



STATE OF ILLINOIS

OFFICE OF THE AUDITOR GENERAL

**MANAGEMENT AUDIT
OF THE
FLU VACCINE PROCUREMENT
AND THE
I-SAVE_RX PROGRAM**

SEPTEMBER 2006

WILLIAM G. HOLLAND

AUDITOR GENERAL

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OFFICE OF THE AUDITOR GENERAL
WILLIAM G. HOLLAND

*To the Legislative Audit Commission, the
Speaker and Minority Leader of the House
of Representatives, the President and
Minority Leader of the Senate, the members
of the General Assembly, and
the Governor:*

This is our report of the Management Audit of the Flu Vaccine Procurement and I-SaveRx Program.

The audit was conducted pursuant to Illinois House of Representatives Resolution Number 394, which was adopted May 30, 2005. This audit was conducted in accordance with generally accepted government auditing standards and the audit standards promulgated by the Office of the Auditor General at 74 Ill. Adm. Code 420.310.

The audit report is transmitted in conformance with Section 3-14 of the Illinois State Auditing Act.

A handwritten signature in blue ink, appearing to read "William G. Holland". The signature is stylized and includes a large, sweeping flourish that extends upwards and to the right.

WILLIAM G. HOLLAND
Auditor General

Springfield, Illinois
September 2006

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SYNOPSIS

House Resolution No. 394 directed the Auditor General to conduct a management audit of the flu vaccine contracting process with Ecosse Hospital Products as well as the operation of the I-SaveRx Program.

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 we 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).

REPORT DIGEST

MANAGEMENT AUDIT OF THE

FLU VACCINE PROCUREMENT AND THE I-SAVE_RX PROGRAM

Released: September 2006



State of Illinois
Office of the Auditor General

WILLIAM G. HOLLAND
AUDITOR GENERAL

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REPORT CONCLUSIONS FLU VACCINE PROCUREMENT

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 (Special Advocate), began taking steps in mid-October 2004 to find additional flu vaccine for Illinois residents. The Special Advocate initiated talks with European wholesalers to locate and procure flu vaccine. Documentation showed:

- On October 22, 2004, seven days after the FDA announcement, the Special Advocate agreed to an initial 35,000 doses of vaccine identified and obtained by Ecosse Hospital Products, Ltd. (Ecosse);
- On October 23, 2004, the Deputy Governor authorized, via e-mail, the purchase of 200,000 doses of flu vaccine from Ecosse;
- On November 1, 2004, the Deputy Governor confirmed for Ecosse officials an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine; and
- Other states and local governments joined Illinois in the effort to procure flu vaccine and documentation showed that Ecosse eventually acquired almost 800,000 doses of vaccine for Illinois and the other governments.

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. Furthermore, documentation showed that at the time State officials signed the contract to purchase the flu vaccine, State officials knew that FDA approval was not likely. 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. An October 28, 2004

Department of Public Health memo to the Governor’s Office indicated that between 160,000 and 200,000 doses would address Illinois’ priority population, as defined by the Centers for Disease Control and Prevention (CDC). By December 2004, Department of Public Health documentation showed that the CDC had located sufficient flu vaccine to cover Illinois’ priority population. Documentation also showed that the CDC would make available an additional 200,000 doses in its December 2004/January 2005 allotment of vaccine to Illinois. Despite the availability of additional vaccine from the CDC, the State continued to proceed with its procurement of flu vaccine from Ecosse.

- Illinois officials negotiating with Ecosse were not aware that to consummate the purchase of the flu vaccine, a contract was necessary. Not until almost three weeks **after** the State agreed to purchase the flu vaccine, did the Special Advocate negotiating the purchase become aware that a contract was needed to purchase the vaccine. On November 10, 2004, the Special Advocate indicated, in an e-mail to an official at the Department of Public Aid, “...I have been talking to the Budget Office, the Dep. Governor, etc. and nobody has said word one about a contract. We have been told several times, the payment would be processed COD. If someone needs a contract, then you or someone else needs to get it done without delay....”
- The contract entered into between the State and Ecosse **was not timely**.
 - The contract with Ecosse to purchase 254,250 doses of the influenza vaccine was signed on January 13, 2005 by an official from the Governor’s Office, which was **2 days after** Ecosse submitted a billing for the vaccine of approximately \$2.6 million.
 - State officials signed the contract **6 days prior to Ecosse officials** signing the contract on January 19, 2005. The term of the contract was for the period October 20, 2004 through June 30, 2005.
 - The amount of the State’s obligation under the contract was **estimated** to be \$2,592,218. This is the **exact amount billed** by Ecosse to the State on an invoice dated January 11, 2005 – **8 days prior** to Ecosse signing the contract with the State.
- Illinois officials took the lead in procuring flu vaccine for other states and local governments but failed to develop agreements

with these entities. Such agreements could have delineated the amount of flu vaccine the various governments would purchase, as well as documented the other governments' fiscal responsibilities for their portion of the procurement. The absence of such agreements, and given that Illinois officials were negotiating with Ecosse, resulted in **Illinois being potentially liable** to pay for the entire cache of vaccine – over \$8.2 million.

Multiple agencies had roles in the attempt to procure the flu vaccine. These parties included the Governor's Office, the Department of Public Aid (later the Department of Healthcare and Family Services), the Special Advocate, and the Department of Public Health. Some of the individuals involved in the procurement process are no longer with the State.

Sixteen months after searching out flu vaccine, the State approved the donation of the vaccine it was responsible for to the country of Pakistan. (pages 1-3)

BACKGROUND

On May 30, 2005, the Illinois House of Representatives adopted House Resolution Number 394 which directs 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. Regarding the contract with Ecosse Hospital Products Limited, the Resolution directed the Auditor General to determine the roles played by the Office of the Governor and the Special Advocate for Prescription Drugs in negotiating and entering into the flu vaccine contract. (page 6)

GOVERNOR'S FLU VACCINE PROCUREMENT

On August 26, 2004, United Kingdom based manufacturer Chiron announced a small quantity of its flu vaccine did not meet sterility specifications and that distribution of Chiron-produced flu vaccine would be delayed until further tests were completed. Less than two months later, on October 5, 2004, Chiron announced that the U.K. Medicines and Healthcare Products Regulatory Agency had temporarily suspended its license to manufacture flu vaccine in its Liverpool, England facility. On October 15, 2004, the FDA announced that none of the flu vaccine manufactured by Chiron for the U.S. market was safe for use – effectively reducing the United States supply by nearly half.

Documentation shows that **4 days later**, on October 19, 2004, State of Illinois officials, primarily from the Office of the Governor and the Special Advocate had already begun taking steps to find additional flu vaccine for Illinois residents. This vaccine was to be distributed to the at-risk population as defined by the CDC.

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. A contract could have laid out details on how much flu vaccine the State was attempting to procure and the price the State was willing to pay for the vaccine. Lacking this information the procurement could be construed as “open-ended” with no clear indication as to what the State’s financial obligation would be for the procurement. A written contract was not put in place until **three months later** – in mid January 2005.

The State had no written agreement with Ecosse for the vaccine when the orders were placed.

Seven days after the FDA announcement regarding Chiron vaccine, on October 22, 2004, the **Special Advocate accepted and agreed** to an initial 35,000 doses of vaccine from Ecosse. 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.

State officials placed orders with Ecosse for over 500,000 doses of vaccine within an 11 day period.

Documentation showed the Deputy Governor also authorized significant purchases of vaccine. On October 23, 2004, in an e-mail to Ecosse, the Deputy Governor authorized the purchase of 200,000 doses of vaccine. Nine days later, on November 1, 2004, the Deputy Governor confirmed for Ecosse officials an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine. Documentation showed that Ecosse eventually acquired almost 800,000 doses of vaccine.

The State did not have approval from the FDA to import any of the flu vaccine.

Illinois officials appeared to be aware that the vaccine would never be delivered, even **prior to being billed** by Ecosse and executing a contract with the vendor in January 2005. In a December 21, 2004 e-mail from the Special Advocate to the Governor’s Office he stated “We probably will never take delivery of these doses so will need to find a way to pay for the ‘service’ they performed (found and secured the doses).”

Sixteen months after searching out the flu vaccine, the State approved the donation of the vaccine it was responsible for to the country of Pakistan. Prior to the donation, and pursuant to Article 4 of the contract

with Ecosse, the vendor attempted to resell the vaccine to German, Italian, and Greek suppliers, Southern Hemisphere commercial parties, and other aid organizations. All resale attempts were unsuccessful.

Documentation obtained in files from the Special Advocate showed that Ecosse sent the Governor a correspondence on February 8, 2005 stating “It is with extreme disappointment that I find myself forced to write to you today to request immediate payment of all monies outstanding to us (in excess of US\$8 million) relating to the above.” The subject of the correspondence was Flu Vaccine Orders. The letter details that Ecosse secured the vaccine “under instruction from your representatives” and mentions that there were “other represented states” when the Illinois senior representatives were seeking flu vaccine. Further, “Your State’s commitment to us has been fully documented between us with full disclosure throughout and backed up by personal representations and commitment to me by ..., your Deputy Governor....”

When the State did not process payment, Ecosse filed suit, on March 15, 2005, in the Court of Claims seeking the \$2.6 million billed to the State. The State petitioned the court to dismiss the suit in October 2005, but, according to officials from the Governor’s Office and the Special Drug Advocate, a ruling has not been forthcoming as of February 8, 2006. While the Governor’s Office entered into an agreement for legal services with a Washington D.C. based firm, the Illinois Attorney General is representing the Governor in this Court of Claims suit.

Multiple agencies had roles in the attempt to procure the flu vaccine from Ecosse. These parties included the Governor’s Office, the Department of Public Aid (later the Department of Healthcare and Family Services), the Special Advocate, and the Department of Public Health. Some of the individuals involved in the procurement process are no longer with the State.

While the Governor’s Office had many roles with respect to the purchase of flu vaccine from Ecosse, the Special Advocate played the lead role in day-to-day negotiations with Ecosse staff. (pages 24-30)

Ecosse requested payment for the vaccine in February 2005 for an amount over \$8 million.

After not receiving payment, Ecosse sued the State for payment of \$2.6 million in the Illinois Court of Claims.

PROCUREMENT TIMING AND PLANNING

The Governor’s Office did not execute a contract with Ecosse until after the State was billed for the flu vaccine.

The Office of the Governor did not execute a contract with Ecosse in a timely manner. 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. Having formal agreements in place not only sets out the responsibilities of each party to that agreement but protects the interests of both parties.

The State’s lead negotiator was not aware that a contract needed to be in place for this purchase.

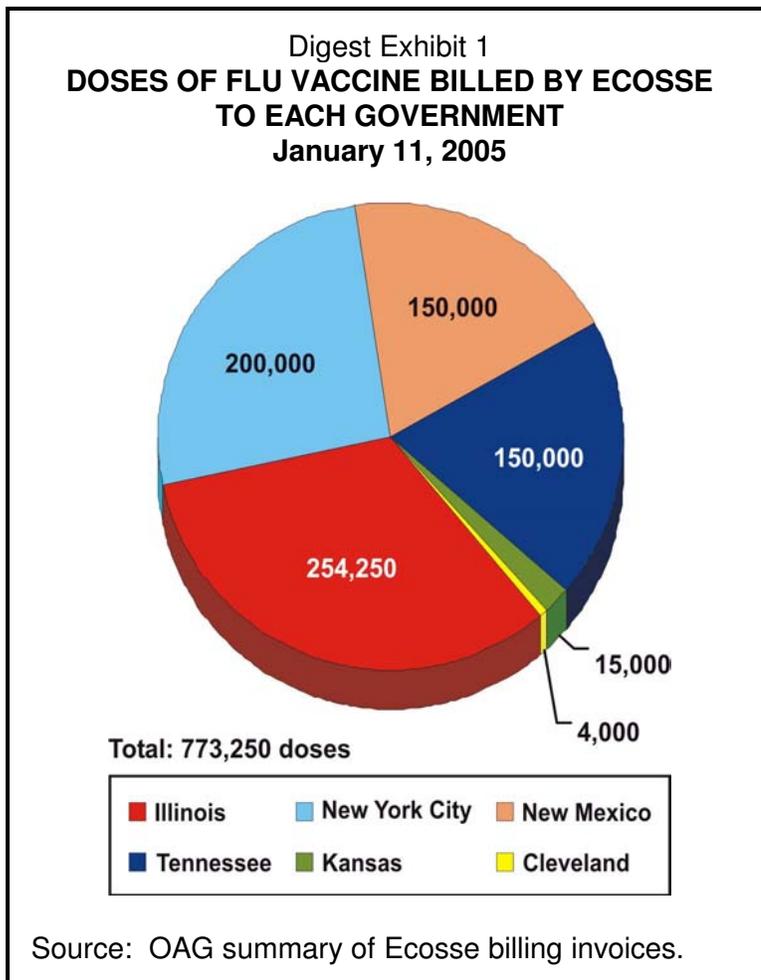
Documentation showed that the State’s lead negotiator on this procurement, the Special Advocate, apparently was not familiar with the procurement processes that guide State purchasing. In a November 10, 2004 communication to the State Purchasing Officer at the Department of Public Aid, the Special Advocate stated *“First time anyone has used the term ‘contract’. I have been talking to the Budget Office, the Dep. Governor, etc. and nobody has said word one about a contract. We have been told several times, the payment would be processed COD. If someone needs a contract, then you or someone else needs to get it done without delay. If the vendor is told this payment will be delayed, Illinois and all the other governments will not have these flu shots shipped.”*

Additionally, staff from the Special Advocate’s Office asked another Public Aid official on November 10, 2004, *“We need to know if there is any way to expedite payment to the vendor. Can payment be made followed by paperwork?”* Per the Procurement Code, the Comptroller may process no payments before a written contract has been filed (30 ILCS 500/20-80 (d)). Further, the State Finance Act (30 ILCS 105/9.05) requires that, generally, payment for services rendered or 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. Good business practice would dictate that the people who negotiate with vendors for goods be educated in terms of the procurement laws of the State. (pages 30-31)

Other Government Participation

State officials attempted to procure vaccine for other governments.

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. The number of doses billed, by government, are presented in Digest Exhibit 1.



We found that:

- While most governments contacted Illinois officials after learning of the procurement attempt through media sources, two – New York City and the State of New Mexico – were approached by an official from the Governor’s Office;
- No written agreements were executed between the other governments and Illinois to secure flu vaccine;
- None of the other governments had any contact with Ecosse officials;
- None of the other governments had any contract with Ecosse to purchase flu vaccine;
- None of the other governments ever received any flu vaccine from Ecosse;
- All of the governments received a billing from Ecosse;
- None of the other governments made payment to Ecosse on the vaccine billings;

Illinois officials had no written agreements with other governments outlining payment responsibilities.

- None of the other governments have been sued by Ecosse for payment; and
- All of the governments reported experiencing a shortage of vaccine during the winter of 2004, but all were able to find additional vaccine through other sources – mainly the federal government. (pages 31-32)

Determination of Vaccine Amount Ordered

The State lacked documentation as to why it was billed for more vaccine than was needed to serve the priority population.

Illinois officials were attempting to purchase flu vaccine to address the priority population as indicated by the CDC. An October 28, 2004 memo from a Department of Public Health official to the Governor’s Office indicated that between 160,000 and 200,000 doses would address our CDC priority population. The State ended up being billed for 254,250 doses, or 50,000 doses more than the upper end of the estimated range.

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 vaccines from Ecosse.

The number of doses billed to Illinois increased by 74,000 in a matter of two weeks – from 180,250 doses on December 23, 2004 to 254,250 doses on the January 11, 2005 invoice. Correspondence dated December 23, 2004, which was accompanied by a spreadsheet showing the vaccine obtained by Ecosse for all governments, from the Special Advocate to an attorney from the Governor’s Office of Management and Budget indicated, “You will note that in addition to the cost for the shots, I have added a rate adjustment needed to cover the major exchange rate movement over the past several weeks, plus the storage costs incurred by the vendor who assumed they were shipping the order when it was placed. [A Governor’s Office official] has signed a letter which basically agrees to allow the vendor these rate adjustments....The vendor would like to issue all invoices prior to the end of the year and I can’t blame them given they are sitting on over 7 million dollars of inventory.”

Documentation did not exist to show why the amount of vaccine Illinois wanted increased by 74,000 doses.

The spreadsheet attached to the correspondence lists the exact amounts billed to other governments for the flu vaccine from Ecosse. However, the amount eventually billed to Illinois increased by 74,000 doses in the two weeks – again without any documentation that explained the adjustment. The Special Advocate was reporting the 180,250 doses as

late as December 29, 2004 to officials at Public Aid. Additionally, we could not find the referenced “letter” where the official from the Governor’s Office agreed to the rate adjustment. All of these activities **occurred without an executed contract in place.** (pages 32-33)

PROCUREMENT PLANNING - APPROVAL

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 FDA approval to import the flu vaccine prior to directing Ecosse officials to locate flu vaccine in mid-October 2004. It is illegal to import flu vaccine into the United States without appropriate FDA approval. 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 (42 USC 262) prohibits the introduction of an unapproved vaccine into interstate commerce. The Food, Drug and Cosmetic (FD&C) Act, section 801(d)(1) (21 USC 381), prohibits the importation of unapproved drugs. The definition of drug in the FD&C Act includes vaccines.

In an October 25, 2004 correspondence to the FDA, the Governor reported that “The Illinois Department of Public Health’s evaluation of the manufacturer’s product descriptions and examinations of dosage, strains of flu, processing and formulation, advisories and contraindications all show that the Aventis vaccine produced for Canada and Europe contain properties that are identical to the Aventis vaccine produced for the United States.” Further, “Our experts from the Illinois Department of Public Health have done an initial assessment of other flu vaccines used in Canada and Europe for the same northern hemisphere flu strains and have concluded that the vaccine made by GlaxoSmithKline likely contains the same properties as those already used here.”

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. The FDA wanted to collect additional information about the quality of the vaccines. This information included the source of the vaccine supply since it came from middlemen and not from the manufacturer; standards to which the vaccines conform; and the integrity of the products (e.g., current storage conditions). (pages 36-38)

Federal law prohibits the importation of vaccine to the U.S. without FDA approval – approval the State did not have.

REPORT CONCLUSIONS

I-SAVeRx PROGRAM

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 United Kingdom. The Program later expanded, in 2005, to include approved pharmacies in Australia and New Zealand. I-SaveRx was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003.

The states of Wisconsin, Vermont, Kansas, and Missouri have also joined the I-SaveRx Program. Documentation received from the Governor's Office in late 2005 listed 28 approved pharmacies in the I-SaveRx Program from the United Kingdom, 15 from Canada, 7 from Australia and 1 from New Zealand. After an inquiry from auditors, the Special Advocate indicated this listing was not accurate.

In the first 19 months that the I-SaveRx Program has been in operation (through April 2006), a total of 17,575 orders for prescription medicine have been placed by residents from the participating states (Illinois, Wisconsin, Kansas, Missouri, and Vermont). This total is comprised of 7,503 new orders and 10,072 repeat orders. There have been 4,954 individuals from the five states that placed orders through the I-SaveRx Program. Illinois has had the largest number of participants with 3,689 unique individuals placing orders. Wisconsin had 321 individuals place orders, Kansas 267, Missouri 460, and 217 citizens from Vermont.

The State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law. 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 (FD&C Act) (21 U.S.C. et.al). 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. The FDA can, under the FD&C Act, bring civil action or criminal prosecution for each violation (21 U.S.C. sections 332/333). 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.

The Office of the Governor was the lead policy maker in the development of a drug importation program beginning in September 2003, when the Special Advocate was directed to explore the idea of having State employees and retirees purchase prescription drugs from abroad.

The Governor's Office also was responsible for developing and entering into a contract with the pharmacy benefit manager for the I-SaveRx Program – CanaRx. The Special Advocate led the State research team that developed reports to the Governor regarding the drug importation initiative, and is responsible for the day-to-day activities and monitoring of the I-SaveRx Program.

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

Our review of Pharmacy Inspection Forms for the pharmacies inspected by the Department of Financial and Professional Regulation (DFPR) found several problems. For 40 percent of pharmacies inspected for the I-SaveRx Program (32 of 80), 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 11 percent (9 of 80) of the inspection forms indicated whether the pharmacy was approved. Inspection forms for approved pharmacies and for pharmacies not approved were often indiscernible.

The State does not monitor whether prescriptions are being filled only by approved pharmacies. Participants not knowing if their prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. A list of approved pharmacies provided by the Governor's Office differed from DFPR's inspected pharmacies log. The Governor's Office list contained fewer approved pharmacies compared to the DFPR inspected pharmacies and even contained one pharmacy that was shown as not approved by DFPR. After we inquired, an updated list was provided that contained all of the pharmacies approved by DFPR. The updated list was provided to our Office on June 20, 2006 by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

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.

We 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 \$488,000. Actual hours worked and actual payroll costs are higher, since some agencies were unable to provide an estimate of hours worked by employees. Due to data limitations, we were unable to calculate an estimated payroll cost for 29 percent of the employees that participated.

There was a lack of coordination of the I-SaveRx promotional activities. Although DHFS was to coordinate the efforts of employees working on the I-SaveRx promotional activities, only two agencies mentioned working with DHFS. Coordination of promotional activities is important to ensure that resources are maximized and efforts are cohesive. Outreach activities were primarily reported to and coordinated by the Governor's Office.

There was no system in place to track the results of the agency outreach. For example, the Governor's Office did not track which applications resulted in successful enrollments or which agencies were more effective in signing up enrollees.

Although the I-SaveRx Program was not approved by the federal Food and Drug Administration, and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities **were paid from federal funds**.

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

While CanaRx is not paid for its services by the State under the contract, we found that there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program. State agency personnel have accumulated over \$111,000 in travel expenses, mainly for out-of-country travel and use of State aircraft, in support of a drug importation program. We also found that most travel was not approved prior to departure as stated in travel regulations.

The State has paid \$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 Program that we were able to identify during the course of the audit. The major cost was a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate’s Office. (pages 3-5)

BACKGROUND

Regarding the I-SaveRx Program, House Resolution Number 394 directed the Auditor General to determine:

- The procedures applicable to, and agencies responsible for, the establishment and operation of the I-SaveRx Program; and
- Whether the entities involved in these Programs followed all applicable laws, regulations, policies, and procedures. (page 6)

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 a correspondence dated June 3, 2004, the Acting Commissioner of Food and Drugs wrote “Although at the Food and Drug Administration (FDA) we share your concern and urgency related to the cost and safety of prescription drugs for our citizens, **we do not believe that a waiver could be granted** (emphasis added) to allow a state’s pilot project for the safe importation of prescription drugs under the current law.” The FDA rationale for the denial was outlined in subsequent pages. Even though the FDA denied the waiver, the Governor’s Office proceeded with the drug importation program.

Federal authorities would not grant a waiver to the Governor to operate a drug importation program.

Through April 2006, 17,575 drug orders had been placed by participating states.

On October 4, 2004, the State of Illinois launched the I-SaveRx Program. As publicized on the I-SaveRx website, the Program was developed by the State of Illinois to allow consumers to purchase safe and affordable refills from licensed, inspected pharmacies in Canada and the United Kingdom. The Program launch was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003. The states of Wisconsin, Vermont, Kansas, and Missouri also joined in the I-SaveRx Program.

In the first 19 months that the I-SaveRx Program has been in operation (through April 2006), a total of 17,575 orders for prescription medicine have been placed by residents from the participating states (Illinois, Wisconsin, Kansas, Missouri, and Vermont). This total is comprised of 7,503 new orders and 10,072 repeat orders. Digest Exhibit 2 breaks down ordering statistics by state, by type. There have been 4,954 individuals from the five states that placed orders through the I-SaveRx Program. Illinois has had the largest number of participants with 3,689 unique individuals placing orders. Wisconsin had 321 individuals place orders, Kansas 267, Missouri 460, and 217 citizens from Vermont.

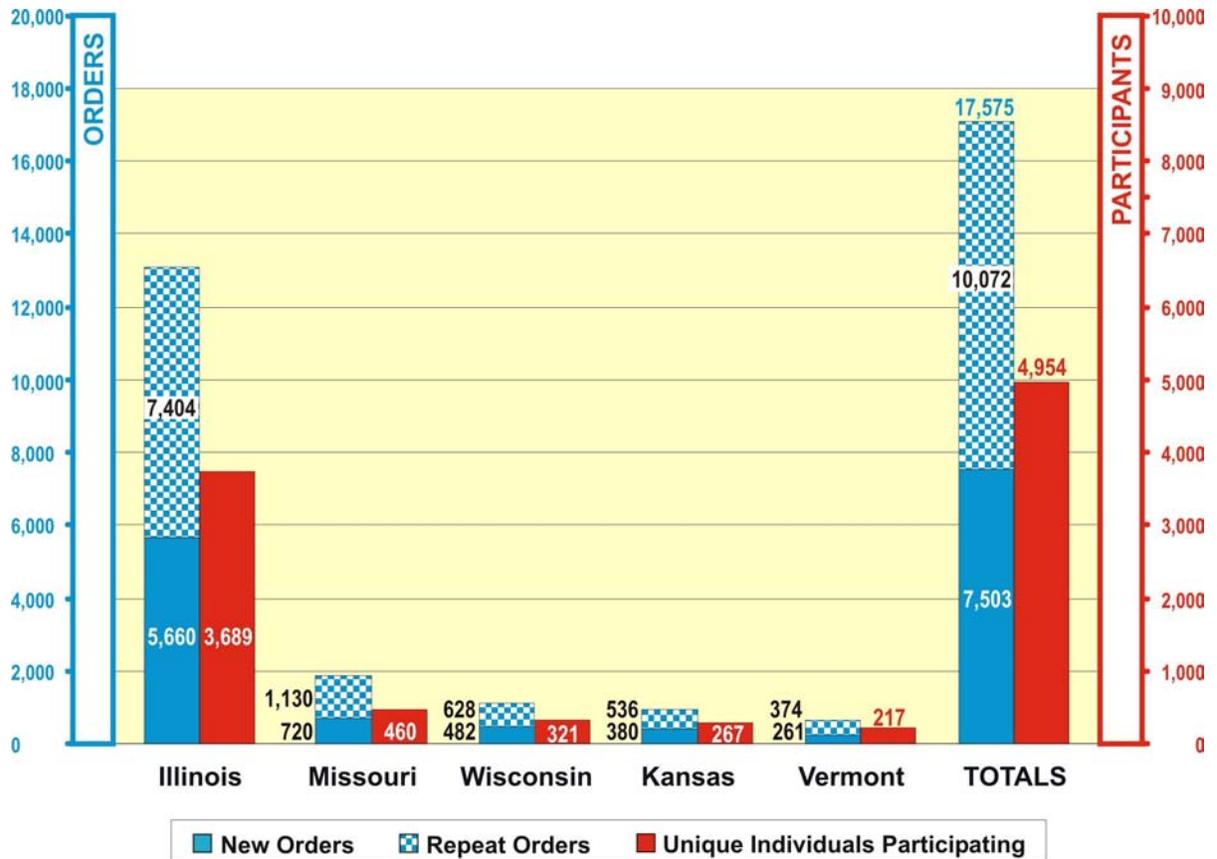
The I-SaveRx Program is administered through a contract between the State of Illinois and CanaRx Services Inc. (CanaRx) – a Canadian-based Pharmacy Benefits Manager. The contract, executed October 4, 2004, was procured by the Governor’s Office through a Sole Economically Feasible Source procurement. The contract is not on file with the Comptroller – since, according to the Governor’s Office, there is no estimated cost to the State. (pages 7-13)

Legality of the I-SaveRx Program

The State’s operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law. Drugs are approved for use in the United States pursuant to the provisions of federal law as stated in the Federal Food, Drug and Cosmetic Act (FD&C Act). Among the provisions of the FD&C Act are:

- Section 384 allows the Secretary to promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products. However, the Secretary has not promulgated such regulations.

