



AUDITOR GENERAL

WILLIAM O. MONROE, CPA



DEPARTMENT OF CORRECTIONS

PHARMACEUTICAL CONTRACTS

AND FOLLOW-UP ON AUDIT REPORT NO. 2005-037

Operational Audit

SUMMARY

This operational audit of the Department of Corrections for the period March 2004 through June 2005 and selected actions taken through November 30, 2005, included a follow-up on prior audit findings related to the pharmaceutical repackaging contract (No. C2116) between the Department and Terry Yon & Associates, Inc. (d/b/a TYA Pharmaceuticals), as well as a determination of the extent to which the Department had implemented corrective actions. This follow-up audit was performed at the request of the Joint Legislative Auditing Committee. In addition, we reviewed the contract (No. C2197) the Department entered into on February 1, 2005, with TYA Pharmaceuticals for filling select prescription orders by halving (splitting) the medications pursuant to orders submitted by Department pharmacies.

Our prior Pharmaceutical Contracts Operational Audit report (No. 2005-037, dated September 2004) disclosed numerous deficiencies related to Department pharmaceutical repackaging contracts with TYA Pharmaceuticals. These deficiencies included the lack of competitive procurement, contract document omissions, nonfulfillment of responsibilities and conditions in accordance with contract terms, ineffective contract monitoring, untimely filling of pharmaceutical orders, pricing that was not in accordance with contract terms, payments made absent adequate invoice support and approval, and

credits not issued in accordance with the contract terms.

Our current audit disclosed that, although the Department has implemented some corrective actions related to the pharmaceutical repackaging contract (No. C2116), including amending the contract effective April 1, 2005, deficiencies still exist. In addition, we noted similar deficiencies related to the recent pill-splitting contract (No. C2197) with TYA Pharmaceuticals.

Finding No. 1: The Department did not utilize a competitive process for selecting TYA Pharmaceuticals as the vendor for the pill-splitting contract (No. C2197) with a 71-month term and an expected cost of \$12 million. In addition, the Deputy Assistant Secretary of Health Services Administration (who has since resigned) had a prior financial relationship with TYA Pharmaceuticals and participated in the decision to contract with TYA Pharmaceuticals for the service. Also, two documents used by the Department to ensure that proper contracting processes are utilized were not adequately completed.

Finding No. 2: The Department was unable to provide records related to the employment of the Deputy Assistant Secretary of Health Services Administration who had a prior financial relationship with TYA Pharmaceuticals.

Finding No. 3: Contrary to the terms of the pill-splitting contract (No. C2197), the Department was not provided the information necessary to perform background checks for

some TYA Pharmaceuticals' employees prior to the individuals being hired or assigned to work under the contract. Additionally, the Department has not requested TYA Pharmaceuticals' staff to submit to fingerprinting.

Finding No. 4: Department records and procedures were not sufficient to ensure that pharmaceutical orders were properly approved, accurately priced, and filled within the time periods prescribed in the contracts (Nos. C2116 and C2197).

Finding No. 5: The Department had not established procedures to effectively measure TYA Pharmaceuticals' performance in timely filling and delivering pharmaceutical orders as stipulated in the performance measure in the contracts (Nos. C2116 and C2197).

Finding No. 6: The Department did not always record contract payments to the applicable pharmaceutical contract in Department accounting records, limiting the Department's decision-making and monitoring abilities (Nos. C2116 and C2197).

Finding No. 7: Although required by the repackaging contracts (most recently by contract No. C2116), the Department did not obtain an annual financial reporting package from TYA Pharmaceuticals until November 2005 (for the year ended December 31, 2004). The provision of an annual financial and compliance audit to the Department has been a contract condition in repackaging contracts between the Department and TYA Pharmaceuticals since January 1998.

Finding No. 8: TYA Pharmaceuticals did not notify the Contract Manager in writing within seven days of receiving a Department of Health inspection report.

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.

The Office of Health Services consists of two management areas:

- The clinical area is the responsibility of the Deputy Assistant Secretary of Health Services.
- The Deputy Assistant Secretary of Health Services Administration manages the health services support activities, including health services contracts. During the audit period, the individual filling the Deputy Assistant Secretary of Health Services Administration position was rehired by the Department on August 23, 2004, to the same position from which he had previously resigned on October 31, 2001. Effective October 6, 2005, this individual resigned from the Department for a second time.

