



AUDITOR GENERAL

WILLIAM O. MONROE, CPA



DEPARTMENT OF CORRECTIONS

PHARMACEUTICAL CONTRACTS

Operational Audit

SUMMARY

As part of our operational audit of the Department of Corrections for the period July 2002 through February 2004 and selected actions taken through June 30, 2004, we reviewed the contracts between the Department and Terry Yon & Associates, Inc. (d/b/a TYA Pharmaceuticals) for unit dosing of pharmaceuticals for the treatment of inmates. Our audit disclosed the following:

Finding No. 1: Contrary to law, the Department did not seek competitive bids for the pharmaceutical contract with an expected value of \$72 million over the term of the contract.

Finding No. 2: The current contract between the Department and TYA Pharmaceuticals has several deficiencies, including omissions of certain items that are necessary for the cost-effective and efficient delivery of pharmaceuticals.

Finding No. 3: The Department could not demonstrate that all contractor responsibilities specified in the contract were met. For example, copies of required licenses and registrations were not available, financial and compliance audits had not been obtained, a current procedure manual had not been

distributed, and order-limit maximums were not recognized.

Finding No. 4: The Department did not have written contract monitoring procedures. In addition, monitoring efforts did not include a verification of TYA Pharmaceuticals status with State and Federal oversight agencies. Also, evidence of monitoring efforts was not sufficient as the frequency of on-site monitoring and the actions taken by TYA Pharmaceuticals to correct any noted deficiencies were not documented.

Finding No. 5: Pharmacy orders were not always filled by TYA Pharmaceuticals within the time periods required by the contracts.

Finding No. 6: The method described in the contract for pricing pharmaceuticals provided to the Department was not being utilized.

Finding No. 7: Invoices were not always adequately supported or approved prior to payment by the Department.

Finding No. 8: Credits for returned pharmaceuticals were not issued in accordance with the contract.

BACKGROUND

The Department’s Office of Health Services is responsible for the delivery of health services to inmates. To distribute prescribed pharmaceuticals, the Department operates four “cluster” pharmacies where health services’ staff, records, equipment, and pharmaceutical inventories are consolidated. These four pharmacies provide pharmacy support to neighboring institutions.

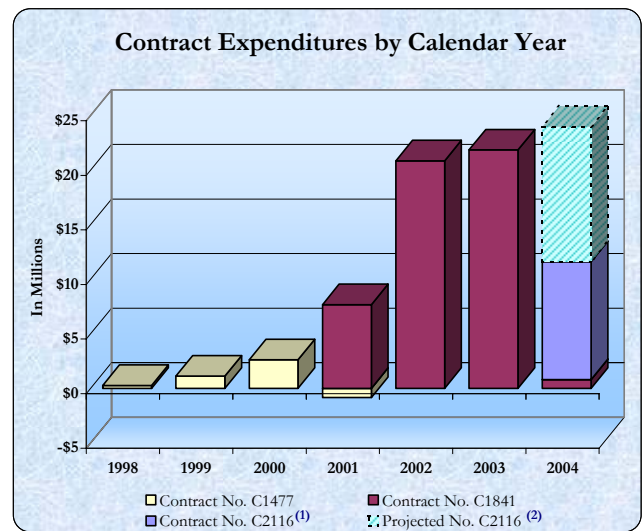
Effective January 1, 2004, the Department entered into a three-year contract (No. C2116) with TYA Pharmaceuticals for the provision of unit dosing¹ of pharmaceuticals pursuant to orders submitted by the four Department pharmacies for the treatment of inmates. Pursuant to the contract, the Department is to compensate TYA Pharmaceuticals for the vendor’s medication acquisition cost plus 1.45 percent plus a fixed rate for repackaging costs (e.g., \$1.15 per bingo card). This contract was procured absent the receipt of any sealed competitive bids or proposals and is the third consecutive Department contract with TYA Pharmaceuticals for unit dosing of pharmaceuticals.

The Department’s first contract (No. C1477) with TYA Pharmaceuticals was effective from January 1998 through December 2000 and was limited to the unit dosing of liquid psychotropic pharmaceuticals. (The term of this contract was one year, but the contract was subsequently renewed for two additional one-year terms.) A second three-year contract (No. C1841) was entered into in January 2001. The second contract was amended in 2002 to change from a fixed price for specific pharmaceuticals to the vendor’s medication acquisition cost plus a fixed rate for repackaging costs (e.g., \$.68 per bingo card), to include the provision of unit dosing for all pharmaceuticals, and

¹ A unit dose is the prescribed amount of each medication dosage in a package such as a blister pack or bingo card (a blister pack sealed into a fold-over card).

to allow the Department to return appropriate unused pharmaceuticals to TYA Pharmaceuticals for credit toward future purchases.

According to Department records, expenditures totaled \$3.2 million over the term of the first contract (No. C1477) and \$51.2 million over the three-year term of the second contract (No. C1841). The Department estimates the value of the current contract (No. C2116) to be approximately \$72 million over the three-year contract term. Contract expenditures to TYA Pharmaceuticals by calendar year are shown in the following graph:



Source: Department Florida Accounting Information Resource Subsystem (FLAIR) records.

Notes:

- (1) Actual expenditures for Contract No. C2116 for the 2004 calendar year are through June 30.
- (2) Expenditures for Contract No. C2116 for July 1 through December 31, 2004, are projected based on the Department annual contract cost estimate.

Our audit focused on the two contracts (Nos. C1841 and C2116) in effect during the period July 2002 through February 2004.