Digest Exhibit 2
I-SAVERX PROGRAM ORDER STATISTICS
 Through April 20, 2006



Source: OAG compilation of CanaRx report obtained from Special Advocate.

- Section 331 provides examples of prohibited acts. The prohibited acts include: the introduction or delivery for introduction into interstate commerce of any drug that is adulterated or misbranded, and the introduction into interstate commerce any article that violates sections 384 or 355 of the Act.

In the October 27, 2003 Special Advocate’s report on the feasibility of importing prescription drugs from Canadian pharmacies it states, “...a drug manufactured in the U.S., with U.S./F.D.A. approval, for the U.S. market may be formulated differently for foreign markets. Therefore, it would be an unapproved drug for reimportation, except for reimportation by the manufacturer, unless the requirements of 21 U.S.C. section 384 can be met.”

Federal officials indicated that virtually every time an individual or entity imports a prescription drug they are in violation of the FD&C Act.

According to federal officials, 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. The FDA can, under this Act, bring civil action or criminal prosecution for each violation (21 U.S.C sections 332/333). 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. (pages 48-52)

AGENCY INVOLVEMENT IN THE I-SAVE Rx PROGRAM

While the Governor’s Office led the policy to institute the I-Save Rx Program, the Special Advocate was responsible for day-to-day activities.

Multiple agencies have been involved in the development and operation of the I-Save Rx Program. These agencies include the Governor’s Office, the Office of the Special Advocate for Prescription Drugs (Special Advocate), the Department of Financial and Professional Regulation (DFPR), and the Department of Public Health (Public Health). The Office of the Governor was the lead policy maker in the development of a drug importation program. In September 2003 the Governor directed the Special Advocate to explore the idea of State employees and retirees purchasing prescription drugs from abroad. Later, the Governor directed the Special Advocate to expand the drug importation research to Europe, Australia and New Zealand. The Governor’s Office also was responsible for developing and entering into a contract with the pharmacy benefit manager for the I-Save Rx Program – CanaRx.

The Governor’s Office also coordinated outreach activities for the I-Save Rx Program. Officials from the Governor’s Office traveled on fact-finding missions regarding the drug importation initiative and later on inspection trips to Europe and Canada. The Special Advocate led the State research team that developed reports to the Governor regarding the drug importation initiative. In addition to extensive global travel for inspections and research gathering, the Special Advocate is responsible for the day-to-day activities and monitoring of the I-Save Rx Program. (pages 52-53)

PROGRAM SAFETY AND INSPECTIONS

Our 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.
- Supervisory review was conducted by the same person that performed the inspection in some cases.

32 of 80 pharmacy inspection forms were not completely filled out by the inspector.

The State does not monitor whether prescriptions are being filled only by approved pharmacies. Participants not knowing if their prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. A list of approved pharmacies provided by the Governor’s Office differed from DFPR’s inspected pharmacies log. The Governor’s Office list contained fewer approved pharmacies compared to the DFPR inspected pharmacies and even contained one pharmacy that was shown as not approved by DFPR. After we inquired, an updated list was provided that contained all of the pharmacies approved by DFPR. The updated list was provided to our Office on June 20, 2006 by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx. (pages 53-60)

Requirements of the Pharmacy Practice Act

The Department of Financial and Professional Regulation (DFPR) is responsible for inspecting and licensing pharmacies in Illinois. The requirements are outlined in the Pharmacy Practice Act (225 ILCS 85). The Pharmacy Practice Act states that it shall be unlawful for any person to engage in the practice of pharmacy unless first authorized to do so under the provisions of this act. Any person who practices pharmacy without being licensed under the act is subject to a civil penalty. In addition, the Act states that pharmacy investigators shall be the only Department investigators authorized to inspect pharmacies.

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.

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. Therefore, the I-SaveRx pharmacies do not meet either of the two ways to be authorized to operate as a pharmacy under the Act.

In a memorandum regarding importation issues by Canadian pharmacies, dated June 24, 2003, DFPR stated: “Per the Act, one must be licensed in Illinois as a pharmacy and a pharmacist to dispense drugs to consumers in Illinois. 225 ILCS 85/5.5. The Canadian pharmacies and pharmacists are not licensed in Illinois and therefore are violating the Act if their activity is construed as dispensing.” The Act defines **dispense** as “...the delivery of drugs and medical devices, in accordance with applicable State and federal laws and regulations, to the patient....”

We 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. During the time period when inspections of I-SaveRx pharmacies occurred, DFPR had seven drug compliance investigators, in addition to the Director of Drug Compliance. However, **none** of the seven regular investigators conducted the inspections. Instead, the Director of Drug Compliance conducted the inspections along with three other individuals who were not the regular investigators. The Act states, “The pharmacy investigators shall be the only Department investigators authorized to inspect, investigate, and monitor probation compliance of pharmacists, pharmacies, and pharmacy technicians.” (pages 54-55)

PROMOTIONAL OUTREACH ACTIVITIES

DHFS, formerly the Department of Public Aid, entered into interagency agreements with other State agencies to perform promotional activities related to the I-SaveRx Program. The interagency agreements stated:

“The goal of the I-Save Rx Program is to greatly reduce the healthcare costs of Illinois residents by acquiring prescription drugs from Canadian and European pharmacies. In furtherance of this goal and to help promote the I-Save Rx Program, it is agreed that employees from certain state agencies will have limited responsibilities to directly advance the Office of the Governor and Special Advocate for Prescription Drugs’ objectives, functions, goals and policies with regard to the I-Save Rx Program.”

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. In our contact with State agencies we found:

- The agencies added a total of 176 employees who participated that were not included on the Governor’s list.
- 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).

We surveyed all 28 agencies that had employees who participated in promotional activities for the I-SaveRx Program. We found:

- The Department of Healthcare and Family Services 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.
- 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, we were unable to calculate an estimated payroll cost for 29 percent of the employees that participated. Digest Exhibit 3 presents the results of what State agency staff reported to us relative to promotional activities for the I-SaveRx Program. Reasons for not being able to calculate

State agency staff performed promotional activities to benefit the I-SaveRx Program.

28 State agencies performed promotional activities.

We estimate that the 521 State employees had a payroll cost of over \$488,000 for the promotional activities.

Agencies reported that promotional outreach activities were coordinated by the Governor’s Office.

Some State staff that participated in promotional activities were paid with federal funds – for a Program that the federal government does not approve.

an estimated payroll cost varied. Some agencies did not provide an estimate of hours worked for many employees that worked on the Program. For some employees, promotional activities were part of regular job duties and time spent related to I-SaveRx was not tracked. Other reasons for not being able to calculate an estimated payroll cost included a lack of salary information and employees that were on leave. In addition, some employees promoted the Program during non-work hours such as on the weekends at local churches. This time spent was not included in the calculations in Digest Exhibit 3.

- There was a lack of coordination of the I-SaveRx promotional activities. Although DHFS was to coordinate the efforts of employees working on the I-SaveRx promotional activities, only two agencies mentioned working with DHFS. Outreach activities were primarily reported to and coordinated by the Governor’s Office.
- There was no system in place to track the results of the agency outreach. For example, the Governor’s Office did not track which applications resulted in successful enrollments or which agencies were more effective in signing up enrollees.
- Although the I-SaveRx Program was not approved by the federal Food and Drug Administration and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities **were paid from federal funds.**
- Promotional activities performed by employees included: attending orientation and training meetings; organizing outreach events; distributing information at outreach events; assisting in printing of promotional material; answering phone calls; and conducting presentations on the program. (pages 65-70)

Digest Exhibit 3 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	5,577.5¹	\$ 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.

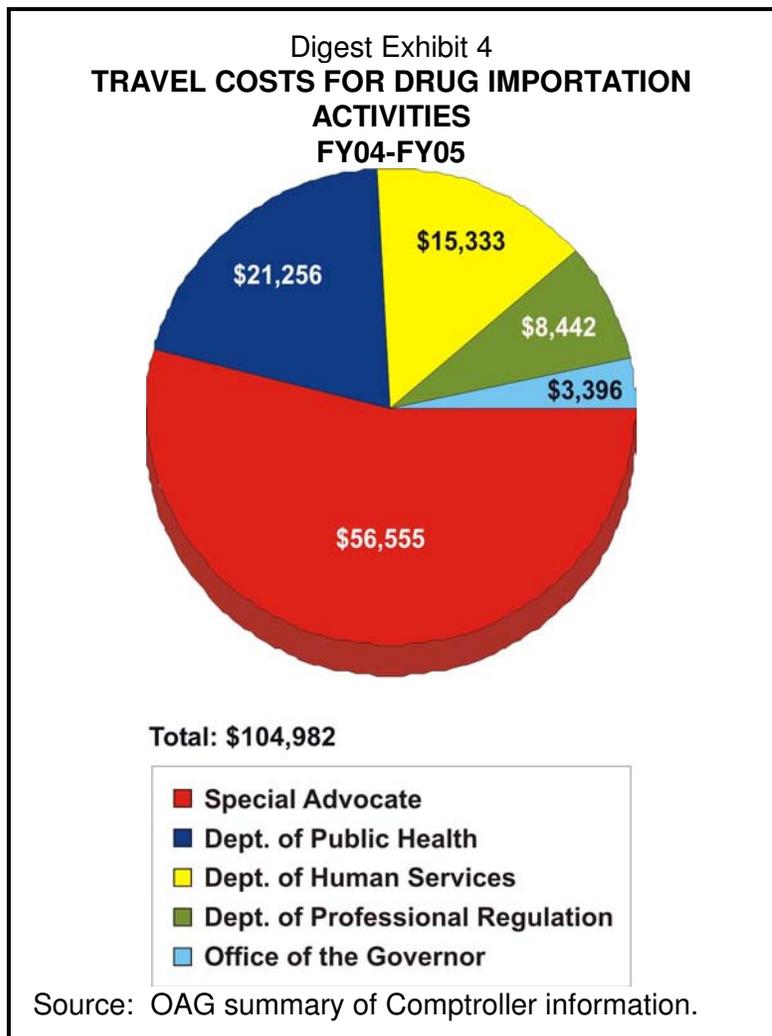
Source: OAG analysis of agency survey responses.

PROGRAM COSTS

While CanaRx is not paid for its services by the State under the contract, we found that there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program. State dollars expended for I-SaveRx Program activities include:

The I-SaveRx Program has resulted in significant expenditures of State funds for Program operation.

- Over \$111,000 in travel expenses, mainly from out-of-country travel and use of State aircraft. We also found that most travel was not approved prior to departure as stated in travel regulations. Digest Exhibit 4 contains information, by agency, on travel costs.



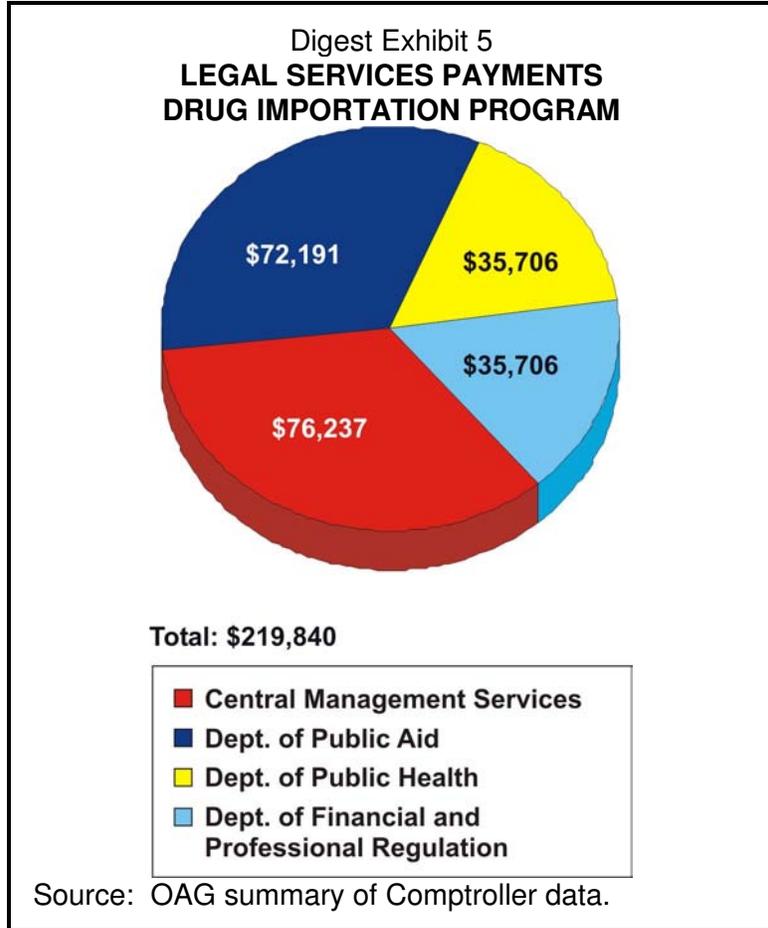
- The Department of Healthcare and Family Services paid \$51,514 for marketing efforts. These activities included direct mailings of I-SaveRx materials as well as advertising in a major Internet search engine.

- The Department of Human Services also estimated that the agency had paid \$2,938.50 in printing costs for enrollment packets, applications, and enrollment cards for the I-SaveRx Program.
- The Special Advocate hired a contractual employee to assist in the management of the I-SaveRx Program with a term beginning September 28, 2004 through June 30, 2005. This contractual employee was paid \$46,800 in gross wages through the end of his contract.
- The Special Advocate also contracted with an individual to provide technical policy writing assistance for the European report on importing prescription drugs. The contractor was paid a flat \$12,350 at the completion of the report. The contract was not executed by the Department of Public Aid until October 14, 2004 – 16 days prior to the end of the agreement’s term. We did not see credit provided for this contractor’s work in the report.
- The Special Advocate contracted with an individual to provide research, writing, and editing services for the prescription drug importation program. Pay documentation showed that the State expended \$8,345 for this assistance for the drug importation program.
- An interagency agreement between the Department of Central Management Services and Public Aid supplied two marketing managers from CMS to assist in the outreach campaign for the I-SaveRx Program. While the term of the agreement was for the period December 13, 2004 through December 31, 2005, the parties did not execute the agreement until June 2005. The two CMS staff were to work for Public Aid 20 percent time for these activities and CMS was to bill for their services/expenses. While we did not find that CMS billed for the services, the two marketing staff were paid a total of \$21,739.85 for services that related to the drug importation program.
- The Special Advocate hired contractual temporary help to answer phones for a physicians toll free number set up for the I-SaveRx Program. These two temporary staff were paid a total of \$3,522.75. The Special Advocate indicated the toll free line was eliminated because they did not have sufficient call volume.
- During FY05 the Governor’s Office entered into an agreement with a Washington D.C. based law firm to provide legal services to the State relative to the drug importation program. Through February 15, 2006, State agencies, through interagency agreements, had paid this vendor \$144,000 for legal services related to drug importation. Additionally, the

CMS supplied two marketing managers to assist in the I-SaveRx Program outreach campaign.

Legal costs to the State for the I-SaveRx Program have totaled \$220,000.

Department of Central Management Services paid another vendor \$76,000 in legal fees for advice relating to a proposed Canadian Drug purchasing program. Digest Exhibit 5 provides a breakdown of spending by agency. (pages 78-87)



AUDIT RECOMMENDATIONS

The Audit contains ten recommendations. The Governor's Office, the Special Advocate, and the Department of Financial and Professional Regulation partially agreed with some of the recommendations, and did not agree with others. Appendix D of the audit report contains the agency responses.



WILLIAM G. HOLLAND
Auditor General

WGHMJM
September 2006

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Chapter One

INTRODUCTION AND BACKGROUND

REPORT CONCLUSIONS

FLU VACCINE PROCUREMENT

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 (Special Advocate), began taking steps in mid-October 2004 to find additional flu vaccine for Illinois residents. The Special Advocate initiated talks with European wholesalers to locate and procure flu vaccine. Documentation showed:

- On October 22, 2004, seven days after the FDA announcement, the Special Advocate agreed to an initial 35,000 doses of vaccine identified and obtained by Ecosse Hospital Products, Ltd. (Ecosse);
- On October 23, 2004, the Deputy Governor authorized, via e-mail, the purchase of 200,000 doses of flu vaccine from Ecosse;
- On November 1, 2004, the Deputy Governor confirmed for Ecosse officials an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine; and
- Other states and local governments joined Illinois in the effort to procure flu vaccine and documentation showed that Ecosse eventually acquired almost 800,000 doses of vaccine for Illinois and the other governments.

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. Furthermore, documentation showed that at the time State officials signed the contract to purchase the flu vaccine, State officials knew that FDA approval was not likely. 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. An October 28, 2004 Department of Public Health memo to the Governor’s Office indicated that between 160,000 and 200,000 doses would address Illinois’ priority population, as defined by the Centers for Disease Control and Prevention (CDC). By December 2004, Department of Public Health documentation showed that the CDC had located sufficient flu vaccine to cover Illinois’ priority population. Documentation also showed that the CDC would make available an additional 200,000 doses in its December 2004/January 2005 allotment of vaccine to Illinois. Despite the availability of additional vaccine from the CDC, the State continued to proceed with its procurement of flu vaccine from Ecosse.
- Illinois officials negotiating with Ecosse were not aware that to consummate the purchase of the flu vaccine, a contract was necessary. Not until almost three weeks **after** the State agreed to purchase the flu vaccine, did the Special Advocate negotiating the purchase become aware that a contract was needed to purchase the vaccine. On November 10, 2004, the Special Advocate indicated, in an e-mail to an official at the Department of Public Aid, “...I have been talking to the Budget Office, the Dep. Governor, etc. and nobody has said word one about a contract. We have been told several times, the payment would be processed COD. If someone needs a contract, then you or someone else needs to get it done without delay....”
- The contract entered into between the State and Ecosse **was not timely**.
 - The contract with Ecosse to purchase 254,250 doses of the influenza vaccine was signed on January 13, 2005 by an official from the Governor’s Office, which was **2 days after** Ecosse submitted a billing for the vaccine of approximately \$2.6 million.
 - State officials signed the contract **6 days prior to Ecosse officials** signing the contract on January 19, 2005. The term of the contract was for the period October 20, 2004 through June 30, 2005.
 - The amount of the State’s obligation under the contract was **estimated** to be \$2,592,218. This is the **exact amount billed** by Ecosse to the State on an invoice dated January 11, 2005 – **8 days prior** to Ecosse signing the contract with the State.
- Illinois officials took the lead in procuring flu vaccine for other states and local governments but failed to develop agreements with these entities. Such agreements could have delineated the amount of flu vaccine the various governments would purchase, as well as documented the other governments’ fiscal responsibilities for their portion of the procurement. The absence of such agreements, and given that Illinois officials were negotiating with Ecosse, resulted in **Illinois being potentially liable** to pay for the entire cache of vaccine – over \$8.2 million.

Multiple agencies had roles in the attempt to procure the flu vaccine. These parties included the Governor’s Office, the Department of Public Aid (later the Department of Healthcare and Family Services), the Special Advocate, and the Department of Public Health. Some of the individuals involved in the procurement process are no longer with the State.

Sixteen months after searching out flu vaccine, the State approved the donation of the vaccine it was responsible for to the country of Pakistan.

I-SAVEX PROGRAM

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 United Kingdom. The Program later expanded, in 2005, to include approved pharmacies in Australia and New Zealand. I-SaveRx was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003.

The states of Wisconsin, Vermont, Kansas, and Missouri have also joined the I-SaveRx Program. Documentation received from the Governor's Office in late 2005 listed 28 approved pharmacies in the I-SaveRx Program from the United Kingdom, 15 from Canada, 7 from Australia and 1 from New Zealand. After an inquiry from auditors, the Special Advocate indicated this listing was not accurate.

In the first 19 months that the I-SaveRx Program has been in operation (through April 2006), a total of 17,575 orders for prescription medicine have been placed by residents from the participating states (Illinois, Wisconsin, Kansas, Missouri, and Vermont). This total is comprised of 7,503 new orders and 10,072 repeat orders. There have been 4,954 individuals from the five states that placed orders through the I-SaveRx Program. Illinois has had the largest number of participants with 3,689 unique individuals placing orders. Wisconsin had 321 individuals place orders, Kansas 267, Missouri 460 and 217 citizens from Vermont.

According to staff from the Governor's Office and the Special Advocate, the I-SaveRx Program does not have any goals to measure the success of the Program. The rationale for not having goals was because it was impossible to get a realistic idea of the number of people that could benefit from the Program (i.e., uninsured, over age of 65), are on medications for longer than 30 days, and would actually utilize the Program. Documentation obtained from the Special Advocate indicated the initial target population for the Program to be 2.8 million people estimated to be without prescription drug coverage in the State of Illinois.

The State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law. 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 (FD&C Act) (21 U.S.C. et.al). 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. The FDA can, under the FD&C Act, bring civil action or criminal prosecution for each violation (21 U.S.C. sections 332/333). 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.

The Office of the Governor was the lead policy maker in the development of a drug importation program beginning in September 2003, when the Special Advocate was directed to explore the idea of having State employees and retirees purchase prescription drugs from abroad. The Governor's Office also was responsible for developing and entering into a contract with the

pharmacy benefit manager for the I-SaveRx Program – CanaRx. The Special Advocate led the State research team that developed reports to the Governor regarding the drug importation initiative, and is responsible for the day-to-day activities and monitoring of the I-SaveRx Program.

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

Our review of Pharmacy Inspection Forms for the pharmacies inspected by the Department of Financial and Professional Regulation (DFPR) found several problems. For 40 percent of pharmacies inspected for the I-SaveRx Program (32 of 80), 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 11 percent (9 of 80) of the inspection forms indicated whether the pharmacy was approved. Inspection forms for approved pharmacies and for pharmacies not approved were often indiscernible.

The State does not monitor whether prescriptions are being filled only by approved pharmacies. Participants not knowing if their prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. A list of approved pharmacies provided by the Governor's Office differed from DFPR's inspected pharmacies log. The Governor's Office list contained fewer approved pharmacies compared to the DFPR inspected pharmacies and even contained one pharmacy that was shown as not approved by DFPR. After we inquired, an updated list was provided that contained all of the pharmacies approved by DFPR. The updated list was provided to our Office on June 20, 2006 by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

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.

We 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 \$488,000. Actual hours worked and actual payroll costs are higher, since some agencies were unable to provide an estimate of hours worked by employees. Due to data limitations, we were unable to calculate an estimated payroll cost for 29 percent of the employees that participated.

There was a lack of coordination of the I-SaveRx promotional activities. Although DHFS was to coordinate the efforts of employees working on the I-SaveRx promotional activities, only two agencies mentioned working with DHFS. Coordination of promotional activities is important to ensure that resources are maximized and efforts are cohesive. Outreach activities were primarily reported to and coordinated by the Governor's Office.

There was no system in place to track the results of the agency outreach. For example, the Governor's Office did not track which applications resulted in successful enrollments or which agencies were more effective in signing up enrollees.

Although the I-SaveRx Program was not approved by the federal Food and Drug Administration and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities **were paid from federal funds**.

The State of Illinois signed a Memorandum of Understanding (MOU) with four states allowing their residents to purchase prescription drugs through the I-SaveRx Program. 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 acquisition fees to the Fund 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 State received no monies from the Fund, thus monies for State activities (travel, marketing, etc.) were paid for from State agency monies. The Special Advocate could not provide documentation to show what CanaRx had expended these up-front monies on.

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

While CanaRx is not paid for its services by the State under the contract, we found that there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program. State agency personnel have accumulated over \$111,000 in travel expenses, mainly for out-of-country travel and use of State aircraft, in support of a drug importation program. We also found that most travel was not approved prior to departure as stated in travel regulations. We identified \$10,662 in excessive per diem reimbursement to six State employees traveling as part of the I-SaveRx Program.

The State has paid \$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 Program that we were able to identify during the course of the audit. The major cost was a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate's Office.

INTRODUCTION

On May 30, 2005, the Illinois House of Representatives adopted House Resolution Number 394 which directs 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 (See Appendix A for a copy of the Resolution). The Resolution directed the Auditor General to determine:

- The roles played by the Office of the Governor and the Special Advocate for Prescription Drugs in negotiating and entering into the flu vaccine contract;
- The procedures applicable to, and agencies responsible for, the establishment and operation of the I-SaveRx Program; and
- Whether the entities involved in these Programs followed all applicable laws, regulations, policies, and procedures.

FLU VACCINE PROCUREMENT

Influenza is associated with an average of more than 200,000 hospitalizations and 36,000 deaths each year in the United States. Most people who get the flu recover completely in 1 to 2 weeks, but some develop serious and life-threatening medical complications, such as pneumonia. People who are aged 65 and older, people of any age with chronic medical conditions, children younger than age 2 years, and pregnant women are more likely to get severe complications from influenza than other people.

The Governor's Office reported, on October 25, 2004, that in 2002, there were nearly 3,000 influenza and pneumonia-related deaths in Illinois. Of those, 2,610 were people over the age of 65, and 10 were children under the age of five.

For the 2004-2005 flu season, the Centers for Disease Control and Prevention (CDC) initially recommended in May 2004 that about 185 million Americans – about 85 million in high-risk groups and over 100 million in other target groups – receive the vaccine, which is the primary method for preventing influenza. Groups at high-risk for flu-related complications included residents of nursing homes and other chronic care facilities, people with chronic asthma and diabetes, and children and adolescents aged 6 months to 18 years who are receiving long-term aspirin therapy.

CDC recommends October through November as the best time to get vaccinated because the flu season often starts in late November to December and peaks between late December and early March.

In a typical year, two manufacturers – one with production facilities in the United States and one with production facilities in the United Kingdom – produce the vast majority of flu vaccine for the United States. For the 2003-2004 flu season, these two manufacturers supplied about 95 percent of the vaccine for the United States. A third manufacturer produced a nasal spray

vaccine product that can be used for healthy persons aged 5 to 49 years. According to the CDC, this manufacturer produced about 4 million doses of the nasal spray vaccine in 2003-2004.

Also in a typical year, most flu vaccine distribution and administration are accomplished within the private sector, with relatively small amounts of vaccine purchased and distributed by the CDC or by state and local health departments.

On August 26, 2004, United Kingdom based manufacturer Chiron announced a small quantity of its flu vaccine did not meet sterility specifications and that distribution of Chiron-produced flu vaccine would be delayed until further tests were completed. Less than two months later, on October 5, 2004, Chiron announced that the Medicines and Healthcare Products Regulatory Agency had temporarily suspended its license to manufacture flu vaccine in its Liverpool, England facility – effectively reducing the United States supply by nearly half.

In October 2004, State of Illinois officials began taking steps to find additional flu vaccine for Illinois residents. The Special Advocate initiated talks with 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 of vaccine Illinois was attempting to procure. A written contract was not put in place until three months later – in mid January 2005. Chapter Two discusses the planning and procurement of the flu vaccine.