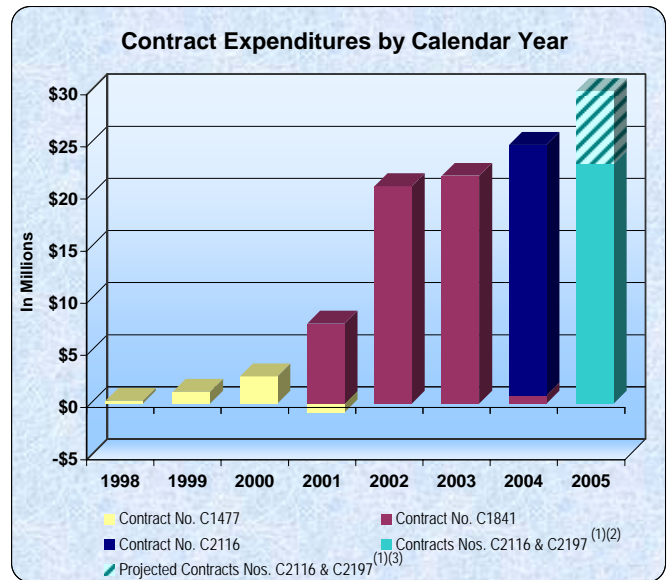
As noted in audit report No. 2005-037, the Department entered into a three-year contract (No. C2116), effective January 1, 2004, with TYA Pharmaceuticals for the provision of unit dosing (repackaging) of pharmaceuticals pursuant to orders submitted by the four Department pharmacies for the treatment of inmates. That audit report disclosed numerous contract deficiencies. In his September 24, 2004, response to our audit findings, the Secretary of the Department proposed several corrective actions, including amending contract No. C2116. Effective April 1, 2005, the contract was amended.

On February 1, 2005, subsequent to our prior audit report (No. 2005-037) and prior to amending contract No. C2116, the Department entered into another contract with TYA Pharmaceuticals. This 71-month contract (No. C2197) is to provide for the filling of select prescriptions, pursuant to orders submitted by Department pharmacies, for the treatment of the Department's inmates. Under the terms of this contract, TYA Pharmaceuticals is to fill the prescriptions by splitting in half the medication requested for the specified inmates. According to the Deputy Assistant Secretary of Health Services Administration, pill-splitting is

utilized by many managed care systems, health maintenance organizations, and corrections systems as a way to save on medication costs. These cost savings can be achieved as many double-strength medications do not cost significantly more than the single-strength dosage (e.g., 30 40-mg tablets of a popular cholesterol-lowering medication may only cost \$1 more than 30 20-mg tablets).

Pursuant to the contract, the Department will compensate TYA Pharmaceuticals for the wholesale acquisition cost of the medication plus a filling fee of \$6.25 plus an administration fee. The administration fee is determined by multiplying the wholesale acquisition cost of the medication plus the filling fee by 1.1 percent. Similar to the Department’s previous three contracts with TYA Pharmaceuticals,¹ this contract was entered into absent the use of competitive bidding. On July 25, 2005, the Department amended contract No. C2197 to address contract deficiencies similar to those addressed in the amendment to contract No. C2116.

The Department estimates the cost of contract No. C2116 to be \$72 million over the three-year contract term (January 2004 through December 2006) and the cost of contract No. C2197 to be \$12 million over the approximately six-year contract term (February 2005 through December 2010). Annual contract expenditures related to the Department’s four contracts with TYA Pharmaceuticals are shown in the following graph:



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

Notes:

- (1) The expenditures for contracts Nos. C2116 and C2197 are combined as Department records did not correctly identify the expenditures related to each contract. (See Finding No. 6.)
- (2) Actual expenditures for contracts Nos. C2116 and C2197 for the 2005 calendar year are through September 30, 2005.
- (3) Expenditures for contracts Nos. C2116 and C2197 for October 1 through December 1, 2005, are projected based on Department annual contract cost estimates.

FINDINGS AND RECOMMENDATIONS

Finding No. 1: Procurement Process

According to the scope of the work described in the pill-splitting contract (No. C2197) and discussions with the Contract Manager and Deputy Assistant Secretary of Health Services Administration, Department physicians examine, diagnose, and write prescriptions for the inmates. TYA Pharmaceuticals fills select prescriptions by splitting in half and repackaging the medications ordered by Department pharmacies for specified inmates. The Department administers and dispenses the medications once received from TYA Pharmaceuticals.

Prior to entering into the pill-splitting contract (No. C2197) with TYA Pharmaceuticals, the Department did not contact any other pharmaceutical vendors regarding the provision of pill-splitting services and cited Section

¹ In addition to contract No. C2116, the Department had entered into two previous repackaging contracts with TYA Pharmaceuticals: the first contract (No. C1477) was effective January 1998 through December 2000 and the second contract (No. C1841) was effective January 2001 through December 2003.

