LEGISLATIVE AUDIT COMMISSION

Management Audit
OF THE
FLU VACCINE PROCUREMENT
AND THE I-SaveRx PROGRAM

September 2006

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MANAGEMENT AUDIT

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Recommendations - 10

Background and Conclusions

Procurement of Flu Vaccine

On October 15, 2004, the United States Food and Drug Administration (FDA) announced that none of the flu vaccine manufactured by a United Kingdom based manufacturer, which supplied approximately half of the flu vaccine used in the United States, was safe for use. State of Illinois officials primarily from the Office of the Governor and the Office of the Special Advocate for Prescription Drugs, began taking steps by October 19, 2004 to find additional flu vaccine for Illinois residents. On October 22, 2004, the Special Advocate accepted and agreed to an initial 35,000 doses of vaccine from Ecosse, a subsidiary of a European wholesaler, and on October 25, 2004, the Governor announced his administration had negotiated a tentative agreement, subject to approval from the FDA, to immediately ship at least 30,000 doses of flu vaccine from Europe for Illinoisans considered in the at-risk population. On October 23, 2004, the Deputy Governor authorized the purchase of 200,000 doses of vaccine and on November 1, 2004, the Deputy Governor confirmed an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine. In a November 10, 2004 communication to the State Purchasing Officer at the Department of Public Aid, the Special Advocate stated that he was unaware of the need for a contract and that he was told the payment would be processed COD.

Federal law governs the importation of vaccine into this country. The State did not have FDA approval to import the flu vaccine prior to directing Ecosse officials to locate flu vaccine in mid-October 2004. On October 27, 2004, the FDA indicated that the flu vaccine was not licensed for use in the United States.

Illinois officials negotiated with Ecosse for vaccine for five additional governments at a cost exceeding $8.2 million for approximately 773,000 doses of vaccine. Illinois officials had no written agreements with other governments outlining payment responsibilities.

By December 2004, based on Department of Public Health documentation, it appeared the CDC had located sufficient flu vaccine to cover the 160,000 to 200,000 doses needed for Illinois' priority population, and the doses would be available to Illinois in December 2004/Janaury 2005.

Prior to being billed by Ecosse and executing a contract with the vendor on January 13, 2005, email from the Special Advocate on December 21, 2004 to the Governor's Office stated, "We probably will never take delivery of these doses so will need to find a way to pay for the 'service' they performed." By January 31, 2005, the Governor's administration and Ecosse began trying to resell the doses of vaccine on the European market, but there were no buyers. Ecosse sent the Governor a correspondence on February 8, 2005 requesting payment in excess of $8 million for the flu vaccine and its services. When the State did not process payment, Ecosse filed suit on March 15, 2005 seeking the $2.6 million billed to the State. The State petitioned the court to dismiss the suit in October 2005. Illinois donated the vaccine to Pakistan in December 2005. Pakistan officials destroyed the vaccine in November 2006 saying they did not realize that when they accepted the donation that most of the vaccine had expired.

I-SaveRx Program

In late 2003, the Governor contacted the FDA to inquire whether the Department of Health and Human Services would approve a demonstration project for the importation of prescription drugs from Canada. In correspondence dated June 3, 2004, the Acting Commissioner of Food and Drugs wrote that while they shared the Governor's concern and urgency related to the cost and safety of prescription drugs, it would not allow a state's pilot project for the safe importation of prescription drugs under the current law.

On October 4, 2004, the State of Illinois launched the I-SaveRx Program to allow consumers to purchase prescription refills from licensed, inspected pharmacies in Canada and the UK. The I-SaveRx Program was administered through a contract between the State of Illinois and CanaRx Services Inc. The contract was procured through a Sole Economically Feasible Source procurement. The contract is not on file with the Comptroller since, according to the Governor, there is no cost to the State. While CanaRx was not paid for its services by the State, there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program.

The Program expanded in 2005 to include approved pharmacies in Australia and New Zealand. The states of Wisconsin, Vermont, Kansas and Missouri have also joined the I-SaveRx Program. In late 2005, the program listed 28 approved pharmacies in the UK, 15 from Canada, seven from Australia and one from New Zealand although the Special Advocate indicated the listing was not accurate. As of April 2006, 4,954 individuals from five states were participating.

Although the State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law, officials from the Governor's Office and the Special Advocate reported that the FDA has chosen not to pursue action against people using imported drugs for personal use.

House Resolution 394 directed the Auditor General to conduct a management audit of the process followed in negotiating and entering into the contract with Ecosse Hospital

Products Limited and in establishing and operating the I-SaveRx Program. The audit made the following conclusions:

Flu Vaccine Procurement

The State's procurement of the flu vaccine was not adequately planned and monitored, resulting in State resources totaling $2.6 million being risked for vaccine that the State never received.

- The State agreed to purchase the flu vaccine even though it did not have federal approval to import such vaccines. Without federal approval, importation of flu vaccine was not legal.
- Documentation was not available that demonstrated how the State determined that it needed the 254,250 doses of vaccine that it agreed to purchase from Ecosse.
- The contract entered into between the State and Ecosse was not timely.
- Illinois officials took the lead in procuring flu vaccine for other states and local governments but failed to develop agreements with these entities, resulting in Illinois being potentially liable to pay for the entire cache of vaccine – over $8.2 million.

I-SaveRx Program

In the first 19 months of the I-SaveRx Program, 17,575 orders for prescription medicine were placed by 4,954 residents from the 5 participating states (3,689 of whom were Illinois residents).

- The State's operation of the Program, which imports prescription drugs into the United States, is in violation of federal law.
- Pharmacies operating under the I-SaveRx Program may be in violation of Illinois' Pharmacy Practice Act.
- 40 percent of Pharmacy Inspection Forms of pharmacies inspected for the I-SaveRx Program (32 of 80) by the Department of Financial and Professional Regulation were not completely filled out.
- The State did not monitor whether prescriptions are being filled only by approved pharmacies.
- The Special Advocate had not adequately monitored CanaRx regarding compliance with provisions of the contract.
- The 28 agencies surveyed that had employees who participated in promotional activities for the I-SaveRx Program reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000 (at least 26 employees were paid from federal funds).
- The State had significant expenditures of State funds on the Program, including travel (over $111,000 mainly for out-of-country travel), contractual services ($71,018), marketing ($54,453), and legal services ($220,000).

Recommendations

The audit includes a total of ten recommendations, which apply to several different agencies including the Office of the Governor, Office of the Special Advocate for Prescription Drugs, Department of Healthcare and Family Services, Department of Financial and Professional Regulation, Department of Human Services and Department of Public Health. The recommendations are classified on the basis of information appearing in the audit report. Updated responses were provided by Carol Krause, Chief Internal Auditor, Illinois Office of Internal Audit.

1. In order to protect State interests and not put State resources at risk, the Office of the Governor should:

- **Timely enter into formal agreements with vendors that define exactly each party's responsibilities, so that the State's interests are protected;**
- **Require appropriate planning, even in emergency procurement situations, before entering into contracts;**
- **Ensure that appropriately qualified State staff participate in the contract negotiation process;**
- **Execute formal agreements with other government entities that delineate each party's responsibilities for participating in any procurements led by the State of Illinois; and**

Maintain appropriate contract files with a clear written determination when there is a need for an emergency procurement.