I-SAVERX PROGRAM

In late 2003, the Governor contacted the Food and Drug Administration (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 a correspondence dated June 3, 2004, the Acting Commissioner of Food and Drugs wrote “Although at the Food and Drug Administration (FDA) we share your concern and urgency related to the cost and safety of prescription drugs for our citizens, **we do not believe that a waiver could be granted** (emphasis added) to allow a state’s pilot project for the safe importation of prescription drugs under the current law.” The FDA rationale for the denial was outlined in subsequent pages. Even though the FDA denied the waiver, the Governor’s Office proceeded with the drug importation program. Legal issues with respect to the I-SaveRx Program will be explored in Chapter Three.

Development of the I-SaveRx Program Canadian Report

In September 2003, the Special Advocate undertook a project and developed an analysis addressing the feasibility of enabling participants in the State of Illinois’ employee and retiree benefit programs to purchase a specified set of prescription medications from Canadian vendors. The analysis was based on information gathered through research; by soliciting the views of major organizations and associations within the United States’ pharmaceutical industry; and through a fact-finding visit to several of Canada’s major pharmaceutical providers. The State delegation included:

- Special Advocates for Prescription Drugs;

- Director of the Department of Public Health and the State’s Chief Medical Officer;
- Assistant Director of the Department of Public Health;
- Pharmacist with the Department of Public Health;
- Legal Counsel from the Department of Professional Regulation;
- Prosecutor from the Department of Professional Regulation;
- Director of Drug Compliance, Department of Professional Regulation;
- Policy Analyst, Office of the Governor; and
- Counsel, Office of the Governor.

The result of this work was a report, issued October 27, 2003, entitled “Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies.” The report found that employees and retirees could safely purchase drugs from Canada, that pharmacy practices in Canada were equal to or superior to pharmacy practices in the State of Illinois, and a formal program to purchase prescription drugs from Canadian pharmacies would likely impact retail pharmacies in Illinois. The Special Advocates, in the report, recommended three actions, which are illustrated in Exhibit 1-1.

<p>Exhibit 1-1</p> <p>PROPOSED RECOMMENDATIONS FROM CANADIAN REPORT</p>
<ul style="list-style-type: none"> ▪ In order to maximize participation and savings we recommend that the State: <ul style="list-style-type: none"> - Contract with a non-domestic Pharmacy Benefits Manager or similar entity; - Establish a Primary Care Pharmacist Model; and - Require the employees and retirees to pay only the shipping cost for drugs obtained from Canadian sources. ▪ Recommend that the Governor direct the Department of Central Management Services (CMS) and the Special Advocate to contract with a vendor as soon as practicable and target implementation of Caremark enrollment under the Quality Care Health Plan on April 1, 2004 for a limited number of drugs. ▪ To enhance patient safety, we further recommend an ingredient and quality assurance-testing program be implemented. The State would work with the Illinois Department of Public Health and the University of Illinois Chicago College of Pharmacy to test drugs to ensure quality of both domestic and non-domestic drug supply purchased by employees and retirees.
<p>Source: Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies.</p>

According to the Special Advocate, the Governor’s Office made the decision not to include State employees and retirees in the I-SaveRx Program. An official from the Governor’s Office explained that the reason State employees were not included in the Program was that the Program was to be completed in phases. The official also indicated he was not sure whether State employees and retirees would be part of the new pharmacy benefit manager agreement that began July 1, 2006.

European Report

In May 2004, the Governor directed his team to turn their research efforts to Europe and revisit the framework developed in the Canadian study. Due to the decision of many pharmaceutical companies limiting drug supplies to Canadian facilities that provide prescription medication to Americans, there was an artificial shortage. The European delegation included members from the Governor's Office, Special Advocates, Department of Public Health, and Department of Professional Regulation.

The central policy question, and title of a report issued August 23, 2004, was "Can Illinois Residents and Businesses Safely and Effectively Purchase Prescription Drugs from Europe?" The delegation again met multiple groups in Belgium, France, Germany, Ireland, the Netherlands, and the United Kingdom. The delegation and report proposed a contractual relationship with a non-domestic Pharmacy Benefits Manager that would act as a clearinghouse for all prescriptions filled through the non-domestic network of approved and vetted pharmacies in Europe and Canada. According to the report, this proposed option would provide stringent safety precautions and consumer protections, and would also achieve significant cost savings for participants.

Program Launch

On October 4, 2004, the State of Illinois launched the I-SaveRx Program. As publicized on the I-SaveRx website, the Program was developed by the State of Illinois to allow consumers to purchase safe and affordable refills from licensed, inspected pharmacies in Canada and the United Kingdom. The Program launch was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003. The states of Wisconsin, Vermont, Kansas, and Missouri also joined in the I-SaveRx Program.

Program Expansion – The Australia and New Zealand Report

It is unclear whether expansion to Australia and New Zealand was necessary. In the Australia and New Zealand Report's Executive Summary, it states that the I-SaveRx Program "has generated significant interest in personal importation" and cites that individuals have requested almost 61,000 enrollment forms for the Program. Further, the summary states, "**over 10,000 orders have been placed.**" However, documentation developed by the Program's pharmacy benefit manager (CanaRx) showed that as of June 28, 2005, **two days prior to the release** of the Australia and New Zealand report, only 3,675 individuals had placed orders to the I-SaveRx Program and the total orders, including repeats, **was 7,782 – not over 10,000 as stated in the expansion report.**

A CanaRx official indicated in a report **five months prior**, in February 2005, that he had been informed, "that a trip to Australia and New Zealand is to take place. I will not attend, I believe this again will be a total waste of money. Australia and New Zealand are two very small countries (by population) that have supplied medications in the past and have been effectively shut down. A simple telephone call will confirm this and save a great deal of time and money which could be re-directed to the success of the Program." In that same report the CanaRx official indicated that only two pharmacies (one in Canada and the other in the United Kingdom) were

currently supplying the Program and “the excess unused available capacity of these two pharmacies is approximately 250 times greater than today’s volumes.”

I-SAVERX PROGRAM ENROLLMENT PROCESS

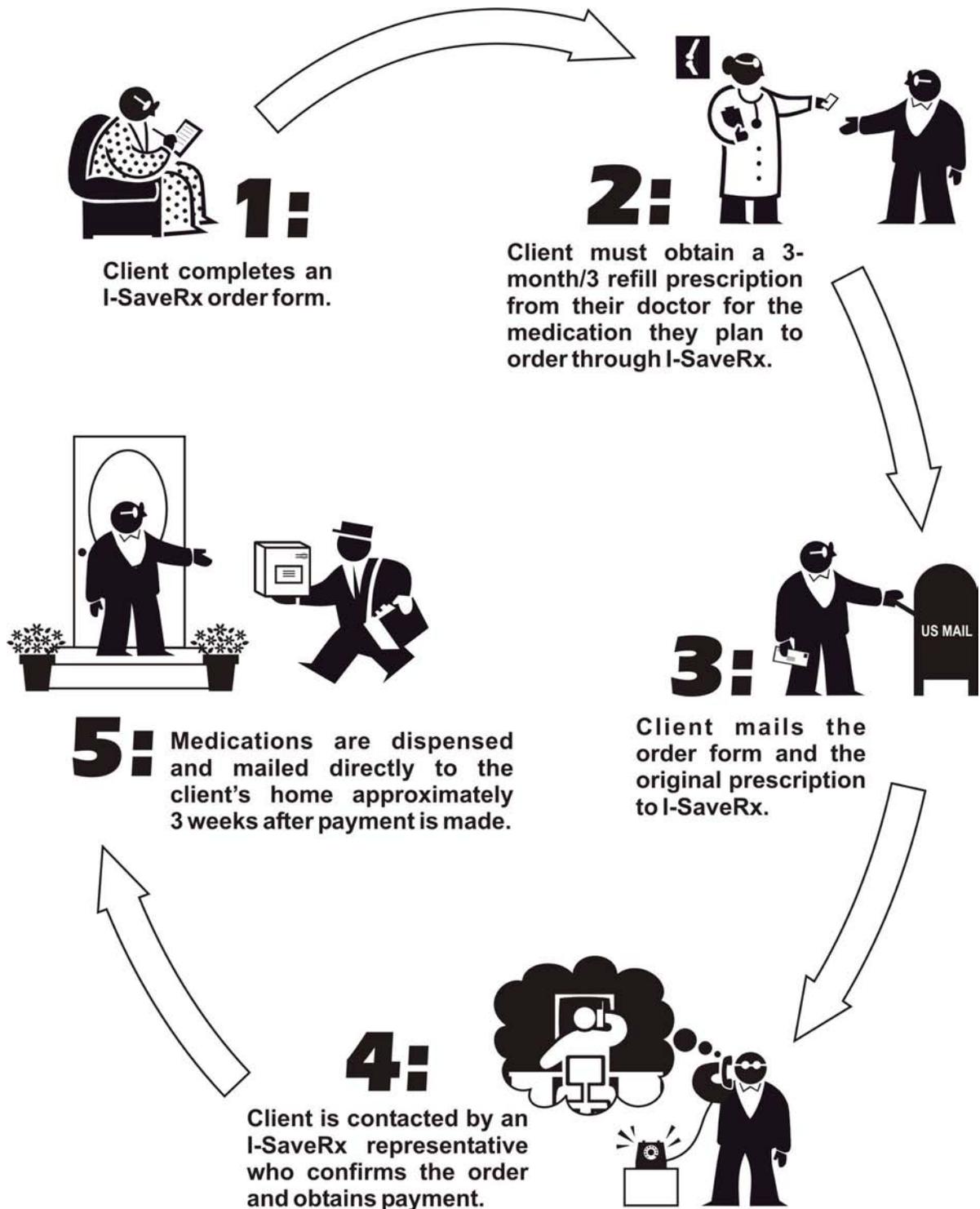
Citizens desiring to use the I-SaveRx Program can find enrollment assistance either on the web at www.i-saverx.net or by dialing a toll-free number (1-866-I-SAVE33). The website provides information about: the I-SaveRx Program and how it works; the safety and convenience of the Program including that refills will be shipped in 3-month supplies; a listing of all the medications covered by the Program so that the participant can determine whether their medicine is available through the Program; frequently asked questions regarding the Program; information on how to contact the Program; and information on how to enroll in the Program. The enrollment process is summarized in Exhibit 1-2.

Process for Filling a Prescription

The Pharmacy Benefits Manager (PBM) performs a variety of activities under the I-SaveRx Program. According to the Special Advocate, after the Program client signs the customer agreement and submits a valid prescription to the PBM via fax, mail, phone or website, the following activities occur.

- The PBM Prescreening Pharmacy technician reviews the prescription for correctness and enters it into the pharmacy software system. The client can only order from the State’s approved list of medications.
- The PBM contacts the client to review information and check to ensure that the information was entered into the system correctly. A Drug Utilization Review is conducted.
- The PBM chooses the pharmacy and the local physician based upon the nation(s) selected by the client in the Customer Agreement.
- The order is passed for final review, to check stock levels/availability. If approved, the prescription is sent to the local physician.
- The local physician reviews the diagnosis, U.S. prescription, patient health/allergy information and makes a decision whether to write a local nation (or non-resident) specific prescription. If approved, the prescription is returned to the local pharmacy for filling. If not approved, the information is sent back to the PBM for more information or for the PBM to notify the client of the reasons for declining.
- A State authorized fulfillment pharmacy validates the prescription information and fills the prescription as requested and approved by the local physician.
- The order is printed off and assembled by the pharmacy.
- The fulfillment pharmacy’s pharmacist reviews and checks the product and information for final inspection and verification that all is accurate to the U.S. originating prescription and then sends it to shipping.
- The shippers pack the product as per the shipping policy.

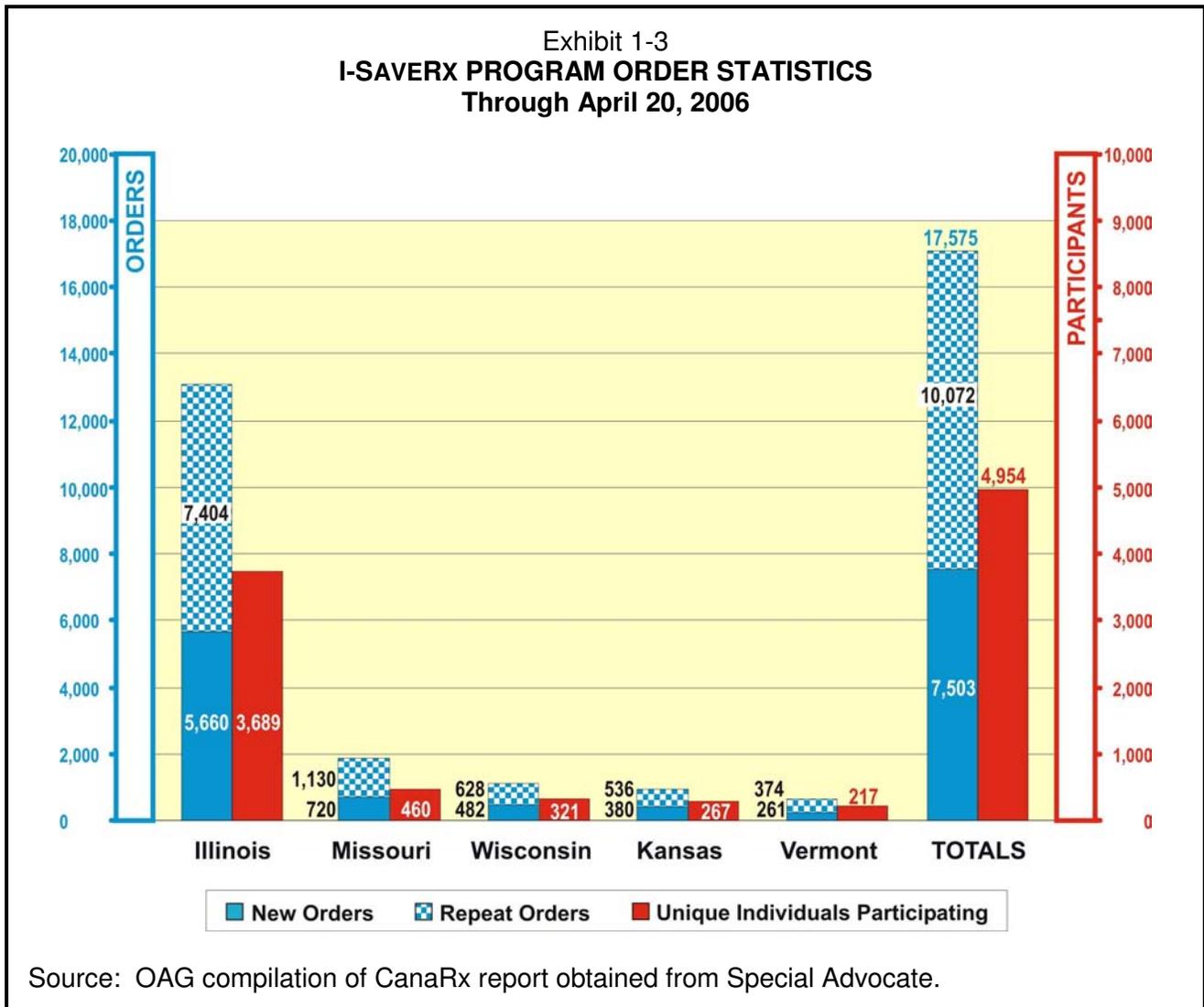
Exhibit 1-2
ENROLLMENT PROCESS FOR I-SEVERX PROGRAM



Source: OAG summary of information from I-SaveRx website.

I-SaveRx Program Utilization

In the first 19 months that the I-SaveRx Program has been in operation (through April 2006), a total of 17,575 orders for prescription medicine have been placed by residents from the participating states (Illinois, Wisconsin, Kansas, Missouri, and Vermont). This total is comprised of 7,503 new orders and 10,072 repeat orders. Exhibit 1-3 breaks down ordering statistics by state by type. There have been 4,954 individuals from the five states that placed orders through the I-SaveRx Program. Illinois has had the largest number of participants with 3,689 unique individuals placing orders. Wisconsin had 321 individuals place orders, Kansas 267, Missouri 460, and 217 citizens from Vermont.



According to staff from the Governor’s Office and the Special Advocate, the I-SaveRx Program does not have any goals to measure the success of the Program. The rationale for not having goals was because it was impossible to get a realistic idea of the number of people that

could benefit from the Program (i.e. uninsured, over age of 65), are on medications for longer than 30 days, and would actually utilize the Program.

Documentation obtained from the Special Advocate indicated the initial target population for the Program to be 2.8 million people estimated to be without prescription drug coverage in the State of Illinois. The 2.8 million Illinois citizens break down as:

- 500,000 senior citizens without prescription coverage;
- 1.7 million non-senior residents without any health or prescription coverage; and
- 600,000 non-senior residents with health coverage but without prescription coverage.

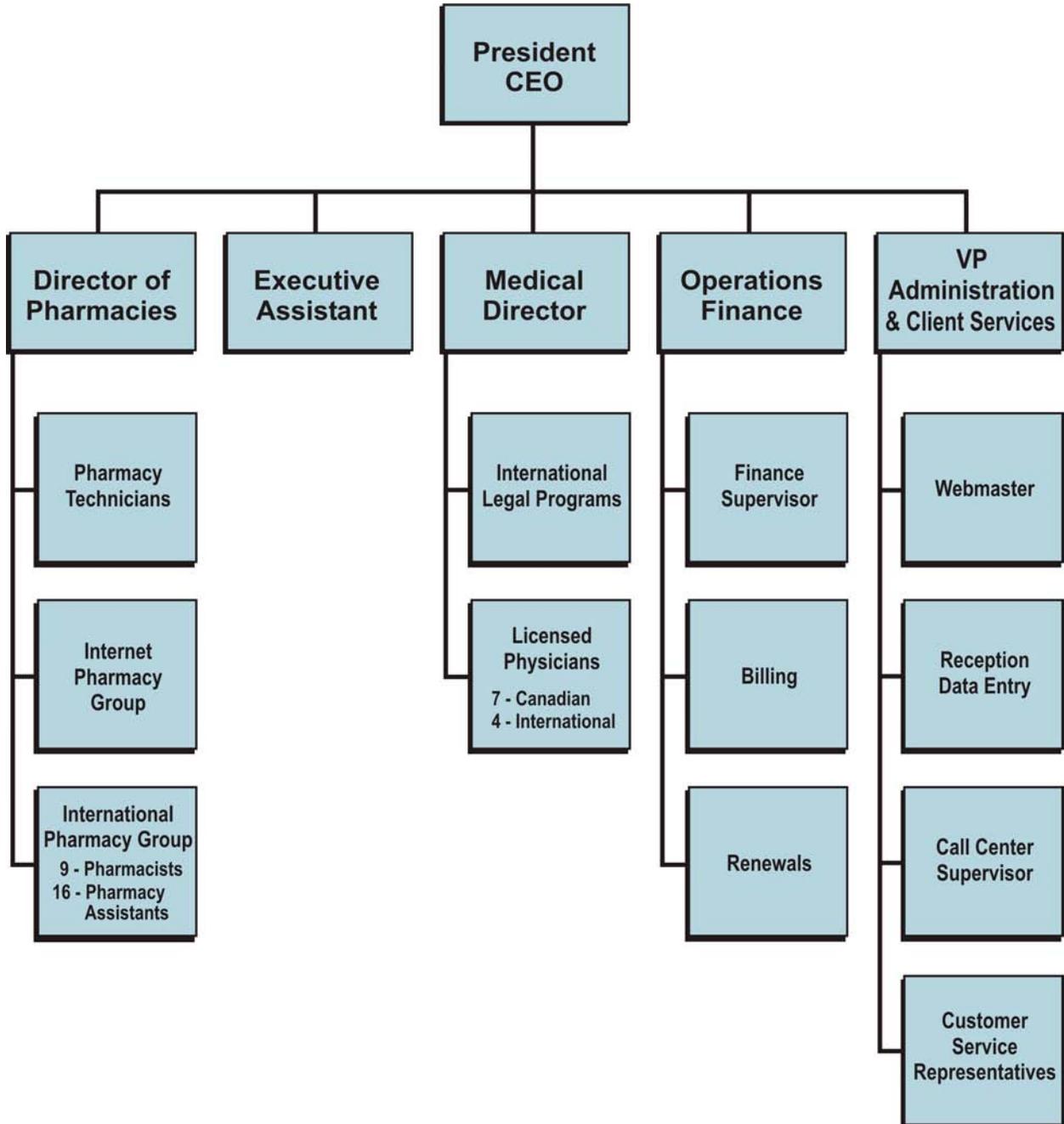
A difficulty in measuring the success of the Program includes not knowing how many of the 2.8 million of the target population of Illinoisans without drug coverage are taking any of the 200 maintenance drugs that are part of the Program. The Special Advocate indicated that it is hard to determine the eligible population that the Program would apply to. Only 3,689 Illinois citizens have taken advantage of the I-SaveRx Program.

I-SaveRx Program Pharmacy Benefit Manager

The I-SaveRx Program is administered through a contract between the State of Illinois and CanaRx Services Inc. – a Canadian-based Pharmacy Benefits Manager. The contract, executed October 4, 2004, was procured by the Governor’s Office through a Sole Economically Feasible Source procurement. The contract is not on file with the Comptroller – since, according to the Governor’s Office, there is no estimated cost to the State. However, Chapter Three of this report examines the actual costs to the State associated with the operation of the I-SaveRx Program.

As published in the Illinois Procurement Bulletin on September 7, 2004, “CanaRx will provide international clearinghouse and Pharmacy Benefits Manager (PBM) services with an international network of pharmacies and wholesalers located in Canada, United Kingdom (UK), and Ireland.” The notice in the Bulletin lays out the reasons for the sole source procurement. The Governor’s Office reported in the Bulletin that there “will be no cost to the State” under this contract. See Exhibit 1-4 for an organizational depiction of CanaRx Services, Inc.

Exhibit 1-4
CANARX SERVICES, INC
PHARMACY BENEFITS MANAGER
Organizational Chart



Source: OAG summary of information from the Special Advocate.

Fiscal Year 2007 RFP – International Clearinghouse

On April 20, 2006, the Department of Healthcare and Family Services (formerly the Department of Public Aid) published a solicitation on the Illinois Procurement Bulletin seeking to obtain proposals from interested and qualified vendors to provide an international clearinghouse for the I-SaveRx Program. Proposals were due May 12, 2006. This competitive procurement was to be awarded through a Request for Proposals (RFP) process. The contract term, which will begin at the end of the current agreement with CanaRx, runs from July 1, 2006 through June 30, 2008. The inset identifies the purpose of the solicitation.

**RFP PURPOSE
INTERNATIONAL CLEARINGHOUSE**

“To continue providing residents of the States of Illinois, Wisconsin, Missouri, Kansas, and Vermont access to safe and affordable drugs via an international clearinghouse contracted and inspected by the State of Illinois. To allow Illinois State employees’ access to international prescription drugs, at the option of the State, at some future date.”

Source: Illinois Procurement Bulletin.

The RFP sets forth vendor responsibilities for the clearinghouse which generally parallel the current Program and that include: maintaining a fully functional software system; the vendor funding all Program related expenses including State associated travel, Program auditing, advertising and Program incentives; developing a minimum number of pharmacies in each nation; reimbursing the State for inspection of network pharmacies; developing an information and outreach Program; and maintaining an internal performance monitoring Program and providing routine Program reports to the State.

The State of Illinois, as the contracting entity under the procurement, will be responsible for: establishment and monitoring of performance standards; developing the Prescription Drug List; conducting pharmacy inspections; and conducting audits to confirm the validity of reported performance results.

As a result of the RFP process, the Department announced on May 18, 2006, that Pegasus Health Services Limited from Calgary, Alberta Canada had been awarded the clearinghouse contract.

OFFICE OF THE SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS

On June 19, 2003, the Governor signed and filed Executive Order 2003-15 establishing the Special Advocate. The Special Advocate, initially located within the Department of Central Management Services (CMS), was created to work with agencies under the Governor and oversee the central purchasing program for prescription drugs created by the Executive Order.

Initially there were two Special Drug Advocate positions at CMS. Effective September 16, 2005, one of the Special Advocates retired and has yet to be replaced. In June 2006, the current

Special Advocate indicated that his work actually began on May 27, 2003 – 23 days prior to the creation of the position by Executive Order.

As reported in Chapters Two and Three of this report, the Special Advocate played major roles in both the attempted procurement of flu vaccine from Ecosse Hospital Products Limited and the creation and operation of the I-SaveRx Program. See Exhibit 1-5 for a listing of powers and duties of the Special Advocate.

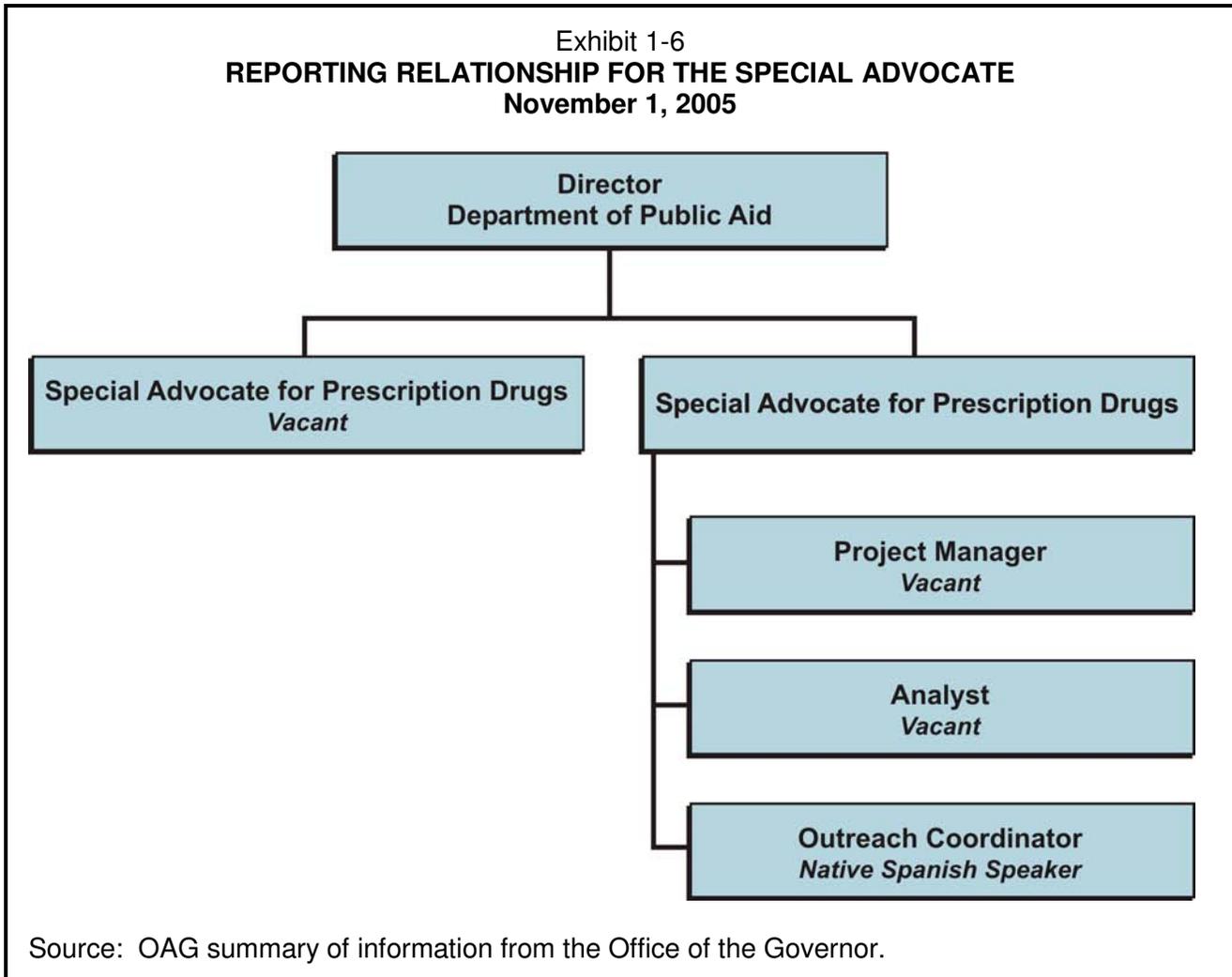
<p>Exhibit 1-5</p> <p>POWERS AND DUTIES OF THE SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS</p>
<ul style="list-style-type: none"> ▪ The Special Advocate shall have the authority to: create a central purchasing program to review all contracts and programs at agencies under the authority of the Governor that relate to the purchase of or payment for prescription drugs; develop and implement policy for such purchases and payments; and negotiate for or coordinate the negotiation of contracts, reimbursement rates and rebates. ▪ The Special Advocate shall review all existing contracts for prescription drugs and shall have the authority to direct the various agencies to continue, freeze, or terminate those contracts, consistent with the applicable contractual terms of such contracts and in consultation with the contracting agency. ▪ The Special Advocate shall have the authority to combine any and all of the programs and contracts at the various agencies for purposes of negotiating reimbursement rates, rebates or other terms, to the extent that the combination is consistent with all applicable federal and state laws. ▪ All state contracts related to the purchase of or payment for prescription drugs shall be subject to the approval of the Special Advocate. ▪ The Special Advocate may propose and adopt rules under the Illinois Administrative Procedure Act regarding the procurement of prescription drugs by state agencies.
<p>Source: Executive Order 2003-15.</p>

The Special Advocate was transferred from CMS to the Department of Public Aid (Public Aid) effective March 24, 2004. The transfer was accomplished through an interagency agreement between the two agencies. While the agreement was effective March 2004, the Public Aid Director did not sign the agreement until November 4, 2004 (the CMS Director failed to date the interagency agreement).