287.057(5)(f)6., Florida Statutes,² as justification for the lack of competitive procurement. Our review of the contract and documentation related to the procurement of the contract and inquiries of Department personnel disclosed that:

- Contracting for pill-splitting services was being contemplated by the Department at least as early as September 2004.³ In a memorandum to the Department's Deputy Secretary dated September 3, 2004, the Deputy Assistant Secretary of Health Services Administration indicated that "the Department's pharmacies have tried to accomplish the task of breaking medication in half, but with consolidation and their overall workload, this has been a task difficult to efficiently accomplish." He further stated that pill-splitting "cannot be accomplished in a cost effective manner without utilizing contracted vendors" and that such a process would result in significant cost savings to the Department. In the memorandum, the Deputy Assistant Secretary of Health Services Administration suggested that the current repackaging contract with TYA Pharmaceuticals (No. C2116) be amended to provide for this pill-splitting service.
- The Department received a document entitled *Proposal for Tablet Splitting per Request of DOC* that had TYA Pharmaceuticals' name at the top and address at the bottom but was not dated or signed by a TYA Pharmaceuticals' representative nor was there a cover letter provided. In response to audit inquiry regarding this document, the Contract Manager indicated that he did not know who had requested the *Proposal* or when; however, he also stated that "the proposal was part of an email sent 9-28-2004 to [the Deputy Assistant Secretary of Health Services Administration]." One of the items in the *Proposal* was to extend and expand

the repackaging contract (No. C2116) to five years.

Rather than amend the repackaging contract (No. C2116) as suggested by the Deputy Assistant Secretary of Health Services Administration and the *Proposal for Tablet Splitting per Request of DOC*, the Department, on February 1, 2005, entered into another contract (No. C2197) with TYA Pharmaceuticals that incorporated the fee structure outlined in the *Proposal*. Department staff signatures on the contract review sheet included that of the Deputy Assistant Secretary of Health Services Administration.

- On his *Form 1 Statement of Financial Interests* submitted to the Commission on Ethics for the 2003 and 2004 calendar years, the Deputy Assistant Secretary of Health Services Administration disclosed that TYA Pharmaceuticals was a primary source of his income.⁴ According to the *Form 1* instructions, the primary sources of income are to be listed in descending order with the largest source first. For both the 2003 and 2004 calendar years, the Deputy Assistant Secretary of Health Services Administration listed TYA Pharmaceuticals in fifth place on the forms. (See related Finding No. 2.)
- Although the splitting of medications in half is not specifically included as a health service in Section 287.057(5)(f)6., Florida Statutes, the Department asserts that, as the filling of a prescription meets both the health services treatment and prevention requirements of the statute, this contract was exempt from the competitive procurement laws.
- Department Procedure No. 205.002, entitled *Acquisition of Contractual Services*, specifies that the Contract Manager is responsible for completing a cost comparison analysis to determine if a service can be performed by the Department more economically and efficiently than by a

² Section 287.057(5)(f)6., Florida Statutes, authorizes certain health services involving examination, diagnosis, treatment, prevention, medical consultation, or administration to be excepted from the competitive-solicitation requirements.

³ This was during the 30-day period in which the Department was preparing its response to the preliminary and tentative findings and recommendations in audit report No. 2005-037. One of the findings was that the Department, contrary to law, did not seek competitive bids for contracts with TYA Pharmaceuticals.

⁴ Primary sources of income, as defined in the *Instructions for Completing Form 1 Statement of Financial Interests*, are those income sources that exceed 5 percent of the gross income received by the State employee or \$2,500. The employee need not list his or her public salary resulting from public employment, but this amount should be included when calculating gross income for the reporting period.

private vendor. Documentation of this analysis is to be maintained in the contract file.

In response to our request for a cost comparison analysis or other documentation to support the Department's decision to enter into contract No. C2197 for the splitting of medications in half, the Department provided a document entitled *Health Services Pharmacy Cost Avoidance*. This document provided a comparison of the costs of smaller doses of medication to the costs of larger doses of the same medication after being split in half and the application of a prescription filling fee. However, the *Health Services Pharmacy Cost Avoidance* document does not contain an estimate of the cost to the Department if the medications were split by Department pharmacy staff.

- Two documents used by the Department during the contracting process, the *Conflict of Interest Questionnaire* (for contracts procured without formal competition) and the *Department of Corrections Health Services Pre-Contract Check List*, were not adequately completed.

The *Conflict of Interest Questionnaire*, signed by the Contract Manager, did not contain the contract number or the name of the contractor; therefore, it was not evident that the form provided for our review pertained to contract No. C2197.