FINDINGS AND RECOMMENDATIONS

Finding No. 1: Lack of Competitive Procurement

The Legislature recognizes, in Chapter 287, Florida Statutes, that fair and open competition is a basic tenet of public procurement; that such competition reduces the appearance and opportunity for favoritism and inspires public confidence that

contracts are awarded equitably and economically; and that documentation of the acts taken and effective monitoring mechanisms are important means of curbing any improprieties and establishing public confidence in the process by which commodities and contractual services are procured. It is essential to the effective and ethical procurement of commodities and contractual services that there be a system of uniform procedures to be utilized by State agencies in managing and procuring commodities and contractual services; that detailed justification of agency decisions in the procurement of commodities and contractual services be maintained; and that adherence by the agency and the vendor to specific ethical considerations be required.²

The Statutes mandate that, unless otherwise authorized by law, all purchases of commodities or contractual services in excess of \$25,000 be awarded by sealed competitive bidding.³ The TYA Pharmaceuticals contracts were entered into absent the use of competitive bidding. In the current and prior contracts, the Department indicated that the contract was for health services involving examination, diagnosis, treatment, prevention, medical consultation, or administration and, therefore, is not subject to the competitive-solicitation requirements of law.⁴ According to Department records, the Department paid TYA Pharmaceuticals \$51.2 million over the term of the previous contract (No. C1841) and expects to pay TYA Pharmaceuticals approximately \$72 million over the term of the current contract (No. C2116).

Based upon our review of the scope of work described in the contracts and interviews with the Department's Contract Manager and TYA

Pharmaceuticals staff, it does not appear that the TYA Pharmaceuticals contracts provide for the health services described in law. TYA Pharmaceuticals is licensed by the Department of Health as a prescription drug manufacturer and is registered with the United States Department of Health and Human Services, Food and Drug Administration, as a drug repackager. Pursuant to State law, drug manufacturers and repackagers are not required to have a licensed pharmacist or other health service professional on staff.⁵ The general service description or purpose specified in the contract is the provision of unit dosing of pharmaceuticals pursuant to orders submitted by Department pharmacies. As such, TYA Pharmaceuticals is providing commodities that are available from other vendors. Further, the repackaging of pharmaceuticals for unit dosing is not included in the statutory list of health services.

Absent competitive procurement, the Department cannot demonstrate that the contract provides the best value for the State or that the contract was equitably awarded. Although competitive procurement procedures were not utilized, prior to entering into the current contract, Department staff prepared a comparison of TYA Pharmaceuticals prices with those of another pharmaceutical vendor. This comparison indicated that the other vendor's repackaging prices were lower (approximately 30 percent less) than those of TYA Pharmaceuticals and that the prices for selected pharmaceuticals were lower for generic medications but higher for brand-name medications. Department staff concluded that TYA Pharmaceuticals offered greater cost savings to the Department because TYA Pharmaceuticals was willing to issue credits for returned pharmaceuticals and the other vendor "currently [did] not have a policy on returned medications." However, the TYA Pharmaceuticals

² Section 287.001, Florida Statutes, *Legislative Intent*.

³ Section 287.057, Florida Statutes.

⁴ Section 287.057(5)(f)6., Florida Statutes.

⁵ Section 499.003(28) and (38), Florida Statutes.

repackaging cost used in the comparison was \$.90 rather than the current contract price of \$1.15 and the comparison of pharmaceutical prices did not take into consideration any percentage markup on vendor medication costs.

Recommendation: We recommend that the procurement of unit dosing of pharmaceuticals by the Department comply with the competitive bid process set forth in law.

In response to Finding No. 1, the Department stated that the Department “reasonably interpreted the statute at face value” and considers that “preparation of accurate dosage of medications to be an integral part” of the medication administration process. While we agree that the accurate dosage of medications is integral to the medical treatment of inmates, TYA Pharmaceuticals does not prescribe or dispense pharmaceuticals to inmates. Pharmaceuticals are prescribed and dispensed to inmates by health services professionals at the Department. TYA Pharmaceuticals purchases pharmaceuticals, places the pharmaceuticals in different containers, and then resells the pharmaceuticals to the Department. We believe that this repackaging of medication does not constitute a health service as the term is utilized in Section 287.057(5)(f)6., Florida Statutes, which exempts health services from the normal competitive purchase requirements applicable to State agencies. Such exemptions must be narrowly construed so as to effectuate the legislative intent set forth in Section 287.001, Florida Statutes, of fostering “fair and open competition” in State procurements.

Finding No. 2: Contract Deficiencies

Our review of the terms and conditions for the current contract (No. C2116) between the Department and TYA Pharmaceuticals disclosed several deficiencies, including omissions of certain items that we believe are necessary for the cost-effective and efficient delivery of pharmaceuticals. These deficiencies are described below:

- The contract indicates that TYA Pharmaceuticals will be paid according to the vendor’s medication cost plus 1.45 percent, plus a fee for the pharmaceutical package. The contract does not address any rebates or discounts that TYA Pharmaceuticals may be entitled to as a result of purchasing pharmaceuticals for resale to the Department. Such rebates and discounts are common in the pharmaceutical industry and can result in significant cost savings. Accordingly, the Department may not be receiving pricing related to TYA Pharmaceuticals actual medication cost.
- Federal and State laws regulate pharmaceutical suppliers, including repackagers, to safeguard the public health and promote public welfare. Federal and State oversight agencies perform inspections and investigations of pharmaceutical suppliers to determine compliance with regulations and good business practices and to resolve complaints. If violations are noted, warning letters, notices of violations, notices of inspection results, or inspections reports may be issued to the supplier.

The contract between the Department and TYA Pharmaceuticals does not contain a provision requiring TYA Pharmaceuticals to notify the Department of any complaints filed, investigations made, warning letters or inspection reports issued, or any disciplinary actions imposed on the company by any Federal or State oversight agency. Absent such a provision, the Department may not be aware of serious complaints against or violations by TYA Pharmaceuticals.

