



# AUDITOR GENERAL

## WILLIAM O. MONROE, CPA



### DEPARTMENT OF HEALTH

### PHARMACEUTICAL CONTRACTS

#### Operational Audit

#### SUMMARY

The Department of Health is responsible for the State's public health system and as such is authorized to provide pharmacy services through Statewide contracts. Our audit included the Department's contract with the State of Minnesota for membership in the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) and the prime vendor contract with Cardinal Health 103, Inc., as well as monitoring activities related to these contracts. According to MMCAP records, Statewide pharmaceutical purchases for the period May 2004 through April 2005 totaled more than \$166 million. Our audit focused on activities and transactions for the period July 2004 through January 2006, and selected actions taken through June 26, 2006.

**Finding No. 1:** Modifications to the standard MMCAP contract and enhancements to the contracting process may have improved the Department's ability to properly administer and monitor the contract.

**Finding No. 2:** The Department did not effectively monitor the Statewide pharmaceutical contracts.

**Finding No. 3:** The Department did not monitor county health department pharmaceutical purchases to determine whether the best prices were received or whether unusual utilization patterns existed.

#### BACKGROUND

The Department of Health is responsible for the State's public health system which shall be designed to promote, protect, and improve the health of all people

in the State.<sup>1</sup> This public health system includes, among other things, pharmacy services, and in order to provide pharmacy services, the Department is authorized to contract on a Statewide basis for the purchase of drugs to be used by State agencies and political subdivisions for the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans.<sup>2</sup> The Bureau of Statewide Pharmaceutical Services (Bureau) is charged with the procurement, administration, and monitoring of the Statewide pharmaceutical services contracts. The Department of Management Services (DMS) maintains information on the Statewide contracts on its Web site.

While the Department administers the Statewide pharmaceutical contracts, other entities, such as county health departments, the Department of Corrections, and the Department of Children and Family Services, may utilize the contracts to purchase pharmaceuticals. The ordering, receiving, payment, and storage of pharmaceuticals is the responsibility of each of these individual entities.

The Statewide pharmaceutical framework consists of two facets: 1) pharmaceutical price negotiation and 2) pharmaceutical distribution. Historically, the Department has negotiated pharmaceutical prices directly with manufacturers and then contracted with a distributor to supply the drugs at the negotiated price.

<sup>1</sup> Section 381.001(1), Florida Statutes.

<sup>2</sup> Section 381.0203(1) and Section 499.003(17)(b), Florida Statutes.

Pharmaceutical Distribution

In 1998, the Department of Health awarded to Bindley Western Drug Company the Statewide pharmaceutical contract for the distribution of pharmaceuticals for the period October 1, 1998, through September 30, 2003 (this contract is also known as the prime vendor pharmaceutical term contract). In October 2001, the contract was amended to acknowledge the acquisition of Bindley Western Drug Company by Cardinal Health, Inc., and to acknowledge contract assignment to Cardinal's wholly owned subsidiary Cardinal Southeast, Inc. In March 2003, the prime vendor contract was again amended to acknowledge the name change of Cardinal Southeast, Inc., to Cardinal Health 103, Inc. (Cardinal Health). Also in March 2003, the option to extend the term of the prime vendor contract was executed, extending the contract through September 30, 2008.

Pharmaceutical Pricing

Until 2003, the Department of Health provided an invitation to bid to numerous pharmaceutical manufacturers for the provision of pharmaceuticals under a Statewide pharmaceutical contract. Beginning in 2003, the Department was required to complete purchases through MyFloridaMarketPlace (MFMP), which also required vendors to be registered and be subjected to the one percent fee for purchases. Several major pharmaceutical manufacturers declined to register and be subjected to the one percent fee for MFMP purchases, and in some cases, these manufacturers were the sole source of needed drugs. Due to the need for the drugs, the Department considered alternative purchasing approaches and, effective September 15, 2003, joined the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP).

MMCAP

MMCAP is a free, voluntary, group-purchasing organization for government-run health care facilities and is operated and managed by the Materials Management Division of the State of Minnesota's Department of Administration. MMCAP is to combine the purchasing power of its members to

obtain the best prices available for the products and services for which it contracts.<sup>3</sup>

The MMCAP organization consists of a manager appointed by the State of Minnesota, an elected vice chairperson, and representatives from participating states. The MMCAP manager, to the extent allowed pursuant to Minnesota laws, renders all decisions relating to MMCAP contracting activities. State members provide representatives who attend an annual meeting and provide evaluations of pricing proposals to the MMCAP manager.