It was during this period at Public Aid that the Special Advocate conducted activities relative to acquiring flu vaccine from Ecosse and the development of the I-SaveRx drug importation program. Additionally, the Special Advocate is charged with administering the day-to-day operations of the I-SaveRx prescription drug importation program. Public Aid, as recommended by the Special Advocate, entered into a personal services contract with an individual in FY05 to assist in managing the I-SaveRx Program. Public Aid approved a maximum amount payable under this contract at \$50,000 for FY05. Additionally, travel expenses totaling \$1,982.16 were paid under this agreement. While the contract term began September 28, 2004, the contract employee did not sign the contract itself until November 15, 2004 – 48 days later. Public Aid executed the contract two days later.

While a February 10, 2004 internal Public Aid memorandum on reorganization indicates the Special Advocate will move to the Medical Division at Public Aid, the organizational chart supplied to auditors shows the Special Advocate reporting to the Director of Public Aid. See

Exhibit 1-6 for an organizational chart depicting the Special Advocate and its reporting relationship at Public Aid.



Prior to the transfer to Public Aid, the Special Advocate was housed within CMS. Personal services, operating costs and administrative support costs during FY04 totaled approximately \$283,000 for the Special Advocate’s Office. CMS paid these expenses from the Efficiency Initiatives Revolving Fund.

AUDIT SCOPE AND METHODOLOGY

This audit was conducted in accordance with generally accepted government auditing standards and the audit standards promulgated by the Office of the Auditor General at 74 Ill. Adm. Code 420.310.

The audit objectives for this management audit were those as delineated in House Resolution Number 394 (see Appendix A), which directs the Auditor General to conduct a management audit of the flu vaccine purchase and the I-SaveRx Program. The audit objectives are listed in the Introduction section of Chapter One. Fieldwork for the audit was completed in June 2006.

We reviewed applicable federal and State laws pertaining to procurement and importation of drugs into the United States. We reviewed compliance with those laws to the extent necessary to meet the audit's objectives. Any instances of non-compliance we identified or noted are included in this report.

We also reviewed management controls and assessed risk relating to the audit's objectives. A risk assessment was conducted to identify areas that needed closer examination. Any significant weaknesses in those controls are included in this report.

During the audit, we met with staff from the Office of the Governor and the Office of the Special Advocate for Prescription Drugs as named entities in House Resolution Number 394. Additionally, we met with staff from State of Illinois agencies that also played roles in the flu vaccine procurement and I-SaveRx Program. These agencies included the Department of Financial and Professional Regulation, Department of Healthcare and Family Services (formerly the Department of Public Aid), the Department of Public Health and the Department of Central Management Services. We also contacted and received information from the Department of Human Services.

We contacted the other governmental entities that received billings for flu vaccine from Ecosse Hospital Products Ltd. These other government agencies were the Kansas Department of Health and Environment, the Tennessee Department of Health, the New Mexico Department of Health, the Department of Public Health from the City of Cleveland, Ohio, and the Department of Health and Mental Hygiene of New York City.

We also contacted the other states that are involved in the I-SaveRx Program. We interviewed and received documentation from representatives of the states of Wisconsin, Kansas, Missouri, and Vermont. Additionally, we contacted the federal Food and Drug Administration to obtain background on the two audit issues.

In order to determine the extent of using State agency personnel to promote the I-SaveRx Program, we surveyed 28 State agencies, identified by the Office of the Governor, which had staff participate in promotional activity. We calculated a cost of using State personnel to promote the I-SaveRx Program.

We examined all contracts, memoranda of understanding and interagency agreements applicable to the audit objectives. Additionally, we reviewed all files at the Office of the Special Advocate for Prescription Drugs relative to the flu vaccine procurement and I-SaveRx Program. The entity that entered into the agreement with Ecosse Hospital Products Ltd. for the flu vaccine, the Office of the Governor, did not maintain a procurement file for that transaction. We did review a procurement file at the Department of Healthcare and Family Services that contained information on the attempted purchase of the flu vaccine.

REPORT ORGANIZATION

The remainder of this report is organized into the following chapters:

- **Chapter Two** examines the attempt to procure flu vaccine starting in October 2004 including the roles played by various agencies and whether these entities followed all applicable laws, regulations, policies and procedures; and,
- **Chapter Three** examines the I-SaveRx Program since its launch in October 2004 including the roles played by various entities in the Program, the procedures applicable to the Program, and whether these entities followed all applicable laws, regulations, policies and procedures.

Chapter Two

FLU VACCINE PROCUREMENT

CHAPTER CONCLUSIONS

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 (Special Advocate), began taking steps in mid-October 2004 to find additional flu vaccine for Illinois residents. The Special Advocate initiated talks with European wholesalers to locate and procure flu vaccine. Documentation showed:

- On October 22, 2004, seven days after the FDA announcement, the Special Advocate agreed to an initial 35,000 doses of vaccine identified and obtained by Ecosse Hospital Products, Ltd. (Ecosse);
- On October 23, 2004, the Deputy Governor authorized, via e-mail, the purchase of 200,000 doses of flu vaccine from Ecosse;
- On November 1, 2004, the Deputy Governor confirmed for Ecosse officials an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine; and.
- Other states and local governments joined Illinois in the effort to procure flu vaccine and documentation showed that Ecosse eventually acquired almost 800,000 doses of vaccine for Illinois and the other governments.

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. Furthermore, documentation showed that at the time State officials signed the contract to purchase the flu vaccine, State officials knew that FDA approval was not likely. 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. An October 28, 2004 Department of Public Health memo to the Governor's Office indicated that between 160,000 and 200,000 doses would address Illinois' priority population, as defined by the Centers for Disease Control and Prevention (CDC). By

December 2004, Department of Public Health documentation showed that the CDC had located sufficient flu vaccine to cover Illinois’ priority population. Documentation also showed that the CDC would make available an additional 200,000 doses in its December 2004/January 2005 allotment of vaccine to Illinois. Despite the availability of additional vaccine from the CDC, the State continued to proceed with its procurement of flu vaccine from Ecosse.

- Illinois officials negotiating with Ecosse were not aware that to consummate the purchase of the flu vaccine, a contract was necessary. Not until almost three weeks **after** the State agreed to purchase the flu vaccine, did the Special Advocate negotiating the purchase become aware that a contract was needed to purchase the vaccine. On November 10, 2004, the Special Advocate indicated, in an e-mail to an official at the Department of Public Aid, “...I have been talking to the Budget Office, the Dep. Governor, etc. and nobody has said word one about a contract. We have been told several times, the payment would be processed COD. If someone needs a contract, then you or someone else needs to get it done without delay...”
- The contract entered into between the State and Ecosse **was not timely**.
 - The contract with Ecosse to purchase 254,250 doses of the influenza vaccine was signed on January 13, 2005 by an official from the Governor’s Office, which was **2 days after** Ecosse submitted a billing for the vaccine of approximately \$2.6 million.
 - State officials signed the contract **6 days prior to Ecosse officials** signing the contract on January 19, 2005. The term of the contract was for the period October 20, 2004 through June 30, 2005.
 - The amount of the State’s obligation under the contract was **estimated** to be \$2,592,218. This is the **exact amount billed** by Ecosse to the State on an invoice dated January 11, 2005 – **8 days prior** to Ecosse signing the contract with the State.
- Illinois officials took the lead in procuring flu vaccine for other states and local governments but failed to develop agreements with these entities. Such agreements could have delineated the amount of flu vaccine the various governments would purchase, as well as documented the other governments’ fiscal responsibilities for their portion of the procurement. The absence of such agreements, and given that Illinois officials were negotiating with Ecosse, resulted in **Illinois being potentially liable** to pay for the entire cache of vaccine – over \$8.2 million.

Multiple agencies had roles in the attempt to procure the flu vaccine. These parties included the Governor’s Office, the Department of Public Aid (later the Department of Healthcare and Family Services), the Special Advocate, and the Department of Public Health. Some of the individuals involved in the procurement process are no longer with the State.

Sixteen months after searching out flu vaccine, the State approved the donation of the vaccine it was responsible for to the country of Pakistan.

INTRODUCTION

House Resolution Number 394 asked us to determine what roles were played by the Office of the Governor and the Special Advocate for Prescription Drugs in negotiating and entering into the flu vaccine contracts and whether the entities involved in the flu vaccine procurement followed all applicable laws, regulations, policies and procedures. This chapter will examine the roles played by the different agencies in the attempted purchase of the flu vaccine beginning in October 2004. Additionally, the chapter discusses the planning efforts surrounding the purchase of flu vaccine from Ecosse by the State. Further, the chapter reports on the approval process with federal authorities to import the flu vaccine.

ROUTINE FLU VACCINE PROCUREMENTS BY THE STATE

Each year, State agencies routinely purchase flu vaccines for various clients they serve. In FY05, the State procured and/or distributed 208,270 doses of flu vaccine. The Departments of Healthcare and Family Services and Human Services purchased (through the Department of Central Management Services) vaccines for long-term care facilities and State-operated facilities. Public Health distributed vaccines obtained from a CDC contract under its Vaccines for Children Program. Exhibit 2-1 provides a historical look at flu vaccines procured/distributed since FY02.

Exhibit 2-1						
FLU VACCINE PROCURED/DISTRIBUTED BY STATE AGENCIES						
FY02-FY06						
		DEPARTMENT OF HEALTHCARE AND FAMILY SERVICES	DEPARTMENT OF HUMAN SERVICES	DEPARTMENT OF PUBLIC HEALTH		TOTAL
FY02	DOSES	70,510	5,000	5,000		80,510
	AMOUNT	\$345,499.00	\$32,500.00		¹	\$377,999.00
FY03	DOSES	70,500	4,600	26,550		101,650
	AMOUNT	\$444,773.10	\$28,980.00		¹	\$473,753.10
FY04	DOSES	70,500	4,340	92,930		167,770
	AMOUNT	\$517,611.00	\$31,864.28		¹	\$549,475.28
FY05	DOSES	70,500	4,450	133,320		208,270
	AMOUNT	\$575,280.00	\$52,227.20		¹	\$627,507.20
FY06	DOSES	20,943	4,330	127,280		152,553
	AMOUNT	\$351,753.58	\$45,049.23		¹	\$396,802.81
TOTAL		302,953	\$2,234,916.68	22,720	\$190,620.71	385,080
Note: ¹ Public Health distributes vaccine obtained from federal authorities at no cost to the State. Source: OAG summary of State Agency and Comptroller data.						

BACKGROUND – GOVERNOR’S OFFICE FLU VACCINE PROCUREMENT

On August 26, 2004, United Kingdom based manufacturer Chiron announced a small quantity of its flu vaccine did not meet sterility specifications and that distribution of Chiron-produced flu vaccine would be delayed until further tests were completed. Less than two months later, on October 5, 2004, Chiron announced that the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) had temporarily suspended its license to manufacture flu vaccine in its Liverpool, England facility. On October 15, 2004, the United States Food and Drug Administration (FDA) announced that none of the flu vaccine manufactured by Chiron for the U.S. market was safe for use – effectively reducing the United States supply by nearly half.

Documentation shows that **4 days later**, on October 19, 2004, State of Illinois officials, primarily from the Office of the Governor and the Special Advocate had already begun taking steps to find additional flu vaccine for Illinois residents. This vaccine was to be distributed to the at-risk population as defined by the CDC.

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. A contract could have laid out details on how much flu vaccine the State was attempting to procure and the price the State was willing to pay for the vaccine. Lacking this information the procurement could be construed as “open-ended” with no clear indication as to what the State’s financial obligation would be for the procurement. A written contract was not put in place until **three months later** – in mid January 2005.

Seven days after the FDA announcement regarding Chiron vaccine, on October 22, 2004, the **Special Advocate accepted and agreed** to an initial 35,000 doses of vaccine from Ecosse. 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.

Documentation showed the Deputy Governor also authorized significant purchases of vaccine. On October 23, 2004, in an e-mail to Ecosse, the Deputy Governor authorized the purchase of 200,000 doses of vaccine. Nine days later, on November 1, 2004, the Deputy Governor confirmed for Ecosse officials an order for the State of Illinois by the Special Advocate for an additional 300,000 doses of flu vaccine. Documentation showed that Ecosse eventually acquired almost 800,000 doses of vaccine.

Illinois officials appeared to be aware that the vaccine would never be delivered; even **prior to being billed** by Ecosse and executing a contract with the vendor in January 2005. In a December 21, 2004 e-mail from the Special Advocate to the Governor’s Office he stated “We probably will never take delivery of these doses so will need to find a way to pay for the ‘service’ they performed (found and secured the doses).”

Sixteen months after searching out flu vaccine, the State approved the donation of the vaccine it was responsible for to the country of Pakistan. Prior to the donation, and pursuant to Article 4 of the contract with Ecosse, the vendor attempted to resell the vaccine to German, Italian and Greek suppliers, Southern Hemisphere commercial parties, and other aid organizations. All resale attempts were unsuccessful.

Contract/Billing/Lawsuit

Public Aid submitted the contract with Ecosse to the Illinois Office of the Comptroller on January 24, 2005. The contract obligation document filed with the contract showed an obligation using the Public Aid Recoveries Trust Fund to pay for vaccine purchased under the contract. However, the **Comptroller refused to accept** the contract with Ecosse and returned it to Public Aid. One reason for the refusal was the late filing affidavit failed to sufficiently explain the rationale for not reducing the services to writing prior to commencement of service. The rationale provided to the Governor’s Office by the Comptroller included:

- The Comptroller did not believe the Governor’s Office could obligate another agency’s appropriations for its own contract liabilities;
- The use of the Public Aid Recoveries Trust Fund for the purpose of acquiring vaccine, at best, represents an extremely broad interpretation of that fund’s allowable utilization; and
- The federal FDA had not yet authorized importation of the flu vaccine purchased under the agreement.

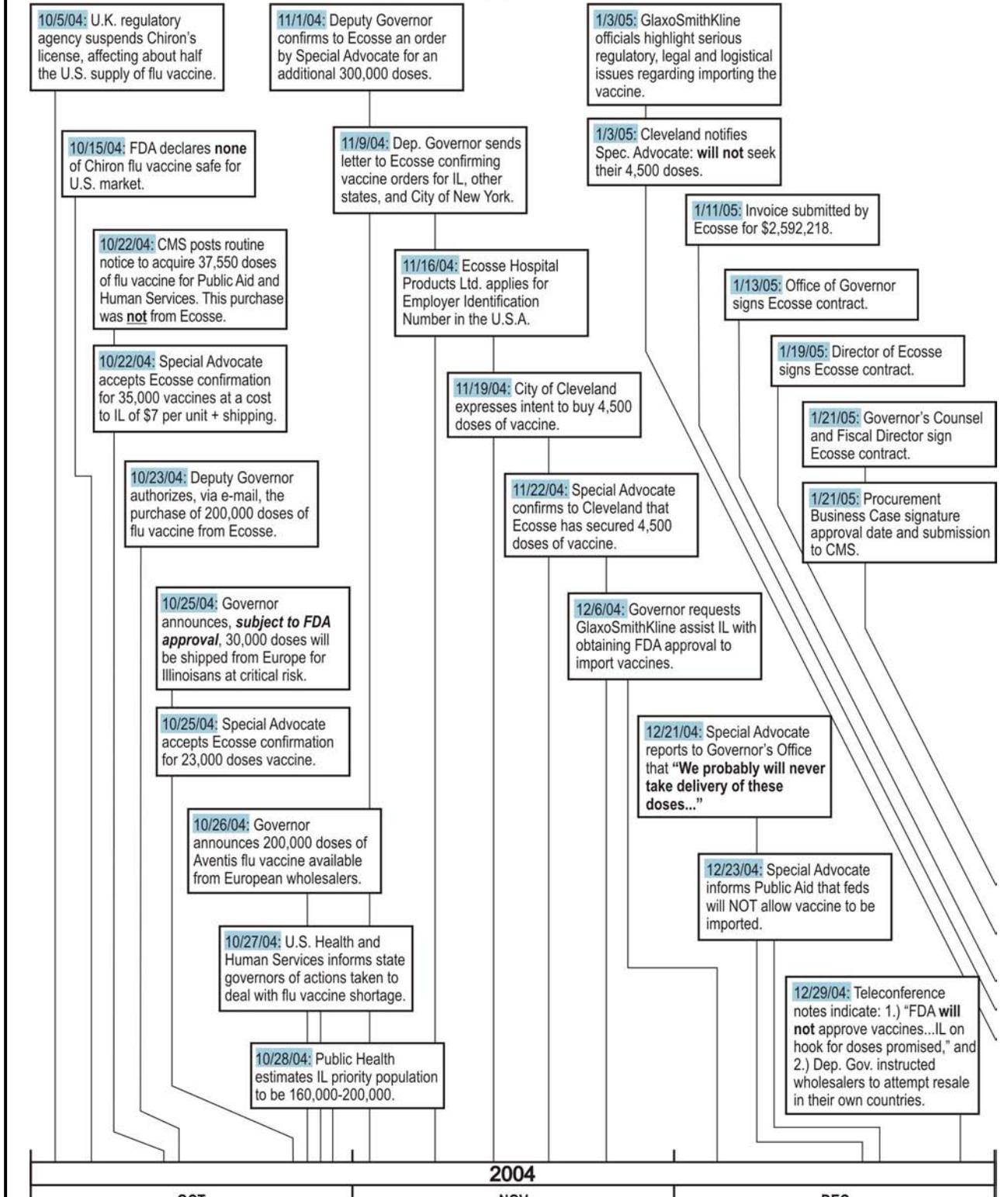
The Comptroller, in a January 31, 2005 correspondence to the Governor’s Office, also cited Article 2.6 of the contract which allows the State to terminate the contract because of “unforeseeable circumstances beyond its reasonable control, including...government regulation.” The Comptroller refused, without some other compelling information, any requests for payment under the contract.

Documentation obtained in files from the Special Advocate showed that Ecosse sent the Governor a correspondence on February 8, 2005 stating “It is with extreme disappointment that I find myself forced to write to you today to request immediate payment of all monies outstanding to us (in excess of US\$8 million) relating to the above.” The subject of the correspondence was Flu Vaccine Orders. The letter details that Ecosse secured the vaccine “under instruction from your representatives” and mentions that there were “other represented states” when the Illinois senior representatives were seeking flu vaccine. Further, “Your State’s commitment to us has been fully documented between us with full disclosure throughout and backed up by personal representations and commitment to me by ..., your Deputy Governor....”

When the State did not process payment, Ecosse filed suit, on March 15, 2005, in the Court of Claims seeking the \$2.6 million billed to the State. The State petitioned the court to dismiss the suit in October 2005, but, according to officials from the Governor’s Office and the Special Drug Advocate, a ruling has not been forthcoming as of February 8, 2006. While the Governor’s Office entered into an agreement for legal services with a Washington D.C. based firm, the Illinois Attorney General is representing the Governor in this Court of Claims suit. Exhibit 2-2 provides a timeline of activities involved in the attempt to purchase flu vaccine from Ecosse.

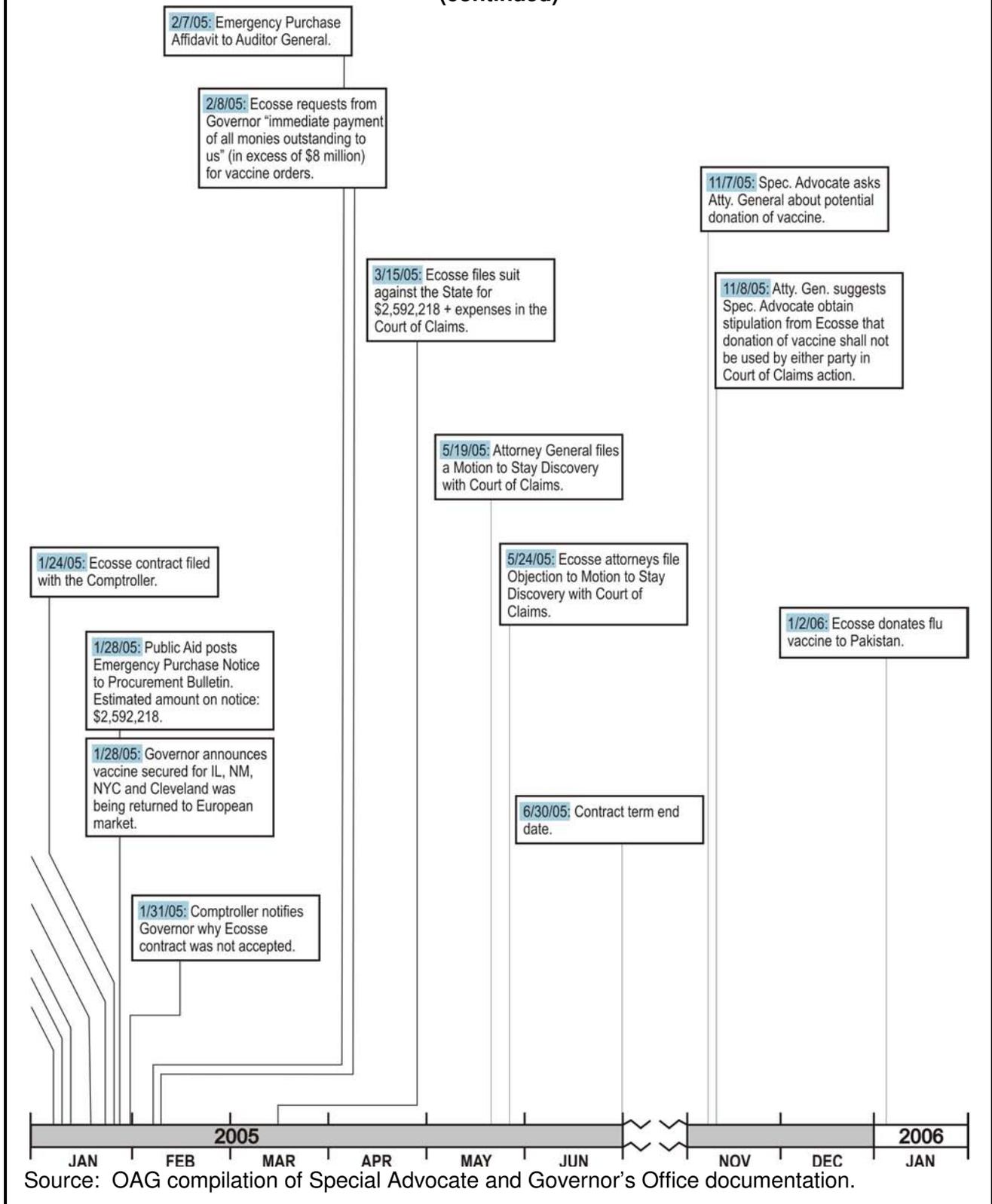
Exhibit 2-2

FLU VACCINE PROCUREMENT TIMELINE



Source: OAG compilation of Special Advocate and Governor's Office documentation.

Exhibit 2-2 FLU VACCINE PROCUREMENT TIMELINE (continued)



AGENCY INVOLVEMENT IN THE FLU VACCINE PROCUREMENT

Multiple agencies had roles in the attempt to procure the flu vaccine from Ecosse. These parties included the Governor’s Office, the Department of Public Aid (later the Department of Healthcare and Family Services), the Office of the Special Advocate for Prescription Drugs (Special Advocate), and the Department of Public Health. Some of the individuals involved in the procurement process are no longer with the State.

Governor’s Office

The Governor’s Office **had many roles** with respect to the attempted purchase of flu vaccine from Ecosse due to the national shortage that occurred in the winter of 2004. While the Special Advocate took the point in the procurement process in Europe, the Deputy Governor directed him. Documentation showed that the responsibility for the procurement transferred during the procurement between the Department of Public Aid (Public Aid) and the Governor’s Office. It was ultimately representatives from the Governor’s Office that negotiated and officially entered into an agreement with Ecosse to purchase \$2.6 million worth of flu vaccine in January 2005. The Governor’s Office also contacted government officials in the State of New Mexico and New York City to seek their involvement in the attempted purchase. The majority of staff that worked on the procurement was from the Governor’s legal team, including an attorney from the Office of Management and Budget – which documentation showed was primarily involved in attempting to get the Illinois Office of the Comptroller to process payment for the vaccine.

Office of the Special Advocate for Prescription Drugs

The Special Advocate **played the lead role in day-to-day negotiations** with Ecosse to procure flu vaccine. According to an official from the Governor’s Office, the Special Advocate was the party that introduced the European wholesaler, and its subsidiary Ecosse, to the State during the development of the I-SaveRx Program. It was the Special Advocate that first contacted European Wholesale personnel to determine whether extra vaccine existed which the State could purchase. It was also **the Special Advocate that signed acceptance/agreement letters with Ecosse** on October 25, 2004 confirming orders for vaccine. The Special Advocate performed inspections of the vaccines that Ecosse acquired. The Special Advocate also interacted with other governments that were interested in obtaining vaccine from the supply uncovered by Illinois officials. Staff from the Special Advocate’s Office assisted Ecosse officials with obtaining a federal taxpayer identification number so that the State could be billed for the vaccine.

Department of Public Aid

Public Aid officials **assisted Governor’s Office staff and the Special Advocate with actions related to the technicalities of the procurement activities**. While not the agency that entered into the formal agreement, Public Aid did maintain a procurement file on this transaction. Public Aid developed the Procurement Business Case for this procurement and filed the contract executed by the Governor’s Office with the Comptroller.