The following sections of the *Department of Corrections Health Services Pre-Contract Check List* were not completed:

- Scope
- Rates (requires an attachment indicating how rates were determined)
- Payee
- Is it Over \$50,000 (requires an estimated yearly amount)
- Term of Contract
- Registered as a Vendor (requires evidence of vendor's MyFloridaMarketPlace registration)
- Signature and Date (requires the Contract Manager or Regional Health Services Administrator to sign and date. This *Check List* should have been signed by the Director of Pharmacy as the designated Contract Manager).

In addition, although the *Check List* requires that approval of the initial scope and compensation schedules be evidenced by the signature of a person in authority from the vendor, these documents were not available and, therefore, there was no evidence of signature by TYA Pharmaceuticals' staff.

Notwithstanding that pill-splitting services may or may not be a health service exempt from State competitive procurement laws, in consideration of the prior audit findings relating to TYA Pharmaceuticals' contract deficiencies, potential cost savings related to pill-splitting, and the Deputy Assistant Secretary of Health Services Administration's prior financial relationship with TYA Pharmaceuticals, good business practices should have dictated that the Department utilize a competitive process to solicit the pill-splitting services. Absent competitive procurement and the preparation and maintenance of proper documentation evidencing decisions made by appropriate Department staff during the contract procurement process, there is increased risk of the appearance of or opportunity for favoritism during the contract process and that the contract does not provide the best value for the State.

In a letter dated July 22, 2005, the Secretary of the Department informed TYA Pharmaceuticals that, pursuant to the Auditor General's recommendation and the proviso language enacted during the 2005 Legislative Session,⁵ the Department will be soliciting bids for pharmaceutical repackaging services "early next year [2006] in order to meet the Legislature's timeline." The Department further stated that "in an effort to comply with the Auditor General's interpretation of the health services exemption and in consideration of the Legislature's directive to bid pharmaceutical repackaging services,

⁵ Chapter 2005-70, Laws of Florida, proviso to Specific Appropriation 656, requires the Department to issue an Invitation to Bid as defined in Section 287.057, Florida Statutes, for pharmaceutical repackaging services beginning July 1, 2006.

[the Department has] also decided to issue an Invitation to Bid for the filling of select prescription orders by cutting medications in half. This Invitation to Bid will also be released early next year [2006] to ensure that services begin by July 1, 2006.”

Recommendation: To ensure that the contracting process is fair and that the contract provides the best value for the State, we recommend that the Department utilize the competitive procurement process set forth in State law for the procurement of all medication and pharmaceutical services. The Department should ensure that there is no appearance of or opportunity for favoritism and that all significant factors considered during the procurement process are adequately documented. We also recommend that, prior to entering into future contracts for services, the Department complete a valid comparison of the cost of the service if performed by Department staff with the cost of acquiring the service from a vendor.

Finding No. 2: Employment Documentation

As previously discussed in Finding No. 1, the Deputy Assistant Secretary of Health Services Administration disclosed on his *Form 1 Statement of Financial Interests* submitted to the Commission on Ethics for the 2003 and 2004 calendar years that TYA Pharmaceuticals was a primary source of his income. As these forms are only required to be submitted to the Commission on Ethics, we reviewed on October 5, 2005, the Deputy Assistant Secretary of Health Services Administration’s personnel file maintained by the Department’s Personnel Office for disclosure of his relationship with TYA Pharmaceuticals on his employment application or resume submitted to the Department upon his rehire on August 23, 2004. Our review disclosed that an application and resume for his rehire were not in the file.

During interviews⁶ with the Deputy Assistant Secretary of Health Services Administration, he asserted to us that he submitted to the Department’s Deputy Secretary an employment application with an attached resume that disclosed his prior relationship with TYA Pharmaceuticals. He also asserted that his relationship with TYA Pharmaceuticals was known by several Department managers. In response to our requests, the Department was unable to provide the employment application and resume for our review. In response to audit inquiry, Department management stated, “We have been unable to locate a copy of [the Deputy Assistant Secretary of Health Services Administration’s] Employment Application and resume he apparently submitted prior to his rehire.” During an interview⁷ with the Deputy Secretary, he stated that the Deputy Assistant Secretary of Health Services Administration may have submitted an application and resume to him, but he does not remember.

Inquiries with the Department Personnel Office disclosed that it is the general practice of the Department to obtain current employment applications for all prospective Department employees. Personnel Office staff indicated that, after the Deputy Assistant Secretary of Health Services Administration’s application and resume could not be located, Personnel Office staff in October 2005 reviewed all personnel files for Department Senior Management Service staff and that the Deputy Assistant Secretary of Health Services Administration’s personnel file was the only file that did not contain an employment application.

