Governor to expand drug imports
Despite criticism by auditor, FDA's disapproval

By TRAVIS HENDERSON
STATE CAPITOL, DECEMBER 9
Thumbing his nose at a state audit that concluded Illinois' program to import prescription drugs violated federal law, Gov. Rod Blagojevich announced Tuesday that he intends to expand it to include state employees and residents.

The audit released Tuesday by Illinois Auditor General Bill Holland also found that the governor's office was in breach of an agreement to import flu vaccine in 2004 even after federal officials had found additional supplies and informed the administration they would not allow the imports.

In a letter informing the Food and Drug Administration of his plan to expand the prescription-importation program, Blagojevich wrote, "We will implement as many of Holland's recommendations as possible, but we fully intend to continue allowing the people of Illinois to purchase safe, affordable medicine from approved pharmacies in Canada, the United Kingdom, Australia, and New Zealand. We will not be bullied or harassed by the FDA."

Expanding the I-SaveRx drug-importation program to state workers will save money for taxpayers, the governor wrote, and reduce or eliminate government management for employers.

An FDA spokesman said the agency would not comment on Blagojevich's plan to proceed without regulations that prohibit the importation of drugs that lack FDA approval.

In his audit, Holland found that in a quarter of days, state officials attempted numerous times to seek FDA approval while attempting to obtain the vaccine, the administration's written response to the audit said.

The audit also said the state did not develop legal agreements with the other governments, even though Illinois took the lead in procuring the flu vaccine. That resulted in Illinois being potentially liable to pay for the entire cache of vaccine, now $8.2 million.

Ottenhoff said the fact that Illinois is seeking only $2.6 million in the Court of Claims "for clear evidence that there was an understanding that such entity was only responsible for the vaccine that was being secured on its behalf." Illinois disbursed the expired vaccine to Pakistan last December, Otto said, after a devastating earthquake in that nation.

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DRUGS

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2,600 residents of Illinois and 1,265 residents of the other participating states—Wisconsin, Kansas, Missouri, and Vermont—had ordered prescriptions during the first 10 months of the I-SaveRx program, which was launched in October 2004.

The audit also said 521 state employees from 28 agencies had spent at least $5,600 to promote I-SaveRx and were paid at least $240,000. It also disclosed that state personnel had spent more than $13,000 in travel expenses, and $11,000 in legal fees related to the program.

In a written response, the administration said management employees performed most of the work on top of their regular duties. Spokeswoman Abby Ottenhoff also questioned the accuracy of calculations concerning employee salaries.

Regarding the legality, Ottenhoff said, "The FDA has allowed millions of Americans to buy their medications from abroad...and since Illinois established the I-SaveRx program, the FDA has never taken steps to stop our program."

The audit also "questions the safety aspect of the I-SaveRx program."

"I don't think that state employees should be used as guinea pigs," said Luke Vander Bie, who operates a pharmacy in Montfort and serves as president of the Illinois Pharmacists Association. "I think this is the auditor's report shows pretty clearly...that the practice has not been carried out and that the governor should think twice before he expands it to allow additional drug availability."

In a letter informing the Food and Drug Administration of his plan to expand the prescription-importation program, Blagojevich wrote, "We will implement as many of Holland's recommendations as possible, but we fully intend to continue allowing the people of Illinois to purchase safe, affordable medicine from approved pharmacies in Canada, the United Kingdom, Australia, and New Zealand. We will not be bullied or harassed by the FDA." Excess is seeking only $2.6 million in the Court of Claims for clear evidence that there was an understanding that such entity was only responsible for the vaccine that was being secured on its behalf. Illinois disbursed the expired vaccine to Pakistan last December, after a devastating earthquake in that nation.

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Audit slams state drug plan

But Blagojevich plans expansion

By Crystal Vedovat and Rick Pearson

Gov. Rod Blagojevich's administration spent nearly $1 million to develop and market a plan to drastically reduce the cost of prescription drugs that ended up serving fewer than 4,700 Illinois residents, Auditor General William G. Haase said Tuesday.

Blagojevich also said his plan would result in millions of dollars being spent on drugs for seniors.