Payment to Ecosse for the flu vaccine was to be made from the Public Aid Recoveries Trust Fund. While the State did not pay the invoiced amount from Ecosse, the Public Aid Recoveries Trust Fund would not have been the appropriate fund to utilize for payment. None of the statutory authorized uses of the fund would have applied to a purchase from Ecosse (305 ILCS 5/12-9).

While multiple Public Aid staff were copied on correspondence, the majority of work was performed by Public Aid’s State Purchasing Officer and Legal Counsel. Additionally, during the time period that this procurement was taking place, the Special Advocate was housed at Public Aid.

Department of Public Health

The Department of Public Health (Public Health) **played a coordinating role** in the estimation and projection of how much vaccine would be needed by the targeted populations specified by the Centers for Disease Control and Prevention (CDC) as priority recipients when the Chiron Corporation announced that it would not be able to deliver one-half of the United State’s influenza vaccine supply for which it had been contracted.

Based upon the research, knowledge, and experience within Public Health regarding European pharmaceutical policies and practices, Public Health assisted the Special Advocate with its interaction between the federal Food and Drug Administration (FDA) and CDC on the European vaccines.

Public Health engaged in planning for the secure receipt and distribution of the vaccines and to strictly ensure maintaining temperature and custody requirements. Additionally, Public Health developed instructions for the handling and administration of the European vaccines to the priority at-risk populations. Roles of specific positions within Public Health are outlined in Exhibit 2-3. The at-risk populations, persons at high risk for complications from influenza, as identified by the CDC are:

Exhibit 2-3 ROLES OF SPECIFIC PUBLIC HEALTH POSITIONS Flu Vaccine Procurement
<ul style="list-style-type: none"> ▪ Director: Primarily monitoring, maintaining communications with ASTHO regarding prioritization and shortages on behalf of the CDC, and assuring that Public Health activities were tracking with CDC and national reports. ▪ Assistant Director: Policy coordination and interactions with Special Advocate including consultation with federal offices. ▪ Medical Director – Communicable Disease: Worked with assessment and ascertainment of comparability and/or equivalence between the approved U.S. versions of the vaccine and the identified European vaccines. ▪ Deputy Director – Office of Health Protection: Interaction with local health departments, estimations, analysis, and planning logistics.
Source: OAG summary of Public Health information.

- Residents of nursing homes and persons aged 65 years of age or older;
- Children aged 6-23 months;
- Chronically ill individuals;
- Women who will be pregnant during flu season;

- Children aged 6 months on chronic aspirin therapy;
- Health care workers involved in direct patient care; and
- Out-of-home caregivers and household contacts of children aged 6 months and under.

PROCUREMENT TIMING AND PLANNING

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.

According to State officials, the 2004-2005 flu season **was not as bad as anticipated** and the shortage was not detrimental to health concerns in the State.

Contract Execution

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. A contract could have laid out details on how much flu vaccine the State was attempting to procure and the price the State was willing to pay for the vaccine. Lacking this information the procurement could be construed as “open-ended” with no clear indication as to what the State’s financial obligation would be for the procurement. 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. Having formal agreements in place not only sets out the responsibilities of each party to that agreement but protects the interests of both parties.

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. In a November 10, 2004 communication to the State Purchasing Officer at the Department of Public Aid, the Special Advocate stated *“First time anyone has used the term ‘contract’. I have been talking to the Budget Office, the Dep. Governor, etc. and nobody has said word one about a contract. We have been told several times, the payment would be processed COD. If someone*

needs a contract, then you or someone else needs to get it done without delay. If the vendor is told this payment will be delayed, Illinois and all the other governments will not have these flu shots shipped.”

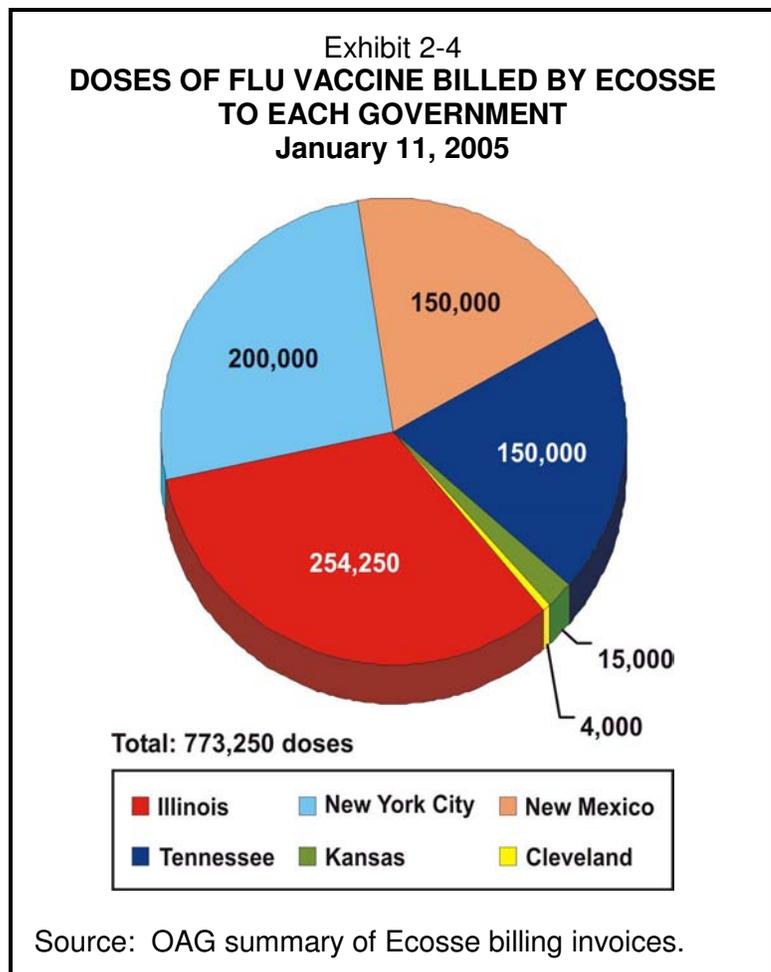
Additionally, staff from the Special Advocate’s Office asked another Public Aid official on November 10, 2004, “We need to know if there is any way to expedite payment to the vendor. Can payment be made followed by paperwork?” Per the Procurement Code, the Comptroller may process no payments before a written contract has been filed (30 ILCS 500/20-80 (d)). Further, the State Finance Act (30 ILCS 105/9.05) 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. Good business practice would dictate that the people who negotiate with vendors for goods be educated in terms of the procurement laws of the State.

Other Government Participation

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. The number of doses billed, by government, are presented in Exhibit 2-4.

We contacted each of the other governments to obtain information on their involvement with Illinois officials and Ecosse. We found that:

- While most governments contacted Illinois officials after learning of the procurement attempt through media sources, two – New York City and the State of New Mexico – were approached by an official from the Governor’s Office;
- No written agreements were executed between the other governments and Illinois to secure flu vaccine. A representative from the Governor’s Office informed Kansas officials that an actual non-contingent order was placed by Kansas through Illinois for the flu vaccine. However, no documentation was ever provided to Kansas officials by the Governor’s Office on this order;



- None of the other governments had any contact with Ecosse officials;
- None of the other governments had any contract with Ecosse to purchase flu vaccine;
- None of the other governments ever received any flu vaccine from Ecosse;
- All of the governments received a billing from Ecosse for the amounts listed in Exhibit 2-4;
- None of the other governments made payment to Ecosse on the vaccine billings;
- None of the other governments have been sued by Ecosse for payment; and
- All of the governments reported experiencing a shortage of vaccine during the winter of 2004, but all were able to find additional vaccine through other sources – mainly the federal government.

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, regarding the flu vaccine orders, wrote, “It is with extreme disappointment that I find myself forced to write to you today to request immediate payment of all monies outstanding to us (in excess of US\$8 million) relating to the above.” Further, the correspondence states, “Your State’s commitment to us has been fully documented between us with full disclosure throughout and backed up by personal representations and commitment to me by ...your Deputy Governor, on Friday 17th December, 200(4).”

It is unclear what **assurances** the Deputy Governor provided to Ecosse. In June 2006, the Deputy Governor reported to us that the **assurances** were for payment for the doses of vaccine that was billed to the State of Illinois. However, the **assurances** referenced in the Ecosse letter were December 17, 2004 – and Illinois **was not billed until after** the date of the **assurances**, on January 11, 2005. Given that Illinois officials were the only party dealing with Ecosse, and Ecosse found over \$8 million of vaccine, it is unclear whether the Deputy Governor’s **assurances** were for the amount Illinois **eventually** was billed, or whether the assurances were **for all the vaccine** Ecosse located.

Determination of Vaccine Amount Ordered

In January 2005, the State of Illinois was billed \$2,592,218 by Ecosse for 254,250 doses of flu vaccine – flu vaccine that 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 vaccine that the State requested Ecosse officials locate. The process appeared to be open-ended.

Illinois officials were attempting to purchase flu vaccine to address the priority population as indicated by the CDC. An October 28, 2004 memo from a Department of Public Health official to the Governor’s Office indicated that between 160,000 and 200,000 doses would address our

CDC priority population. The State ended up being billed for 254,250 doses, or 50,000 doses more than the upper end of the estimated range.

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 vaccines from Ecosse.

The number of doses billed to Illinois increased by 74,000 in a matter of two weeks – from 180,250 doses on December 23, 2004 to 254,250 doses on the January 11, 2005 invoice. Correspondence dated December 23, 2004, which was accompanied by a spreadsheet showing the vaccine obtained by Ecosse for all governments, from the Special Advocate to an attorney from the Governor’s Office of Management and Budget indicated, “You will note that in addition to the cost for the shots, I have added a rate adjustment needed to cover the major exchange rate movement over the past several weeks, plus the storage costs incurred by the vendor who assumed they were shipping the order when it was placed. [A Governor’s Office official] has signed a letter which basically agrees to allow the vendor these rate adjustments....The vendor would like to issue all invoices prior to the end of the year and I can’t blame them given they are sitting on over 7 million dollars of inventory.”

The spreadsheet attached to the correspondence lists the exact amounts billed to other governments for the flu vaccine from Ecosse. However, the amount eventually billed to Illinois increased by 74,000 doses in the two weeks – again without any documentation that explained the adjustment. The Special Advocate was reporting the 180,250 doses as late as December 29, 2004 to officials at Public Aid. Additionally, we could not find the referenced “letter” where the official from the Governor’s Office agreed to the rate adjustment. All of these activities **occurred without an executed contract in place.**

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.”

Emergency Purchase Procedures

The flu vaccine was to be procured under the **emergency provisions of the Illinois Procurement Code** – due to dangers to public health/safety. The rationale stated in the Procurement Business Case, which was developed in January 2005 – **three months after** the procurement was initiated, is shown on the inset.

Flu Vaccine Purchase – Emergency Rationale

“The recent announcement that influenza vaccines would be in short supply due to the contamination (more than 40 million doses) issue at British-based Chiron.... If the vaccine is not purchased, hundreds of thousands of residents may not receive an influenza vaccine, which could increase their risk of contracting the illness and the possible complications.”

Source: Public Aid Procurement Business Case.

While the Governor’s Office executed the contract with Ecosse, the Department of Public Aid (Public Aid) developed the Procurement Business Case and maintained a procurement file for the purchase. The Governor’s Office did not maintain a procurement file for this transaction. Administrative rules (44 Ill. Adm. Code 1500.2030 (e)(1)) require a written determination stating the basis for an emergency procurement and the selection of a particular vendor be kept in the contract file of the Procurement Officer. 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 in accordance with the Illinois Procurement Code (30 ILCS 500/20-30(a)) and standard procurement rules (44 Ill. Adm. Code 1.2030(b)(1)(A)): public health or safety, including the health or safety of any particular person, is threatened. Public Aid also published notice of the purchase on the Illinois Procurement Bulletin on January 28, 2005.

The procurement of the flu vaccine was not adequately planned and documented, and resulted in State resources being placed at risk. Developing a contract that included payment for services for locating flu vaccine even though the vaccine was not delivered to the State or used for the intended population would have been a questionable use of State dollars. While Ecosse filed suit against the State in the Illinois Court of Claims, it was only able to seek recovery of the amount of vaccine that was ultimately written into the contract – almost \$2.6 million.

PROCUREMENT TIMING AND PLANNING	
<p style="text-align: center;">RECOMMENDATION NUMBER</p> <p style="text-align: center; font-size: 2em; font-weight: bold;">1</p> <p style="text-align: center; margin-top: 20px;">Agency Response on Next Page</p>	<p><i>In order to protect State interests and not put State resources at risk, the Office of the Governor should:</i></p> <ul style="list-style-type: none"> ▪ <i>Timely enter into formal agreements with vendors that define exactly each party’s responsibilities, so that the State’s interests are protected;</i> ▪ <i>Require appropriate planning, even in emergency procurement situations, before entering into contracts;</i> ▪ <i>Ensure that appropriately qualified State staff participate in the contract negotiation process;</i> ▪ <i>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</i> ▪ <i>Maintain appropriate contract files with a clear written determination when there is a need for an emergency procurement.</i>

**OFFICE OF THE
GOVERNOR
RESPONSE**

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

**Agency Response
Continued on Next Page**

<p>Agency Response (continued)</p>	<p>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.</p> <div data-bbox="673 495 1313 705" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Auditor Comment #2 <i>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.</i></p> </div> <p>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.</p> <div data-bbox="673 875 1313 1020" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Auditor Comment #3 <i>The contract was signed by the Governor's Office; however, the Governor's Office did not maintain a file related to this procurement.</i></p> </div>
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PROCUREMENT PLANNING - APPROVAL

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 (42 USC 262) prohibits the introduction of an unapproved vaccine into interstate commerce. The Food, Drug and Cosmetic (FD&C) Act, section 801(d)(1) (21 USC 381), prohibits the importation of unapproved drugs. The definition of drug in the FD&C Act includes vaccines. Further, section 501 of the FD&C Act (21 USC 355) prohibits the introduction of unapproved drugs into interstate commerce. An organization attempting to import an unapproved vaccine is required to have an approved Investigational New Drug (IND) application on file with the FDA. The State had no such IND application for the vaccine it was attempting to import from Ecosse.

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’s evaluation of the manufacturer’s product descriptions and examinations of dosage, strains of flu, processing and formulation, advisories and contraindications all show that the Aventis vaccine produced for Canada and Europe contain properties that are identical to the Aventis vaccine produced for the United States.” Further, “Our experts from the Illinois Department of Public Health have done an initial assessment of other flu vaccines used in Canada and Europe for the same northern hemisphere flu strains and have concluded that the vaccine made by GlaxoSmithKline likely contains the same properties as those already used here.”

However, a series of e-mail correspondence between officials from Public Health six days earlier, on October 19, 2004 indicate a lack of knowledge of the vaccine being procured. Public Health’s chief-of-staff requested the Medical Director put together a series of questions to determine if this is the right vaccine or not for Illinois residents. The Medical Director indicated that FDA licensure of a vaccine requires demonstration of safety, purity and potency. Further, the Medical Director developed eight questions, which are presented in Exhibit 2-5.

A Public Health Assistant Director, who was involved with policy coordination and interactions with Special Advocate for the flu vaccine procurement, responded to questions 4 through 7 with “**Don’t Know**” in correspondence dated October 19, 2004. Further, he indicated that there was a limited window to purchase the flu vaccine and that the supplier has stated there is other interest in the vaccine the State was attempting to purchase. A correspondence later that same day stated, “We are dealing with the mythology that somehow Glaxo and Aventis do something different for the United States and non-US markets (Canadian, Australian New Zealand and European). They don’t. We know it. We have published it. We just cannot bring ourselves to believe it.”

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. The FDA wanted to collect additional information about the quality of the vaccines. This information included the source of the vaccine supply since it came from middlemen and not from

Exhibit 2-5 DEPARTMENT OF PUBLIC HEALTH QUESTIONS REGARDING THE FLU VACCINE	
1.	Bottom line: Is it real flu vaccine, is it safe, and does it work.
2.	Re: Inspections, etc. This is critical and state pharmacist would be best to comment.
3.	Who’s the manufacturer and need a copy of the manufacturer’s package insert.
4.	What antigens were used to make the vaccine?
5.	Is it a whole virus, split virus preparation of the vaccine?
6.	What compounds were used to inactivate influenza viruses and were antibiotics added to prevent bacterial contamination? Does it contain thimersol?
7.	For what groups is efficacy data available from this manufacturer and has this efficacy data been submitted to the FDA?
8.	Is it packaged in multidose vials or individual syringes? What is the dose and recommended dose interval?
Source: OAG summary of Public Health information.	

the manufacturer; standards to which the vaccines conform; and the integrity of the products (e.g., current storage conditions).

PROCUREMENT PLANNING – APPROVAL	
RECOMMENDATION NUMBER 2	<p><i>The Office of the Governor should take steps to obtain the necessary approval from appropriate federal authorities, when such approval is required, prior to committing State resources to procurements.</i></p>
OFFICE OF THE GOVERNOR RESPONSE	<p>The Office of the Governor agrees with this finding and did take the necessary steps to seek approval from the FDA.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Auditor Comment #4 <i>The auditors believe the State should obtain, not just seek, approval from appropriate regulatory authorities before committing State resources to a procurement.</i></p> </div> <p>Once the vaccine we secured was proven to be safe, and after the FDA did not respond to our <u>repeated</u> 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)</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Auditor Comment #5 <i>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 (see agency notation below dated 11/24/04).</i></p> </div> <p>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.</p>
Agency Response Continued on Next Page	

<p>Agency Response (continued)</p>	<p>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.”</p> <p>12/09/04— Written declaration of the Prescription Drug Advocate Scott McKibbin supplied to FDA via Zuckerman Spaeder.</p> <p>12/15/04— Email from Zuckerman Spaeder legal counsel and former FDA employee Lisa Barclay— “FDA is asking additional questions about documents previously supplied.”</p> <p>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.</p> <div data-bbox="683 879 1323 1157" style="border: 1px solid black; padding: 5px;"> <p><i>Auditor Comment #7</i> <i>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.</i></p> </div>
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LEGAL COSTS

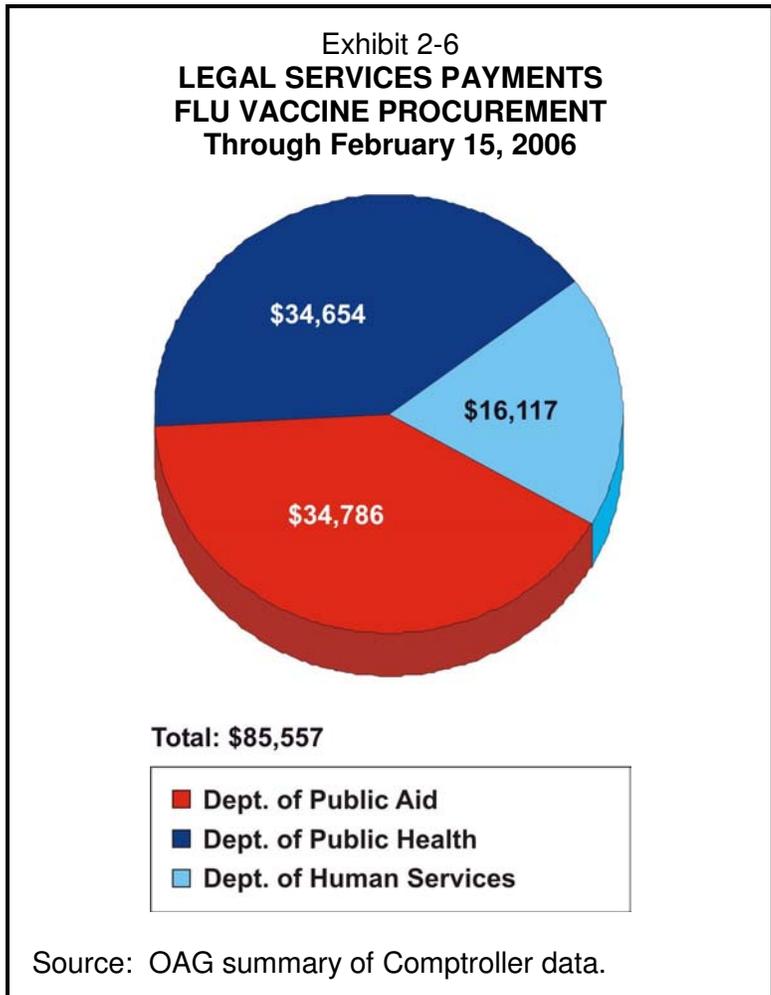
On December 26, 2004, the Governor’s Office entered into an agreement with a Washington D.C based law firm to provide legal services to the State relative to the flu vaccine procurement. Through February 15, 2006, State agencies had paid the firm \$86,000 for billings applicable to the flu vaccine procurement. This included State funds paid in penalty under the State Prompt Payment Act. Exhibit 2-6 provides a breakdown of spending by agency.

Relative to the Ecosse Hospital Products Ltd. contract, the firm was to **“review Illinois’ flu shot importation program and represent the State, the Governor of Illinois, the Office of Special Drug Advocates and any other State officials in connection with any enforcement action brought by the federal Food and Drug Administration.”**

The vendor services were not competitively procured due to an exemption in the Procurement Code (30 ILCS 500/1-10 (b)(7)) that was authorized by the Governors Acting General Counsel. This exemption relates to the anticipation of potential litigation. The vendor was to be compensated at a rate of \$350 per hour. An official from the Governor’s Office stated that no litigation was ever initiated by the federal government under the flu importation procurement.

The contracts with the firm contained no scope of services section nor tasks or deliverables due to the State. An official from the Governor’s Office indicated that firm staff were given direction by various staff from the Governor’s Office or the Special Advocate.

On October 1, 2004, **Interagency Agreements** were entered into between the Office of the Governor and the Departments of Public Aid, Public Health, and Human Services pursuant to the Intergovernmental Cooperation Act (5 ILCS 220). The agencies agreed to make all payments to the firm under the agreements. For the flu vaccine review: 40 percent of the responsibility for billings was allocated to Public Aid, 40 percent to Public Health, and 20 percent to Human Services.



Public Aid made its payments (\$34,786) under the interagency agreement from the Public Aid Recoveries Trust Fund. 305 ILCS 5/12-9 describes the uses of the Public Aid Recoveries Trust Fund. While not specifically designated in 305 ILCS 5/12-9, Public Aid's position is that the language is broad enough to cover paying for legal services contracted by the Governor for these legal fees.

Pursuant to the agreement, the *role* of the Governor's Office was to act as the coordinating agency "responsible for the preparation of the underlying contract, centralizing communications between the firm and the Agencies, offering guidance and direction relating to the flu shot importation program and other administrative functions in connection with these legal services." The Interagency Agreements expired June 30, 2005.

Chapter Three

I-SAVE Rx PROGRAM

CHAPTER CONCLUSIONS

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 United Kingdom. The Program later expanded, in 2005, to include approved pharmacies in Australia and New Zealand. I-SaveRx was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003.

The states of Wisconsin, Vermont, Kansas, and Missouri have also joined the I-SaveRx Program. Documentation received from the Governor's Office in late 2005 listed 28 approved pharmacies in the I-SaveRx Program from the United Kingdom, 15 from Canada, 7 from Australia and 1 from New Zealand. After an inquiry from auditors, the Special Advocate indicated this listing was not accurate.

The State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law. 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 (FD&C Act) (21 U.S.C. 355). 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. The Food and Drug Administration (FDA) can, under the FD&C Act, bring civil action or criminal prosecution for each violation (21 U.S.C. sections 332/333). 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.

The Office of the Governor was the lead policy maker in the development of a drug importation program beginning in September 2003, when the Special Advocate was directed to explore the idea of having State employees and retirees purchase prescription drugs from abroad. The Governor's Office also was responsible for developing and entering into a contract with the pharmacy benefit manager for the I-SaveRx Program – CanaRx. The Special Advocate led the State research team that developed reports to the Governor regarding the drug importation initiative, and is responsible for the day-to-day activities and monitoring of the I-SaveRx Program.

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

Our review of Pharmacy Inspection Forms for the pharmacies inspected by the Department of Financial and Professional Regulation (DFPR) found several problems. For 40 percent of pharmacies inspected for the I-SaveRx Program (32 of 80), 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 11 percent (9 of 80) of the inspection forms indicated whether the pharmacy was approved. Inspection forms for approved pharmacies and for pharmacies not approved were often indiscernible.

The State does not monitor whether prescriptions are being filled only by approved pharmacies. Participants not knowing if their prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. A list of approved pharmacies provided by the Governor's Office differed from DFPR's inspected pharmacies log. The Governor's Office list contained fewer approved pharmacies compared to the DFPR inspected pharmacies and even contained one pharmacy that was shown as not approved by DFPR. After we inquired, an updated list was provided that contained all of the pharmacies approved by DFPR. The updated list was provided to our Office on June 20, 2006 by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

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.

We 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 \$488,000. Actual hours worked and actual payroll costs are higher, since some agencies were unable to provide an estimate of hours worked by employees. Due to data limitations, we were unable to calculate an estimated payroll cost for 29 percent of the employees that participated.

There was a lack of coordination of the I-SaveRx promotional activities. Although DHFS was to coordinate the efforts of employees working on the I-SaveRx promotional activities, only two agencies mentioned working with DHFS. Coordination of promotional activities is important to ensure that resources are maximized and efforts are cohesive. Outreach activities were primarily reported to and coordinated by the Governor's Office.

There was no system in place to track the results of the agency outreach. For example, the Governor's Office did not track which applications resulted in successful enrollments or which agencies were more effective in signing up enrollees.

Although the I-SaveRx Program was not approved by the federal Food and Drug Administration and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities **were paid from federal funds**.

The State of Illinois signed a Memorandum of Understanding (MOU) with four states allowing their residents to purchase prescription drugs through the I-SaveRx Program. 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 acquisition fees to the Fund 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 State received no monies from the Fund, thus monies for State activities (travel, marketing, etc.) were paid for from State agency monies. The Special Advocate could not provide documentation to show what CanaRx had expended these up-front monies on.

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

While CanaRx is not paid for its services by the State under the contract, we found that there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program. State agency personnel have accumulated over \$111,000 in travel expenses, mainly for out-of-country travel and use of State aircraft, in support of a drug importation program. We also found that most travel was not approved prior to departure as stated in travel regulations. We identified \$10,662 in excessive per diem reimbursement to six State employees traveling as part of the I-SaveRx Program.

The State has paid \$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 Program that we were able to identify during the course of the audit. The major cost was a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate's Office.

INTRODUCTION

House Resolution Number 394 asked the Office of the Auditor General to determine what agencies were responsible for the establishment and operation of the I-SaveRx Program, what procedures were applicable to the Program, and whether the entities involved in the Program followed all applicable laws, regulations, policies and procedures. This chapter will examine the roles played by the different agencies in establishing and monitoring the Program. Additionally, the chapter discusses the monitoring and safety issues involved in the Program. Further, the chapter reports on the costs to the State of the Program.

BACKGROUND: I-SAVE Rx PROGRAM

On October 4, 2004, the State of Illinois launched the I-SaveRx Program. As publicized on its website, the Program was “developed by the State of Illinois” to allow “consumers to purchase safe and affordable prescription refills from licensed, inspected pharmacies in Canada and the United Kingdom.” The Program launch was the culmination of efforts of many groups, primarily the Special Advocate, which initiated work on a drug importation program in September 2003.

