

(d) 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.

(e) The advisory committee may adopt rules necessary for its operation.

(f) A member of the advisory committee is not entitled to compensation, but in the discretion of the department may be reimbursed from funds available to the department for actual and necessary travel and other expenses incurred by the member in the performance of the member's official duties as provided in s. 112.061.

(8) REPORTS.--The department shall submit a preliminary report to President of the Senate and the Speaker of the House of Representatives by January 31, 2011, and a final report by January 31, 2012, concerning the effectiveness of the pilot project in meeting its recovery goals. In addition, the final report shall make recommendations on expanding the project to other parts of the state.

(9) TERMINATION AND REPEAL.--Unless renewed by the Legislature, the pilot project shall terminate December 31, 2012, and this section is repealed on that date.

Section 2. Notwithstanding the term of office specified by s. 499.0295, Florida Statutes, as created by this act, for the members first appointed to the Advisory Committee on Pharmaceutical Take-Back Programs:

(1) Three members shall serve for a term ending June 30, 2010.

(2) Four members shall serve for a term ending June 30, 2011.

(3) Four members shall serve for a term ending June 30, 2012.

Section 3. The registration requirements contained in s. 499.0295, Florida Statutes, as created by this act, apply to manufacturers whose drugs are sold in the pilot project area on or after January 1, 2010.

Section 4. This act shall take effect July 1, 2009.