To pay the costs incurred in the operation of MMCAP, the State of Minnesota receives a two percent administrative fee from the participating manufacturers for all drugs sold through the MMCAP contract. Under the terms of the MMCAP contract, amounts received above the costs to administer the program are to be returned to participating facilities (for example, a county health department) as credits through the distributors (for example, in Florida, the distributor was Cardinal Health).

MMCAP membership consisted of 43 entities (including Florida) and thousands of participating facilities. Services provided through the MMCAP contract include selecting commodities or services for cooperative contracting; contracting with product vendors; providing copies of contract documents; maintaining vendor performance records; assisting in resolving administrative, contract, or supplier problems; providing product information to participating facilities via the Internet; collecting administrative fees from MMCAP contracted vendors; and distributing any unused fees to participating facilities as credits through the distributors.

The State of Minnesota also entered into a contract in August 2002 with Guaranteed Returns to provide member services for returned pharmaceutical goods for a fee of 6.9 percent of actual credits received from manufacturers.

In September 2003, the Department's contract with Cardinal Health was again amended to acknowledge the agreement with MMCAP and that Cardinal Health,

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<sup>3</sup> MMCAP agreement with the Department of Health

as an MMCAP distributor, would provide pharmaceuticals to Florida eligible users at the MMCAP awarded price less the prime vendor handling fee in the original prime vendor contract (a markdown of 1.12 percent).

Statewide pharmaceutical purchases for the period May 2004 through April 2005 totaled \$166,026,326, of which \$57,356,725 was purchased through the MMCAP contract. The remaining pharmaceuticals purchased were obtained through Public Health Services Act pricing (340B), the Centers for Disease Control, or were items not available through the MMCAP contract.

The Department of Health, the Department of Children and Family Services, and the Department of Corrections are the largest purchasers of pharmaceuticals dispensed by the State. The Department of Health purchases pharmaceuticals for sexually transmitted diseases, family planning, children’s immunizations, flu vaccines, and a myriad of other conditions for the prevention or treatment of disease. The Department of Children and Family Services and the Department of Corrections purchase pharmaceuticals to treat individuals under their care.

**FINDINGS AND RECOMMENDATIONS**

**Finding No. 1: MMCAP Contract Framework**

The State of Minnesota provided a template MMCAP contract to member states, and the Department utilized the template contract without modification. Our review of the Department’s MMCAP contract disclosed the following instances in which modifications to the standard contract and the contracting process may have improved the Department’s ability to properly administer and monitor the contract:

- The contract did not contain terms that would have further ensured the State’s interests were properly safeguarded, including:
  - Provisions allowing access to records, documents, or other materials pursuant to Chapter 119, Florida Statutes, by the

public, Department personnel, or auditors.

- Provisions allowing an independent verification of the calculation and distribution of unused fees to participating facilities.
- A description of how goods and services were to be provided. For example, the contract did not specify that pharmaceuticals were to be purchased through the MMCAP selected distributor and that returns were to be processed through the MMCAP selected contractor.
- As discussed in the BACKGROUND section, numerous parties are involved with the administration and utilization of the MMCAP contract. Duties necessary and proper to the administration of the contract include those relating to dispute resolution, dissemination of contract information, monitoring of drug utilization, and processing of applications for new facilities. With respect to these and other duties incumbent in the administration of the contract, we noted that neither the contract nor any other documents clearly assigned these responsibilities among:
  - The Department, as the Statewide oversight agency.
  - The participating facilities.
  - The Department of Management Services.
- The MMCAP contract was not reviewed by the Department’s Contract Administration Office as a part of the contract approval process.

Absent contract terms and conditions ensuring records access and independent verification of contract compliance, contract terms and other written materials clearly defining each party’s duties, and evidence of the Contract Administration Office’s review of the contract, the Department has reduced

assurance that it will be able to efficiently and effectively administer and monitor the contract.

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**Recommendation:** We recommend that the Department seek amendments to the contract to provide for records access and independent verifications. We also recommend that the duties and responsibilities of each party to the contract be fully documented and communicated. Further, we recommend that the contract be submitted for review to the Contract Administration Office to identify any other issues that may require the Department's action.