Findings: The Office of the Governor did not execute a contract with Ecosse Hospital Products, Ltd. in a timely manner. A written agreement was executed three months after procurement activities were initiated. Documentation was not available that demonstrated how the State determined that it needed the 254,250 doses of vaccine that it agreed to purchase from Ecosse. Additionally, while other governments were involved in the attempted procurement, Illinois officials were the only group negotiating with Ecosse; Illinois was the only government that developed a contract with Ecosse; and Illinois officials failed to develop agreements with these other governments, potentially putting Illinois funds at risk of paying for the entire cache of vaccine – over $8.2 million.

The Office of the Governor did not execute a contract with Ecosse in a timely manner. State of Illinois officials, primarily from the Office of the Governor and the Special Advocate, began taking steps in mid-October 2004 to find additional flu vaccine for Illinois residents. The Special Advocate initiated talks with officials from a European wholesaler and its subsidiary Ecosse to locate and procure flu vaccine. These activities were undertaken without a contract in place indicating the number of doses Illinois was

attempting to procure. These activities were also undertaken without approval from the FDA for the vaccine.

The contract with Ecosse was signed January 13, 2005 by an official from the Governor's Office. Not only was this contract executed approximately 3 months after the State initiated activities on the procurement, it was 2 days after Ecosse submitted a billing for the vaccine of approximately $2.6 million. The term of the contract was for the period October 20, 2004 through June 30, 2005. Documentation showed that the State's lead negotiator on this procurement, the Special Advocate, apparently was not familiar with the procurement processes that guide State purchasing. Per the Procurement Code, the Comptroller may process no payments before a written contract has been filed, and further, the State Finance Act requires that, generally, payment for services rendered on goods delivered cannot be made in advance but only after the goods or services for which payment is being made have been provided unless the terms of the contract require advance payment.

Illinois officials negotiated with Ecosse for vaccine for five additional governments. The total amount of vaccine billed by Ecosse to the governments was over $8.2 million for approximately 773,000 doses of vaccine. Ecosse officials appeared to be under the impression that the State of Illinois was responsible for all 773,000 doses of vaccine. In a payment demand letter to the Governor dated February 8, 2005, Ecosse's director, requested immediate payment in excess of $8 million.

In January 2005, the State of Illinois was billed $2,592,218 by Ecosse for 254,250 doses of flu vaccine which was never received by the State of Illinois. Documentation was not available to demonstrate how much flu vaccine State officials actually ordered from Ecosse. However, the amount of vaccine billed by Ecosse exceeded the Illinois estimate of the priority population to serve with the vaccine.

An official from the Governor's Office indicated that the amount of vaccine needed in Illinois and available was a very fluid number – it continually changed based on additional available vaccine from the CDC and the actual amounts located by Ecosse. No documentation was provided by the Special Advocate to demonstrate the amount of vaccines that the State requested Ecosse officials locate. The process appeared to be open-ended.

By December 2004, based on Department of Public Health documentation, it appeared that the CDC had located sufficient flu vaccine to cover the 160,000 to 200,000 doses needed for Illinois' priority population. Also, documentation shows that the CDC would be making available an additional 200,000 doses in its December 2004/January 2005 allotment of vaccine to Illinois. Despite the availability of additional vaccine to adequately cover Illinois' high risk population, the State continued to proceed with its procurement of flu vaccine from Ecosse.

As early as December 23, 2004, State officials did not believe the federal government would approve the vaccine to be imported to the United States. The Special Advocate informed the State Purchasing Officer at Public Aid "We need to recast this as services given it would appear the Feds are not going to allow the importation of the shots."

While the Governor's Office executed the contract with Ecosse, the Department of Public Aid developed the Procurement Business Case and maintained a procurement file for the purchase. The Governor's Procurement Officer, who executed the contract with Ecosse, did not maintain any such written determination or contract file.

Public Aid submitted an emergency purchase affidavit to the Auditor General on February 7, 2005 for an estimated $2,592,218 purchase of influenza vaccine and specified services to vaccinate residents who are at the greatest risk of contracting the virus. According to the Public Aid State Purchasing Officer, the emergency purchase was for public health or safety. Public Aid also published notice of the purchase on the Illinois Procurement Bulletin on January 28, 2005.

Response: Accepted. The Office of the Governor's agreement with this recommendation is limited to certain aspects, identified below.

We agree that formal agreements with vendors were not entered into in accordance with the procurement act's provisions on timeliness – but we also believe that the act as written does not take into account the real world timeframe of an emergency. As it stands, **the procurement code does not allow the State to make commitments or enter into agreements to procure goods and services in situations that require immediate action, instead requiring a minimum of two weeks notice before entering into a contract.** Legislation is needed to allow the Procurement Code to reflect the true nature of emergencies.

> ***Auditor Comment #1:*** *The Procurement Code currently permits agencies to make purchases under emergency circumstances, such as when an agency believes a threat to public health exists (30 ILCS 500/20-30). No advance notice of an emergency purchase is necessary; however, the Code does require the agency to complete an affidavit and publish in the Illinois Procurement Bulletin a written description and reasons and the total cost of each emergency procurement made during the previous month. In this case, although the State placed its first order for overseas vaccine on October 22, 2004, it was not until January 28, 2005, that notice of the emergency purchase was published in the Illinois Procurement Bulletin and the required affidavit was not filed until February 7, 2005.*
>
> *We do not question the administration's designation of the flu vaccine shortage as an emergency necessitating immediate action. However, we believe the process it followed in negotiating and executing the contract did*

not provide timely notice to the public of the nature of the procurement and its cost.

The contract was negotiated by appropriately qualified staff, which included a team of attorneys handling the written contract and providing guidance on legal procurement issues, as well as pharmaceutical experts researching and negotiating with the manufacturers on the type of flu vaccine, the production, and the shipping requirements.

The manufacturer, as well as the other states involved, was aware that each state was to be billed by the manufacturer separately, and that Illinois was not liable for acting as the spokesperson. All communications were verified in written email with the dosage, billing contacts, and addresses for the manufacturers to send the invoices. In addition, very early in the process (November 1), legal staff explained to the Special Advocate, to the participating states and to the manufacturer, that under Illinois law, we did not have the appropriation authority to pay the manufacturer and be reimbursed by the other states. This is further evidenced by the lawsuit filed by the wholesaler for nonpayment, which only seeks payment from Illinois for the portion of vaccine that was acquired for distribution in Illinois.

Auditor Comment #2: *The manufacturers of the vaccine being purchased were GlaxoSmithKline and Aventis Pasteur. Neither of the manufacturers was involved in this procurement. Rather, the vendor, Ecosse, was an independent supplier of pharmaceutical products.*

Finally, the Department of Healthcare and Family Services was required to, and did, maintain contract files for the flu vaccine procurement. This information was given to the Office of the Auditor General.

Auditor Comment #3: *The contract was signed by the Governor's Office; however, the Governor's Office did not maintain a file related to this procurement.*

2. Take steps to obtain the necessary approval from appropriate federal authorities, when such approval is required, prior to committing State resources to procurements.

Findings: The State of Illinois, through the Special Advocate and the Governor's Office, attempted to procure flu vaccine from Ecosse as an emergency procurement. The State did not have Food and Drug Administration (FDA) approval to import the flu vaccine prior to directing Ecosse officials to locate flu vaccine in mid-October 2004. Since it is illegal to import flu vaccine into the United States without appropriate FDA approval, the contract between the State and Ecosse was illegal. Inadequate planning and monitoring resulted in State resources totaling $2.6 million being risked for vaccine that the State never received.