- The contract requires that TYA Pharmaceuticals abide by all the pertinent requirements of specified chapters in the Florida Statutes and the Florida Administrative Code. However, as shown in the following table, the Florida Administrative Code rules cited in the contract were repealed or transferred prior to the effective date of the contract:

Florida Administrative Code Cited in Contract No. C2116	Status of Rules
Department of Health and Rehabilitative Services Rules, Chapter 10D-45, <i>Regulations for Drugs, Devices and Cosmetics</i>	Repealed or Transferred to Department of Health Rules, Chapter 64F-12 (1997)
Agency for Health Care Administration Rule 59X-28.118, <i>Unit Dose Returns by In-Patients</i>	Transferred to Department of Health Rule 64B16-28.118 (1997)

By not appropriately addressing the issues discussed above, the Department has limited assurance that the contract for the unit dosing of pharmaceuticals provides Department pharmacies with pharmaceuticals in the most cost-effective and efficient manner.

Recommendation: To ensure that unit-dosed pharmaceuticals are procured at the best available prices, we recommend that the Department consider the impact of any discounts or rebates earned by TYA Pharmaceuticals as a result of the pharmaceuticals purchased for resale to the Department. The terms and conditions of the pharmaceutical contract should address the effect of any such rebates and discounts on the prices paid by the Department. In addition, the contract language should be revised to require TYA Pharmaceuticals to timely notify the Department of any complaints filed, investigations made, warning letters or inspection reports issued, or any disciplinary actions imposed by Federal or State oversight agencies for the company or any of the company’s key employees. Also, the Department should communicate the correct Florida Administrative Code cites to TYA Pharmaceuticals and, in all future contracts, the Department should ensure that applicable laws and rules are appropriately cited.

Finding No. 3: Contractor Responsibilities and Contract Conditions

The current contract (No. C2116) with TYA Pharmaceuticals describes various *Contractor’s Responsibilities* and conditions. Our review of the contract management file and inquiries of Department staff indicated that TYA

Pharmaceuticals did not always fulfill the responsibilities and conditions in accordance with the contract terms. Specifically:

- The contract requires that TYA Pharmaceuticals provide a copy of all required State and Federal licenses including, but not limited to, a current Department of Health Pharmacy license and Federal Drug Enforcement Agency (DEA) registration. However, the Department did not obtain a copy of the Board of Pharmacy license in effect for the period July 1, 2002, through January 29, 2003, for any TYA Pharmaceuticals employee. In response to audit inquiries, Department staff indicated that a copy of the license was not obtained because “a Pharmacy License is not needed to provide the contracted services.”

In addition, the Department did not obtain a copy of a DEA Registration from TYA Pharmaceuticals. The DEA Registration is required for the sale of pharmaceuticals included in the DEA’s schedules of controlled substances. According to Department staff, during the audit period, TYA Pharmaceuticals did not have a DEA Registration. In response to audit inquiry, Department staff indicated that the Department purchases needed controlled substances from the State’s Prime Vendor contract.

- Although the contract requires TYA Pharmaceuticals to provide a financial and compliance audit to the Department or to the Auditor General and ensure that all related-party transactions are disclosed to the auditor, the Department has not obtained financial and compliance audit reports from TYA Pharmaceuticals and TYA Pharmaceuticals has not provided copies of any audit reports to the Auditor General.
- TYA Pharmaceuticals is required by the contract to provide, by January 30, 2004, a procedure manual to all four participating

Department pharmacies and the Pharmaceutical Services Director (Contract Manager). The procedure manual is to include, among other things, a description of the process to resolve problems and issues between TYA Pharmaceuticals and the pharmacy or Department, and provide the name of a contact person, address, telephone number, and facsimile number. The procedure manual is to be updated expeditiously as changes occur and copies of changed procedures or other updates are to be provided.

At the time of our initial inquiries, two of the four pharmacies did not have a TYA Pharmaceuticals procedure manual and the other two pharmacies had an outdated manual. The Contract Manager had a copy of a procedure manual that was purported to be the current, up-to-date manual. This manual addresses most of the required items identified in the contract. However, as the manual was not dated, we could not determine whether it had been timely provided. In addition, the TYA Pharmaceuticals procedure manual provided for our review by the Contract Manager did not include the name of a contact person and related data for use in the resolution of problems and issues between TYA Pharmaceuticals and the Department.

- TYA Pharmaceuticals is required by the contract to recognize the order-limit maximums set by the Department. TYA Pharmaceuticals is to notify the Contract Manager of any orders that exceed the order-limit maximum on the same date that the order is received. The Contract Manager indicated that authorized pharmacy staff set order limits in the pharmacy computer system so that pharmacy stock levels do not exceed a 14-day supply. In response to audit inquiries, the Contract Manager also indicated that the order-limit maximum is not provided to TYA Pharmaceuticals for each order placed because “this would

restrict a pharmacy’s ability to adjust to ordering trends.”

Obtaining and reviewing applicable licenses, registrations, and audit reports would provide assurances that TYA Pharmaceuticals is in compliance with the regulations of the pharmaceutical manufacturing and repackaging industry and is in sound financial condition. Reliance on TYA Pharmaceuticals for ensuring that order-limit maximums are not exceeded, as contemplated in the contract, does not appear practicable, especially as the Department does not inform TYA Pharmaceuticals of the order-limit maximums. To better monitor the order-limit maximums, the Department should review existing practices or consider the use of a pharmacy computer system with appropriate order-limit maximums that cannot be exceeded (or changed inappropriately), thus restricting the orders to only those pharmaceuticals needed. To ensure Department pharmacy staff are aware of proper ordering, delivery, return-of-goods, and credit procedures, pharmacy staff should have access to an up-to-date TYA Pharmaceuticals procedure manual.