The Illinois Department of Revenue also was said to have failed to ensure that the individuals enrolled in the plan were actually taking the drugs prescribed.

The plan, which was developed in partnership with the Illinois State Hospital Association and the Illinois Medical Association, was intended to reduce the cost of prescription drugs for seniors.

Haase said the plan was designed to save money for seniors by negotiating lower prices for the drugs.

Blagojevich said he was disappointed with the results of the audit.

"We're disappointed with the Auditor General's report," he said. "We've taken steps to improve the plan and we've made changes to ensure that it works better for seniors."
Gov's drug program illegal, state auditor says
September 20, 2006 by AMI RITTER Health Reporter

Gov. Blagojevich's highly touted drug-import pharmacy is little used and illegal, the state auditor said in a blistering report Tuesday. Auditor General William Holland also nipped the governor for trying to buy flu shots overseas during a 2004-2005 vaccine shortage. State officials "knew FDA approval was not likely," but went ahead anyway, and now the state is on the hook for as much as $8.2 million for unused shots.

Few use import pharmacy

"I knew we were going to find some problems," said state Rep. Jack Franks (D-Woodstock), who requested the audit. "But I was stunned to learn how badly our government acted." Nevertheless, Blagojevich announced the import pharmacy, I-SaveRX, now will be offered to state employees and their dependents. I-SaveRX lets patients buy low-cost prescription drugs from Canada, the United Kingdom, Australia and New Zealand. State employees who use I-SaveRX will pay smaller co-pays. Blagojevich launched I-SaveRX in October 2004 to great fanfare. Consumers could save up to 50 percent by importing prescriptions from foreign pharmacies approved by the state, he said. But the auditor's report said importing prescription drugs "is in violation of federal law."

The Food and Drug Administration has yet to crack down on Illinois. In a letter to the FDA, Blagojevich vowed to keep pushing I-SaveRX. He said he would not put "drug company profits ahead of the basic needs of senior citizens and the uninsured." The state has spent nearly $1 million promoting the I-SaveRX program. But as of April, only 3,689 Illinois residents had ordered prescriptions, the audit found. Blagojevich spokeswoman Abby Ottenhoff said I-SaveRX is just "one piece of a much bigger effort to meet health care needs in Illinois. It's one of the services we offer. It's not for everyone." During a 2004-2005 vaccine shortage, the state contracted to buy flu shots from a British wholesaler for Illinois and several other states. Illinois' share was $2.6 million, and the total came to $8.2 million.

Vaccine purchase defended

When the FDA balked, Illinois donated its doses to Pakistan. The audit report found that by the time the state signed a contract to buy the flu shots, the federal government already had procured enough shots to cover the state's high-risk population. Franks said Blagojevich "obligated millions of dollars for something we didn't need and couldn't get." But Ottenhoff said Blagojevich acted in response to "reports of potential influenza outbreaks and widespread sickness and even deaths."

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Drug program declared illegal: Blagojevich pushes to extend benefits despite audit saying plan violates state, federal laws

By KURT ERICKSON - H&R Springfield Bureau Chief

SPRINGFIELD - Despite an audit that says a state-run prescription drug plan violates state and federal law, Gov. Rod Blagojevich wants to expand the program. The governor, in an announcement Tuesday, said he wants to include state workers and their dependents in the I-SaveRx program, which he created in 2004 to help senior citizens buy cheaper prescription drugs from outside the United States. The announcement came as Illinois Auditor General William Holland issued a report outlining a laundry list of problems with the program. Holland said I-SaveRx not only violates federal law barring the importation of drugs, but the program also appears to violate the Illinois Pharmacy Practice Act based on a lack of oversight. Holland also determined the program has served fewer than 4,000 Illinois residents since it was unveiled two years ago. That number comes despite heavy promotion on the part of the Blagojevich administration. Holland found that the state has spent an estimated $944,000 to create and publicize the initiative. Holland’s report also said there was little coordination between state agencies that were promoting the program. “There was no system in place to track the results of the agency outreach,” he wrote.

