

**REPORT TO THE TWENTY-FIFTH HAWAII
STATE LEGISLATURE 2009**

**IN ACCORDANCE WITH THE PROVISIONS OF
ACT 59, SESSION LAWS OF HAWAII 2008, ON THE I-SAVERX
PRESCRIPTION DRUG PROGRAM**

**DEPARTMENT OF HUMAN SERVICES
MED-QUEST DIVISION
December 2008**

REPORT ON THE I-SAVERX PRESCRIPTION DRUG PROGRAM PURSUANT TO ACT 58, SESSION LAWS OF HAWAII (SLH) 2008

Act 59, SLH 2008, directed the Governor to enter into the appropriate written agreement that authorizes Hawaii residents to participate in the I-SaveRx prescription drug program.

The Department of Human Services (DHS) is required to submit a written report to the Legislature that includes but is not limited to the following:

- (1) The status of the I-SaveRx prescription program in the State, including the number of consumers participating in the program, consumer demographics, and consumer satisfaction with the program;
- (2) Any problems implementing the I-SaveRx prescription program, including any lawsuits, consumer complaints, and other factors that contributed to impeding the access to or enrollment in the program;
- (3) Any consumer outreach and educational program regarding the I-SaveRx prescription program implemented by the working group pursuant to section 346-N, Hawaii Revised Statutes, and the effectiveness of these outreach and educational programs; and
- (4) Any recommendations regarding the feasibility of the I-SaveRx prescription program, including any proposed legislation.

To address the challenges of prescription medication affordability that Hawaii residents increasingly face, the Legislature passed Act 59 which directed the Governor to enter into the appropriate written agreement that authorizes Hawaii residents to participate in the I-SaveRx prescription drug program. Through this program, it was intended that Hawaii residents could order less costly prescription drugs, imported from Europe and Canada, through the Internet or toll-free telephone number. While the State has every interest in helping residents access prescription medications, the State has a responsibility to protect its residents and operate in a legal manner.

To seek clarification of the patient safety and legal issues surrounding the I-SaveRx program, the State contacted the U.S. Food and Drug Administration (FDA). In the FDA's response to the Governor, dated August 14, 2008, the FDA cited patient safety and legal concerns regarding Hawaii's participation in the I-SaveRx prescription drug program. The FDA was very concerned that the importation of prescription drugs from foreign countries presented significant risks to Hawaii's citizens and concluded that imported drug shipments under Hawaii's importation program would most likely violate federal law.

The December 2004 U.S. Department of Health and Human Services Task Force Report on Drug Importation found that the unregulated importation of prescription drugs poses serious health risks. The FDA's investigation of drugs imported from Canada found that some drugs were actually shipped from other countries such as India and Costa Rica, many had incorrect or incomplete labeling including an absence of the listing of potential side effects, and in some cases the medication and number of pills dispensed was not what was prescribed.

The FDA also stated in its letter to the Governor that it is illegal to import drugs in violation of the Federal Food, Drug, and Cosmetic Act. To ensure a safe and effective domestic drug supply, Congress enacted Act 21, 21 U.S.C. §301 et. Seq., which strictly limits the types of drugs that may be sold and imported into the United States and who may import them. The August 14th FDA letter stated that importing or causing the importation of a drug into the United States that is unapproved and/or does not comply with the labeling requirements and dispensing requirements in the Act is a prohibited act under 21 U.S.C. §§331(a) and/or (d), and may be enjoined or prosecuted. See also 21 U.S.C. §332(a), 333(a).”

Also, the FDA letter stated that:

“...it is virtually certain that a foreign wholesaler or pharmacy would fail to comply with all of these applicable requirements, and therefore virtually every importation of prescription drugs for personal use would violate federal law.”
In addition, the Illinois Auditor General issued a report in September 2006 concluding that the I-SaveRx program is in violation of federal law.

The Administration supports the Legislature’s concern for providing access to affordable prescription drugs for Hawaii residents, and we are interested in continuing to work to find viable solutions. However, we have a primary responsibility for the safety of our residents, and we believe it is important to abide by Federal law so as not to jeopardize Federal funding for State healthcare programs, including but not limited to our Medicaid programs.