REPORT DIGEST

MANAGEMENT AUDIT OF THE

FLU VACCINE PROCUREMENT AND THE I-SAVERX PROGRAM

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State of Illinois
Office of the Auditor General

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

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.

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

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.

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…."

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

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.

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

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)

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."*

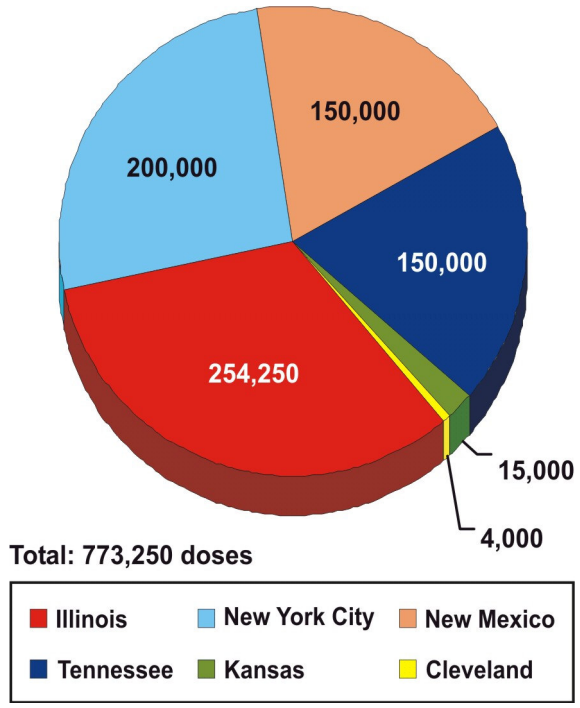
Additionally, staff from the Special Advocate's Office asked another Public Aid official on November 10, 2004, *"We need to know if there is any way to expedite payment to the vendor. Can payment be made followed by paperwork?"* Per the Procurement Code, the Comptroller may process no payments before 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.

Digest Exhibit 1
DOSES OF FLU VACCINE BILLED BY ECOSSE TO EACH GOVERNMENT
January 11, 2005



Source: OAG summary of Ecosse billing invoices.

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.

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

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

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)

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

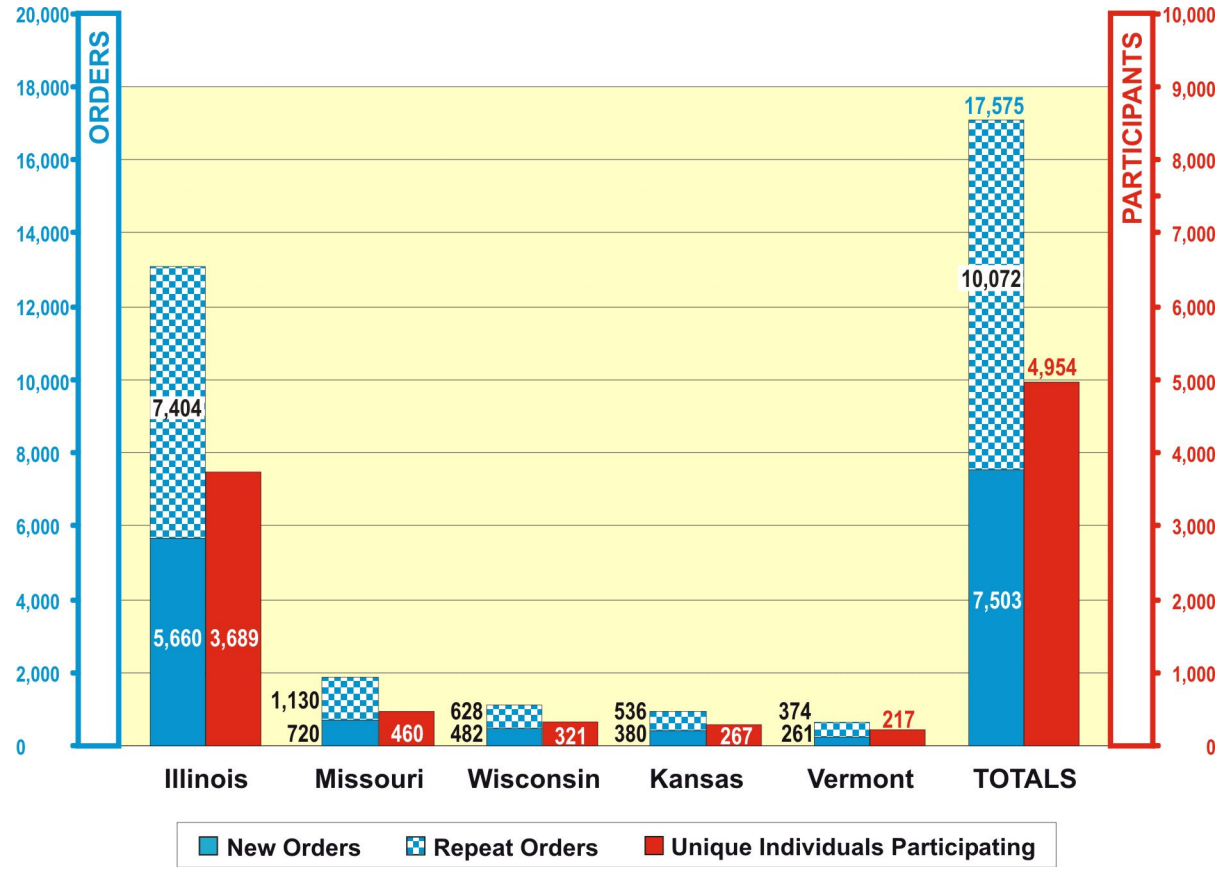
The State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law. Drugs are approved for use in the United States pursuant to the provisions of federal law as stated in the Federal Food, Drug and Cosmetic Act (FD&C Act). Among the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