The states of Wisconsin, Vermont, Kansas, and Missouri also joined the I-SaveRx Program. In June 2005, the Special Advocates recommended Illinois proceed with the expansion of the Program to include approved pharmacies in Australia and New Zealand. Documentation received from the Governor’s Office in late 2005 listed 8 pharmacies in the Program from Australia and New Zealand, 15 from Canada, and 28 from the United Kingdom. However, as discussed later in this chapter, the Special Advocate updated that list on June 16, 2006 – 14 days prior to the end of the contractual agreement with the Canadian pharmacy benefit manager.

The I-SaveRx Program is not a unique drug importation program. Our research during the audit identified other governments that also import drugs from Canada. Governments such as the City of Springfield, MA and Caldwell County, NC have drug importation programs.

The I-SaveRx Program is administered through a contract between the State of Illinois and CanaRx Services Inc. (CanaRx) – a Canadian-based Pharmacy Benefits Manager. The contract, executed October 4, 2004, was procured by the Governor’s Office through a Sole Economically Feasible Source procurement. The contract is not on file with the Comptroller – since, according to the Governor’s Office, there is no estimated cost to the State.

As published in the Illinois Procurement Bulletin on September 7, 2004, “CanaRx will provide international clearinghouse and Pharmacy Benefits Manager (PBM) services with an international network of pharmacies and wholesalers located in Canada, United Kingdom (UK), and Ireland.” The Notice in the Bulletin lays out the reasons for the sole source procurement. The Bulletin notice stated, “CanaRx is the Sole Economically Feasible Source for these services based on an extensive survey of the market place no other vendor is capable of performing the scope of services required by the State in the time frame desired and in the locations requested by the State.” Exhibit 3-1 provides a timeline of activities involved in the development of the drug importation program and subsequent I-SaveRx Program.

Legality of the I-SaveRx Program

The State’s operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law.

Drugs are approved for use in the United States pursuant to the provisions of federal law as stated in the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355). Section 355 requires, among other things, submission to the Secretary of the Department of Health and Human Services (DHHS) as part of the application:

- A. Full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;
- B. A full list of the articles used as components of such drug;
- C. A full statement of the composition of such drug;
- D. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug;
- E. Such samples of such drug and of the articles used as components thereof as the Secretary may require; and
- F. Specimens of the labeling proposed to be used for such drug.

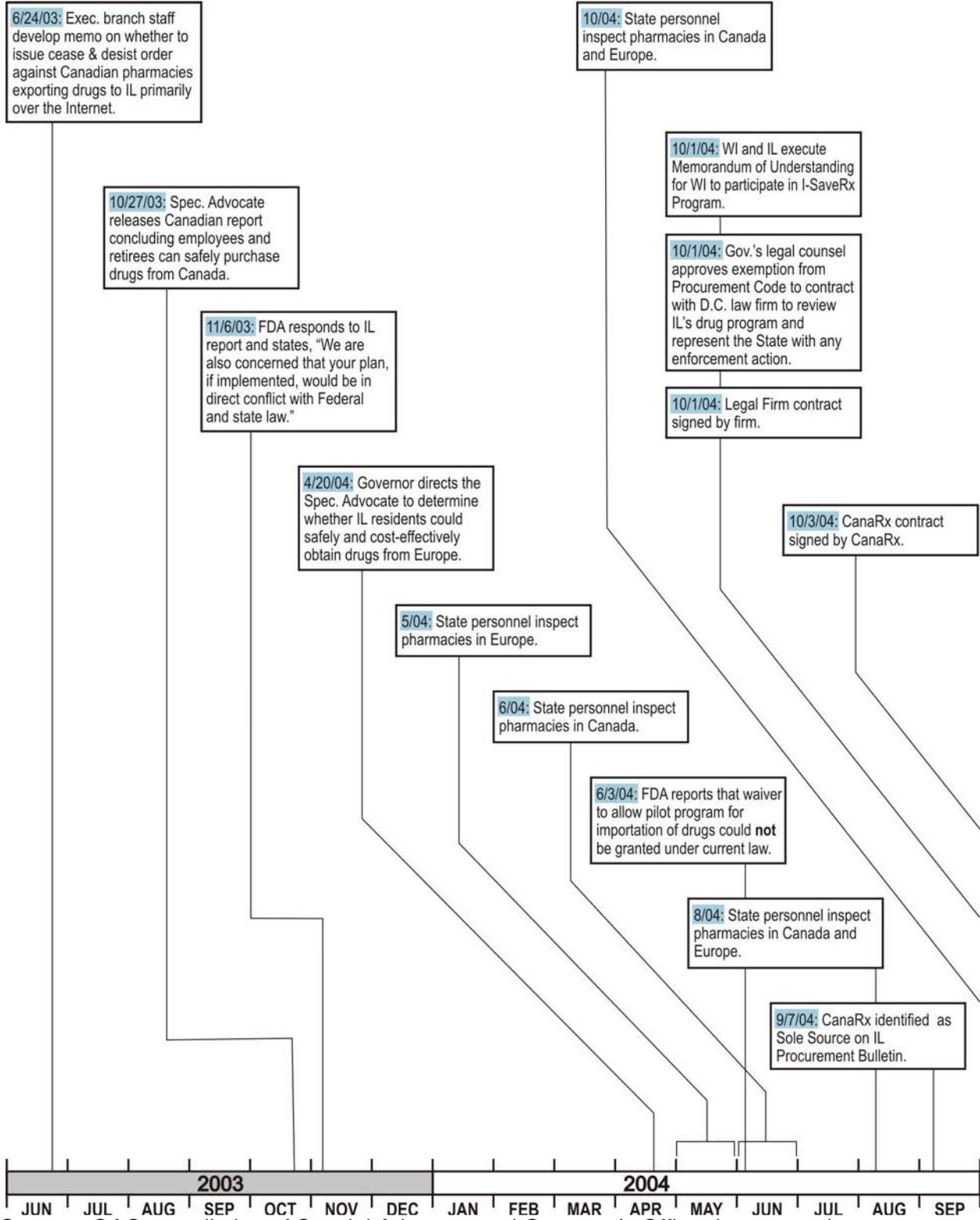
Section 384 of the FD&C Act allows the Secretary to promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products. However, the Secretary has not promulgated such regulations.

Section 331 of the FD&C Act provides examples of prohibited acts. The prohibited acts include: the introduction or delivery for introduction into interstate commerce of any drug that is adulterated or misbranded, and the introduction into interstate commerce any article that violates sections 384 or 355 of the Act.

On September 16, 2003, prior to the launch of the I-Save_RX Program, the FDA issued a warning letter to CanaRx. The FDA stated, “Frequently, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all the requirements of the U.S. approval, and thus it is considered to be unapproved.”

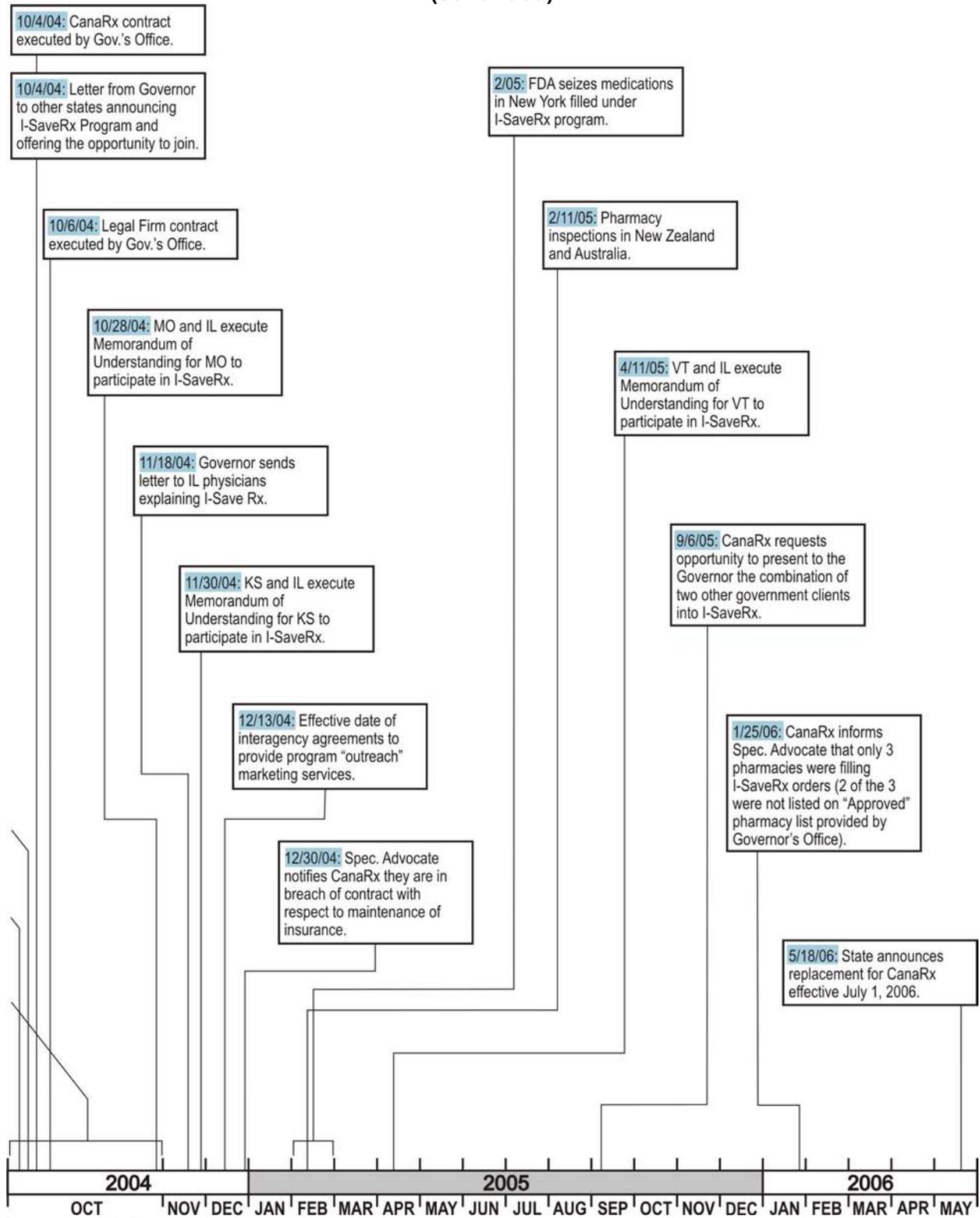
In the October 27, 2003 Special Advocate’s report on the feasibility of importing prescription drugs from Canadian pharmacies it states, “...a drug manufactured in the U.S., with US./F.D.A. approval, for the U.S. market may be formulated differently for foreign markets. Therefore, it would be an unapproved drug for reimportation, except for reimportation by the manufacturer, unless the requirements of 21 U.S.C. section 384 can be met.”

Exhibit 3-1 I-SAVE Rx PROGRAM TIMELINE



Source: OAG compilation of Special Advocate and Governor's Office documentation.

Exhibit 3-1
I-SAVE_{RX} PROGRAM TIMELINE
 (continued)



Source: OAG compilation of Special Advocate and Governor's Office documentation.

In late 2003, the Governor contacted the FDA to inquire whether DHHS would approve a demonstration project for the importation of prescription drugs from Canada. In a correspondence dated June 3, 2004, the Acting Commissioner of the FDA wrote “Although at the Food and Drug Administration (FDA) we share your concern and urgency related to the cost and safety of prescription drugs for our citizens, **we do not believe that a waiver could be granted** (emphasis added) to allow a state’s pilot project for the safe importation of prescription drugs under the current law.” The FDA outlined its rationale in subsequent pages. Despite the FDA’s denial of a waiver, the Governor’s Office proceeded with a drug importation program.

According to federal officials, 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. The FDA can, under this Act, bring civil action or criminal prosecution for each violation (21 U.S.C sections 332/333). 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.

AGENCY INVOLVEMENT IN THE I-SAVE Rx PROGRAM

Multiple agencies have been involved in the development and operation of the I-Save Rx Program. These agencies include the Governor’s Office, the Office of the Special Advocate for Prescription Drugs (Special Advocate), the Department of Financial and Professional Regulation (DFPR), and the Department of Public Health (Public Health).

Office of the Governor

The Office of the Governor was the lead policy maker in the development of a drug importation program. In September 2003 the Governor directed the Special Advocate to explore the idea of State employees and retirees purchasing prescription drugs from abroad. Later, the Governor directed the Special Advocate to expand the drug importation research to Europe, Australia and New Zealand.

The Governor’s Office also was responsible for developing and entering into a contract with the pharmacy benefit manager for the I-Save Rx Program – CanaRx. The Governor’s Office also coordinated outreach activities for the I-Save Rx Program. Officials from the Governor’s Office traveled on fact-finding missions regarding the drug importation initiative and later on inspection trips to Europe and Canada.

Office of the Special Advocate for Prescription Drugs

The Special Advocate led the State research team that developed reports to the Governor regarding the drug importation initiative. In addition to extensive global travel for inspections and research gathering, the Special Advocate is responsible for the day-to-day activities and monitoring of the I-Save Rx Program.

Department of Financial and Professional Regulation

DFPR officials assisted in the gathering of information that became part of the Canadian Report on importing prescription drugs by State employees and retirees. Additionally, DFPR staff were involved in performing inspections of pharmacies that were to operate in the I-Save_{Rx} Program. DFPR’s Director of Drug Compliance, General Counsel, and Pharmacy Manager were mainly associated with the Program.

Department of Public Health

The Special Advocate requested that the Department of Public Health (Public Health) participate in researching potential issues and the feasibility of potential applications for: (1) the use of and importation of fully accredited prescription drugs for the beneficiaries of the State’s benefits plans; (2) using fully accredited European medications for Illinois residents without prescription insurance coverage; (3) based upon the research, contributing to the development of program options in order to facilitate the benefits for Illinois’ residents; and (4) researching the feasibility of expanding the sources of fully accredited pharmaceuticals deemed appropriate for Illinois residents from markets beyond those previously explored. Roles of specific positions within Public Health are outlined in Exhibit 3-2.

Public Health maintains the responsibility for the safe practice in manufacturing, warehousing, and storage of pharmaceuticals in Illinois. In relation to inspections for those foreign pharmacies that participate in the I-Save_{Rx} Program, Public Health was responsible for assessing Good Manufacturing Practices under U.S. and Illinois law at each of the Canadian site visits. Public Health reported that during site visits in Europe, this responsibility was transferred to staff from the Department of Financial and Professional Regulation.

Exhibit 3-2 ROLES OF SPECIFIC PUBLIC HEALTH POSITIONS I-Save _{Rx} Program
<ul style="list-style-type: none"> ▪ Director: Participated prior to the implementation of the Program, specifically on the Canadian and European site visits in which the safety of the pharmaceutical and regulatory practices affecting the I-Save_{Rx} Program were established. ▪ Assistant Director: Participated in the research, policy analysis, program design and development throughout. ▪ Pharmacy Manager: Participated during the site visits and inspections of Canadian pharmacies. ▪ Special Assistant to the Director: Coordinated activities within Public Health to promote the I-Save_{Rx} Program.
Source: OAG summary of Public Health information.

PROGRAM SAFETY AND INSPECTIONS

The pharmacies operating under the I-Save_{Rx} 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-Save_{Rx} pharmacies were not conducted by drug compliance investigators as is required in the Act.

Our 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 prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRx Program. A list of approved pharmacies provided by the Governor's Office differed from DFPR's inspected pharmacies log. The Governor's Office list contained fewer approved pharmacies compared to the DFPR inspected pharmacies and even contained one pharmacy that was shown as not approved by DFPR. After we inquired, an updated list was provided that contained all of the pharmacies approved by DFPR. The updated list was provided to our Office on June 20, 2006 by the Special Advocate and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

Requirements of the Pharmacy Practice Act

The Department of Financial and Professional Regulation (DFPR) is responsible for inspecting and licensing pharmacies in Illinois. The requirements are outlined in the Pharmacy Practice Act (225 ILCS 85). The Pharmacy Practice Act states that it shall be unlawful for any person to engage in the practice of pharmacy unless first authorized to do so under the provisions of this act. Any person who practices pharmacy without being licensed under the act is subject to a civil penalty. In addition, the Act states that pharmacy investigators shall be the only Department investigators authorized to inspect pharmacies.

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. Therefore, the I-SaveRx pharmacies do not meet either of the two ways to be authorized to operate as a pharmacy under the Act.

In a memorandum regarding importation issues by Canadian pharmacies, dated June 24, 2003, the Department stated: "Per the Act, one must be licensed in Illinois as a pharmacy and a pharmacist to dispense drugs to consumers in Illinois. 225 ILCS 85/5.5. The Canadian pharmacies and pharmacists are not licensed in Illinois and therefore are violating the Act if their activity is construed as dispensing." The Act defines **dispense** as "...the delivery of drugs and medical devices, in accordance with applicable State and federal laws and regulations, to the patient..."

We 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. During the time period when inspections of I-SaveRx pharmacies occurred, DFPR had seven drug compliance investigators in addition to the Director of Drug Compliance. However, **none** of the seven regular investigators conducted the inspections. Instead, the Director of Drug Compliance conducted the inspections along with three other individuals who were not the regular investigators. The Act states, “The pharmacy investigators shall be the only Department investigators authorized to inspect, investigate, and monitor probation compliance of pharmacists, pharmacies, and pharmacy technicians.”

COMPLIANCE WITH PHARMACY PRACTICE ACT	
RECOMMENDATION NUMBER 3	<i>The Department of Financial and Professional Regulation should 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.</i>
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION RESPONSE	<p>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.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Auditor Comment #8 <i>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 <u>not</u> been authorized under the Pharmacy Practice Act either as licensed foreign pharmacies or as domestic mail order pharmacies.</i></p> </div>
Agency Response Continued on Next Page	

<p>Agency Response (continued)</p>	<p>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.</p> <p>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.</p> <p>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.</p> <div style="border: 2px solid black; padding: 10px; margin-top: 20px;"> <p><i>Auditor Comment #9</i> <i>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.</i></p> </div>
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Pharmacy Inspection Form

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 top part of the form contains basic information about the pharmacy being inspected such as the address, owners, and licensed pharmacists in charge. The remainder of the form consists of requirements from the Pharmacy Practice Act and related administrative rules. A requirement is listed in one column with adjoining columns labeled yes and no. A check in the yes column would indicate a violation of the requirement while a check in the no column would indicate compliance.

I-SaveRx Pharmacies

We 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. Exhibit 3-3 shows the number of pharmacies approved or not approved in each location. Seventy-four of the 80 pharmacies inspected were approved while 6 were not approved.

The Pharmacy Inspection Form contains requirements that apply to DFPR licensing the pharmacy. However, as noted above, the I-SaveRx pharmacies are not licensed in Illinois. For example, one requirement on the form states: “All pharmacy technicians must have valid certificates of registration issued by the Department.” Since these pharmacies are not licensed in Illinois, they would not meet this requirement. An examination of the inspection forms showed that this and other similar requirements were usually checked ‘no’ indicating no violation.

Our examination of the I-SaveRx inspections found several other 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. For 9 of the 80 inspections, it was handwritten whether the pharmacy was approved or not but in the remaining cases there was no indication. For the pharmacies that were not approved, the forms were filled out similarly to the pharmacies that were approved. The only difference was that “not approved” was written on the form in some of those cases. If not for that label, a reviewer could not tell the approved forms from the not approved forms;
- 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

Exhibit 3-3 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.			

- 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).

PHARMACY INSPECTIONS	
<p>RECOMMENDATION NUMBER</p> <p style="font-size: 2em;">4</p>	<p><i>The Department of Financial and Professional Regulation should ensure that inspection forms of pharmacies inspected for the I-SaveRx Program:</i></p> <ul style="list-style-type: none"> ▪ <i>Are filled out properly with all requirements completed;</i> ▪ <i>Indicate whether the pharmacy has been approved and, if not, the reasons for not approving; and</i> ▪ <i>Are reviewed by someone other than the person who performed the initial inspection.</i>
<p>OFFICE OF THE GOVERNOR</p> <p style="text-align: center;">AND</p> <p>DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION RESPONSES</p> <p style="text-align: center;">Agency Responses Continued on Next Page</p>	<p>The Office of the Governor’s agreement with this recommendation is limited to certain aspects, identified below.</p> <p>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.</p> <p>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. <u>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.</u></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p><i>Auditor Comment #10</i> <i>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.</i></p> </div> <p>The Department also agrees that pharmacy inspection forms should indicate whether a pharmacy has been approved or, if not, the reasons</p>

<p>Agency Responses (continued)</p>	<p>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.</p> <div data-bbox="683 327 1325 638" style="border: 1px solid black; padding: 5px;"> <p><i>Auditor Comment #11</i> <i>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.</i></p> </div> <p>It is currently standard practice – <u>and has always been standard practice</u> – 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.</p> <div data-bbox="683 1144 1325 1856" style="border: 1px solid black; padding: 5px;"> <p><i>Auditor Comment #12</i> <i>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.</i></p> </div>
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Monitoring Approved Pharmacies

The Special Advocate is responsible for the day-to-day monitoring of the I-SaveRx Program. We found that 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. Although the name of the pharmacy would be shown on the label of the prescription sent to Program participants, the participants would not know whether the pharmacy was an approved pharmacy since a list of approved pharmacies is not publicly available. Participants not knowing if their prescription was filled at an approved pharmacy raises questions about the safety of the I-SaveRx Program.

At our request, 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.

When we inquired about the differences between the Governor’s Office list of approved pharmacies and the DFPR inspected pharmacies log, the Special Advocate provided an updated list of approved pharmacies. The updated list contained all of the pharmacies approved by DFPR. While that listing contained 74 approved pharmacies, only 2-3 pharmacies have been filling prescriptions since the launch of the Program. The updated list was provided to our Office on June 20, 2006 and was marked as revised on June 16, 2006, two weeks prior to the end of the contract with CanaRx.

MONITORING APPROVED PHARMACIES	
RECOMMENDATION NUMBER 5	<i>The Special Advocate for Prescription Drugs should monitor the I-SaveRx Program to ensure that only approved pharmacies are filling prescriptions.</i>
OFFICE OF THE GOVERNOR AND SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS RESPONSES Agency Responses Continued on Next Page	<p>The Office of the Governor’s agreement with this recommendation is limited to certain aspects, identified below.</p> <p>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:</p> <p>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.</p>

**Agency Responses
(continued)**

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.

Medication Testing

The State has not tested medications Illinois citizens receive from the I-SaveRx Program for effectiveness and efficacy to ensure that the customers are getting exactly the drugs they think they are getting. While the recommendation for order testing was made for an I-SaveRx type of program for employees/retirees (based on the anticipated number of orders and funding generated by overall program savings), 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 that is provided in the I-SaveRx Enrollment process is presented in Exhibit 3-4. A December 22, 2003 correspondence from the Governor to the Secretary of the U.S. Department of Health and Human Services (DHHS) offered to work with DHHS staff and the

**Exhibit 3-4
I-SAVE Rx ENROLLMENT WARNING**

WELCOME TO I-SaveRx

I-SaveRx is a program designed to save you 25 to 50 percent on safe prescription medication refills.

ENROLLMENT INSTRUCTIONS

1. Complete and Sign the Enclosed Enrollment Form
2. Return the signed and completed Form to an I-SaveRx Representative OR Submit the signed and completed enrollment form by mail or fax to the address and fax number on the front of this packet.

or

1. Call I-SaveRx toll-free 24 hours a day and 7 days a week at 1-866-I-SAVE33 (1-866-472-8333). The completed Enrollment Form will be forwarded to you by mail, fax or email for your signature.
2. Return the signed and completed Form to an I-SaveRx Representative OR Submit the signed and completed enrollment form by mail or fax to the address and fax number on the front of this packet.

(Additional Forms for Family and Friends can be obtained by calling toll-free 1-866-I-SAVE33 (1-866-472-8333) or by visiting www.i-saverx.net.)

ORDERING INSTRUCTIONS

1. Complete ALL information on the enclosed Medical History Form.
2. Visit your doctor to review the Medical History Form, and
3. Obtain an original refill prescription for all medications you want to order through I-SaveRx from your doctor. Each prescription should be written for a 3-month supply of the medication with three refills.
4. Submit your completed Medical History form AND the original refill prescription(s) to I-SaveRx by either Mail/Health your Doctor's office for these materials to 1-866-795-6337 OR by Mailing these materials to I-SaveRx, PO. Box 21086, McCormick, Ontario Canada N0M 4S5. (Please note that international postage rates apply.)
5. An I-SaveRx representative will contact you when your order has been received to confirm the order and take payment.
6. Your medications will arrive in the mail directly from the pharmacy in about 20 days.

IMPORTANT WARNING AND INFORMATION REGARDING THE SAFETY AND LEGALITY OF PRESCRIPTION DRUGS PURCHASED FROM OTHER COUNTRIES
Purchasing prescription drugs by mail order from another country involves certain unavoidable risks. As with any prescription drug purchase, you should educate yourself about your needs and the product to be purchased to minimize your risks. You should always inspect your purchases carefully to ensure that you have received the correct quantity of the correct medication in the correct dosage. You should also check your shipping packages carefully to ensure that your purchases have not been damaged or tampered with during shipping. If you have any questions or doubts about any prescription drugs received through the mail, you should talk to a doctor or pharmacist before you begin taking the medication. Take medication only as instructed by your doctor. Do not take medication that has not been prescribed for you, that does not match your prescription, or that appears to have been damaged or tampered with. If you have symptoms after you begin taking a new medication, talk to a doctor or pharmacist right away. Failure to follow these warnings could result in serious injury or death.
The Canadian, Irish, or United Kingdom regulatory bodies have approved all medications available through this program to be safe for use within their own respective countries. Prescription drugs purchased from other countries fall outside of the regulatory system for prescription drugs purchased in the United States. Canada and United Kingdom have their own regulatory systems to protect the safety of prescription drugs, and those systems differ in certain respects from the system in the United States. Prescription drugs purchased from other countries, for example, may be labeled or packaged differently than prescription drugs purchased in the United States, or manufactured in different facilities. The State of Illinois has investigated the regulatory systems of Canada, Ireland, and the United Kingdom, and believes that they are safe and effective.
The United States Food and Drug Administration (the "FDA"), however, has taken the position that the purchase of prescription drugs from outside of the United States can be unsafe and illegal. To learn more about the FDA's position, please go to <http://www.fda.gov/importeddugs/>. The State of Illinois, its officers, and its employees make no representation as to the legality of the importation or reimportation of pharmaceuticals from other countries.
The State of Illinois does not license pharmacies outside of Illinois, and the pharmacies in Canada and United Kingdom participating in this program are not licensed Illinois pharmacies. All pharmacies participating in this program are required to consent to regular inspections by Illinois pharmacy inspectors. The State of Illinois has inspected all of the participating pharmacies, and has concluded that they meet the same conditions required of licensed Illinois pharmacies. The State of Illinois will continue to inspect those pharmacies in the future, and to remove from this program any pharmacy that does not comply with Illinois standards. Nevertheless, the State of Illinois cannot guarantee the safety of any particular prescription drug purchase. The State of Illinois makes no representations or warranties as to the safety or efficacy of prescription drugs purchased from foreign sources.
The I-SaveRx program is not a licensed pharmacy and is not engaged in the practice of pharmacy.

1-866-I-SAVE33 • www.I-SaveRx.net

Warning box from I-SaveRx web page enlarged below.