Recommendation: We recommend that the Department’s Contract Manager ensure that copies of all TYA Pharmaceuticals licenses and registrations required by law or specifically referred to in the contract are timely obtained and reviewed. In addition, the Department should also obtain and review audit reports for any reportable conditions or instances of noncompliance and utilize the information in the audit reports when monitoring TYA Pharmaceuticals or negotiating contract amendments. Also, the Department should ensure that the current TYA Pharmaceuticals procedure manual is provided to pharmacy staff and that future updates to the manual are timely distributed. Requiring that the manual be dated would help ensure that the current version of the manual is being used by the pharmacies. Further, as the Department requires TYA Pharmaceuticals to recognize the order-limit maximums set by the Department,

the Department should provide reasonably established order limits to TYA Pharmaceuticals, or amend the contract to exclude that requirement.

Finding No. 4: Contract Monitoring

Throughout the duration of a contract, contract monitoring is necessary to ensure that the contractor provides high quality products and services in accordance with the contract terms and applicable laws and rules. To ensure that contract monitoring is performed in a comprehensive and consistent manner, it is essential that written policies, procedures, and standards be developed and communicated to contract managers. The Contract Manager for the contract between the Department and TYA Pharmaceuticals has developed a monitoring process that utilizes a checklist that includes all the items described in the section of the contract titled *Contractor's Responsibilities*. However, the Department does not have written monitoring procedures and had not provided the Contract Manager with any recent contract monitoring training.

Although the Contract Manager utilized a checklist to document the monitoring of TYA Pharmaceuticals, the completed checklists were not signed or dated. As such, the frequency of the monitoring visits is not documented.

According to the Contract Manager, when deficiencies are noted during a monitoring visit, a follow-up site visit will be conducted to specifically address the deficiencies. However, the follow-up site visits are not documented and TYA Pharmaceuticals is not required to prepare a written corrective action plan or otherwise document corrective actions taken.

As discussed in Finding No. 2 above, the contract does not require TYA Pharmaceuticals to notify the Department of any complaints filed, investigations made, warning letters or inspection reports issued,

or any disciplinary actions imposed for the company by any Federal or State oversight agency. Whether or not such notification is provided, the Contract Manager should periodically check TYA Pharmaceuticals status with oversight agencies. For example, the FDA has a Web site where warning letters are posted. Our review of this Web site disclosed that the FDA issued a warning letter to TYA Pharmaceuticals on August 6, 2002. However, the Department's contract file did not contain a copy of the warning letter or any indication that the FDA inspection results were considered during monitoring of the prior contract (No. C1841) or when entering into the current contract (No. C2116).

Absent effective monitoring procedures, Department management has limited assurance that the terms and conditions of the contract are being met.

Recommendation: We recommend that the Department develop written monitoring procedures and provide the Contract Manager with applicable training. Such training should include proper monitoring procedures (e.g., conduct of site visits, verification of TYA Pharmaceuticals status with applicable oversight agencies, evaluation of overall TYA Pharmaceuticals performance, etc.) and requirements for documenting monitoring results and any resulting corrective actions. To demonstrate that monitoring is performed timely and at proper intervals, we also recommend that monitoring instruments be dated and signed. In future contracts, the Department should consider including provisions relating to contractor corrective action requirements.

Finding No. 5: Timeliness of Pharmaceutical Orders

Department pharmacy staff submit pharmaceutical orders directly to TYA Pharmaceuticals. According to the terms of the respective contracts and

applicable amendments, TYA Pharmaceuticals is to ensure that all orders are timely filled as follows:

Contract Period	Contractor's Responsibility to Fill Orders
January 1, 2001, through December 19, 2002	Two (2) calendar days from time of order to time of receipt by Department pharmacies.
December 20, 2002, to Present	Forty-eight (48) hours, excluding holidays and weekends, from time of order to time of receipt by Department pharmacies. All orders placed after 1:00 PM will be considered as received on the following day.

Eight of the 40 orders we reviewed were not timely filled by TYA Pharmaceuticals. These 8 orders were filled 1 to 10 days late. The order forms utilized by the Department varied from pharmacy to pharmacy and did not always contain the time and date of the order or the name of the person approving the order. (Two order forms we reviewed did not include the pharmacy location placing the order.) In addition, the date stamped on the receiving reports did not always agree with the date stamped on the invoice as the date the goods were received. Accordingly, for another 22 orders, the timeliness of the order could not be determined.

While the contracts do not specify any penalties should TYA Pharmaceuticals fail to timely fill pharmaceutical orders, proper contract monitoring includes an evaluation of the contractor's performance and compliance with all contract terms. Failing to properly record the time and date the order was placed and the date the order was received hinders the contract monitoring process. On the three monitoring checklists provided for our review, the Contract Manager indicated that the contractor responsibility related to timely filling orders was "Met." One of the checklists included a notation that there had been "no complaints from pharmacies."

Recommendation: We recommend that the Department ensure that the time and date for all orders are appropriately noted on the order forms and that the receiving reports and invoices both reflect the proper date the pharmaceuticals are received. To improve the

quality of the documentation needed to evaluate TYA Pharmaceuticals performance in timely filling the pharmacies' orders and help ensure the accuracy of the orders, we recommend that the Department implement the use of properly designed standard order documents at all four pharmacies. We also recommend that the Department amend the contract to allow the Department to impose penalties should TYA Pharmaceuticals fail to timely fill pharmaceutical orders.