Federal law governs the importation of vaccine into this country. The Public Health Service Act prohibits the introduction of an unapproved vaccine into interstate commerce. The Food, Drug and Cosmetic Act prohibits the importation of unapproved drugs. The definition of drug in the FD&C Act includes vaccines. Further, the Food, Drug and Cosmetic Act prohibits the introduction of unapproved drugs into interstate commerce.

In its haste to procure the vaccine, the State appeared to overstate its review of the vaccine to be purchased from Ecosse. In an October 25, 2004 correspondence to the FDA, the Governor reported that the Illinois Department of Public Health had evaluated the vaccine. However, a series of email correspondence between officials from Public Health six days earlier on October 19, 2004 indicate a lack of knowledge of the vaccine being procured. In its response, the FDA, on October 27, 2004, indicated that the flu vaccine was not licensed for use in this country. While the FDA was interested in the vaccine that Illinois officials had located; it expressed concern that the vaccine was already in the distribution chain.

Response: The Office of the Governor agrees with this finding and did take the necessary steps to seek approval from the FDA.

> ***Auditor Comment #4:*** *The auditors believe the State should* ***obtain****, not just seek, approval from appropriate regulatory authorities before committing State resources to a procurement*

Once the vaccine we secured was proven to be safe, and after the FDA did not respond to our repeated requests, the Governor utilized the Supreme Executive Authority granted to him through the Constitution of the State of Illinois to protect the health and welfare of the citizens of Illinois and authorized the procurement of flu shots for Illinois' most vulnerable population. (Article V, section 8 of the Illinois Constitution provides that the Governor has the supreme executive power and the responsibility for the faithful execution of the laws.)

> ***Auditor Comment #5:*** *It is our understanding that the vaccine involved in this procurement was never "proven to be safe," as stated in the agency's response. Rather, as noted in the agency's response, the manufacturer of the vaccine never provided certain information necessary to document how each lot/batch had been held and transported - information necessary to determine that the vaccine was safe and effective as originally manufactured.*

In October 2004, the United States' flu vaccine supply was decimated after British health officials found that some doses produced by Chiron Corp., a manufacturer that was expected to produce nearly half of the 100 million doses needed for U.S. residents, were infected by bacteria and its entire supply was condemned. As a result, the United States had only the 55 million doses of vaccine manufactured by its other supplier – the French drug maker Aventis Pasteur – to meet its entire demand.

While the FDA announced it had asked Aventis Pasteur to manufacture an additional 2.6 million doses of vaccines to address shortages across the United States, the new shots were not expected to be ready until January. Flu season in Illinois lasts from November to April, peaking in January and February. State health officials encourage the elderly and young children to get vaccinated early in the winter to allow the vaccine at least two weeks to become effective before peak season.

When news of the flu vaccine shortage was made public, we turned to suppliers outside the U.S. that we had developed relationships with while establishing the I-SaveRx prescription drug importation program. We had the opportunity to purchase flu vaccine from Europe because of our prescription drug program, I-Save Rx. Our inspectors happened to be in the United Kingdom to inspect more pharmacies for our program, and identified at least 30,000 doses that could be shipped within hours of approval by the FDA.

By immediately obtaining existing Aventis vaccine from European countries not facing shortages, we could provide Illinois' most vulnerable residents -- senior citizens in nursing homes -- with flu shots within days, long before peak flu season.

To obtain FDA approval to import the vaccine we took the following steps:

> ***Auditor Comment #6:*** *While none of the e-mails referred to in the agency's response were provided to the auditors and we do not know to whom they were sent, they do not change the audit conclusion that these activities should have taken place prior to the commitment of significant State resources.*

10/25/04— The Governor sent letter to FDA, requesting approval of the flu vaccine and meeting to discuss this critical need.

10/26/04— Letter to FDA Acting Commissioner Crawford from Illinois Senator Durbin, and Illinois Representatives Emanuel and Gutierrez, urging FDA approval of the importation of flu vaccine.

10/29/04— Representatives from the Illinois Department of Healthcare and Family Services and the Office of the Prescription Drug Advocate, along with legal representation from Zuckerman Spaeder (including former FDA employees) meeting in Washington with representatives from the FDA seeking approval for flu vaccine importation.

11/05/04— Call with FDA Associate Commissioner John Taylor regarding documentation needed for approval of flu vaccine importation.

11/5-11/19— Multiple documents provided to FDA in support of flu vaccine importation, including lot numbers and cold chain.

11/19/04— Email from Zuckerman Spaeder legal counsel and former FDA employee William Schultz—"yesterday the FDA asked Glaxo for info and Glaxo responded."

11/24/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—"I spoke with Bill Hubbard at FDA this afternoon. Apparently the person reviewing the data has started to do a chart of every lot number that IL has purchased and is going through the task of attempting to trace every step of the process for how each lot/batch was held and transported. Manufacturers are not supplying "Masterfile" info FDA needs to approve and FDA doesn't seem to be pushing very hard."

11/29/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—"I just spoke to Caroline Becker, John Taylor's special assistant, who is conducting FDA's review of our first data submission."

11/29/04— Letter to Acting FDA Commissioner Crawford from Zuckerman Spaeder legal counsel and former FDA employee William Schultz—requesting a final decision by 12/15/04 on vaccine.

12/02/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—Phone call with FDA regarding Investigational New Drug (IND) application.

12/07/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—"FDA has not yet authorized IL to import the GSK vaccines that it purchased. We have informed FDA that we have purchased all of these vaccine products, FDA has asked GSK and Aventis for certain information, but it has not received anything." Meanwhile, FDA announces GSK 1.2 and 4 million dose purchases with the IND.

12/07/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—"I haven't heard anything re the GSK pedigree info…, On another note, apparently the formal written request to GSK is going out under Bill Hubbard's signature within the hour. That should place GSK in a box."

12/07/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay— "FDA has additional question on documents already provided."

12/09/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay—to the FDA, requesting status or update from FDA on whether a decision has been made pertaining to flu vaccine importation.

12/09/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay— "FDA is requesting Prescription Drug Advocate Scott McKibbin provide an additional declaration for information previously supplied about the flu vaccines."

12/09/04— Written declaration of the Prescription Drug Advocate Scott McKibbin supplied to FDA via Zuckerman Spaeder.

12/15/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay— "FDA is asking additional questions about documents previously supplied."

12/27/04 — Email from Zuckerman Spaeder legal counsel and former FDA employee Willaim [sic] Schultz—"We may get a reply from FDA but it seems highly unlikely that they will approve our importing the product particularly since there now appears to be an oversupply." The oversupply comes from the 5.2 million GSK doses the FDA purchased from GSK. **These doses were purchased well after the FDA knew that Illinois had already secured the vaccines.**

> ***Auditor Comment #7:*** *Despite recognition that the FDA would not permit the flu vaccine to be imported and that the domestic market was now in an "oversupply" situation, the amount of flu vaccine doses being purchased on Illinois' behalf increased from 180,250 at December 23, 2004, to 254,250 doses per the vendor's January 11, 2005, invoice.*

3. Ensure that I-SaveRx pharmacies are authorized under the Pharmacy Practice Act. Inspections of these pharmacies should be conducted by duly authorized pharmacy investigators as required under the Act.

Finding: The pharmacies operating under the I-SaveRx Program may be in violation of the Pharmacy Practice Act (Act). The pharmacies have not met either of the two provisions to be authorized under the Act. Additionally, inspections of the I-SaveRx pharmacies were not conducted by drug compliance investigators as is required in the Act.