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### **Finding No. 2: Statewide Monitoring**

Effective monitoring is essential to ensuring that contractors conform to contract terms and conditions and provide all goods and services required by contracts. Also, as administrator of the Statewide contracts, the Department should provide appropriate oversight and guidance to all parties utilizing the contracts. With regard to the Department's monitoring of the MMCAP and Cardinal Health contracts, our audit disclosed the following:

- The Department had not established policies and procedures for monitoring the contracts. Monitoring procedures should include criteria against which performance is measured, the mechanism for conducting the monitoring, and the methods for communicating results.
  - The Department did not perform a periodic evaluation of the pharmaceutical prices paid to ensure that the State received the best price. The last comparison of the prices paid to wholesale acquisition cost was performed in July 2005.
  - The Department received quarterly data from Cardinal Health regarding the types and quantities of pharmaceuticals purchased by all participating facilities. However, this information was not analyzed by the Department nor was it provided to participating entities for their analysis. The Department indicated that, in the past, this information had been used for preparation of invitations to bid; however, since participating
- with the MMCAP, data analysis was limited to infrequent querying for specific drugs. Additionally, the Department did not utilize the quarterly data in preparation for the annual MMCAP meeting to better ensure the State received competitive pricing (the annual meeting is held to review competitive bids for recommendations to the MMCAP manager regarding pharmaceutical contracts).
- Pricing errors for some pharmaceuticals were identified by Department staff and other errors were reported by Cardinal Health. An example of a pricing error is the use of an outdated manufacturer price that results in incorrect payment for a particular pharmaceutical. Once identified, the error is to generate a credit or invoice for the amount of the error. The Department indicated that due to limited resources, it has been unable to determine if the total amount due, as a result of identified errors, has been received. The Department was considering an invoice analysis system to assist in identifying pricing errors.
  - Pharmaceuticals may be returned to a manufacturer due to, for example, the drug's expiration. As indicated under the BACKGROUND heading, pharmaceutical returns are processed through Guaranteed Returns. Utilization of this contract for the State of Florida's returns was implemented in 2004 and the Department of Children and Family Services and the Department of Corrections were notified of the Guaranteed Returns contract. However, other entities were not informed of the availability of these services. A memo dated June 26, 2006, regarding the Guaranteed Returns contract has been posted to the DMS Statewide contracts Web site to alert other entities using the Statewide pharmaceutical contract of this service.

**Recommendation:** We recommend the Department develop procedures to monitor the performance of MMCAP and Cardinal Health. Such procedures should address price and utilization analyses and the communication of the availability of related services, such as pharmaceutical returns, to all entities accessing the Statewide pharmaceutical contracts. To ensure the State receives all appropriate adjustments, we also recommend the Department continue efforts to identify and obtain credits for pricing errors either through an invoice analysis system or other management tools.

### **Finding No. 3: Department Monitoring**

In addition to providing Statewide oversight, the Bureau of Statewide Pharmaceutical Services is also responsible for the administration of the Central Pharmacy and oversight of pharmacy operations at the CHDs. While the Department performed periodic monitoring of the CHDs, this monitoring addressed adherence to pharmacy policies and procedures and did not include a review of the CHDs' pharmaceutical vendor selection, volume, or pricing. Specifically, with regard to drug acquisitions by the CHDs, we noted the following:

- The Department did not monitor drug purchases made through Cardinal Health or other sources, including, in particular, the quantities of controlled substances purchased. Such monitoring procedures may include analyses of patterns and trends and comparisons of the drugs used by each CHD.
- The Department did not perform a periodic evaluation of pharmaceutical costs to ensure that the CHDs received competitive pharmaceutical prices. Since CHD purchasing may be conducted by the individual CHD, pharmaceuticals can be purchased from vendors other than those engaged through Statewide contracts. Thus, monitoring CHD costs may identify opportunities to reduce costs.
- The Department did not ensure that all CHDs had properly completed the required MMCAP paperwork to indicate which portion of the

MMCAP contract each intended to access. As a result, two CHDs did not initially receive the benefit of MMCAP prices. Cardinal Health subsequently provided a credit for the difference between the prices paid and the MMCAP prices once the properly completed paperwork was verified by MMCAP.

**Recommendation:** We recommend the Department implement procedures that provide for routine monitoring of the types, quantities, and pricing of pharmaceuticals purchased by the CHDs through invoice analysis or other management tools. We also recommend the Department improve its oversight of the MMCAP application process.

### **OBJECTIVES, SCOPE, AND METHODOLOGY**

The overall objectives related to our audit of pharmaceutical contracts were to obtain an understanding of internal controls, make judgments as to the effectiveness of those internal controls, and to evaluate management's performance in achieving compliance with controlling laws, administrative rules, and other guidelines; the economic, efficient, and effective operation of the Department's pharmaceutical contracts; the validity and reliability of records and reports; and the safeguarding of assets.