IMPORTANT WARNING AND INFORMATION REGARDING THE SAFETY AND LEGALITY OF PRESCRIPTION DRUGS PURCHASED FROM OTHER COUNTRIES

Purchasing prescription drugs by mail order from another country involves certain unavoidable risks. As with any prescription drug purchase, you should educate yourself about your needs and the product to be purchased to minimize your risks. You should always inspect your purchases carefully to ensure that you have received the correct quantity of the correct medication in the correct dosage. You should also check your shipping packages carefully to ensure that your purchases have not been damaged or tampered with during shipping. If you have any questions or doubts about any prescription drugs received through the mail, you should talk to a doctor or pharmacist before you begin taking the medication. Take medication only as instructed by your doctor. Do not take medication that has not been prescribed for you, that does not match your prescription, or that appears to have been damaged or tampered with. If you have symptoms after you begin taking a new medication, talk to a doctor or pharmacist right away. Failure to follow these warnings could result in serious injury or death.

The Canadian, Irish, or United Kingdom regulatory bodies have approved all medications available through this program to be safe for use within their own respective countries. Prescription drugs purchased from other countries fall outside of the regulatory system for prescription drugs purchased in the United States. Canada and United Kingdom have their own regulatory systems to protect the safety of prescription drugs, and those systems differ in certain respects from the system in the United States. Prescription drugs purchased from other countries, for example, may be labeled or packaged differently than prescription drugs purchased in the United States, or manufactured in different facilities. The State of Illinois has investigated the regulatory systems of Canada, Ireland, and the United Kingdom, and believes that they are safe and effective.

The United States Food and Drug Administration (the "FDA"), however, has taken the position that the purchase of prescription drugs from outside of the United States can be unsafe and illegal. To learn more about the FDA's position, please go to <http://www.fda.gov/importeddugs/>. The State of Illinois, its officers, and its employees make no representation as to the legality of the importation or reimportation of pharmaceuticals from other countries.

The State of Illinois does not license pharmacies outside of Illinois, and the pharmacies in Canada and United Kingdom participating in this program are not licensed Illinois pharmacies. All pharmacies participating in this program are required to consent to regular inspections by Illinois pharmacy inspectors. The State of Illinois has inspected all of the participating pharmacies, and has concluded that they meet the same conditions required of licensed Illinois pharmacies. The State of Illinois will continue to inspect those pharmacies in the future, and to remove from this program any pharmacy that does not comply with Illinois standards. Nevertheless, the State of Illinois cannot guarantee the safety of any particular prescription drug purchase. The State of Illinois makes no representations or warranties as to the safety or efficacy of prescription drugs purchased from foreign sources.

The I-SaveRx program is not a licensed pharmacy and is not engaged in the practice of pharmacy.

Source: I-SaveRx Enrollment Package.

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**Agency Response
(continued)**

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 ¹	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 ²	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.

**Agency Response
Continued on Next Page**

<p>Agency Response (continued)</p>	<p>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.</p> <p>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.</p> <p>¹ MEDCO is the current Pharmacy Benefits Manager (PBM) for the State of Illinois Group Insurance Programs. Information on MEDCO standards was obtained from the current MEDCO contract with CMS.</p> <p>² Ingredient testing in the United States does not occur once the drug enters the supply chain.</p>
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PROMOTIONAL OUTREACH ACTIVITIES

We 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, we were unable to calculate an estimated payroll cost for 29 percent of the employees that 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.

There was a lack of coordination of the I-SaveRx promotional activities. Although DHFS was to coordinate the efforts of employees working on the I-SaveRx promotional activities, only two agencies mentioned working with DHFS. Coordination of promotional activities is important to ensure that resources are maximized and efforts are cohesive. Outreach activities were primarily reported to and coordinated by the Governor’s Office.

There was no system in place to track the results of the agency outreach. For example, the Governor’s Office did not track which applications resulted in successful enrollments or which agencies were more effective in signing up enrollees.

Although the I-SaveRx Program was not approved by the federal Food and Drug Administration and violates federal laws governing importation of drugs, at least 26 employees that participated in promotional activities **were paid from federal funds**.

State Agency Promotional Activity

We sent questionnaires to agencies to determine their involvement in the I-SaveRx Program. We also provided to each agency the names of employees that, according to the Governor’s Office, participated in promotional activities. For each employee, we asked for the activities undertaken, the hours spent on those activities, and when those activities took place. We also asked the agencies to provide any additional employees that participated in promotional activities regarding the I-SaveRx Program that were not on the list provided by the Governor’s Office.

All of the agencies surveyed responded to our request. Promotional activities performed by employees included:

- Attending orientation and training meetings;
- Organizing outreach events;
- Distributing information at outreach events;
- Assisting in printing of promotional material;
- Answering phone calls; and
- Conducting presentations on the program.

Interagency Agreements

DHFS, formerly the Department of Public Aid, entered into interagency agreements with other State agencies to perform promotional activities related to the I-SaveRx Program. As shown in Exhibit 3-5, DHFS entered into agreements with 15 other agencies. The interagency agreements stated:

“The goal of the I-Save Rx Program is to greatly reduce the healthcare costs of Illinois residents by acquiring prescription drugs from Canadian and European pharmacies. In furtherance of this goal and to help promote the I-Save Rx Program, it is agreed that employees from certain state agencies will have limited responsibilities to directly advance the Office of the Governor and Special Advocate for Prescription Drugs’ objectives, functions, goals and policies with regard to the I-Save Rx Program.”

Exhibit 3-5 AGENCIES WITH INTERAGENCY AGREEMENTS WITH DEPARTMENT OF PUBLIC AID FOR PROMOTIONAL ACTIVITIES FOR THE I-SAVERX PROGRAM	
Agriculture	Fire Marshal
Capital Development Board	Historic Preservation
Central Management Services	Human Services
Commerce and Economic Opportunity	Labor
Corrections	Military Affairs
Emergency Management Agency	Natural Resources
Environmental Protection Agency	Revenue
Financial and Professional Regulation	
Source: I-SaveRx Interagency Agreements.	

A total of 28 agencies had employees that participated in promotional activities. Many agencies that did not have interagency agreements in place still provided employees to assist in outreach efforts. The agencies are listed in Exhibits 3-6 and 3-7.

Activities also took place prior to any interagency agreements being in place. The interagency agreements covered the period from March 1, 2005 to December 31, 2005 and were all signed from April 27 to May 3, 2005. A total of 30 employees from 5 agencies worked on promotional activities prior to March 1, 2005, the effective date of the interagency agreement. A total of 282 employees from 19 agencies participated prior to the agreements being signed at the end of April.

Coordinating Activities

There was a lack of coordination of the I-Save_{Rx} promotional activities. Coordination of promotional activities is important to ensure that resources are maximized and efforts are cohesive. The interagency agreements specified that Public Aid would coordinate the duties and involvement of agency employees working on the I-Save_{Rx} Program. Our survey questionnaire asked agencies who they worked with to coordinate activities (See Exhibit 3-6).

Of the 28 agencies that responded, only 2 (7 percent) noted working with DHFS to coordinate activities, one of which also mentioned the Governor’s Office, Human Services, and Insurance-SHIP. Seventeen agencies (61 percent) said that they coordinated activities only with officials from the Governor’s Office. Five of 28 (18 percent) responded that they did not coordinate activities or did not know whom the activities were coordinated through. Of the remaining agencies, two (DHFS and the Governor’s Office) responded that they

Exhibit 3-6 COORDINATING ACTIVITIES	
Agency	Coordinated Activities With
Aging	Governor’s Office; DHS; Insurance-SHIP; DHFS
Agriculture	Governor’s Office
Capital Development Board	Governor’s Office
Central Management Services	None
Children and Family Services	Governor’s Office
Commerce and Economic Opportunity	Governor’s Office
Corrections	Governor’s Office
Emergency Management Agency	CMS
Employment Security	Governor’s Office
Environmental Protection Agency	None
Financial and Professional Regulation	Governor’s Office
Fire Marshal	None
Governor’s Office	Agencies that signed interagency agreements
GOMB	CMS
Healthcare and Family Services	Agencies that signed interagency agreements; GOMB
Historic Preservation	Governor’s Office
Housing Development Authority	Governor’s Office
Human Rights	Governor’s Office
Human Rights Commission	Governor’s Office
Human Services	Governor’s Office
Labor	Governor’s Office
Natural Resources	Unknown
Public Health	Governor’s Office
Revenue	Governor’s Office
State Police	Governor’s Office
Toll Highway Authority	None
Transportation	Healthcare and Family Services
Veteran’s Affairs	Governor’s Office
Source: OAG analysis of agency survey responses.	

coordinated with the agencies that signed interagency agreements and two agencies responded that they coordinated with Central Management Services.

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).

Agencies Participating in Promotional Activities

At the 28 agencies, 521 employees provided almost 5,600 hours of assistance for I-SaveRx promotional activities at an estimated payroll cost of over \$488,000. Actual hours worked and actual payroll costs are higher, since some agencies were unable to provide an estimate of hours worked by employees. Exhibit 3-7 shows participation by agency. Approximately half of the estimated payroll cost (\$224,000 of \$488,000) was incurred by four DHFS employees who spent a substantial amount of time on the Program. However, the total hours spent do not include the hours from these four employees of DHFS. The time spent for these employees was not broken out by hours but instead by percent of total time spent.

The totals shown in Exhibit 3-7 understate the actual costs incurred by the State for a variety of reasons. For example, 79 employees that were shown on the list from the Governor's Office as participating were no longer with their respective agency. In these cases, information on participation was not available. Also, even for employees that participated, an estimated payroll cost could not always be made. We were unable to calculate an estimated payroll cost for 151 of the 521 (29 percent) employees that participated.

Reasons for not being able to calculate an estimated payroll cost varied. Some agencies did not provide an estimate of hours worked for many employees that worked on the Program. For some employees, promotional activities were part of regular job duties and time spent related to I-SaveRx was not tracked. Other reasons for not being able to calculate an estimated payroll cost included a lack of salary information and employees that were on leave. In addition, some employees promoted the Program during non-work hours such as on the weekends at local churches. This time spent was not included in the calculations in Exhibit 3-7.

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. The source of funds to pay employees that participated varied greatly.

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.

Results of Agency Outreach

The Governor's Office provided a summary spreadsheet of agency outreach activities. The summary showed the weekly number of applications or information cards submitted by the agencies from March 2005 to March 2006. However, there was no system in place to track the results of the agency outreach. For example, once the application or information cards were submitted, whether the application became a successful enrollment was not tracked. Therefore, it was not known if the outreach was successful or which agencies were more effective in signing-up enrollees. In addition, 14 agencies that provided employees to assist in outreach were not included on the agency outreach spreadsheet.

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.

Exhibit 3-7
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	5,577.5¹	\$ 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.

PROMOTIONAL OUTREACH ACTIVITIES	
RECOMMENDATION NUMBER 7	<p><i>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.</i></p>
OFFICE OF THE GOVERNOR RESPONSE	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><i>Auditor Comment #18</i> <i>Records provided by the various State agencies involved in I-SaveRx promotional outreach indicate that all levels of employees participated in the Program activities.</i></p> </div> <ul style="list-style-type: none"> • 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.
Agency Response Continued on Next Page	

<p>Agency Response (continued)</p>	<ul style="list-style-type: none"> • 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. <p>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.</p>
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I-SAVERX PROGRAM MONITORING

The State of Illinois signed a Memorandum of Understanding (MOU) with four states allowing their residents to purchase prescription drugs through the I-SaveRx Program. As illustrated in Exhibit 3-8, the first state to join Illinois in the Program was Wisconsin followed by Missouri, Kansas, and Vermont. We 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.

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

Exhibit 3-8 OTHER STATES IN I-SAVERX PROGRAM	
State	Effective Date of MOU
Wisconsin	October 1, 2004
Missouri	October 28, 2004
Kansas	November 30, 2004
Vermont	April 11, 2005
Source: Memoranda of Understanding.	

within the first 60 days of the Program’s start date. All materials used to advertise and promote the Program were to be approved by the Governor’s Office. We requested documentation from the Special Advocate to support CanaRx’s activities using these start-up fees but officials could not provide this information.

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.

In addition, other information provided by CanaRx was circulated internally among State of Illinois officials. According to June 2005 correspondence from the prior I-SaveRx Manager for the State of Illinois, CanaRx provided the number of individuals placing orders through the Program as well as the number of new and repeat orders placed. This information was used to create a report that included information such as total enrollees, total enrollees with orders, and total enrollees and orders for each participating state. The Special Advocate stated that it was their decision to keep this report private and not release it to the press or other states. Officials said there was no real reason to distribute this information, as there was no benefit to participants. However, when we followed-up with each participating state, we found that one state had requested data related to its number of Program participants but was informed this data could not be provided on a regular basis.

Other MOU Requirements

In addition, we found the following areas of concern related to other MOU requirements in our survey of other states.

- The MOU established a Joint Work Group composed of two representatives from each participating state and listed their required activities such as determining specific types of data included in monitoring reports and when such reports should be issued. However, we found other states had minimal involvement on the Joint Work Group.
- Although the MOU invited other states to participate in pharmacy inspections, no inspections were conducted by the four participating states.
- The MOU provided some guidelines regarding Program operation requirements such as independent promotion efforts and website maintenance. However, we found that promotion efforts and Program websites varied significantly from state to state.

MONITORING ACQUISITION FUND MONIES	
<p>RECOMMENDATION NUMBER</p> <p style="font-size: 2em;">8</p>	<p><i>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.</i></p>
<p>SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS RESPONSE</p> <p style="text-align: right;">Agency Response Continued on Next Page</p>	<p>The Special Advocate for Prescription Drugs partially disagrees with this finding.</p> <p>Regarding the monitoring of the acquisition fund, the Special Advocate for Prescription Drugs does require the 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</p>

<p>Agency Response (continued)</p>	<p>to the Office of the Auditor General. This contract and the invoices are a complete summary of the money spent from the acquisition fund.</p> <div data-bbox="683 296 1325 640" style="border: 1px solid black; padding: 5px;"> <p>Auditor Comment #19 <i>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.</i></p> </div> <p>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.</p>
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Contract Provision Monitoring

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 (see Appendix C for a complete listing of the requirements). The Special Advocate is responsible for monitoring the I-SaveRx Program. We found that the Special Advocate had not adequately monitored CanaRx regarding compliance with provisions of the contract.

I-SaveRx Management Database

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.

“Audit” of CanaRx

Pursuant to Section III-19 of the contract, the Special Advocate stated they performed an “audit”, in February 2005, of CanaRx related to the I-SaveRx Program. Documentation obtained from the Special Advocate included correspondence from a CanaRx representative, which stated the Special Advocate “would be issuing a draft report concerning your findings from the audit of the I-SaveRx Program. As of this date, neither CanaRx Services Inc. nor myself have received a copy of this draft report.” In a June 2006 meeting with our Office, the Special Advocate explained that the results of the audit never became a written document; they were merely communicated verbally to CanaRx.

Without a formal audit document, it is difficult to ensure that CanaRx is aware of all audit issues. Additionally, having a formal audit report would allow third parties to verify that the Special Advocate adequately monitored CanaRx's noted areas of concern. Furthermore, without having a formal report, CanaRx could not be held responsible for fixing problems verbally communicated to them by the Special Advocate, as they could deny having been informed of an issue. In responding to whether or not CanaRx met each service requirement outlined in the contract, the Special Advocate stated that the "audit" they performed verified that the service had been met. While the Special Advocate indicated an "audit" was performed, it is difficult to verify these contract requirements were met when we cannot determine the results of this "audit".

No-Notice Pharmacy Inspections

When we inquired as to whether CanaRx had performed the 21 required elements in the contract, the Special Advocate indicated, for many of the requirements, that monitoring was performed via "no-notice" pharmacy inspections. A "no-notice" inspection would be when no prior notice was given to the pharmacy by the State before initiation of the inspection. While a "no-notice" method of inspection would be a good monitoring control, we found no documentation to support this type of inspection was actually utilized.

According to the Special Advocate, pharmacies became involved in the I-SaveRx Program through either contacting the State of Illinois and expressing their desire to be involved, or CanaRx already had contacts with the pharmacies. 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 our review of the Special Advocates files, we 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.

Monthly Reporting

Pursuant to the contract, management reports were to be provided. The Program began in October 2004. According to an official with the Special Advocate, reports showing ordering information were not provided by CanaRx until six months later, in March 2005. The March 2005 report included cumulative ordering information and CanaRx provided this type of information monthly thereafter. In responding to whether or not 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. Exhibit 3-9 provides a summary of monitoring issues.

Exhibit 3-9 CONTRACT MONITORING ISSUES CANARX AGREEMENT	
Contract Service Requirement	Monitoring Issue
<ul style="list-style-type: none"> ▪ Certify that only pharmacies and pharmaceutical entities inspected and certified by IDPR and/or IDPH or their designee and approved for participation in the network shall fill and mail prescriptions for the Illinois “I-SaveRx” Program Participants. 	<p>Lack of access to the I-SaveRx management database makes this difficult to determine.</p>
<ul style="list-style-type: none"> ▪ Maintain a history of all transactions conducted on behalf of Program Participants, and periodically report on the utilization and ordering activity of the Program Participants by prescription drugs, demographics, expense and coverage categories, as well as by source country. CanaRx, in conjunction with the Advocates, will design the management reports. CanaRx will provide the report monthly for the first nine months, at which point the Advocates may elect to adopt quarterly reporting. Management Reports will be provided in electronic format. All reports must comply with U.S. HIPAA and Canadian PIPEDA laws. 	<p>The Special Advocate claimed monthly reporting, on site audit and no notice inspections demonstrate compliance. While some overall statistics were reported by CanaRx, we saw no evidence that the Special Advocate had access to historical transactions.</p>
<ul style="list-style-type: none"> ▪ Preapprove all labeling on the filled prescriptions and all materials included in the shipping package. ▪ The Network Pharmacy shall fill all prescription orders cleared through CanaRx, unless they are unable to fill the prescription with the precise medicine that has been prescribed to the Program Participant. ▪ Ensure that fully qualified physicians, who must continuously maintain licensure under both provincial and national standards, as may be required, will review and evaluate each prescription written by a U.S. physician and/or submitted by either the Program Participant or the physician. ▪ Ensure that potential drug interactions have been screened at least once, checking not only for interactions between multiple prescriptions in the order but against all medications, herbal products, over-the-counter medications and nutritional supplements on the patient profile. 	<p>The Special Advocate reported CanaRx complied with these requirements through verification during no-notice pharmacy inspections. However, we found no documentation to support this type of inspection was actually utilized.</p>
<ul style="list-style-type: none"> ▪ CanaRx contracted physicians will address any uncertainty or identified questions with the Program Participant or U.S. attending physician prior to rewriting and re-issuing the prescription. ▪ Ensure that only those prescription drugs that are approved by the State and communicated to CanaRx by the Advocates will be filled by their Network Pharmacies for the I-SaveRx Program Participants. ▪ Maintain with all of its Network Pharmacies the right and capability to audit inventory and invoices to assure all dispensed prescriptions are from the domestic supply approved for sale in each program country. 	<p>The Special Advocate stated compliance was established through the on site audit and no-notice pharmacy inspections. However, we found no documentation to support this type of inspection was actually utilized, and the audit never became a written document.</p>
<p>Source: OAG summary of CanaRx contract and Special Advocate information.</p>	

CanaRx Insurance

The Special Advocate informed CanaRx they were in material breach of the contract because Section VII.1 (Insurance) 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, this section referred to additional coverage and was available when the contract was being written, but not when CanaRx tried to acquire the insurance. Originally there was additional coverage for the pharmacists, but never for the physicians. According to the Special Advocate, the insurance carrier dropped additional coverage for the pharmacists as well. 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. When asked if CanaRx was in breach of the contract since its inception with respect to the insurance issue, a clause that CanaRx agreed to when it signed the contract, the Special Advocate stated they would have been in breach since the beginning.

CONTRACT MONITORING PROVISIONS	
<p>RECOMMENDATION NUMBER</p> <p style="font-size: 2em;">9</p>	<p><i>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:</i></p> <ul style="list-style-type: none"> ▪ <i>having access to the I-SaveRx pharmacy benefit manager management database in order to allow for better monitoring;</i> ▪ <i>conducting no-notice pharmacy inspections; and</i> ▪ <i>performing and documenting an audit of the I-SaveRx Program.</i>
<p>SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS RESPONSE</p>	<p>The Special Advocate for Prescription Drugs agrees, and as a result, has consistently monitored the I-SaveRx Program in the following ways:</p> <p>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.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Auditor Comment #20 <i>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.</i></p> </div> <p>Inspections and Audits. The Special Advocate for Prescription Drugs will continue to conduct no-notice inspections and will implement</p>
<p>Agency Response Continued on Next Page</p>	

<p>Agency Response (continued)</p>	<p>procedures to ensure that all future audits and inspections are adequately documented.</p> <div style="border: 2px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p><i>Auditor Comment #21</i> <i>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.</i></p> </div>
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PROGRAM COSTS

While CanaRx is not paid for its services by the State under the contract, we found that there have been significant expenditures of State funds for travel, contractual services, and marketing associated with the Program. State agency personnel have accumulated over \$111,000 in travel expenses, mainly from out-of-country travel and use of State aircraft, in support of a drug importation program. We also found that most travel was not approved prior to departure as stated in travel regulations. We identified \$10,662 in excessive per diem reimbursement to six State employees traveling as part of the I-SaveRx Program.

The State has paid \$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 Program that we were able to identify during the course of the audit. The major cost was a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate's Office.

Travel

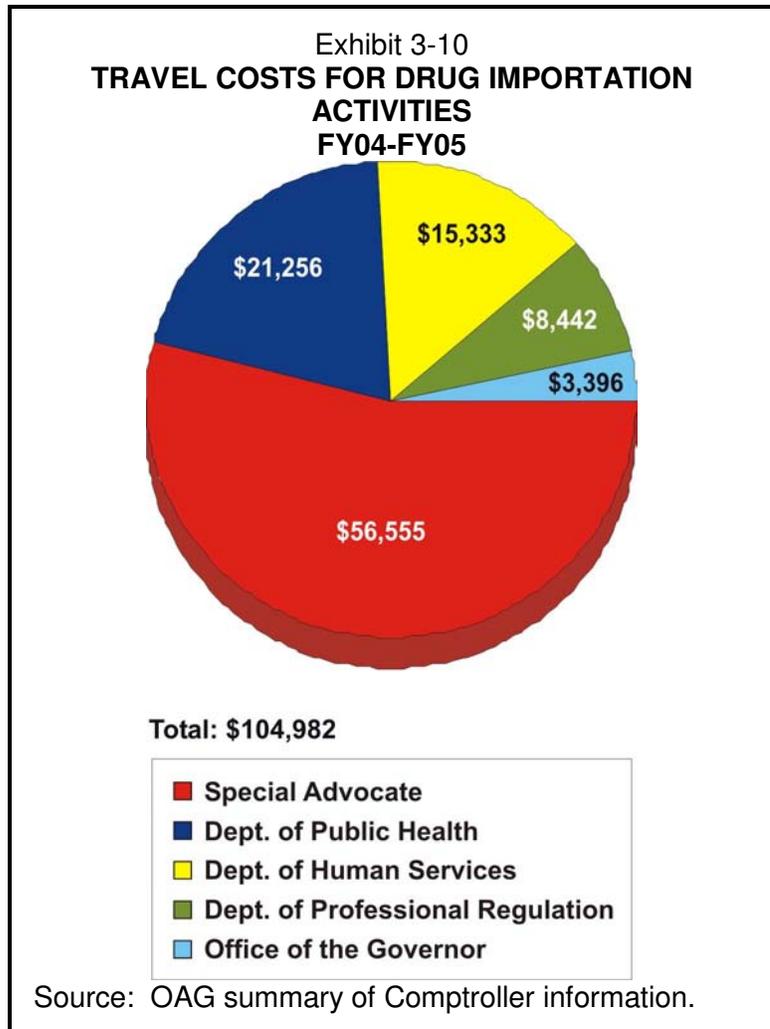
The State paid a total of \$104,982.07 in travel reimbursement costs for the I-Save_{Rx} Program. This total is a conservative amount in that not all agencies were able to provide complete travel information to us. Travel purposes ranged from a Governor’s fact-finding mission to Canada for a drug importation 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. Agency travel costs are presented in Exhibit 3-10. In addition to the amounts listed in the Exhibit are costs to use State aircraft totaling \$6,384.85.

These individuals traveled to locations such as Canada, Europe, Australia, and New Zealand, as well as locations within the United States. The most costly of the trips were two out-of-country trips that included pharmacy inspections. These two trips cost the State more than \$58,000, over half of the total travel cost for the I-Save_{Rx} Program.

The more costly of the two trips was a trip to the United Kingdom and Europe from May 3, 2004 to May 15, 2004. Nine employees from five State agencies made the trip to Europe. Over the 13 days of the trip, the nine employees accumulated \$37,050.51 in costs. Specifically, the individuals visited Dublin, Glasgow, London, Paris, Brussels, and Amsterdam and investigated and inspected pharmacies and wholesale drug distributors for the I-Save_{Rx} Program. Of the nine State staff on the trip, only three were involved in the pharmacy inspection activity.

The second trip consisted of a trip to Australia and New Zealand from February 11, 2005 to February 23, 2005, totaling \$21,661.37. This time, only four employees from three agencies participated. Specifically, the trip consisted of visiting and inspecting pharmacies in places such as Sydney, Melbourne, and Auckland.

Total out-of-country travel for pharmacy inspections totaled almost \$84,000 for the period October 7, 2003 to April 29, 2005. While costs for pharmacy inspections contributed to 80 percent of the total travel costs for the Program, documentation indicated that there were limited



pharmacies even filling prescriptions throughout the course of the Program. In its first quarterly report – for the period of October 2004 through December 2004 – CanaRx reported that **only two pharmacies were actively filling** prescriptions. **Over a year later**, in January 2006, there were still only two pharmacies dispensing medications – one from Canada and one from the UK. CanaRx officials viewed the expansion into Australia and New Zealand as unnecessary. The Special Advocate and other State officials disagreed and added more pharmacies to the Program.

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. The Special Advocate added that it was good to have numerous pharmacies able to fill prescriptions in case one pharmacy were to get suspended because of a complaint.

Out-of-Country and Out-of-State Travel Approval

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 – 68 percent – **never received** required approval from the Governor's Travel Control Board at any point in time.

The Governor's Travel Control Board delineates specific guidelines that State employees must follow when traveling in its "Travel Guide for State Employees." Specifically, in the March 27, 2003 Travel Update, the Board laid out specific requirements for all out-of-state and out-of-country travel. Exhibit 3-11 outlines these requirements.

<p>Exhibit 3-11 GOVERNOR'S TRAVEL CONTROL BOARD 2003 TRAVEL UPDATE</p>
<p><i>Out-of-State:</i> "All requests for travel outside the borders of the State of Illinois must be received by the Bureau of the Budget not later than three (3) weeks prior to the anticipated departure date. The Bureau of the Budget will provide a recommendation to the Office of the Governor for a final decision."</p>
<p><i>Out-of-Country:</i> "... all requests for travel outside the contiguous United States must be submitted at least 30 days in advance of the departure date. The Bureau of the Budget will provide a recommendation to the Office of the Governor for a final decision. The Bureau will notify the Governor's Travel Control Board of the approval or denial of each request. The Board will notify the agency."</p>
<p>Source: Travel Control Board's 2003 Travel Update.</p>

The Board also released a 2005 Travel Guide for State Employees that contained similar language. It required the approval of the Chairman of the Governor's Travel Control Board prior to all out-of-country travel. It stated that all requests were to be submitted **at least 30 days in advance** of the departure date.