⁶ These interviews were conducted subsequent to the Deputy Assistant Secretary of Health Services’ resignation on October 6, 2005.

⁷ This interview was conducted subsequent to the Deputy Secretary’s resignation effective June 30, 2005.

Recommendation: As the employment application contains important information that should be retained, we recommend that the Department's Inspector General consider reviewing the Department's Personnel Office records requirements and procedures, including any situations that may allow documents not to be obtained or retained.

Finding No. 3: Criminal Records Checks

Contract No. C2197 requires that TYA Pharmaceuticals' staff assigned to the contract be subject, at the Department's discretion and expense, to a Department of Law Enforcement Florida Crime Information Center/National Crime Information Center (FCIC/NCIC) background/criminal records check. This background check will be conducted by the Department and may occur or reoccur at any time during the contract period. The Department has "full discretion to require [TYA Pharmaceuticals] to disqualify, prevent, or remove any staff from any work under the contract."

TYA Pharmaceuticals is to ensure that the Contract Manager (or designee) is provided the information needed to have the FCIC/NCIC background check conducted prior to any new staff being hired or assigned to work under the contract. In addition, TYA Pharmaceuticals is not to offer employment to any individual to work under the contract who has not had an FCIC/NCIC background check conducted.

We reviewed information related to the background checks for 10 individuals considered for hire by TYA Pharmaceuticals during the audit period and noted that:

- Four of the 10 individuals were hired by TYA Pharmaceuticals and assigned to work under contract No. C2197 before the Department was provided the necessary information to conduct an FCIC/NCIC background check.

- We could not determine whether another individual was hired before the FCIC/NCIC background check was completed as we were only provided with the month of hire rather than the date of hire.
- One individual was not hired as a result of the background check.

Additionally, the contract states that TYA Pharmaceuticals' staff shall submit to fingerprinting by the Department for submission to the Federal Bureau of Investigation (FBI) and that TYA Pharmaceuticals "shall not consider new employees to be on permanent status until a favorable report is received by the Department from the FBI." According to the Contract Manager, the Department has not requested any TYA Pharmaceuticals' staff to submit to fingerprinting as the Department considers this contract requirement to be optional.

Recommendation: We recommend that the Department more closely monitor and enforce specific contract requirements regarding TYA Pharmaceuticals' employee background checks and fingerprinting.

Finding No. 4: Pharmaceutical Orders and Invoice Support

Department pharmacy staff submit pharmaceutical orders directly to TYA Pharmaceuticals. Under the terms of the amended repackaging contract (No. C2116), the pharmacies compile a list of needed pharmaceuticals and then fax the list to TYA Pharmaceuticals. Under the terms of the amended pill-splitting contract (No. C2197), prescriptions for each inmate are separately printed from the Correctional Institutional Pharmacy System (CIPS) and then faxed to TYA Pharmaceuticals by the pharmacies. Department procedures require that, prior to faxing the orders, the date and time be placed on the order along with the signature of the person preparing the order and that of the person approving the order.

According to the terms of the amended repackaging contract (No. C2116), TYA Pharmaceuticals is to ensure that all orders are filled within 48 hours (excluding holidays and weekends) from the time of order to the time of receipt by Department pharmacies. The terms of the pill-splitting contract (No. C2197) require TYA Pharmaceuticals to ensure that all orders are filled within 24 hours (excluding holidays and weekends) from the time of order to the time of receipt by Department pharmacies. Under the terms of both contracts, all orders placed after 1:00 P.M. will be considered by TYA Pharmaceuticals to have been placed on the following day.

Weekly, TYA Pharmaceuticals provides to the Contract Manager a dated Item Listing along with copies of invoices from suppliers to support the Item Listing prices. A signed statement is also provided that certifies that copies of all supplier invoices for that week's Item Listing are included. The Department's Contract Manager verifies the accuracy of the weekly Item Listings and certifies same to Department pharmacies. Upon receipt of medications, pharmacy staff use the applicable Item Listings to verify the charges invoiced by TYA Pharmaceuticals.