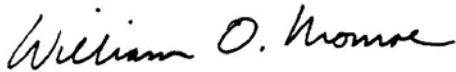
The scope of this audit focused on 1) determining whether the Department managed the Statewide pharmaceutical contracts in compliance with governing laws; 2) reviewing the execution of the Statewide pharmaceutical contracts; and 3) evaluating the adequacy of the Department's Statewide pharmaceutical contract monitoring.

In conducting our audit, we interviewed Department personnel and completed various analyses and other procedures as determined necessary. Our audit included examinations of various transactions (as well as events and conditions) occurring during the period July 2004 through January 2006, and selected actions taken through June 26, 2006.



**AUTHORITY**

Pursuant to the provisions of Section 11.45, Florida Statutes, I have directed that this report be prepared to present the results of our operational audit.



William O. Monroe, CPA  
Auditor General

**MANAGEMENT RESPONSE**

In a letter dated November 22, 2006, the Secretary provided responses to our findings. The letter is included in its entirety at the end of this report as Appendix A.

To promote accountability in government and improvement in government operations, the Auditor General makes operational audits of selected programs, activities, and functions of State agencies. This operational audit was conducted in accordance with applicable **Generally Accepted Government Auditing Standards**. This audit was conducted by Cheryl B. Jones, CPA, and supervised by Lisa Norman, CPA. Please address inquiries regarding this report to Jane Flowers, CPA, Audit Manager, via E-mail at [janeflowers@aud.state.fl.us](mailto:janeflowers@aud.state.fl.us) or by telephone at (850) 487-9136.

This report and other audit reports prepared by the Auditor General can be obtained on our Web site (<http://www.state.fl.us/audgen>); by telephone (850 487-9024); or by mail (G74 Claude Pepper Building, 111 West Madison Street, Tallahassee, Florida 32399-1450).

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APPENDIX A  
MANAGEMENT RESPONSE



Jeb Bush  
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.  
Secretary

November 22, 2006

Mr. William O. Monroe, C.P.A.  
Auditor General  
Room G74, Claude Pepper Building  
111 West Madison Street  
Tallahassee, FL 32399-1450

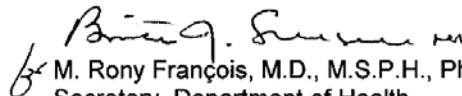
Dear Mr. Monroe:

This letter is in response to your October 31, 2006 correspondence regarding the preliminary and tentative findings of your report entitled, *Operational Audit of Pharmacy Contracts*. The agency's response and corrective action plans to your findings and recommendations may be found in the enclosed document.

We appreciate the work of your staff and will diligently pursue appropriate resolution to the findings.

If I may be of further assistance, please let me know.

Sincerely,

  
for M. Rony François, M.D., M.S.P.H., Ph.D.  
Secretary, Department of Health

MRF/kir  
Enclosure



Operational Audit - Pharmaceutical Contracts

Para. # Finding: Recommendation: Management Response: Corrective Action Plan:

<p>1 Modifications to the standard MMCAP contract and enhancements to the contracting process may have improved the Department's ability to properly administer and monitor the contract.</p>	<p>We recommend that the Department seek amendments to the contract to provide for records access and independent verifications. We also recommend that the duties and responsibilities of each party to the contract be fully documented and communicated. Further, we recommend that the contract be submitted for review to the Contract Administration Office to identify any other issues that may require the Department's action.</p>	<p>The DOH Bureau of Statewide Pharmaceutical Services (BSPS), through its Contract Administrator and Contract Manager of record, shall assure compliance with DOH Accounting Procedures Manual 75APM2, as periodically revised and amended, and will staff any and all appropriate contractual item and service contracts through DOH HQ Contract Administration. Any executed MMCAP Participating Addendums (PAs) or other written agreements, regarding drug procurement or return thereof shall be communicated to DMS for posting on their World Wide Web site for "State Contracts, Agreements and Price Lists." Further, immediate action shall be taken to secure a fully executed Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) PA, for each agreement hereby entered in the past and future, which will address all corrective actions identified below. First, pursuant to Chapter 119, F.S. and 45 CFR Part 92.36(i)(10), records access and review, financial compliance and audit and record keeping requirements will be amended into each MMCAP contract. Second, as per DOH 75APM2, "Manner of Service Provision" and "Services to be Provided" will be amended into each MMCAP contract to clearly delineate and document DOH's and the providers' roles and responsibilities, how the goods and services are to be provided and to duly inform all Florida MMCAP Facility Members regarding Method of Procurement regulations under said contracts.</p>	<p>(1-A) Assure Access to contract providers' records.  (1-B) Delineate roles, responsibilities and duties of DOH and the MMCAP provider.  (1-C) Assure independent financial disclosure regarding all aspects of the MMCAP contract administration's activities and that of each provider.  (1-D) Assure review of contract documents by DOH HQ Contract Administration.</p>
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**Para. # Finding:**