The auditors' review of Pharmacy Inspection Forms for the pharmacies inspected by the Department of Financial and Professional Regulation (DFPR) found several problems. For 32 of 80 pharmacies inspected for the I-SaveRx Program, the form was not completely filled out with one or more requirements left blank. The form also contained requirements that applied to pharmacies being licensed in Illinois, which the I-SaveRx pharmacies are not. In addition, only 9 of 80 inspection forms indicated whether the pharmacy was approved. Inspection forms for approved pharmacies and for pharmacies not approved were often indiscernible.

The Special Advocate is responsible for day-to-day monitoring of the I-SaveRx Program. The State does not monitor whether prescriptions are being filled only by approved pharmacies. Participants not knowing if their prescriptions were filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. An updated list was provided to the auditors by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

There are two ways to be authorized under the Act for out-of-state pharmacies. The Department may **license** as a pharmacist, without examination, an applicant who is licensed under the laws of another U.S. jurisdiction or another country if the requirements are deemed substantially equivalent. However, the I-SaveRx pharmacists are not licensed in Illinois.

The Act also provides for an annual nonresident special pharmacy registration for all pharmacies located outside of this State. These are granted to "mail-order" pharmacies, which the Act defines as a pharmacy that is located in a state of the United States, other than Illinois. Since I-SaveRx pharmacies are located out of the country, they do not meet this definition.

The auditors asked the Special Advocate about this licensure requirement and whether the I-SaveRx pharmacies are violating the Act. An attorney working for the Special Advocate responded: *"We do not have jurisdiction to enforce the Pharmacy Practice Act in foreign countries. Since we do not have jurisdiction over foreign pharmacies, the foreign pharmacies are not violating the Act by shipping into Illinois. As for the dispensing issue, it is our position that the Canadian imports are not dispensing under Illinois law."*

While not meeting the above requirements, the I-SaveRx pharmacies have been inspected by representatives from Illinois and deemed that they meet the same conditions required of licensed Illinois pharmacies. However, the inspections were not conducted by the drug compliance investigators at DFPR.

Response: Accepted. The Department of Financial and Professional Regulation agrees that I-SaveRx pharmacies are authorized under the Pharmacy Practice Act, and has done so accordingly. **I-SaveRx pharmacies are licensed and regulated by their jurisdictional authorities whose standards are equal to or exceeding those under the Illinois Pharmacy Act.** That includes Canada, Australia and New Zealand, and the standards of the European Union, which cover England, Scotland and Ireland. Additionally, I-SaveRx pharmacies are contractually obligated to comply with the Illinois Pharmacy Practice Act. Pharmacies that fail to comply with the Pharmacy Practice Act will lose their contracts. **This means that pharmacies participating in I-SaveRx meet both the standards of Illinois and their host countries, each of whom have equally or more stringent standards than those required in the United States.**

> ***Auditor Comment #8:*** *The audit report expressly does not conclude that the pharmacies participating in the I-SaveRx program are authorized under the Pharmacy Practice Act. Rather, our audit report notes that the international pharmacies participating in the I-SaveRx program have not been authorized under the Pharmacy Practice Act either as licensed foreign pharmacies or as domestic mail order pharmacies.*

Inspections of I-SaveRx pharmacies meet the requirements of the Pharmacy Practice Act. The inspections of foreign pharmacies were all either personally conducted by the

Department's Director of Drug Compliance, or were reviewed and approved by him. The Director of Drug Compliance has significant experience conducting pharmacy investigations, because all inspections of pharmacies in Illinois are either personally conducted by the Department's Director of Drug Compliance or reviewed and approved by him. As the Department's Director of Drug Compliance, he is the "chief enforcement officer of the Pharmacy Practice Act of 1987." (225 ILCS 85/10), and is appropriately conducting pharmacy investigations. Moreover, he meets the qualifications established in the Pharmacy Practice Act for pharmacy investigators.

Because the Director of Drug Compliance has a Ph.D. in pharmacy and more than 29 years of practical experience working as a pharmacist and a pharmacist-in-charge, he actually exceeds the qualifications of any investigator currently employed by the Department.

The three other individuals that assisted the Director of Drug compliance in conducting the pharmacy inspections have between 18 to 20 years of experience as licensed pharmacists and managers in a variety of settings including retail, hospital, manufacturing, quality control, pharmacy administration, and managed care. One of the individuals that assisted, in addition to the experience mentioned above, is also an attorney that works for the prosecution division of the Department. In each case, these individuals meet or exceed the required qualifications of an investigator.

> ***Auditor Comment #9:*** *Several inspections were completed by individuals who may have the qualifications required of pharmacy investigators (i.e., a graduate of an accredited college of pharmacy who is registered and in good standing in Illinois and has at least 5 years of experience practicing pharmacy) but they were not designated as "duly authorized" pharmacy investigators on a list provided by the Department of Financial and Professional Regulation. The Pharmacy Practice Act states that "[t]he duly authorized pharmacy investigators of the Department shall have the right to enter and inspect. . .any pharmacy or any other place in the State of Illinois holding itself out to be a pharmacy. . .The pharmacy investigators shall be the only Department investigators authorized to inspect, investigate, and monitor probation compliance of pharmacists, pharmacies, and pharmacy technicians." 225 ILCS 85/10.*

4. The Department of Financial and Professional Regulation should ensure that inspection forms of pharmacies inspected for the I-SaveRx Program:

- **Are filled out properly with all requirements completed;**
- **Indicate whether the pharmacy has been approved and, if not, the reasons for not approving; and**
- **Are reviewed by someone other than the person who performed the initial inspection.**

Finding: The Pharmacy Inspection Form is a one-page form used when inspecting pharmacies. No other policies and procedures exist to guide inspectors through the inspection process. The same form was used to inspect I-SaveRx pharmacies as is used to inspect Illinois pharmacies.

The auditors reviewed the Pharmacy Inspection Forms for all of the pharmacies inspected for the I-SaveRx Program. Illinois officials inspected 80 pharmacies in Canada, the United Kingdom, Australia, and New Zealand. Seventy-four of the 80 pharmacies inspected were approved while six were not approved.

RESULTS OF PHARMACIES INSPECTED FOR THE I-SAVERX PROGRAM

Location	Approved	Not Approved	Total Inspected
Canada	20	4	24
United Kingdom	46	2	48
Australia	7	0	7
New Zealand	1	0	1
Total	**74**	**6**	**80**

Source: OAG analysis of Pharmacy Inspection forms.

The auditors' examination of the I-SaveRx inspections found several problems:

- Many of the inspection forms were not completely filled out. One or more requirements were left blank in 32 of the 80 inspections;
- The inspection form did not include a place to indicate whether the pharmacy was approved or not approved;
- Some forms (5 of 80) contained checkmarks indicating a violation but were still approved. One of these pharmacies had five violations and was to be reinspected but was approved with no evidence to show that it was reinspected; and
- In 21 of the 80 inspection forms, the supervisory review was conducted by the same person that performed the inspection. In addition, some forms did not contain information on the date of inspection (22 of 80), who was the inspector (2 of 80), the date of the review (4 of 80), and who was the reviewer (3 of 80).

Response: The Office of the Governor's agreement with this recommendation is limited to certain aspects, identified below.

The Department of Financial and Professional Regulation agrees that inspection forms should be properly completed to ensure that all **relevant** information is collected. That was exactly the case with the inspection of participating pharmacies.