In our examination of 52 out-of-country and out-of-state travel vouchers relating to the drug importation/I-SaveRx Program, 51 vouchers were deficient in seeking approval for the travel prior to the actual departure. Forty Exception Requests were submitted by agencies but were late

anywhere from 6 to 175 days. For the additional 11 vouchers examined we could not determine timely pre-approval because Exception Requests did not exist for six of the vouchers and Exception Requests were not dated for the remaining five vouchers.

Another problem existed in terms of getting required prior approval by both the Office of the Governor and the Board. Agencies did not receive appropriate approval before the travel commenced in 94 percent of the vouchers examined (49 of 52). In terms of out-of-country travel, no approval from the Board was granted at any time in over two-thirds (27 of 40) of the vouchers examined. Out-of-country travel represented more than \$97,000 of the \$104,982.07 of total travel costs examined.

Per Diem/Meals Overpayments

Of the \$105,000 in travel costs incurred by the State for the drug importation/I-Save_{RX} Program, \$10,662 (10 percent) was a result of overpayments in meals and per diem reimbursements to six State employees. According to the Board’s 2005 Travel Guide for State Employees, individuals are entitled to \$32.00 per day for travel outside the State of Illinois. However, these six employees used a federal reimbursement rate up to \$138 per day. No exceptions to the Governor’s Travel Control Board regulations were filed for this excess per diem. Exhibit 3-12 summarizes the total per diem overpayments by agency. Not all State employees that traveled out-of-country used the federal rate utilized by these six individuals; they used the travel guide amount.

An examination of the out-of-country travel vouchers showed that two out-of-country trips accounted for more than \$6,300 of the total overpayments. In February 2005, four individuals traveled to Australia and New Zealand to inspect and certify pharmacies, as previously mentioned. During this 13 day trip that cost the State over \$21,000 in total cost, per diem was overpaid by almost \$3,400.

Exhibit 3-12 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 second trip consisted of nine employees going to Europe in May 2004. While travel costs for these nine individuals cost the State over \$37,000, overpayments for per diem were nearly \$3,000 for just three employees on this trip. Six of the nine employees were correctly reimbursed the \$32 allowance each day. However, three individuals received payments exceeding \$130 a day for per diem while on the 13-day trip. Total reimbursement for meals and per diem alone for these three individuals reached nearly \$4,400, as a result of using federal reimbursement rates.

Funds Used to Reimburse for Travel

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. All fees (licensure, renewal and restoration) collected under the Wholesale Drug Distribution Licensing Act are deposited into the Illinois State Pharmacy Disciplinary Fund **for the ordinary and contingent expenses of the Department of Financial and Professional Regulation in the administration of the Act.** Out-of-country pharmacies do not pay into this fund and are also not licensed under the Pharmacy Practice Act, which Illinois pharmacies must adhere to. All of these funds were used to pay for trips to Canada and Europe. More than \$6,600 was appropriated from the Fund to pay for three trips to Canada and over \$10,600 was used for travel to Europe. Of these totals, one individual took three trips to Canada, costing more than \$3,300. The same individual inspected pharmacies in Europe, this time drawing on more than \$3,600 from the Fund.

TRAVEL	
<p>RECOMMENDATION NUMBER</p> <p>10</p>	<p><i>With respect to travel:</i></p> <ul style="list-style-type: none"> ▪ <i>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 it's 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;</i> ▪ <i>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 it's staff follow travel regulations when being reimbursed for per diem when traveling out of country, or seek appropriate exceptions to the travel regulations; and</i> ▪ <i>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.</i>
<p>AGENCY RESPONSES</p> <p>Agency Responses Continued on Next Page</p>	<p>The Office of the Governor's agreement with this recommendation is limited to certain aspects, identified below.</p> <p>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.</p>

**Agency Responses
(continued)**

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. The Office of the Governor, Special Advocate, and the Department of Financial and Professional 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.**

Legal Costs

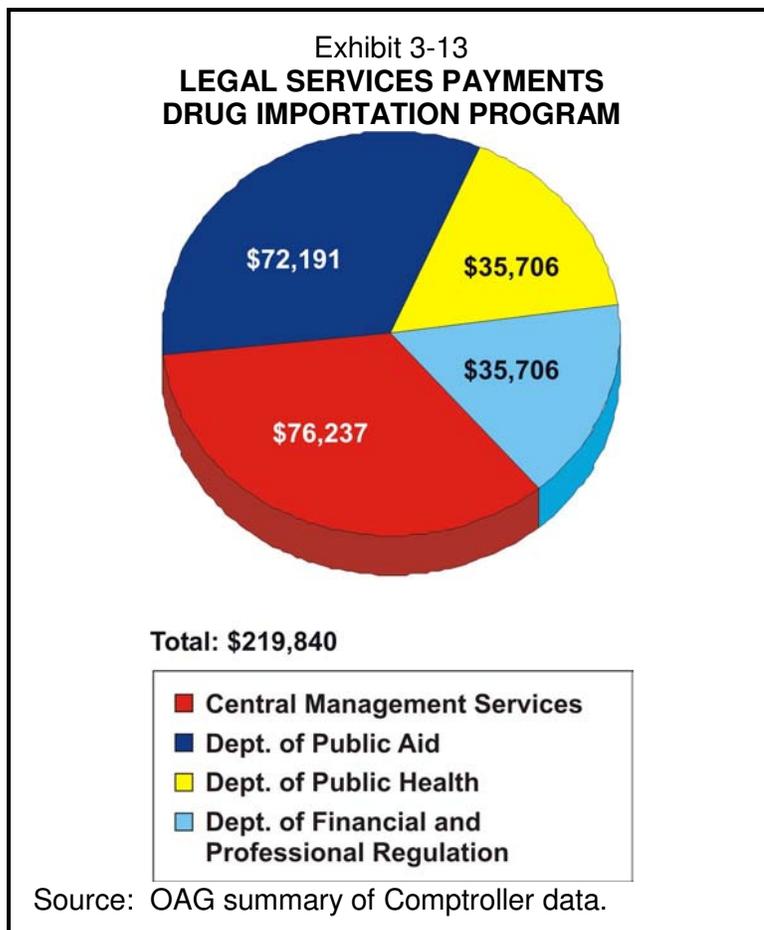
During FY05 the Governor’s Office entered into an agreement with a Washington D.C. based law firm to provide legal services to the State relative to the drug importation program. Through February 15, 2006, State agencies had paid this vendor \$144,000 for legal services related to drug importation. This included State funds paid in penalty under the State Prompt Payment Act. Additionally, the Department of Central Management Services paid another vendor \$76,000 in legal fees for advice relating to a proposed Canadian Drug purchasing program. Exhibit 3-13 provides a breakdown of spending by agency.

Relative to the drug importation program, the Washington D.C. based firm was to **“review Illinois’ prescription drug importation program”** and again represent the State in any enforcement action brought by the federal Food and Drug Administration.

The vendor services were not competitively procured due to an exemption in the Procurement Code (30 ILCS 500/1-10 (b)(7)) that was authorized by the Governor’s Acting General Counsel. This exemption relates to the anticipation of potential litigation. The vendor was to be compensated at a rate of \$350 per hour. An official from the Governor’s Office stated that no litigation was ever initiated by the federal government under this contract.

The contract contained no scope of services section nor tasks or deliverables due to the State. An official from the Governor’s Office indicated that the firm took direction from officials in the Governor’s Office and the Special Advocate.

On October 1, 2004, **Interagency Agreements** were entered into between the Office of the Governor and the Departments of Public Aid, Public Health, and Financial and Professional Regulation (DFPR) pursuant to the Intergovernmental Cooperation Act (5 ILCS 220). The agencies agreed to make all payments to the firm under the agreements. For the drug importation review: 50 percent of the payments were allocated to Public Aid; 25 percent to Public Health; and 25 percent to Financial and Professional Regulation.



Financial and Professional Regulation utilized the Professions Indirect Cost Fund to pay the firm almost \$36,000. Moneys in this fund are “to pay the ordinary and necessary allocable indirect expenses associated with each of the regulated professions, trades, occupations, and industries.” (20 ILCS 2105/2105-300 (b)) The Professions Indirect Cost Fund is generally comprised of transfers of fines and fees associated with the individual professions. (20 ILCS 2105/2105-300 (b)) Public Aid paid over \$72,000 in firm billings from the Public Aid Recoveries Trust Fund.

The *role* of the Governor’s Office, as stated in the interagency agreement, was to act as the coordinating agency “responsible for the preparation of the underlying contract, centralizing communications between the firm and the Agencies, offering guidance and direction relating to the drug importation program and other administrative functions in connection with these legal services.” The Interagency Agreements expired June 30, 2005.

Central Management Services

In August 2004, the Department of Central Management Services (CMS) executed a contract with a firm to provide legal advice relating to a proposed Canadian drug purchasing program to minimize its potential legal and financial exposure. While the contract initially began in October 2003, the firm did not sign and return the contract until July 2004. From October 2003 through October 2004, CMS paid the firm \$76,237.50 for these legal services. The firm was compensated at a rate of \$285 per hour.

CMS reported that the purchasing of imported drugs was one of the cost cutting initiatives proposed by the Governor and CMS was charged with exploring the possibility of such a program. The invoices for services were initially approved by the Governor’s Office.

The vendor services were not competitively procured due to an exemption in the Procurement Code (30 ILCS 500/1-10) approved by the Governor’s Chief Legal Counsel at CMS’ request. This exemption is used to prepare for anticipated litigation, enforcement actions, or investigations.

While the State spent \$220,000 on legal services, for two legal firms, that were exempt from the competitive processes of the Procurement Code, there has not been any instance of litigation, enforcement actions, or investigations.

Marketing

The State incurred additional marketing costs for the I-Save_{Rx} Program. During FY06 the State, through the Department of Healthcare and Family Services (DHFS), paid \$51,514 for marketing efforts. These activities included direct mailings of I-Save_{Rx} materials as well as advertising in a major Internet search engine. An official from the Department of Human Services also estimated that his agency had paid \$2,938.50 in printing costs for enrollment packets, applications, and enrollment cards for the I-Save_{Rx} Program.

Between November 30, 2005 and January 11, 2006, an I-Save_{Rx} marketing group met to discuss additional ways to publicize the Program. The group was comprised of staff from the

Governor's Office and the Office of the Special Advocate. A major group marketing effort was to be a direct mailing of 350,000 materials. Committee meeting minutes from the January 4, 2006 meeting show that the Deputy Governor made a couple of changes and then approved the material. At the January 11, 2006 meeting, it was reported that printing on this material would commence that week. The total project cost was to be between \$78,000 and \$95,485 – with the printing cost to be done as a small dollar purchase and the postage to be paid by DHFS. However, on May 25, 2006, the Governor's Office reported to us that "This mailing campaign was never started, nor was it completed."

Other Costs

The State has incurred other contractual service costs totaling \$71,018 relative to the operation of the I-SaveRx Program that we were able to identify during the course of the audit. The major cost was a contractual employee hired to manage the day-to-day activity of the Program within the Special Advocate's Office.

Even though the contract was not executed until November 2004, the Special Advocate hired a contractual employee to assist in the management of the I-SaveRx Program with a term beginning September 28, 2004 through June 30, 2005. This contractual employee was paid \$46,800 in gross wages through the end of his contract. According to the Special Advocate, this position was not filled during FY06, but the activities were absorbed by the Special Advocate and other staff within his office.

The Special Advocate also contracted with an individual to provide technical policy writing assistance for the European report on importing prescription drugs. The contractor was paid a flat \$12,350 at the completion of the report. The contract was not executed by the Department of Public Aid until October 14, 2004 – 16 days prior to the end of the agreement's term. In an affidavit, the Special Advocate stated the contract was not reduced to writing before services commenced because "expediency was required due to an abbreviated time span between the assignment date and the deadline for the product, which was commissioned by the Governor." We did not see credit provided for this contractor's work in the report.

The Special Advocate contracted with an individual to provide research, writing, and editing services for the prescription drug importation program. The contract, executed by the Department of Public Aid on November 8, 2004, was for FY05. Pay documentation showed that the State expended \$8,345 for this assistance for the drug importation program.

An interagency agreement between the Department of Central Management Services and Public Aid supplied two marketing managers from CMS to assist in the outreach campaign for the I-SaveRx Program. While the term of the agreement was for the period December 13, 2004 through December 31, 2005, the parties did not execute the agreement until June 2005. The two CMS staff were to work for Public Aid 20 percent time for these activities and CMS was to bill for their services/expenses. While we did not find that CMS billed for the services, the two marketing staff were paid a total of \$21,739.85 for services that related to the drug importation program.

Lastly, the Special Advocate hired contractual temporary help to answer phones for a physicians toll free number set up for the I-SaveRx Program. These two temporary staff were paid

a total of \$3,522.75. The Special Advocate indicated the toll free line was eliminated because they did not have sufficient call volume.

APPENDIX A
House Resolution No. 394



STATE OF ILLINOIS
NINETY-FOURTH GENERAL ASSEMBLY
HOUSE OF REPRESENTATIVES

House Resolution No. 394

Offered by Representative Jack D. Franks

WHEREAS, In January 2005, the State of Illinois, through its representatives in the Office of the Governor, signed a \$2.6 million contract with Ecosse Hospital Products Limited of England for the purchase of 300,000 doses of influenza vaccine; and

WHEREAS, The start date on the contract was retroactive to October 20, 2004; and

WHEREAS, The State of Illinois has not received the contracted-for vaccine; and

WHEREAS, In October 2004, the I-SaveRx program was created to allow Illinois citizens to obtain prescription drugs through a network of pharmacies in Canada, the United Kingdom, and Ireland; and

WHEREAS, In Executive Order 2003-15, the Governor established a Special Advocate for Prescription Drugs; and

WHEREAS, The Office of the Governor and the Special Advocate for Prescription Drugs have been involved in the flu vaccine procurement process and in the I-SaveRx and other prescription drug programs; and

WHEREAS, There are questions concerning the State's obligation to pay on a contract for which the purchased goods were not received and for which the State did not receive any benefit; and

WHEREAS, Enrollment in the I-SaveRx program has been low; therefore, be it

RESOLVED, BY THE HOUSE OF REPRESENTATIVES OF THE NINETY-FOURTH GENERAL ASSEMBLY OF THE STATE OF ILLINOIS, that the Auditor General shall 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; and be it further

RESOLVED, That the audit include, but not be limited to, the following determinations:

(1) The roles played by the Office of the Governor and the Special Advocate for

Prescription Drugs in negotiating and entering into the flu vaccine contract;

(2) The procedures applicable to, and agencies responsible for, the establishment and

operation of the I-SaveRx program; and

(3) Whether the entities involved in these programs followed all applicable laws,

regulations, policies, and procedures; and be it further

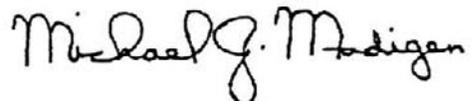
RESOLVED, That the Office of the Governor, the Office of the Special Advocate for

Prescription Drugs, and any other entity that may have relevant information pertaining to this audit cooperate fully and promptly with the Auditor General's Office in the conduct of this audit; and be it further

RESOLVED, That the Auditor General commence this audit as soon as possible and report his

findings and recommendations upon completion in accordance with Section 3-14 of the Illinois State Auditing Act.

Adopted by the House of Representatives on May 30, 2005.



Michael J. Madigan, Speaker of the House



Mark Mahoney, Clerk of the House

APPENDIX B

Audit Methodology

AUDIT METHODOLOGY

This audit was conducted in accordance with generally accepted government auditing standards and the audit standards promulgated by the Office of the Auditor General at 74 Ill. Adm. Code 420.310.

The audit objectives for this management audit were those as delineated in House Resolution Number 394, which directs the Auditor General to conduct a management audit of the flu vaccine purchase and the I-SaveRx Program. Fieldwork for the audit was completed in June 2006.

We reviewed applicable federal and State laws pertaining to procurement and importation of drugs into the United States. We reviewed compliance with those laws to the extent necessary to meet the audit's objectives. Any instances of non-compliance we identified or noted are included in this report.

We also reviewed management controls and assessed risk relating to the audit's objectives. A risk assessment was conducted to identify areas that needed closer examination. Any significant weaknesses in those controls are included in this report.

During the audit, we met with staff from the Office of the Governor and the Office of the Special Advocate for Prescription Drugs as named entities in House Resolution Number 394. Additionally, we met with staff from State of Illinois agencies that also played roles in the flu vaccine procurement and I-SaveRx Program. These agencies included the Department of Financial and Professional Regulation, the Department of Healthcare and Family Services (formerly the Department of Public Aid), the Department of Public Health, and the Department of Central Management Services. We also contacted and received information from the Department of Human Services.

We contacted the other governmental entities that received billings for flu vaccine from Ecosse Hospital Products Ltd. These other government agencies were the Kansas Department of Health and Environment, the Tennessee Department of Health, the New Mexico Department of Health, the Department of Public Health from the City of Cleveland, Ohio, and the Department of Health and Mental Hygiene of New York City.

We also contacted the other states that are involved in the I-SaveRx Program. We interviewed and received documentation from representatives of the states of Wisconsin, Kansas, Missouri, and Vermont. Additionally, we contacted the federal Food and Drug Administration to obtain background on the two audit issues.

In order to determine the extent of using State agency personnel to promote the I-SaveRx Program, we surveyed 28 State agencies, identified by the Office of the Governor, which had staff participate in promotional activity. We calculated a cost of using State personnel to promote the I-SaveRx Program.

We examined all contracts, memoranda of understanding, and interagency agreements applicable to the audit objectives. Additionally, we reviewed all files at the Office of the Special Advocate for Prescription Drugs relative to the flu vaccine procurement and I-SaveRx Program. The entity that entered into the agreement with Ecosse Hospital Products Ltd. for the flu vaccine, the Office of the Governor, did not maintain a procurement file for that transaction. We did review a procurement file at the Department of Healthcare and Family Services that contained information on the attempted purchase of the flu vaccine.

APPENDIX C
CanaRx Services, Inc.
Contract Requirements

CanaRx Services, Inc.

Contract Requirements

Section III. Scope of Services

CanaRx will provide the following services:

1. CanaRx will contract with licensed pharmacies in the countries approved by the State for dispensing medications on the Drug List to Program Participants.
2. CanaRx will certify that only pharmacies and pharmaceutical entities inspected and certified by IDPR and/or IDPH or their designee and approved for participation in the network shall fill and mail prescriptions for the Illinois “I-SaveRx” Program Participants.
3. CanaRx is responsible for ensuring that the approved entities participating in the CanaRx network continue to operate in compliance with the State’s standards. CanaRx further commits that any failure of a network pharmacy or pharmaceutical entity to meet the State’s standards shall be both reported to the State within twenty-four (24) hours of discovery and immediately suspended until review by the Office of the Special Advocate for Prescription Drugs, which may result in either reinstatement or exclusion from participation in the Program.
4. CanaRx will ensure that this international provider network prioritizes all Illinois “I-SaveRx” Program Participants prescriptions before any other similar program.
5. CanaRx will make available and maintain for Program Participants operational access to an interactive Website on which there are links and pages for the sole use of Program Participants who have accessed it via the I-SaveRx site. At least one page will enable a program Participant to easily compare prescription prices from appropriate countries, initially specified as Canada, the United Kingdom and Ireland. The Website will maintain interactive software that will accept multiple price quote requests and through an algorithm to recommend to the Program Participant the lowest overall cost of the prescriptions when ordered from a single source.
6. CanaRx will act to ensure that the average prescription processing time upon receiving a Clean Prescription will be 10 business days or less, in the absence of backorders, out-of-stock items or other cause of untoward delay, that prescription will be filled promptly and professionally and shipped by the designated network pharmacy. The consumer shall receive prompt notification of any delay.
7. CanaRx shall require the network pharmacies to arrange for customer delivery of prescriptions by means of prepaid shipping services using the information provided by CanaRx. These services must include delivery-tracking processes available to CanaRx personnel and the Program Participant.

8. The shipping fees are listed in Schedule C of this Agreement. Any increase to the shipping fees during the term of this agreement must be communicated to the State 10 days prior to implementation and must be justified by a documented increase in shipping costs.
9. All labeling on the filled prescriptions and all materials included in the shipping package must be as pre-approved by CanaRx and must meet the standards prescribed in Schedule A. No more than one individual's prescriptions may be included in any package shipped.
10. The Network Pharmacy shall fill all prescription orders cleared through CanaRx, unless they are unable to fill the prescription with the precise medicine that has been prescribed to the Program Participant.
11. CanaRx will ensure that fully qualified physicians, who must continuously maintain licensure under both provincial and national standards, as may be required, will review and evaluate each prescription written by a U.S. physician and/or submitted by either the Program Participant (as an original) or faxed by the U.S. prescribing physician. The submitted prescription will be evaluated in terms of the medicine, the Program Participant's history as presented and maintained on file, for drug-drug, drug-allergy, interactions with any other medications, supplements, and herbal products used by the Program Participant, and to ascertain that the prescription is a renewal and not a first time use of the medicine.
12. CanaRx will ensure that potential drug interactions have been screened at least once, checking not only for interactions between multiple prescriptions in the order but against all medications, herbal products, over-the-counter medications and nutritional supplements on the patient profile. The network physician and pharmacy shall have access to the complete and current patient profile under the terms of CanaRx's agreement (Pharmacy Referral Agreement).
13. The CanaRx contracted physicians will address any uncertainty or identified questions with the Program Participant or U.S. attending physician prior to rewriting and re-issuing the prescription.
14. CanaRx will ensure that only those prescription drugs that are approved by the State and communicated to CanaRx by the Advocates will be filled by their Network Pharmacies for the "I-SaveRx" Program Participants. CanaRx will handle no orders for refrigerated items, controlled medication or narcotics, biological products, an infused drug, an intravenously injected drug, a medication that is inhaled during surgery, or a parenteral drug manufactured through biotechnology processes unless approved in writing by both Parties.
15. CanaRx will maintain a history of all transactions conducted on behalf of the Program Participants, and will periodically report on the utilization and ordering activity of the

Program Participants by prescription drugs, demographics, expense and coverage categories, as well as by source country. CanaRx in conjunction with the Advocates will design the management reports. CanaRx will provide the report monthly for the first nine months, at which point the Advocates may elect to adopt quarterly reporting. Management Reports will be provided in electronic format. All reports must comply with U.S. HIPAA and Canadian PIPEDA laws.

16. CanaRx will maintain active licensure files of the physicians who are engaged in re-prescribing, copy of active license of each Network Pharmacy and of the managing pharmacists responsible for each Network Pharmacy. These files will be regarded as proprietary, but may be audited by the State or its designee.
17. On-site inspections of the pharmacies and pharmaceutical entities by the State or on behalf of the State may be conducted with or without advance notice. Following the initial inspection of a pharmaceutical entity, re-inspections may be conducted periodically. Physical and/or electronic files relating to all aspects of services performed by the Network pharmacy under this Agreement will be available to the State's inspectors or auditors.
18. CanaRx will provide a fully functional software system that will include the ability to process Program Participant cash payments (credit card, money order, etc.) and store all data integral to the system. Daily system backups of all data will be stored in two off-site locations.
19. Financial auditing of the "I-SaveRx" Program will be provided after a two week notice to CanaRx. Audit documents will be limited to the Illinois "I-SaveRx" Program only.
20. CanaRx will maintain with all of its Network Pharmacies the right and capability to audit inventory and invoices to assure all dispensed prescriptions are from the domestic supply approved for sale in each program country. Parallel imported products from Ireland may be dispensed through the United Kingdom Network pharmacies.
21. In accordance with Section VI-4-D, \$1,000,000 USD for advertising is budgeted to be paid out of the Illinois Acquisition Fee Fund in the first (9) months of this program. CanaRx will pre-fund \$300,000 USD in the first 60 days of this program. It is understood that, after the first 60 days, any additional advertising costs will be paid out of the Illinois Acquisition Fee Fund.

It is further understood that priority will be given by the fund to repayment of the CanaRx advertising expenditures, as per Schedule C. All materials used to advertise/promote this program must be approved by the Governor's office and CanaRx and must have the union bug affixed. The Governor's names and seals for the States of Illinois and Wisconsin may be affixed as well.

APPENDIX D

Agency Responses

Note: This Appendix contains the complete written responses of the Office of the Governor, Special Advocate, and Departments of Financial and Professional Regulation, Human Services, and Public Health. When Auditor Comments are included, the Agency's responses appear on the left-hand pages and the Auditor Comments appear on the right-hand pages.

Recommendation #1

- *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 procurement led by the State of Illinois.*
- *Maintain appropriate contract files with a clear written determination when there is a need for an emergency procurement.*

Response:

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.

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.

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 Comments

#1

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.

#2

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.

#3

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.

Recommendation #2

The Office of the Governor should take steps to obtain the necessary approval from appropriate federal authorities, when such approval is required, prior to committing State resources to procurements.

Response:

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

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)

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 Comments

#4

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.

#5

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 (see agency notation below dated 11/24/04).

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.

Auditor Comments

#6

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.

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 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 Comments

#7

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.

Recommendation #3:

The Department of Financial and Professional Regulation should 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.

Response:

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.**

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 Comments

#8

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.

#9

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.

Recommendation #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;*
- *Are reviewed by someone other than the person who performed the initial inspection.*

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.**

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.**

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 Comments

#10

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.

#11

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.

#12

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.

Recommendation #5

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

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.

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.

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.

Auditor Comments

#13

Auditor Comment13: 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.

#14

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.

Recommendation #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.

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
- Manufacturing requirements
- Storage requirements
- Distribution requirements
- Dispensing requirements
- Packing requirements
- Pricing systems

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.

Auditor Comments

No Auditor Comments have been included for this page.

Standard	MEDCO¹	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 ²	Approximately 1% of all orders have been tested by the US Food and Drug Administration

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.

¹ MEDCO is the current Pharmacy Benefits Manager (PBM) for the State of Illinois Group Insurance Programs. Information on MEDCO standards was obtained from the current MEDCO contract with CMS.

² Ingredient testing in the United States does not occur once the drug enters the supply chain.

Auditor Comments

#15

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.

#16

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.

#17

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.

Recommendation #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.

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.
- 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

Auditor Comments

#18

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.

federally funding within the amount allowable under the federal regulations of the program.

Auditor Comments

No Auditor Comments have been included for this page.

Recommendation #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.

Response:

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

Regarding the monitoring of the acquisition fund, the Special Advocate for Prescription Drugs does require the 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.

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.

Auditor Comments

#19

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.

Recommendation #9

The Special Advocate should perform and document adequate monitoring of the pharmacy benefit manager for the I-SaveRx Program to ensure that 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*

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.

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 Comments

#20

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.

#21

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.

Recommendation #10

- A. *The Office of the Governor, Special Advocate, and the Department of Human Services, Financial and Professional Regulation and Public Health should take the steps necessary to ensure that their 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.*
- B. *The Office of the Governor, Special Advocate, and the Department of Financial and Professional Regulation and Public Health should take the steps necessary to ensure that their staff follows travel regulations when being reimbursed for per diem when traveling out of the country, or seek appropriate exceptions to the travel regulations.*
- C. *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 subject to the State Pharmacy Act and would not be considered ordinary and contingent expenses of the Department.*

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.**
- B. The Office of the Governor, Special Advocate, and the Department of Financial and Professional 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.
- 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.**

Auditor Comments

#22

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

#23

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.