Finding No. 6: Pharmaceutical Pricing

The contracts between the Department and TYA Pharmaceuticals establish the method for pricing pharmaceuticals. As shown in the following table, over the terms of the two most recent contracts, the pricing methods and amounts have been revised:

Contract Number	Pricing Effective Dates	Type of Package	Pricing ⁽¹⁾	
C1841:	01/01/2001 - 01/09/2002	All Types:	Fixed Price Per Contract Attachment A with an annual increase not to exceed 3 percent.	
		Amendment No. 2	01/10/2002 - 12/19/2002	Bingo Card:
	Unit dosed tablets/capsules:		Medication Cost plus \$6 per one hundred.	
	Unit dosed liquids:		Medication Cost plus \$18 per one hundred.	
	Amendment No. 4	12/20/2002 - 12/31/2003	Bingo Card:	Medication Cost plus \$.90 per card, 30 count or less. Medication Cost plus \$1.04 per card, 60 count.
			Unit dosed tablets/capsules:	Medication Cost plus \$6 per one hundred.
Unit dosed liquids:			Medication Cost plus \$18 per one hundred.	
C2116:	01/01/2004 - Present	Bingo Card:	Medication Cost plus 1.45 percent plus \$1.15 per card.	
		Unit dosed tablets/capsules:	Medication Cost plus 1.45 percent plus \$6 per one hundred.	
		Unit dosed liquids:	Medication Cost plus 1.45 percent plus \$18 per one hundred.	

Note:
⁽¹⁾ Medication Cost is defined in the contracts as the vendor's Medication Acquisition Cost. According to the contracts and amendments, this cost can be verified using invoices from the vendor's suppliers.

We examined 40 invoices that were paid by the Department during the audit period (July 2002 through February 2004) to determine whether the pricing agreed with the method described in the

respective contract or contract amendment. Based upon our review of the invoices and inquiries of Department personnel, we determined that the Department uses a method whereby “Item Listings” support the prices billed by and paid to TYA Pharmaceuticals. These Item Listings are prepared by TYA Pharmaceuticals and are generally updated weekly for price changes. TYA Pharmaceuticals provides copies of invoices from suppliers to support Item Listing price changes. The Contract Manager reviews and approves the Item Listings. Once the Item Listing is approved, the Listing is dated and is in effect for orders placed on or after that date and until a new Item Listing is approved.

Utilizing this method, the Department cannot be assured that the prices on the Item Listing correspond with the actual vendor acquisition cost for the pharmaceuticals purchased by the Department. For example, a Department order may be filled from existing TYA Pharmaceuticals inventory, but the price on an Item Listing may relate to a recent acquisition of the same pharmaceutical. As the Item Listings are only periodically updated, the Listings may not accurately reflect pharmaceutical price fluctuations. In addition, small quantity purchases of pharmaceuticals may have a higher acquisition cost than those acquired through bulk purchase. Although a supplier’s invoice accompanies the changes to the Item Listings, as TYA Pharmaceuticals has numerous other customers, the Department cannot be assured that the price on the invoice provided specifically relates to the price for the quantity purchased by the Department.

We also noted that, for 4 of the 40 invoices we examined, an incorrect Item Listing was used to price at least one item on the invoice. For another 8 invoices, the correct prices could not be determined because the Department order was not dated and, therefore, could not be correlated to the appropriate Item Listing.

Recommendation: We recommend that the Department require TYA Pharmaceuticals to bill the Department in accordance with the contract terms. Alternatively, the Department could revise the contract terms to reflect an agreed-upon procedure for establishing the pharmaceutical prices. We also recommend that the Department take more care to verify pricing when approving invoices for payment.

In response to Finding No. 6, the Department stated that it believes that TYA Pharmaceuticals is billing the Department in accordance with contract terms. However, use of Item Listings to support the prices billed by and paid to TYA Pharmaceuticals may not ensure that the prices specifically relate to the vendor’s medication acquisition costs for the pharmaceuticals purchased by the Department. The contract amendments described in the Department’s response that will incorporate references to the use and approval of Item Listings will more accurately portray the actual method employed by TYA Pharmaceuticals and the Department for the pricing of pharmaceuticals.

Finding No. 7: Invoice Support and Approval

Thirty-four of the 40 invoices from TYA Pharmaceuticals that we reviewed were not supported by adequate documentation. Specifically, the order forms or receiving reports for these 34 invoices were not available; did not identify the pharmacy placing the order; or were not properly signed to indicate the person who placed the order, authorized the order, accepted the order, or approved the order as received. In addition, the duties of Department employees were not always properly separated in that, at one pharmacy, the persons placing and approving the orders also accepted and approved the orders received.

We also noted that 37 of the 40 invoices were not approved in accordance with the contract terms. The contract specifies that a Department Lead Pharmacist (or designee) is to review and approve the invoices prior to payment. These 37 invoices

were not approved by a Lead Pharmacist nor was there a formal document evidencing the delegation of this responsibility to a designee.

Absent adequate documentation, the Department cannot demonstrate that the payments made were properly authorized and in the correct amounts. In addition, lack of appropriate separation of duties may allow the misappropriation of pharmacy supplies to occur and not be timely detected.

Recommendation: We recommend that the Department ensure that adequate documentation is retained to support the accuracy and approval of the pharmaceutical invoices paid. As recommended in Finding No. 5 above, use of properly designed standard order documents at all four pharmacies would improve the quality of the supporting documentation. In addition, the Department should ensure that responsibilities for placing, authorizing, and accepting orders and approving orders as received are adequately separated to the extent possible.

Finding No. 8: Credits for Returned Pharmaceuticals

Prior to the second amendment to contract No. C1841, a return for credit policy was not addressed in the contracts between the Department and TYA Pharmaceuticals. As shown in the following table, the credit policy has been revised over the terms of the two most recent contracts:

Contract Number	Effective Dates	Credit Policy and Amendments Thereto
C1841:	01/01/2001 - 01/09/2002	Credit policy not addressed.
	Amendment No. 2 01/10/2002 - 03/31/2002	Added that all appropriate unused medications will be returned for credit against future invoices. Each credit will be issued at the Medication Acquisition Cost.
	Amendment No. 3 04/01/2002 - 12/19/2002	Added a reference to Section 465.016(1)(l), Florida Statutes, for the definition of "appropriate unused medications."
	Amendment No. 4 12/20/2002 - 12/31/2003	Added that Bingo Card Credits will be \$0 if medication cost does not exceed \$.50. Cards returned, due to vendor error, will be credited the Medication Acquisition Cost and packaging cost, with no return fee.
C2116:	01/01/2004 - Present	All appropriate unused medications, as defined in Section 465.016(1)(l), Florida Statutes, will be returned for a credit against future invoices. Each credit will be issued at the Medication Acquisition Cost.
		Bingo Card credits will be 100 percent of Medication Acquisition Cost, less \$1 per card for medication that can be credited pursuant to State and Federal laws. Cards returned, due to vendor error, will be credited the Medication Acquisition Cost, plus 1.45 percent, and packaging cost, with no return fee. The Department will attempt to notify vendor, in writing, 20 days in advance of any formulary action. ⁽⁹⁾

Note:
⁽⁹⁾ A formulary is a list of pharmaceuticals a physician may prescribe without prior permission. Pharmaceuticals are periodically added to or deleted from the Department formulary.