Some of the fields on the inspection forms are simply not relevant to foreign pharmacies and can therefore be eliminated from the forms used when such an inspection takes place. For example, a foreign pharmacy will not have a U.S. DEA number. **The only way to ensure that is to not allow individuals to purchase prescription drugs from foreign pharmacies, which condemns them to the artificially high prices of prescription drugs in the United States.**

> ***Auditor Comment #10:*** *Of the 80 pharmacies inspected to participate in the I-SaveRx program, the auditors found the inspections forms were incompletely and/or inconsistently filled out in 32 of the 80 inspections. With regard to the U.S. DEA number, this field was completed on some forms but not on others, however, in no case, was it counted as an exception by the auditors. We did question why certain information related to violations was filled in (indicating the information was relevant to patient safety) for some foreign pharmacies and not for others located in the same country.*

The Department also agrees that pharmacy inspection forms should indicate whether a pharmacy has been approved or, if not, the reasons for not approving the pharmacy. **State forms have never previously had this field, nor is this information required by statute or rule, but we will update the form to include it nonetheless.**

> ***Auditor Comment #11:*** *In some cases, the forms for pharmacies that were not approved were filled out the same way as forms for pharmacies that were approved. This lack of consistent documentation led the auditors to recommend that the agency clearly indicate whether the inspected pharmacy was approved or not approved for participation in the I-SaveRx Program.*

It is currently standard practice – and has always been standard practice – for the Director of Drug Compliance to sign pharmacy inspection reports, where he has not completed the inspection himself. He also signs the reports when he has completed an inspection. This is so because the Director of Drug Compliance is "the executive administrator and the chief enforcement officer of the Pharmacy Practice Act of 1987." (225 ILCS 85/10). **There is no statutory requirement that the form be reviewed and approved by another person.** Additionally, the supervisor of the Director of Drug Compliance is not a licensed pharmacist and is therefore prohibited by the Pharmacy Practice Act from conducting any pharmacy investigations. We will look to see if legislation incorporating the Auditor General's recommendation can be enacted in the next legislative session.

> ***Auditor Comment #12:*** *In 21 of 80 inspections, the inspector signed the form both as inspector and as reviewer. Subsequently, at some point after the inspection forms were prepared and signed by the inspector, they were reviewed by another State employee and changes/corrections were made to some of the forms based on his comments. However, this secondary review was not documented and the secondary reviewer did not sign the forms. While the agency indicates in its response that legislation would be required to permit a review of the forms by someone other than the person who performed the inspection, the above process indicates that, at least informally, such a review is already taking place in some instances. Our recommendation is that the review currently being undertaken by the Department for **some** inspection forms be documented and extended to **all** inspection forms pertaining to pharmacies being reviewed for participation in the I-SaveRx Program.*

Updated Response: The Department of Financial and Professional Regulation developed a new form for non-domestic pharmacies that has only relevant fields. Additionally, the forms specifically indicate whether the pharmacy has been approved.

It is currently standard practice – and has always been standard practice – for the Director of Drug Compliance to sign pharmacy inspection reports, where he has not completed the inspection himself. He also signs the reports when he has completed an inspection. This is so because the Director of Drug Compliance is "the executive administrator and the chief enforcement officer of the Pharmacy Practice Act of 1987." (225 ILCS 85/10). There is no statutory requirement that the form be reviewed and approved by another person**.** Additionally, the supervisor of the Director of Drug Compliance is not a licensed pharmacist and is therefore prohibited by the Pharmacy Practice Act from conducting any pharmacy investigations. We will consider pursuing legislation incorporating the Auditor General's recommendation can be enacted in the next legislative session.

5. The Special Advocate for Prescription Drugs should monitor the I-SaveRx Program to ensure that only approved pharmacies are filling prescriptions.

Finding: The Special Advocate is responsible for the day-to-day monitoring of the I-SaveRx Program. However, the Special Advocate does not monitor whether prescriptions are being filled only by approved pharmacies. According to the Special Advocate, Illinois does not receive any type of report that shows what pharmacies are being used for each prescription filled.

The Governor's Office provided a list of pharmacies approved to participate in the I-SaveRx Program. This **list did not agree** with the DFPR inspected pharmacies. DFPR **inspected and approved many more pharmacies** than were indicated on the Governor's list. One of the pharmacies on the Governor's List was **shown as not approved** when inspected by DFPR. In addition, DFPR inspection forms indicated **24 additional** approved pharmacies that were not on the Governor's list. An updated list was provided to the auditors on June 20, 2006 and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

Response: The Office of the Governor's agreement with this recommendation is limited to certain aspects, identified below.

The Special Advocate for Prescription Drugs agrees that only approved pharmacies should fill prescriptions, and after reviewing documentation from tens of thousands of I-SaveRx orders, there is no evidence to show that even one prescription was filled from any pharmacy outside of the network. Monitoring occurs in the following ways:

Inspections and Audits. The Special Advocate for Prescription Drugs conducted no-notice inspections and an audit of the I-SaveRx Program to ensure that only approved pharmacies were filling prescriptions. **Update:** Since the audit, the Special Advocate for Prescription Drugs has conducted two no-notice pharmacy inspections and a no-notice inspection of the pharmacy benefits manager.

> ***Auditor Comment #13:*** *While a "no-notice" method of inspection would be a good monitoring control, the auditors were provided no documentation to support that this type of inspection was actually utilized during the first 21 months of the I-SaveRx Program. Additionally, while the State indicated an "audit" of the then-Pharmacy Benefit Manager for the I-SaveRx Program had been conducted in February 2005, no audit document was ever produced and the results were apparently verbally communicated to the vendor.*

Regular Pharmacy Benefit Manager Reports. The Special Advocate for Prescription Drugs receives regular reports that provide information about patient orders.

Database access to prescription fulfillment system. The Special Advocate for Prescription Drugs has direct access to the Pharmacy Benefit Manager's database. This ensures that all prescriptions are being filled by approved pharmacies.

> ***Auditor Comment #14:*** *Effective July 1, 2006, the Pharmacy Benefit Manager for the I-SaveRx Program was changed from CanaRx to Pegasus. While the new contract does permit the Special Advocate for Prescription Drugs to have direct access to the Pharmacy Benefit Manager's database, this was* ***not*** *the case during the first 21 months of the Program.*

Correspondence with Program Participants. The Special Advocate for Prescription Drugs also set up and monitored a toll free telephone number and an email system for all I-SaveRx Program Participants to use to report any problems.

Contractual Obligations ensure compliance. I-SaveRx Program Pharmacy Benefit Manager Agreement has contractual obligations in which the vendor is required to only use the pharmacies that are approved by the Special Advocate for Prescription Drugs.

At the recommendation of the OAG, the Special Advocate for Prescription Drugs is also in the process of formalizing the monitoring system to ensure that we maintain adequate documentation of our monitoring. **Update:** This monitoring system includes a new contract monitoring policy, no-notice inspection policy, and a pharmacy compliance policy

6. **The Special Advocate for Prescription Drugs should take the necessary steps to monitor and test the safety and efficacy of medications provided to I-SaveRx Program participants to ensure that the participants are getting medications as advertised.**

Finding: The State has not tested medications Illinois citizens receive from the I-Save Rx program for effectiveness and efficacy to ensure that the customers are getting exactly the drugs they think they are getting. While the recommendations for order testing was made for an I-SaveRx type of program for employees/retirees, no such testing has been recommended for the current I-SaveRx Program.

The State of Illinois' desire has always been to provide a safe importation program for its participants. Participants that enroll in the Program are reminded of the safety and legality of prescription drugs purchased from other countries. A warning is provided in the I-SaveRx Enrollment process.