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

Multiple agencies have been involved in the development and operation of the I-SaveRx 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-SaveRx Program – CanaRx.

The Governor's Office also coordinated outreach activities for the I-SaveRx 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-SaveRx 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.

I-SaveRx pharmacists are not licensed in Illinois.

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, 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."*

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

28 State agencies performed promotional activities.

- 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

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

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.

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

- 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.

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

- 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**	**5,577.5[1]**	**$ 488,262.08**	

Notes:

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

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

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

Source: OAG analysis of agency survey responses.

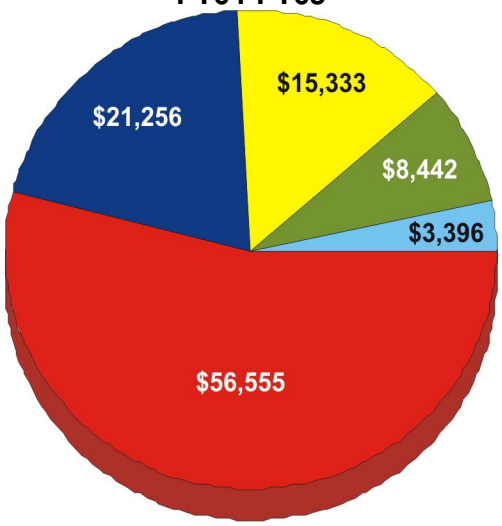
PROGRAM COSTS

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.

Digest Exhibit 4
TRAVEL COSTS FOR DRUG IMPORTATION ACTIVITIES FY04-FY05



Total: $104,982

- Special Advocate
- Dept. of Public Health
- Dept. of Human Services
- Dept. of Professional Regulation
- Office of the Governor

Source: OAG summary of Comptroller information.

- 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.

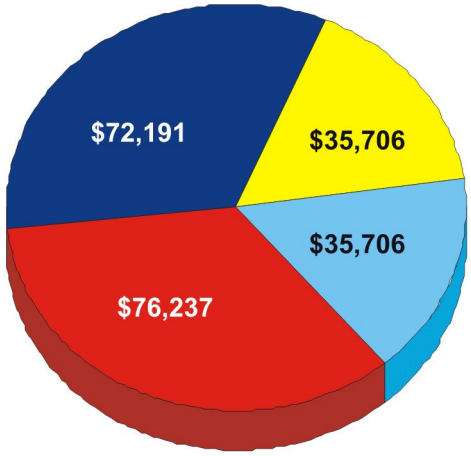
- The Department of Human Services also estimated that the agency had paid $2,938.50 in printing costs for enrollment packets, applications, and enrollment cards for the I-SaveRx Program.
- The Special Advocate hired a contractual employee to assist in the management of the I-SaveRx Program with a term 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)

Digest Exhibit 5
LEGAL SERVICES PAYMENTS
DRUG IMPORTATION PROGRAM



Total: $219,840

- Central Management Services
- Dept. of Public Aid
- Dept. of Public Health
- Dept. of Financial and Professional Regulation

Source: OAG summary of Comptroller data.

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

WGH\MJM
September 2006