Senate Bill 598

Sponsored by COMMITTEE ON HUMAN SERVICES AND RURAL HEALTH POLICY

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Requires drug manufacturers to establish pharmaceutical take-back programs approved and regulated by Department of Human Services. Creates Advisory Committee on Pharmaceutical Take-Back Programs.

Establishes Pharmaceutical Take-Back Program Fund in State Treasury. Continuously appropriates moneys in fund to department for purpose of regulating pharmaceutical take-back programs.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to pharmaceutical take-back programs; appropriating money; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. As used in sections 1 to 9 of this 2009 Act:

(1) "Drug" has the meaning given that term in ORS 689.005.

(2) "Manufacturer" has the meaning given that term in ORS 689.005.

(3) "Nonprescription drugs" has the meaning given that term in ORS 689.005.

(4) "Pharmaceutical take-back program" means a service that collects and disposes of a consumer's drugs.

(5) "Prescription drug" has the meaning given that term in ORS 689.005.

(6) "Retail drug outlet" has the meaning given that term in ORS 689.005.

SECTION 2. (1) 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 of Human Services. The pharmaceutical take-back program must:

(a) Accept prescription and nonprescription 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;

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

(c) 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;

(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 drug outlets, 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

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

collectively with other manufacturers.

SECTION 3. (1) A manufacturer that sells drugs in this state shall submit a plan describing the manufacturer's proposed pharmaceutical take-back program to the Department of Human Services for approval. The plan must:

(a) Describe how the program meets the requirements of section 2 of this 2009 Act;

(b) Include recovery goals for the first, second and third 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 by the Department of Human Services; and

(f) Be accompanied by a fee determined by the department under section 8 of this 2009 Act.

(2) The Department of Human Services shall review the disposal proposal in the plan in consultation with the Department of Environmental Quality.

(3) Within 60 days after a manufacturer submits a plan under subsection (1) of this section, the Department of Human Services 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 of the date of the written statement of rejection. The department shall approve or reject the revised plan within 60 days of its submission.

(4) 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 of Human Services shall review the disposal proposal in the updated plan in consultation with the Department of Environmental Quality, and shall approve or reject the updated plan as provided in subsection (3) of this section.

(5) If at the time the plan is due for submission to the Department of Human Services 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 one year.

(6) 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. The department shall comply with ORS chapter 183 in withdrawing approval of a plan.

SECTION 4. The Department of Human Services shall adopt rules requiring retail drug outlets to post a sign to inform consumers of the availability of pharmaceutical take-back programs. The department shall make an example of the sign available on the Internet.

SECTION 5. The Department of Human Services shall establish a full-time position to oversee pharmaceutical take-back programs described in section 2 of this 2009 Act.

SECTION 6. In addition to any other liability or penalty provided by law, the Director of Human Services may impose a civil penalty on a person for violation of sections 2 to 4 of this 2009 Act or of the rules adopted under sections 2 to 4 of this 2009 Act. The director may impose a penalty of up to $250 for each violation. Civil penalties under this section shall be imposed as provided in ORS 183.745.

SECTION 7. The Pharmaceutical Take-Back Program Fund is established in the State Treasury, separate and distinct from the General Fund. Interest earned by the Pharmaceutical Take-Back Program Fund shall be credited to the fund. Moneys in the fund are continuously appropriated to the Department of Human Services for the purpose of regulating pharmaceutical take-back programs.

SECTION 8. The Department of Human Services shall adopt rules establishing the application fee for submission of a pharmaceutical take-back program plan under section 3 of this 2009 Act. The application fee must be designed to recover the cost to the department of regulating pharmaceutical take-back programs, including the cost of funding the position established under section 5 of this 2009 Act.

SECTION 9. Moneys received under sections 3 and 6 of this 2009 Act shall be paid into the State Treasury and credited to the Pharmaceutical Take-Back Program Fund.

SECTION 10. (1) There is created the Advisory Committee on Pharmaceutical Take-Back Programs, consisting of 11 members appointed by the Director of Human Services.

(2) The term of office of each member is three years, but a member serves at the pleasure of the director. Before the expiration of the term of a member, the director 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.

(3) The advisory committee shall advise the Department of Human Services on issues relating to pharmaceutical take-back programs.

(4) A majority of the members of the advisory committee constitutes a quorum for the transaction of business.

(5) Official action by the advisory committee requires the approval of a majority of the members of the advisory committee.

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

(7) If there is a vacancy for any cause, the director shall make an appointment to become immediately effective.

(8) 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.

(9) The advisory committee may adopt rules necessary for the operation of the advisory committee.

(10) 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 in the manner and amount provided in ORS 292.495.

(11) All agencies of state government, as defined in ORS 174.111, are directed to assist the advisory committee in the performance of its duties and, to the extent permitted by laws relating to confidentiality, to furnish such information and advice as the members of the advisory committee consider necessary to perform their duties.

SECTION 11. Notwithstanding the term of office specified by section 10 (2) of this 2009 Act, of the members first appointed to the advisory committee:

(1) Three shall serve for a term ending June 30, 2011.

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

(3) Four shall serve for a term ending June 30, 2013.

SECTION 12. **Section 2 of this 2009 Act applies to manufacturers whose drugs are sold in this state on or after July 1, 2011.**

SECTION 13. **(1) Section 3 of this 2009 Act becomes operative January 1, 2010.**

(2) The Department of Human Services may take any action before January 1, 2010, that is necessary to enable the department to exercise, on and after January 1, 2010, all the duties, functions and powers conferred on the department by section 3 of this 2009 Act.

SECTION 14. **This 2009 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect on its passage.**