Officials from the Special Advocate's Office indicated that chemical testing has never been part of the regulation of pharmacy in Illinois. While State officials believe that pharmacy practices in Canada and the United Kingdom are equal or superior to that which occurs in Illinois, the fact is that Program Participants do not know who the pharmacies received the medicines from.

Response: The Special Advocate for Prescription Drugs agrees with the Office of the Auditor General that every reasonable step should be taken to ensure that I-SaveRx Program provides prescription drugs that are as safe as or safer than prescription drugs available in the United States. **The I-SaveRx safety standards are based on the requirements for mail order prescription drug programs in the United States, and exceed the U.S. safety standards.** To ensure the highest level of safety, the I-SaveRx program:

Relies on higher standards. Canadian and United Kingdom pharmacy standards are equal or superior to those in Illinois on all levels including the:

- Approval process requirements
- Distribution requirements
- Manufacturing requirements
- Storage requirements
- Distribution requirements
- Dispensing requirements
- Packing requirements
- Pricing requirements

Inspects Pharmacies to ensure pharmacies operate at the same standards as Pharmacies in the U.S.

Completes Drug Interaction checks to ensure patient safety.

Has Licensed Physicians review prescriptions and enrollment forms.

Packing Requirements exceed U.S. standards. I-SaveRx prescriptions are packaged by the manufacturer in sealed "unit of use" blister packs or "stock bottles", which work to prevent tampering. In contrast, U.S. packaging and pharmacy practice requires pharmacists to count out pills from larger "bulk" containers; these pharmacists must then ensure that the pills are bottled and labeled correctly. Prescription drugs dispensed from bulk containers are more likely to be counterfeit or tampered with because they are dispensed to the patient only after the drug has moved through a complex supply chain of wholesalers and repackers.

Tests. At the suggestion of the OAG, as the I-SaveRx Program grows and the threat of tampering manifests, the Special Advocate for Prescription Drugs will perform medication testing.

The following chart compares the pharmacy inspection/audit standards of the US versus the International I-SaveRx Program.

Standard		
	MEDCO	**I-SaveRx**
Percentage of Pharmacies Inspected/Audited	1%	100%
Pharmacies Inspected/Audited By	Internal MEDCO Personnel	State Approved Inspectors
Contract Required Performance Standards, with Penalties	Yes	Yes
Prescription Ingredients Tested in the Supply Chain	none	Approximately 1% of all orders have been tested by the US Food and Drug Administration

Auditor Comment #15: *All 60,000 pharmacies participating in Illinois' Group Insurance Program are inspected by appropriate officials in the State in which the pharmacy is located. By contrast, there were only 80 pharmacies inspected for participation in the I-SaveRx Program and only two of these were being used to dispense drugs to participants in the Program.*

Auditor Comment #16: *See comments 10, 11 and 12 concerning problems noted by the auditors with the inspection forms for pharmacies being reviewed for participation in the I-SaveRx Program.*

Auditor Comment #17: *According to the Special Advocate, approximately 1% of drugs in the I-SaveRx program have been seized. However, we have no information indicating the seized drugs were tested by the FDA.*

The I-SaveRx Program has committed to inspect all dispensing pharmacies with the same standards as the Illinois based pharmacies. I-SaveRx pharmacies are subject to: pre-program; no-notice; and periodic re-inspection on a more frequent basis than Illinois pharmacies.

The current Pharmacy Benefits Management contract for the I-SaveRx Program provides for Ingredient testing by the State of Illinois in the event the program is expanded to include State employees.

7. **The Office of the Governor should ensure that no State employees paid with federal funds work on I-SaveRx promotional outreach activities since the I-SaveRx Program is not approved by the federal government. Additionally, when interagency agreements are used, the Office of the Governor should ensure that agreements exist with all State agencies contributing personnel.**

Findings: The auditors surveyed agencies that had employees who participated in promotional activities for the I-SaveRx Program. From the 28 agencies surveyed, 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of over $488,000. Actual hours worked and payroll costs are higher. Due to data limitations, the auditors were unable to calculate an estimated payroll cost for 29% of the employees who participated.

The Department of Healthcare and Family Services (DHFS) entered into interagency agreements with 15 other agencies to provide employees for promotional activities for the I-SaveRx Program. Although 15 agreements were in place, 28 agencies, including DHFS, had employees that participated. Activities also took place **prior** to any agreements being in place. A total of 30 employees from 5 agencies worked on promotional activities prior to the time period covered by the agreements.

While it appears that officials from the Governor's Office worked to coordinate activities, the list of participating employees provided by the Governor's Office was incomplete and not always accurate. Agencies added a total of 176 employees that participated that were not included on the Governor's list. Also, in some instances, officials responded that the employee on the list provided had never worked at their agency (17 employees) or had not performed any activities related to the I-SaveRx Program (14 employees).

Although the I-SaveRx Program was not approved by the FDA and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities were paid from federal funds. Additionally, all 22 IDOT staff were paid from the Road Fund. Agencies did not receive any reimbursement for employees that worked on the I-SaveRx Program.

Seven agencies reported that 111 total employees had some ongoing responsibilities related to the I-SaveRx Program. For those seven agencies, responsibilities include

outreach and marketing; distributing application forms; educating potential applicants in their prescription drug options; and acting as a liaison for the agency.

Many of the applications or information cards submitted were unusable because of incorrect contact information or illegible handwriting. According to an official from the Governor's Office, approximately 15,000 of the 40,000 shown in the report were unusable. The source of these applications and information cards and when they were turned in was not tracked.

I-SAVERX PROGRAM PROMOTIONAL ACTIVITIES BY AGENCY [1]

SINCE PROGRAM INCEPTION

Based on Responses from Survey Sent May 9, 2006

Agency	Employees Participating	*Estimated Hours Spent* [1]	Estimated Payroll Cost [1]	Ongoing Responsibilities [2]
Aging	21	518.2	$ 12,682.19	Yes
Agriculture	18	75.0	$ 1,952.81	Yes
Capital Development Board	18	33.0	$ 1,036.31	No
Central Management Services	13	15.0	$ 588.27	No
Children and Family Services	16	25.5	$ 845.37	No
Commerce and Econ. Opportunity	48	636.5	$ 19,159.79	No
Corrections	8	49.0	$ 1,228.26	No
Emergency Management Agency	2	11.5	$ 348.75	No
Employment Security	18	348.0	$ 10,890.73	Yes
Environmental Protection Agency	1	1.0	$ 24.91	No
Financial and Prof. Regulation	35	201.0	$ 4,979.90	No
Fire Marshal	2	3.0	$ 42.40	No
Governor's Office	53	1,520.0	$ 45,623.70	Yes
GOMB	3	3.0	$ 38.40	No
Healthcare and Family Services	16	See Footnote 3	$ 244,374.80	Yes
Historic Preservation	3	6.0	$ 175.55	No
Housing Development Authority	5	25.0	$ 886.48	No
Human Rights	15	153.5	$ 4,256.60	No
Human Rights Commission	1	32.0	$ 1,200.00	No
Human Services	77	1,432.0	$ 45,159.38	Yes
Labor	4	78.0	$ 2,322.35	No
Natural Resources	11	23.5	$ 679.28	No
Public Health	24	123.0	$ 81,333.63	No
Revenue	29	172.0	$ 5,862.52	No
State Police	2	5.0	$ 154.81	No
Toll Highway Authority	1	2.0	$ 52.90	No
Transportation	22	70.8	$ 1,754.14	No
Veteran's Affairs	55	15.0	$ 607.85	Yes
Total	**521**	**5,577.5**[1]	**$ 488,262.08**	

Notes:

[1] The estimated number of hours and payroll costs spent on promotional activities is understated since some agencies could not provide complete information.