As similarly noted in audit report No. 2005-037, Findings Nos. 5 and 6, Department records and procedures were not sufficient to ensure that pharmaceutical orders were properly approved, timely received, and properly priced. Specifically, we noted:

- For the eight invoices and support reviewed relating to the amended repackaging contract (No. C2116), we could not determine whether the orders billed on one invoice were timely filled as there was no time of order receipt noted on the documentation.
- For the eight invoices (totaling \$47,586) and support reviewed relating to the pill-splitting contract (No. C2197):

- We could not determine whether the orders billed on six invoices were timely filled as there was no time of order receipt noted on the documentation.
- We could not determine whether the orders billed on three invoices were timely filled as there was no documentation provided to indicate the date and time the order was placed.
- For seven of the eight invoices, the number of prescriptions included in the support for the Department orders did not agree with the number of prescriptions billed by TYA Pharmaceuticals. For these seven invoices, the charges for the prescriptions included on the invoices but not included in the order documentation ranged from \$737 to \$108 and resulted in unsupported charges totaling \$3,116.
- The faxed prescription orders for six of the eight invoices did not contain the required preparer or approver signatures.
- We could not determine the correct prices for three of the eight invoices because the date and time of the order was not adequately documented and, therefore, could not be correlated to the appropriate dated Item Listing.
- The duties of Department pharmacy employees were not always properly separated. At two pharmacies, the persons preparing the order also accepted and approved the orders received.

Absent adequate documentation, the Department cannot effectively demonstrate that payments made were properly authorized and in the correct amounts. The lack of adequate documentation also limits the Department's ability to effectively monitor whether TYA Pharmaceuticals is timely filling and delivering pharmaceutical orders. Inappropriate separation of duties among pharmacy employees may allow the misappropriation of pharmacy supplies to occur and not be timely detected.

Recommendation: We again recommend that the Department ensure that documentation containing the required order information including time, date, and appropriate signatures is maintained. The Department should also ensure that expenditures are adequately supported. In addition, the responsibilities for preparing and authorizing orders and accepting and approving orders as received should be separated to the extent possible.

Finding No. 5: Contract Performance Measure

Both the repackaging and pill-splitting contracts (Nos. C2116 and C2197, respectively), as amended, contain a performance measure requiring that 98 percent of all orders be timely filled and delivered to the ordering pharmacy. The amended contracts stipulate that the Department may impose liquidated damages if TYA Pharmaceuticals fails to meet this performance measure Statewide on a monthly basis. However, the Department has never sought any such damages.

We noted in Finding No. 4 that Department pharmacies do not consistently list the date and time on orders faxed to TYA Pharmaceuticals and, as a result, the Department cannot effectively monitor whether TYA Pharmaceuticals is timely filling and delivering pharmaceutical orders. To determine the effectiveness of any other Department procedures for monitoring TYA Pharmaceuticals' compliance with the timeliness performance measure, we inquired of Department staff at each of the four Department cluster pharmacies and the Contract Manager.

In response to audit inquiries, the pharmacy staff indicated that they had not been given any oral or written instructions on how to document and report the extent of compliance with the performance measure. In addition, the pharmacy staff indicated that they had not been provided contract copies and, therefore, were not aware of the Department's

and TYA Pharmaceuticals' contractual responsibilities. The Contract Manager confirmed that he had not issued any instructions to pharmacy staff regarding performance measure monitoring and that the pharmacies had not been provided with copies of the contracts.

Recommendation: We recommend that the Department implement procedures for evaluating and documenting TYA Pharmaceuticals' performance related to the timely filling and delivering of pharmaceutical orders. This documentation should be retained for use in enforcing the liquidated damages provisions of the contracts when warranted.

Finding No. 6: Contract Payment Records

Section III.C.3. of Amendment 1 to the repackaging contract (No. C2116) requires TYA Pharmaceuticals to include the contract number on all invoices submitted to the Department for payment. Our review of eight invoices disclosed that none included the contract number. Payments for four of these invoices (totaling \$298,794) were charged to the incorrect contract (No. C2197) and improperly recorded in Department accounting records.

The terms of the pill-splitting contract (No. C2197) do not require the contract number to be recorded on the invoices, and we noted that payments for two of the eight invoices tested (totaling \$14,565) were charged to the incorrect contract (No. C2116) and, therefore, improperly recorded in Department accounting records.

The failure to record expenditures to the correct contract limits the usefulness of the expenditure data for monitoring and decision-making purposes. After we notified Department staff of these accounting record errors, the expenditures were reclassified on a supplemental spreadsheet.

Recommendation: We recommend that the Department take appropriate measures to ensure that payments are properly charged to the correct contract in Department accounting records. Such measures should include enforcing the invoicing provisions of contract No. C2116 and amending contract No. C2197 to require TYA Pharmaceuticals to include the contract number on applicable invoices.