Blagojevich said the program will go forward. “Please understand that while we will do everything in our power to implement some of the auditor general’s recommendations, we will not cease operation of the I-SaveRx program,” the governor said. Spokeswoman Abby Ottenhoff said the fact that the federal government hasn’t pursued legal action is evidence that I-SaveRx has the government’s “tacit approval.” Blagojevich said adding state workers to the program could help the state save money on prescription drug costs. Participants in the program can access the program via its Web site at www.i-saverx.net. The site connects users with a Canadian pharmaceutical clearinghouse that handles orders from pharmacies in Canada and the United Kingdom.

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FOR IMMEDIATE RELEASE
September 19, 2006

Governor Blagojevich announces plans to expand I-SaveRx drug importation program to State employees, retirees and others

In letter to the FDA, Governor vows that I-SaveRx will continue and expand operations despite finding by Auditor General that the program violates federal law

CHICAGO – Governor Rod R. Blagojevich today announced that the State of Illinois will expand its innovative I-SaveRx drug importation program to state employees and dependents. Currently, the program is available and intended for senior citizens and the uninsured, and covers the citizens of Illinois, Kansas, Wisconsin, Missouri and Vermont.

The program’s expansion will allow the State to reduce its annual prescription drug costs and reduce, and sometimes even eliminate, co-payments for state employees and dependents (currently, co-payments on brand name prescription drugs for those in the state’s health insurance range from $20-80). The expanded program for employees will be voluntary. Illinois was the first state in the nation to make safe, affordable prescription drugs from other countries available to its citizens.

The announcement comes in the wake of a report released today by the Illinois Auditor General that the I-SaveRx program violates federal law. In a letter to FDA Acting Commissioner Andrew von Eschenbach, Blagojevich vowed to continue the importation program that helps senior citizens and the uninsured afford the medications prescribed by their doctors.

Blagojevich wrote, "Please be advised that while we highly respect and very much appreciate our Auditor General’s work, and while we will implement as many of his recommendations as possible, we fully intend to continue allowing the people of Illinois to purchase safe, affordable medicine from approved pharmacies in Canada, the United Kingdom, Australia and New Zealand. We will not be bullied or pressured by the FDA into choosing drug company profits ahead of the basic needs of senior citizens and the uninsured.

"In addition, we are also going to move forward and expand the I-SaveRx program by making it available to state employees and dependents. Given that the State’s annual costs for providing prescription drugs to employees, dependents, and others (prisoners, patients in state facilities, and others whose care is covered by the State) has increased by an average of 15% per year over the last five years, and given that employees and retirees often face brand name co-payments of $40-80, broadening the scope of I-SaveRx will help the taxpayers save money by reducing the State’s prescription drug costs. It will also help employees save money because they would no longer have to make co-payments when the medication they need is available at far less cost from pharmacies in Canada, United Kingdom, Australia or New Zealand. As we implement as many of the Auditor General’s findings as possible for our program, we will keep those recommendations in mind as we expand the program to State employees, dependents and others."

The Governor also called on the FDA to drop its stance opposing importation of prescription drugs, and develop a national program that all states can participate in, rather than forcing states to construct
their own programs – programs that could conflict with local rules and forms that were created long before the concept of importation was envisioned.

Blagojevich wrote, "When states like Illinois take on a responsibility that ought to belong to the federal government, that requires creating a complicated program that will not be in lock step with every local rule and regulation created a time before anyone envisioned the concept of re-importation of prescription drugs.

"No Governor and no administration wants to incur audit findings saying that they are operating a program in violation of federal law. But when the choice is helping people afford the medicine they need or incurring audit findings, there’s really no choice. Please understand that while we will do everything in our power to implement some of the Auditor General’s recommendations, we will not cease operation of the I-SaveRx program.

"Your decision to make Plan B available over-the-counter indicates that you are willing to look at issues in a way different from your predecessors. Hopefully you will take a look at the FDA’s policy opposing re-importation of prescription drugs and recognize that a national policy that helps our citizens access the global marketplace is the better approach."

The Governor launched I-SaveRx in October 2004 to provide Illinoisans a safe and affordable way to purchase many of the most common name-brand prescription drugs from pharmacies in Canada and Europe, where they cost up to 70 percent less.