[2] Ongoing responsibilities include outreach and marketing; distributing application forms; educating potential applicants in their prescription drug options; and acting as a liaison for the agency.

[3] Healthcare and Family Services had four employees that spent a substantial amount of time on the Program. However, time spent was not broken out by hours but instead by percent of total time spent. The remaining 12 employees spent a minimal amount of time and hours were not provided.

Source: OAG analysis of agency survey responses.

Response: The Office of the Governor agrees that interagency agreements should exist with all State agencies contributing personnel. **However, the Office of the Governor disagrees that State employees paid with federal funds should not work on I-SaveRx. The Food and Drug Administration has never made any attempt to halt or shut down I-SaveRx, just as it has tacitly permitted the importation of drugs by over one million Americans each year for the past decade. I-SaveRx presents an opportunity for senior citizens and the uninsured to save money on the cost of their medicine. The State of Illinois should do everything in its power to help them take advantage of this opportunity.**

Many employees were paid through the use of both federal and state funds, and in cases where there were federally funded employees, there were no restrictions on the use of federal dollars received that would prohibit State employee participation in a State sponsored program. Specifically:

- Employees that are funded 100% or combination of federal and state match funds are all allowed under the Federal Code of Regulation, State Statute and grant agreement clauses to provide information regarding other state and federal assistance programs.

- The majority of employees were management and supervisory level employees who do not work normal working hours. Any of the hours used during the normal work day were made up by working overtime that is not compensated to complete all required tasks under the federal funded program.

  Auditor Comment #18: *Records provided by the various State agencies involved in I-SaveRx promotional outreach indicate that all levels of employees participated in the Program activities.*

- Some of the employees' responsibilities include promoting public health at community education, information health fairs and bringing primary health care to rural communities; supporting that I-SaveRx promotion is clearly within the scope of their normal work duties

- Information provided by the agencies (except DHFS) indicated that the hours employees spent on the I-SaveRx program ranged from one one-hundredth of a percent - 0.0001 to 1.44% of the total hours worked by staff during the period in question.

When other agencies are contributing personnel, the Office of the Governor will ensure that interagency agreements are in place for all contributing State agencies and include in the agreement a clause limiting the amount of participation of employees that are federally funding within the amount allowable under the federal regulations of the program.

8. **In order to monitor Acquisition Fund requirements in the Memorandum of Understanding, the Special Advocate should require the I-SaveRx pharmacy benefit manager, and its successors, to provide documentation to support their activities using start-up acquisition fees and the Program's total amount of prescription drug sales on an ongoing basis. In addition, the total amount of prescription drug sales should be broken-down by state and forwarded to other participating states so they can track the percentage of acquisition fees attributable to their state's zip codes.**

Finding: The State of Illinois signed a Memorandum of Understanding (MOU) with Wisconsin, Missouri, Kansas and Vermont allowing their residents to purchase prescription drugs through the I-SaveRx Program. The auditors followed-up with each of these states to obtain information necessary for the completion of a state survey. We found that the Special Advocate was not monitoring all requirements in the MOU, including those related to the Acquisition Fund.

The MOU stated that CanaRx would pay I-SaveRx acquisition fees to the Program for such activities as marketing, outreach, and additional inspections. CanaRx was to provide a minimum of $1 million for Program advertising in the first nine months of Program operation with no less than $300,000 available for payment within the first 60 days of the Program's start date.

The MOU also stated that each state was entitled to a pool of acquisition fees in an amount proportional to the percentage of I-SaveRx prescription drug sales attributable to that state's zip codes. The Special Advocate stated that the fund had not reached the $300,000 amount initially invested due to low prescription drug sales. As a result, acquisition fees were not available for distribution to other states. However, CanaRx did not provide the total amount of prescription drug sales to the Special Advocate so the Advocate could not monitor CanaRx's responsibilities related to Acquisition Fund requirements in the MOU. Moreover, other participating states could not track the percentage of acquisition fees attributable to their state's zip codes.

Updated Response: The Special Advocate for Prescription Drugs partially disagrees with this finding.

The Special Advocate for Prescription Drugs required the former I-SaveRx pharmacy benefits manager, and its successors, to provide documentation to support their activities using start-up acquisition fees and the program's total amount of prescription drug sales on an ongoing basis. The contract and invoices between the former vendor and its advertising firm were given to the Office of the Auditor General. This contract and the invoices are a complete summary of the money spent from the acquisition fund.

> ***Auditor Comment #19:*** *State officials responsible for monitoring the program obtained this information from the vendor only after the auditors requested it. The auditors requested the information several times over a*

period of months; however, the State did not receive the information and provide it to the auditors until August 22, 2006 - after our audit fieldwork had ended and a draft report had been provided to the agency.

Regarding the notification to other states, the Special Advocate for Prescription Drugs followed the contract with the Pharmacy Benefits Manager and the State of Illinois and the agreements between Illinois with the participating states which only requires this information to be provided after the program has generated over $21 million in sales.

9. The Special Advocate should perform and document adequate monitoring of the pharmacy benefit manager for the I-SaveRx Program to ensure the vendor meets all contract requirements. Monitoring should include:

- **having access to the I-SaveRx pharmacy benefit manager management database in order to allow for better monitoring;**
- **conducting no-notice pharmacy inspections; and performing and documenting an audit of the I-SaveRx Program.**

Finding: The State and CanaRx entered into a contract on October 4, 2004 to provide services for the operation of the I-SaveRx Program. The contract contained 21 service requirements for CanaRx to provide as part of the Program. The auditors found that the Special Advocate had not adequately monitored CanaRx regarding compliance with provisions of the contract.

The Special Advocate reported that no officials from Illinois had access to the CanaRx management database that would track orders, specific Program participant information, filling information, etc. Without having this access, it is difficult to ensure that some of the service requirements were met.

Pursuant to the contract, the Special Advocate stated they performed an “audit”, in February 2005, of CanaRx related to the I-SaveRx Program. In a June 2006 meeting with the auditors, the Special Advocate explained that the results of the audit never became a written document; they were merely communicated verbally to CanaRx.

The Special Advocate indicated, for many of the requirements, that CanaRx monitoring was performed via “no-notice” pharmacy inspections. While a “no-notice” method of inspection would be a good monitoring control, the auditors found no documentation to support this type of inspection was actually utilized.

An official from the Department of Financial and Professional Regulation who supervised or oversaw the inspections of these pharmacies stated that the pharmacies in the Program had only been inspected once and that any second inspection would occur without any notification to the pharmacies. During a review of the Special Advocates files, the auditors

found correspondence showing itineraries for traveling from one pharmacy to another and notifying the pharmacies of the dates they would be arriving, in order to coordinate travel.

Pursuant to the contract, management reports were to be provided; however, reports showing ordering information were not provided by CanaRx until March 2005. The March 2005 report included cumulative ordering information and CanaRx provided this type of information monthly thereafter. In responding to whether CanaRx met each service requirement outlined in the contract, the Special Advocate stated that these monthly reports verified compliance with some of the service requirements. Since these reports were not provided to the Special Advocate since the inception of the Program, it cannot be determined that CanaRx was always in compliance.