Finding No. 7: Contractor Audit Report

In audit report No. 2005-037, Finding No. 3, we reported that the Department had not obtained a financial and compliance audit from TYA Pharmaceuticals as required by contract No. C2116. The provision of a financial and compliance audit and that all related-party transactions be disclosed to the auditor were also contract conditions related to records in the prior repackaging contracts (No. C1477, effective January 1998 through December 2000, and No. C1841, effective January 2001 through December 2003) between the Department and TYA Pharmaceuticals. The lack of a financial and compliance audit has also been repeatedly noted by Department staff during contract monitoring. Although the contracts include a provision for the assessment of liquidated damages or a determination of contract breach and termination of services should TYA Pharmaceuticals fail to timely correct a deficiency, the Department has not exercised either of these options.

In correspondence dated May 19, 2005, to the Joint Legislative Auditing Committee, TYA Pharmaceuticals' General Counsel stated that a CPA firm had been engaged to perform the audit. On June 13, 2005, TYA Pharmaceuticals accepted an engagement letter from a CPA firm for the required audit with the anticipated completion date of October 15, 2005, for the December 31, 2004, audit and March 31, 2006, for the December 31, 2005, audit.

The CPA firm delivered a financial reporting package, including financial statements, an independent auditor's report (dated September 29, 2005), and management letter to TYA Pharmaceuticals for the year ended December 31, 2004. A copy of the financial reporting package was received by the Department on November 10, 2005, and by our Office on November 14, 2005. See Appendix A for information contained in the financial reporting package that is relevant to TYA Pharmaceuticals' contractual relationship with the Department.

Recommendation: The Department should continue to monitor the timely submission of the contractually required audit reports by TYA Pharmaceuticals. Once obtained, the Department should review the reports for any reportable conditions, related-party transactions, or instances of noncompliance and utilize this information during contract monitoring and when negotiating future contracts.

Finding No. 8: Inspection Reports

Section II.B.10. of Amendment 1 to contract No. C2116 (effective April 1, 2005) requires TYA Pharmaceuticals to notify the Contract Manager in writing of any complaints filed, investigations made, warning letters or inspection reports issued, or any disciplinary actions imposed by Federal or State oversight agencies for TYA Pharmaceuticals or any of its key employees within seven working days of the notification or receipt of a report. When notifying the Contract Manager, a copy of the complaint, report, etc., is to accompany the notification.

On June 28, 2005, an inspection of TYA Pharmaceuticals was conducted by the Department of Health (DOH) and the ensuing *Inspection Report* noted deficiencies in the areas of medication labeling and "prepacking logs." Although we requested, the Department did not provide evidence

that TYA Pharmaceuticals notified the Contract Manager in writing of the DOH *Inspection Report* within seven working days. To the contrary, the Department received a letter dated July 1, 2005, from TYA Pharmaceuticals' General Counsel stating, "as of the end of the second quarter of 2005 [June 30, 2005], there have been no complaints filed, investigations made, warning letters or inspection reports issued, or any disciplinary actions imposed by the Federal or State oversight agencies for TYA or any of our key employees."

Subsequent to our audit inquiry, the Department provided us with a copy of the DOH *Inspection Report* dated June 28, 2005. The aforementioned letter from TYA Pharmaceuticals' General Counsel and the DOH *Inspection Report* copy were not date stamped by the Department when received. In response to audit inquiry, the Deputy Assistant Secretary of Health Services Administration indicated that, to the best of his recollection, the Director of Pharmacy Services received a copy of the DOH *Inspection Report* on June 29, 2005.

Recommendation: We recommend that the Department take the necessary actions to ensure that TYA Pharmaceuticals notifies the Contract Manager in writing within seven days of any complaint filed, investigation made, warning letters, or inspection reports issued or any disciplinary actions imposed and include a copy of any related documentation with the notification. In addition, the Contract Manager should evaluate the sufficiency of TYA Pharmaceuticals' planned corrective actions and then ascertain whether those actions sufficiently resolved the noted deficiencies. The Contract Manager should also ensure that all documentation is properly dated and retained in the contract file.

Follow-Up to Management Response:

The Secretary, in his written response to this finding, stated that the Department of Health inspection conducted on June 28, 2005, was on the vendor's pharmacy site where the pill-splitting services of contract No. C2197 are provided, not where the repackaging services of contract No. C2116 are provided. As the contract terms for contract No. C2116 require TYA Pharmaceuticals to notify the Contract Manager in writing of any inspection reports issued for TYA Pharmaceuticals, we believe that, no matter which contract the inspection related to, TYA Pharmaceuticals should have notified the Department of the inspection and should have also included details of the inspection in its General Counsel's letter dated July 1, 2005, to the Department.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our audit of Department pharmaceutical contracts were:

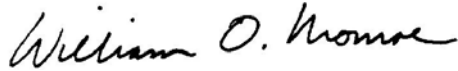
- To evaluate the effectiveness of established internal controls in achieving management's control objectives in the categories of compliance with controlling laws, administrative rules, and other guidelines; the economic, efficient, and effective operation of State government; the validity and reliability 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 management has corrected, or is in the process of correcting, all deficiencies disclosed in audit report No. 2005-037 for those operating units, programs, activities, functions, and classes of transactions within the scope of audit.