**Management Response:**

**Recommendation:**

**Corrective Action Plan:**

<p>2</p> <p>The Department did not effectively monitor the Statewide pharmaceutical contracts.</p>	<p>We recommend the Department develop procedures to monitor the performance of MMCAP and Cardinal Health. Such procedures should address price and utilization analyses and the communication of the availability of related services, such as pharmaceutical returns, to all entities accessing the Statewide pharmaceutical contracts. To ensure the State receives all appropriate adjustments, we also recommend the Department continue efforts to identify and obtain credits for pricing errors either through an invoice analysis system or other management tools.</p>	<p>The BSPS, through its Contract Administrator and Contract Manager of record, shall employ the standard DOH program monitoring process, as prescribed by DOH 75APM2 and the DOH HQ Contract Administrator to monitor all MMCAP contracts and the existing State Term Contract for procurement of drugs. First, all terms and conditions, performance standards, financial compliance requirements, price, utilization analyses of services provided and communication of all services available to all MMCAP Facility members, etc., specified in Para 1 above, will be included in the standard program monitoring tool, narrative report and transmittal letter. The standard program monitoring process provides for developing corrective actions to allow a provider to reach compliance with terms and conditions, should there be a need to do so. To this extent, the existing Quarterly Customer Satisfaction Survey has been enhanced to provide additional performance details, which will be included in the program monitoring tool to assess the performance of the provider. Specifically, all complaints and other issues will be followed-up and reported on a monthly basis, Cardinal Health has added a dedicated Key Account Manager, solely responsible for interfacing, on a daily basis, with all Florida MMCAP Facility members. Finally, daily and monthly results will be communicated by the Key Account Manager to each MMCAP entity regarding issue/complaint resolution. Second, the BSPS will continue to negotiate and execute a contract to obtain a Web-based invoice analyses system, as a model contract, available to all MMCAP covered entities for individual execution. This system will automatically reconcile all prices paid for MMCAP covered products, including 340B PHS priced items, to assure the State of Florida has paid the proper price for each drug.</p>	<p>(2-A) Assure program monitoring of MMCAP and Cardinal Health Contracts.</p> <p>(2-B) Negotiate and execute an invoice analyses system contract.</p> <p>(2-C) Enhance Quarterly Customer Satisfaction Survey to evaluate provider performance and communicate results to MMCAP entities.</p>
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**Para. # Finding:**

**Management Response:**

**Recommendation:**

**Corrective Action Plan:**

<p>3 The Department did not monitor county health department pharmaceutical purchases to determine whether the best prices were received or whether unusual utilization patterns existed.</p>	<p>We recommend the Department implement procedures that provide for routine monitoring of the types, quantities, and pricing of pharmaceuticals purchased by the CHDs through invoice analysis or other management tools. We also recommend the Department improve its oversight of the MMCAP application process.</p>	<p>First, the BSPS, through its Contract Administrator and Contract Manager of record, has negotiated with Cardinal Health to provide monthly sales data to include types, quantities, and pricing of drug procurements. This monthly report will include a separate listing of all controlled substances procured by the CHDs. Within three months, a weekly download of this information will be provided to HQ DOH listing all Florida MMCAP entities procurements. This data will be uploaded to a relational database, such as MS Access or Oracle to allow for real-time data querying, thereby providing insight, overview and regulation of CHDs regarding drug vendor selection, volume and pricing. This data will be used in conjunction with the invoice analyses system cited in Para 2-B above. Second, the BSPS shall devise a process to assure that all eligible State entities are aware of the MMCAP contract and understand how to apply for facility membership. The BSPS will assure representation on weekly teleconference meetings for CHD Director/Administrators and Business Managers to assure all CHDs are aware of the procurement laws regarding the procurement of drugs in the State of Florida. In addition, a MS PowerPoint presentation will be developed to "market" the MMCAP contract to all other State entities and political subdivisions. This presentation will be continuously provided throughout the State, at County level, via email and/or Web-conferencing communication channels. Presently, the MMCAP organization will not process any Florida MMCAP Facility Membership application without the approval of the BSPS contract manager of record.</p>	<p>(3-A) Monitor CHD drug procurement, including controlled substances. (3-B) Improve MMCAP application process and oversight thereof.</p>
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