As similarly noted for the pharmaceutical pricing in Finding No. 7 above, we found that the 20 credits we reviewed were issued at the prices on the Item Listing in effect on the date the return items were received by TYA Pharmaceuticals. As the Department does not necessarily know the date that TYA Pharmaceuticals receives the returned pharmaceuticals, the Department cannot ensure that the applicable Item Listing is used.

Utilizing the Item Listings provided for the 20 credits we reviewed, we still noted some minor errors in pricing and instances in which the number or type of items credited did not agree with Department records of the number or types of items returned.

Recommendation: We recommend that the Department require TYA Pharmaceuticals to issue credits in accordance with the contract terms or revise the contract terms to state an agreed-upon procedure that would enable the

Department to verify the pricing of credits. We also recommend that the Department more closely review the credits issued to ensure that credits are properly priced and issued for the appropriate quantities and types of returned pharmaceuticals.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our audit of Department unit dosing of pharmaceuticals contracts were:

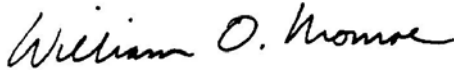
- To evaluate the effectiveness of established internal controls in achieving management's control objectives in the categories of compliance with controlling laws, administrative rules, and other guidelines; the economic, efficient, and effective operation of State government; the validity and reliability of records and reports; and the safeguarding of assets.
- To evaluate management's performance in achieving compliance with controlling laws, administrative rules, and other guidelines; the economic, efficient, and effective operation of State government; the validity and reliability of records and reports; and the safeguarding of assets.

- To determine whether the Department had adequate documentation to support the selection of the contractor and the contract payments made and to determine whether the contract was administered and goods and services were provided in accordance with contract terms.
- To evaluate the Department process for monitoring contract compliance.

The scope of our audit included various aspects related to the contract for unit dosing of pharmaceuticals including the negotiation and contracting processes, contractor responsibilities and contract deliverables, compensation, and monitoring. In conducting our audit, we interviewed Department personnel, tested selected Department records, visited the Contractor's repackaging facility, and completed various analyses and other procedures. Our audit included examinations of various documents (as well as events and conditions) applicable to the period July 2002 through February 2004 and selected actions taken through June 30, 2004.

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

DEPARTMENT RESPONSE

In a response letter dated September 24, 2004, the Secretary of the Department provided responses to our findings and recommendations. This letter is included in its entirety at the end of this report.

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 made in accordance with applicable **Government Auditing Standards** issued by the Comptroller General of the United States. This audit was conducted by Stanley E. Mitchell, CPA, and supervised by Sherrill F. Norman, CPA. Please address inquiries regarding this report to Dorothy R. Gilbert, CPA, Audit Manager, via E-mail (dorothygilbert@aud.state.fl.us) or by telephone (850-488-5444).

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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September 24, 2004

The Honorable William O. Monroe, CPA
Auditor General
Office of the Auditor General
G74 Claude Pepper Building
111 West Madison Street
Tallahassee, FL 32399-1450

RE: Department of Corrections Pharmaceutical Contracts

Dear Mr. Monroe:

We have reviewed the preliminary and tentative findings and recommendations included with your letter dated August 24, 2004. As required by Section 11.45(4)(d), Florida Statutes, our response is attached and corrective action will be taken as indicated.

We appreciate the recommendations and constructive comments provided by your staff. If further information is needed, please contact Mr. Gerald H. Abdul-Wasi, our Inspector General, at **(850) 410-4302**.

Sincerely,

James V. Crosby, Jr. *for JVC*
Secretary

JVC/RP/cw
Attachment

cc: C. George Denman, Deputy Secretary
Gerald H. Abdul-Wasi, Inspector General
Dave Mecusker, Chief, Internal Auditor

Response to Audit Finding No. 1: Lack of Competitive Procurement:

The department disagrees with this finding.

The Audit recommends that unit dosing of pharmaceuticals be procured by competitive bid.

In 1998, the Florida Department of Corrections (department) determined that the procurement of unit dosing of pharmaceuticals was exempt from competitive procurement requirements by statute, and contracted with TYA Pharmaceuticals (TYA) to provide such services to fill orders from department pharmacies for the medical treatment of inmates. TYA is a re-packager responsible for ensuring accurate dosage of medications. The Company is licensed by the Department of Health and is registered with the United States Department of Health and Human Services. Further, the company is headed by a licensed pharmacist.

The department agrees that Section 287.057 (5) (f) does not specifically list the repackaging of pharmaceuticals for unit dosing or, for that matter, any other specific individual health service. The department reasonably interpreted the statute at face value when it considered this pharmaceutical service to be: "...a health service which involves examination, diagnosis, treatment, prevention, medical consultation, or administration". Medication administration incorporates every aspect of medication delivery from the time a doctor writes a prescription to when the drug is given to a patient. Accordingly, the department considers the preparation of accurate dosage of medications an integral part of this process.