The Special Advocate informed CanaRx they were in material breach of the contract because Section VII.1 required CanaRx to maintain professional liability insurance covering all network physicians and pharmacies for one million dollars per incident. In January 2005, solicitors for CanaRx responded that this coverage was not available by any insurance provider. According to the Special Advocate, if something were to happen, CanaRx would be liable and would have to pay for damages because the contract required this insurance.

Response: The Special Advocate for Prescription Drugs agrees, and as a result, has consistently monitored the I-SaveRx Program in the following ways:

Database access to prescription fulfillment system. The Special Advocate for Prescription Drugs has direct access to the new Pharmacy Benefit Manager's database to ensure that all prescriptions are being filled by approved pharmacies.

> ***Auditor Comment #20:*** *Effective July 1, 2006, the Pharmacy Benefit Manager for the I-SaveRx Program was changed from CanaRx to Pegasus. While the new contract does permit the Special Advocate for Prescription Drugs to have direct access to the Pharmacy Benefit Manager's database, this was* ***not*** *the case during the first 21 months of the Program.*

Inspections and Audits. The Special Advocate for Prescription Drugs will continue to conduct no-notice inspections and will implement procedures to ensure that all future audits and inspections are adequately documented.

> ***Auditor Comment #21:*** *The auditors were provided no documentation indicating that any no-notice inspections were performed during the first 21 months of the I-SaveRx Program's operation. Additionally, while the State indicated an "audit" of the then-Pharmacy Benefit Manager for the I-SaveRx Program had been conducted in February 2005, no audit document was ever produced and the results were apparently verbally communicated to the vendor.*

10. With respect to travel:

- **The Office of the Governor, Special Advocate, and the Departments of Human Services, Financial and Professional Regulation and Public Health should take the steps necessary to ensure that its staff seek documented prior approval when traveling out of State or out of country, as outlined in the Governor's Travel Control Board Travel Guide for State Employees;**

- **The Office of the Governor, Special Advocate, and the Departments of Financial and Professional Regulation and Public Health should take the steps necessary to ensure that its staff follow travel regulations when being reimbursed for per diem when traveling out of country, or seek appropriate exceptions to the travel regulations; and**

- **The Department of Financial and Professional Regulation should refrain from using monies from the Illinois State Pharmacy Disciplinary Fund for travel to out-of-country pharmacies if those pharmacies are not licensed under the State Pharmacy Act and would not be considered ordinary and contingent expenses of the Department.**

Finding: While CanaRx is not paid for its services by the State under the contract, there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program.

The State paid a total of $104,982.07 in travel reimbursement costs for the I-SaveRx Program. This total is a conservative amount in that not all agencies were able to provide complete travel information to us. Travel purposes ranged from a Governor's fact-finding mission to Canada for a drug importation program to pharmacy inspections to meetings with other states and federal officials. Travel included a total of 15 employees from five agencies during the time period of October 7, 2003 to May 4, 2005. The auditors identified $10,662 in excessive per diem reimbursement to six State employees traveling as part of the I-SaveRx Program.

TOTAL COST OF PER DIEM OVERPAYMENT BY AGENCY

Agency	Overpayment
Special Advocate	$ 8,105.25
Office of the Governor	$ 1,000.00
Department of Public Health	$ 975.75
Department of Professional Regulation	$ 581.00
Total	$ 10,662.00

Source: OAG summary of travel voucher information.

The Department of Financial and Professional Regulation used monies from the Illinois State Pharmacy Disciplinary Fund to reimburse staff for travel on nine occasions in support of a drug importation/I-SaveRx Program. The funds totaled over $17,000. Out-of-country pharmacies do not pay into this fund and are also not licensed under the Pharmacy Practice Act.

Total out-of-country travel for pharmacy inspections totaled almost $84,000 for the period October 7, 2003 to April 29, 2005. However, only two pharmacies were filling prescriptions. According to the Special Advocate, the State decided to go to other countries and many other pharmacies when the Program was starting because they didn't know the volume they would have and wanted to have the supply.

State employees participating in out-of-country and out-of-state travel did not submit required travel pre-approval documents timely in 98 percent (51 of 52) of the travel vouchers examined. Of the 40 out-of-country travel vouchers examined, 27, or 68% **never received** required approval from the Governor's Travel Control Board at any point in time.

Response: The Office of the Governor's agreement with this recommendation is limited to certain aspects, identified below.

A. The Office of the Governor, Special Advocate, and the Department of Human Services, Financial and Professional Regulation and Public Health partially agree with this finding and will seek prior approval 30 days prior to traveling out of State or country, as outlined in the Governor's Travel Control Guide for State Employees. We will also seek a remedy for allowing exceptions to the 30 day rule when deemed necessary. **However, all out of country and state travel was approved prior to submission of the travel voucher.**

   Auditor Comment # 22: *Approval should be obtained **prior** to the travel taking place, not after the travel has occurred and reimbursement is being sought.*

B. Regulation and Public Health disagree with this finding and consistently followed travel regulations when being reimbursed for per diem when traveling out of the country. Specifically, CMS informed travelers that they could use the "actual reasonable" rule to account for expenses or the federal per diem rate when traveling out of the country. The travelers followed this guideline.

   Auditor Comment #23: *Travel by executive branch employees is governed by rules and regulations promulgated by the Travel Regulation Council and Governor's Travel Control Board. The Travel Regulation Council rules provide that the "per diem allowances specified in Appendix A, Reimbursement Schedule are the maximums allowed by the Travel Control Boards." 80 Ill.Adm.Code 3000.500 (a). Schedule A sets forth a maximum per-diem for out-of-state travel of $32.00 per day. (By contrast, foreign lodging is allowed at an "actual reasonable" rate.) Further, we noted that a per diem rate was not consistently applied to all persons traveling to foreign countries for the I-SaveRx program. Per diem paid ranged from $32 per day to $138 per day depending upon the employee submitting the travel voucher.*

C. The Department of Financial and Professional Regulation disagrees with this finding. **The Illinois Pharmacy Practices Act states that the Illinois State Pharmacy Disciplinary Fund should be used for pharmacy inspections.**

Updated Response: The Special Advocate, currently seeks approval at least 30 days prior to all out of country and state travel, as outlined in the Governor's Travel Control Guide for State Employees. In an emergency situation, we seek a justification for allowing exceptions to the 30 day rule. Additionally, all out of country and state travel was approved prior to actual travel.

The Special Advocate has consistently followed travel regulations when being reimbursed for per diem when traveling out of the country. Specifically, CMS informed travelers that they could use the "actual reasonable" rule to account for expenses or the federal per diem rate when traveling out of the country. The travelers followed this guideline.

The Department of Public Health used the "actual reasonable" rule instead of the per diem rate for meals. Actual reimbursements were $32.90 and $32.92 per day for the IDPH Director and Deputy Director.

Other Costs

The State incurred many other service costs for the I-SaveRx Program. The State has paid almost $220,000 in legal fees related to the drug importation program to vendors that were awarded these engagements via an exemption to competitively procuring these services due to potential litigation concerns.

Further, the State incurred additional marketing costs for the I-SaveRx Program. During FY06, the Department of Healthcare and Family Services paid $51,514 for marketing efforts for direct mailings of I-SaveRx materials as well as advertising in a major Internet search engine. The Department of Human Services also estimated it paid $2,938.50 in printing costs for enrollment packets, applications and enrollment cards for the I-SaveRx Program.

The State has incurred other contractual service costs totaling $71,018 relative to the operation of the I-SaveRx for a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate's Office.