Under the expanded program, which will be in operation by Spring 2007, employees who choose to fill eligible prescriptions through I-SaveRx will pay a reduced co-payment, or no co-payment at all. Currently, participants in the State’s health insurance programs pay anywhere between $20-80 in co-payments for brand name prescription drugs, depending on whether the drug is on the state’s formulary. If the prescription is for a maintenance drug, the patient is allowed only two retail fills, then they are required to use mail-order, or else they must pay $40 retail for a formulary drug and $80 retail for non-formulary. The co-pay for mail-order is lower, $40 for a 3-month supply of a formulary drug and $80 for a 3-month supply of a non-formulary drug.

Over the last five years, the State has seen its prescription drug costs increase by an average of 15% per year, far outpacing the cost of Medicaid, which increased in Fiscal Year 2006 by just 1.4% -- the sixth lowest increase in the nation. The same prescription drugs that are sold in the United States are available at prices up to 70 percent cheaper outside the United States. For example, Prevacid, a name brand medication used to treat heartburn and acid reflux, costs 64 percent less in Australia than in the U.S., 55 percent less in the United Kingdom, and 44 percent less in Canada.

Employees and taxpayers alike will benefit from the I-SaveRx expansion. State employees can save at least $160 annually on out-of-pocket costs for co-payments, while the State will be able to save hundreds annually on the cost of common maintenance medications that are filled through the importation program. For example, for each prescription, the State can save:

Save $890 annually on Advair Diskus (used to treat asthma) when purchased from Australia,

Save $340 annually on Actos (used to treat diabetes) when purchased from the UK,

Save $1,017 annually on Casodex (used to treat Prostate Cancer) when purchased from

Canada,

Save $250 annually on Nexium (used to treat Heartburn and acid reflux disease) when purchased from UK,

Save $675 annually on Zyprexa (used to treat mental health issues) when purchased from the UK,

Employees who use I-SaveRx will save at least $160 annually in co-payments

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The text of the Governor's letter to FDA Acting Commissioner von Eschenbach is below:

Dear Commissioner von Eschenbach:

Over the last several years, your predecessors and I have disagreed strongly on the issue of re-importation of prescription drugs. I have been a strong advocate for opening the global marketplace to American consumers, while the Food and Drug Administration (FDA) has consistently sided with the drug manufacturers in keeping the marketplace closed and forcing consumers to pay artificially high prices.

Today, the Auditor General of Illinois will release a report about I-SaveRx, our prescription drug re-importation program that cites my administration for facilitating the importation of prescription drugs without FDA approval. His report argues that the I-SaveRx program is in violation of federal law. It reads, "Drugs are approved for use in the United States pursuant to the provisions of federal law as stated in the Food, Drug and Cosmetic Act. Virtually every time an individual or entity imports or causes the importation of a prescription drug, they are in violation of the FD&C Act."

We respectfully disagree with the Auditor General's finding, given that the FDA has tacitly permitted more than one million Americans each year to import prescription drugs from abroad, and given that the FDA has never taken steps to prevent the I-SaveRx program from operating in Illinois, Wisconsin, Kansas, Missouri and Vermont. In fact, you and I both know that the FDA has seized and tested approximately 1% of the prescription drugs imported through I-SaveRx and has never found fault with any of the medications. We also both know that, in recent months, the FDA has increased the number of seizures of medications both for programs like I-Save Rx and other importation programs across the nation.

Please be advised that while we highly respect and very much appreciate our Auditor General's work, and while we will implement as many of his recommendations as possible, we fully intend to continue allowing the people of Illinois to purchase safe, affordable medicine from approved pharmacies in Canada, the United Kingdom, Australia and New Zealand. We will not be bullied or pressured by the FDA into choosing drug company profits ahead of the basic needs of senior citizens and the uninsured.

In addition, we are also going to move forward and expand the I-SaveRx program by making it available to state employees and dependents. Given that the State's annual costs for providing prescription drugs to employees, dependents, and others (prisoners, patients in state facilities, and others whose care is covered by the State) has increased by an average of 15% per year over the last

five years, and given that employees and retirees often face brand name co-payments of $40-80, broadening the scope of I-SaveRx will help the taxpayers save money by reducing the State’s prescription drug costs. It will also help employees save money because they would no longer have to make co-payments when the medication they need is available at far less cost from pharmacies in Canada, United Kingdom, Australia or New Zealand. As we implement as many of the Auditor General’s findings as possible for our program, we will keep those recommendations in mind as we expand the program to State employees, dependents and others.