The audit notes that "absent competitive procurement, the department cannot demonstrate that the contract provides the best value for the State or that the contract was equitably awarded." The department disagrees both in general, and as to this specific contract. Although the department considered the pharmaceutical service exempt by statute, the Office of Health Services, nonetheless, conducted a price comparison with another pharmaceutical vendor, prior to awarding of the contract. The department was aware of only a very limited number of vendors who could perform this service as required, including the application of credits. TYA's price, when compared to the services offered, was a better value to the state and the contract was awarded accordingly.

Subsequent to the 1998 contract, the department entered into two additional contracts with TYA under the same exemption, again because this was a service integral to the medical treatment of inmates; C1841 was entered into on January 1, 2001 and C2116 on January 1, 2004.

Whereas the department still considers that contracting with TYA was appropriate under the provisions of Chapter 287, Florida Statutes, we recognize the concerns of the Auditor General and will consider all possible procurement options upon termination of the current contract in 2006 in order to obtain the most cost-effective service to the department.

Response to Finding No.2: Contract Deficiencies

The Audit recommends that the department consider the impact of any discounts or rebates earned by TYA as a result of the pharmaceuticals purchased for resale to the department and that the terms and conditions of the contract address the effect of any such rebates and discounts on the prices paid by the department.

The department concurs.

The Audit recommends that the contract language be revised to require TYA to timely notify the department of any complaints filed, investigations made, warning letters or inspection reports issued, or any disciplinary actions imposed by Federal or State oversight agencies for the company or any of the company's key employees.

The department concurs.

The Audit recommends that the department communicate the correct Florida Administrative Code cites to TYA.

The Florida Administrative Code cite, 59X-28.118, will be amended to substitute the correct cite, F.A.C. 64B16-28.118. The department will also amend the contract to replace the 10D-45 cite with the correct Department of Health Rule, Chapter 64F-12(1997) and 64B16-28.118 (1997).

Finding No.3 Contractor Responsibilities and Contract Conditions.

To the extent indicated below the department agrees with this finding.

The Audit recommends that the department's Contract Manager ensure that copies of all TYA licenses and registrations required by law or specifically referred to in the contract are timely obtained and reviewed.

The department's file for contract C2116, containing permits, licenses, and registrations, is current. The department will amend the language under II.B.1, Contractor's Responsibilities, to read, "Prior to the provision of any services under this Contract, the Contractor shall provide, to the Contract Manager, a current copy of all required state and federal licenses, permits, and registrations including but not limited to, a State of Florida Department of Health Drugs, Devices, and Cosmetics license for the establishment, a Department of Health and Human Services Public Health Service, Food and Drug Administration registration, a United States Department of Justice Drug Enforcement Administration registration, and a face-sheet of the liability insurance policy coverage."

The Audit recommends that the department should obtain and review audit reports for any reportable conditions or instances of noncompliance and utilize the information in the audit reports when monitoring TYA or negotiating contract amendments.

The department shall include language in the contract under Section II, Scope of Work, to require the Contractor to provide copies of any audit reports for any reportable condition, including reports of “no findings”, to the Contract Manager within seven working days of the Contractor receiving such report.

The Contract currently states that the contractor “[shall] provide a financial and compliance audit to the department or the Office of the Auditor General.” The department will stress the importance of contract compliance with this section to the Contract Manager to ensure that this requirement is met.

The Audit recommends that the department ensure the current TYA procedure manual is provided to pharmacy staff and the future updates to the manual are timely distributed, and that the manual be dated.

This recommendation has been addressed and implemented. The Contractor has agreed to provide to the department a cover sheet for each procedure manual indicating the current date of the manual. The Contractor has also agreed to provide all updates to the manual to each pharmacy within seven working days, along with the cover sheet indicating the current date of the manual. The Contractor has further agreed to provide annually, in the month of January, new manuals to each pharmacy and the Contract Manager.

The Audit recommends that the department provide reasonably established order limits to TYA, or amend the contract to exclude that requirement.

The contract will be amended to remove Section II. B.7, Contractor’s Responsibilities, which refers to order limit maximums. The department’s pharmacies currently utilize a pharmacy computer software system (CIPS) that has, as part of the system, an inventory management function. This CIPS function has been password protected. Thus, only a Pharmacy Manager or designated pharmacist has access to that area of the CIPS software. Managing inventory in this manner has allowed the department to be proactive with changes in medication use, and to keep inventories under control. Using this inventory method, the department’s pharmacies achieved a 21.27 rate of inventory turns this past fiscal year. The efficacy of this program can be seen when compared to an anecdotal reported industry average of 14 turns per year.

Finding No. 4: Contract Monitoring

To the extent indicated below the department agrees with this finding.

The Audit recommends that the department develop written monitoring procedures and provide the Contract Manager with applicable training, including proper monitoring procedures and requirements for documenting monitoring results and any resulting corrective actions.

On October 8, 2002 Contract Management Training was provided by the Bureau of Purchasing (now the Bureau of Procurement and Supply) to all Office of Health Services (OHS) Contract Managers and other staff sent by the OHS. The presentation included issues such as: the definition and duties of a Contract Manager; review of the various sections of a contract document; and, contents and purposes of the Contract Manager's file and the official contract file. The responsibilities of the contract manager were presented, including: the duty of serving as the liaison between the department and the contractor; verifying receipt of deliverables from the contractor; monitoring the contractor's progress; evaluation of the contractor's performance; minimum monitoring requirements; how to request renewals, amendments and termination of the contract, review, verification and approval of invoices; and, evaluation of contractor performance upon completion of the contract. Samples of a contract monitoring tool were given as a handout to those in attendance. The current Contract Manager did attend this training.

Further, the department has created a Contract Management Assistance Section (CMAS) which is developing training procedures and which when fully staffed, will provide regular contract manager training statewide to all contract managers and contract manager designees. Training will include all of the above subjects. In addition, CMAS will assist Contract Managers in preparing contract monitoring tools, and corrective action plans and will provide training in the conducting of cost benefit analyses and on compliance with the FSAA (Florida Single Audit Act).

The Audit recommends that the department require monitoring instruments to be dated and signed. The Audit recommends that the department consider including provisions relating to contractor corrective action requirements.

The department will monitor contract C2116 quarterly. All monitoring documents will be dated and signed by the Contract Manager. Any deficiencies will be placed in writing, potential corrective actions will be noted and the contractor will be given 21 days to respond and make corrective actions as required.

Finding No.5: Timeliness of Pharmaceutical Orders

To the extent indicated below the department agrees with this finding.

The Audit recommends the department ensure that the time and date for all orders are appropriately noted on the order forms and that both the receiving reports and invoices reflect the proper date the pharmaceuticals are received.

The department is aware of and acknowledges the confusion that can arise by not having documents properly signed and dated. This issue has been addressed. As of June 2004, the department's pharmacies implemented the following ordering procedure: All orders to the Contractor are computer generated and the department employee placing the order signs and dates the order sheet; another department pharmacy employee then verifies and approves the order and also signs and dates the order sheet; lastly, the date and time the order was sent/faxed to the Contractor is noted on the order form.

The Audit recommends that the department implement the use of properly designed standard order documents at all four pharmacies.

Currently, the department is developing, with input from the Contractor, an item- listing date sticker, to be placed on the back of each card purchased. This item- listing date sticker will then be used to establish those credits that will be provided by the Contractor to the department. The department's pharmacies will return items for credit using the appropriate department form (DC4-551), ensuring beforehand that the form does not contain any references to inmate identity. The form will indicate, card -by- card, the medication name and strength, the quantity of medication returned and the name of the preparer. The preparer will sign and date each completed form. A second pharmacy employee will review that all items being returned are accurately reflected on the completed form. That employee will then prepare the medications to be shipped, and sign and date the credit return form. Before the container with the medications being returned is sealed, the last signer will indicate the shipping date on the form, and a copy of the form will be placed in the shipping container. In the transition period, until the stickers system is in full effect, if any stickers fall off the card, the shipping date listed on the credit form and placed in the container will serve as the date of the item- listing to provide amounts for credits.

The Audit recommends that the department amend the contract to allow the department to impose penalties should TYA fail to timely fill pharmaceutical orders.

There are factors beyond the contractor's control that have affected timely filling of orders. These include: loss of deliveries by the contracted delivery service; and, the failure of some health service administrators to certify orders in a timely manner. The latter has been removed in Contract C2116 which provides that health service administrators no longer approve orders. Lost orders have historically been quickly

addressed by the Contractor. Accordingly, the department does not believe such an amendment is necessary at this time.

Finding No.6: Pharmaceutical Pricing

To the extent indicated below the department agrees with this finding.

The Audit recommends that the department require TYA to bill the department in accordance with the contract terms or revise the contract terms to reflect an agreed-upon procedure for establishing the pharmaceutical prices. The Audit recommends that the department exercise more care in verifying pricing when approving invoices for payment.

The department believes that TYA Pharmaceuticals is billing the department in accordance with contract terms. However, the department's pharmacies have been reminded that they are to check the price of each medication against the item listing in the contract. If any problems are noted, they are to be reported to the Contract Manager or designee who will contact the contractor by letter or email. The contractor shall quickly resolve any pricing issues as they arise and resubmit a corrected invoice to the receiving pharmacy. The pharmacy staff shall only certify correct invoices.

The department will amend the contract to state that the Contractor will weekly (unless variance given in writing) provide item listings to the Contract Manager along with any invoices relating to that weeks item listing. The Contract Manager will verify the correctness of the item listing and certify such to pharmacy and service center staffs. The Contractor will also include with any item listing submitted for approval a signed statement that all invoices for purchases by the Contractor related to the submitted item listing are included.

Finding No.7: Invoice Support and Approval

To the extent indicated below the department agrees with this finding.

The Audit recommends that the department ensure that adequate documentation is retained to support the accuracy and approval of the pharmaceutical invoices paid and utilize standardized ordering documents at all four pharmacies. The Audit also recommends that the department ensure that, to the extent possible, responsibilities for placing, authorizing, accepting and approving orders as received are adequately separated.

The department will amend the contract to provide language authorizing an employee other than the contract manager to approve invoices.

All pharmacies use computer-generated orders to place order requests and are currently implementing use of a credit return form as well. The pharmacies now attach the

computer-generated receiving report, the signed invoices, and any other pertinent documentation, to a signed order form. This is also the procedure for all medications returned for credit. All documentation relating to any particular credit is filed and secured to that credit form to include the approved credit invoice.

Pursuant to departmental procedure, the department's pharmacies separate the ordering and receiving functions within each pharmacy. See T.I. 15.14.04 Appendix C.

The contract manager and the contractor have approved a procedure where the department's pharmacy staff will place on each invoice, the date of the item listing used to prepare that invoice; the contract will be amended to include this procedure. The item listing used will be determined by the date the order was sent to the contractor by the department pharmacy. The department's pharmacies, on receiving an order, will verify that the correct item listing has been used to price the invoice.

Finding No.8 Credits for Returned Pharmaceuticals

To the extent indicated below the department agrees with this finding.

The audit recommends that the department require TYA to issue credits in accordance with the contract terms or revise the contract terms to state an agreed-upon procedure that would enable the department to verify the pricing of credits. The audit also recommends that the department more closely review the credits issued to ensure that credits are properly priced and issued for the appropriate quantities and types of returned pharmaceuticals.

As previously mentioned, the department's pharmacies will be using a standard credit return form (DC4-551). In a line-by-line format, pharmacy employees will list on the form each card to be returned and any relevant information relating to that card.

The department will amend the contract to include language regarding procedures to issue credits.