The report also says that because our I-SaveRx program works with foreign pharmacies, their inspection makes it impossible to fully complete the forms used to inspect pharmacies in Illinois. Also, because pharmacies in the United Kingdom, Canada, Australia and New Zealand are governed by their own national standards, that differs from the standards in the Illinois Pharmacy Practice Act.

As you know, the standards for inspections and regulations required in each of those nations exceed those used here in the United States.

It is not surprising that the Auditor General found this, given that the forms used in Illinois include fields that are specific to United States based pharmacies (for example, requiring a Drug Enforcement Agency number). Nor is it surprising that the Illinois Pharmacy Practice Act is not identical in word and verse to the regulations of four different nations. The Auditor General finds that an out-of-state pharmacist can only dispense medication if licensed by the State of Illinois or, as a “mail order” pharmacy, be located within the United States.

Those are reasonable standards if the State of Illinois were only working with domestic pharmacies. But there is no way for a re-importation program operated on a state level to comply in every way, shape and form with rules that were written long before the concept of re-importation was developed. As a result, when one or several states acts in a way that differs from the federal government, each state participating in a non-federal re-importation program runs the risk of its Auditor General finding that the regulation of foreign pharmacies in some way differ from local regulations.

Our Auditor General also issued a finding saying that no State employee paid for with federal funds should be used to advance the I-SaveRx program in any way. If you believe that the I-SaveRx program violates federal law, as the Auditor General does, than this finding makes sense. But because the FDA refuses to publicly embrace a concept that would significantly reduce prescription drug prices for tens of millions of people, we have no choice but to act on our own and operate the program ourselves.

That includes using all of the resources of state government to make the program available to as many people as possible, including employees of the Illinois Department of Employment Security (IDES), who spend their day dealing with the unemployed – people who don’t have jobs and therefore don’t have health insurance or prescription drug coverage. Yes, IDES employees are federally funded. But they are also the ideal candidates to help people afford the medicine their doctor prescribes.

In addition, because the FDA refuses to permit the re-importation of prescription drugs, our request to import vaccines purchased abroad in the fall of 2004 was also denied. Our Auditor General found that we should have obtained your approval before purchasing the vaccines. When the nation was facing a shortage of 55 million doses of flu vaccine and through our own devices, we were able to procure vaccines for Illinois and put several other states in a position to procure vaccines for themselves as well.

Rather than erecting every conceivable roadblock to stop the importation of the vaccines, the FDA

should have thanked us for addressing the problem ourselves and immediately approved it. Instead, we
faced bureaucratic hurdle and delay after bureaucratic hurdle and delay, only to ultimately be denied.
Incredibly, the FDA used the excuse of oversupply as one reason to deny our application, even though
it purchased vaccines from the same manufacturers as we did after they knew we already had the
vaccines available.

Our Auditor General is doing his best, and while we agree with some of his recommendations and
disagree with others, he is ultimately trying to audit a program that fundamentally is at odds with the
approach taken by the FDA – an approach that denies consumers access to the global marketplace for
prescription drugs.

When states like Illinois take on a responsibility that ought to belong to the federal government, that
requires creating a complicated program that will not be in lock step with every local rule and
regulation created a time before anyone envisioned the concept of re-importation of prescription
drugs.

No Governor and no administration wants to incur audit findings saying that they are operating a
program in violation of federal law. But when the choice is helping people afford the medicine they
need or incurring audit findings, there’s really no choice. Please understand that while we will do
everything in our power to implement some of the Auditor General’s recommendations, we will not
cease operation of the I-SaveRx program.

Your decision to make Plan B available over-the-counter indicates that you are willing to look at
issues in a way different from your predecessors. Hopefully you will take a look at the FDA’s policy
opposing re-importation of prescription drugs and recognize that a national policy that helps our
citizens access the global marketplace is the better approach.

Thank you for your time and consideration.

Sincerely,

Rod Blagojevich

Governor