The scope of our audit included a review of the actions taken by the Department to correct the deficiencies disclosed in the prior operational audit (report No. 2005-037) relating to TYA Pharmaceuticals' contract No. C2116. Our audit also focused on a review of TYA Pharmaceuticals' contract No. C2197 relating to the procurement method utilized, contractual provisions related to contractor responsibilities, compensation terms, and the Department's contract monitoring process.

In conducting our audit, we interviewed Department personnel, tested selected Department records, and completed various analyses and other procedures. Our audit included examinations of various documents (as well as events and conditions) applicable to the period March 1, 2004, through June 30, 2005, and selected Department actions taken through November 30, 2005.

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 response letter dated December 30, 2005, the Secretary of the Department generally concurred with our audit findings and recommendations. The Secretary's response is included in its entirety at the end of this report as Appendix B.

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 Charles G. Gaboardi, 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).

APPENDIX A

RESULTS OF FINANCIAL AND COMPLIANCE AUDIT BY INDEPENDENT AUDITOR
RETAINED BY TYA PHARMACEUTICALS

Items Relevant to TYA Pharmaceuticals' Contractual Relationship with the Department	
Sales	Substantially all the 2004 sales of TYA Pharmaceuticals were derived from the pharmaceutical repackaging contract with the Department. Sales to the Department represented in excess of 95 percent of TYA Pharmaceuticals' sales during 2004.
Gross Margin and Net Income	TYA Pharmaceuticals' 2004 gross margin (revenues less costs of goods sold) totaled in excess of \$3.4 million (approximately 14.7 percent). TYA Pharmaceuticals' 2004 net income totaled approximately \$2.2 million.
Contingent Liability	A contingent liability exists in that in July 2005 a civil action was brought against TYA Pharmaceuticals on behalf of the United States Drug Enforcement Administration. The action seeks recovery of civil penalties relating to registration and recordkeeping requirements. The action alleges 10 violations with a maximum penalty of \$25,000 per violation plus a 10 percent surcharge for a maximum loss exposure of \$275,000. According to the Notes to the Financial Statements, TYA Pharmaceuticals' legal counsel believes that if any violations did occur with respect to recordkeeping for controlled substances, such occurrences were minor. Also, legal counsel will be seeking mediation of the action and believes that any monetary damages awarded would be significantly less than the maximum amounts sought.
Material Weakness - Need for Segregation of Duties	A material weakness relating to the need for segregation of duties was noted in the Independent Auditor's Report on Internal Control Over Financial Reporting and on Compliance and Other Matters. Separation of certain accounting and administrative duties among employees was not considered feasible by TYA Pharmaceuticals due to the limited number of personnel and certain incompatible duties were being performed by the same employee. A material weakness is a reportable condition in which the design or operation of one or more of the internal control components does not reduce to a relatively low level the risk that misstatements caused by error or fraud in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.
Discounts and Rebates	In the Notes to the Financial Statements, it was disclosed that TYA Pharmaceuticals' contract with the Department provides for the Department to consider the amounts of all applicable discounts and rebates received on pharmaceutical purchases by TYA Pharmaceuticals when determining the amount of the Department's final payment under the contract. The Notes also refer to the amended contract provision that states that "any discounts/rebates received by [TYA Pharmaceuticals] as a result of pharmaceutical orders placed or processed on behalf of the Department will be reported to the Contract Manager on a quarterly basis listing each pharmaceutical company and the corresponding total discount/rebate amount received." ¹ Additionally, TYA Pharmaceuticals "passes through to the Department discounts it receives from Gerimed, a Group Purchasing Organization for member businesses, which is otherwise unavailable to governmental entities. During 2004, the Department received the benefit of approximately \$1,150,000 in Gerimed discounts. Nevertheless, [TYA Pharmaceuticals'] sales amounts to the Department are subject to renegotiation and possible adjustments at the end of the contract."
Related Parties	No related-party transactions were disclosed in the financial reporting package.
Status of Prior Audit Findings - Auditor General Operational Audit of the Department of Corrections	The Independent Auditor indicated that the audit was the initial annual financial audit of TYA Pharmaceuticals and addressed the status of the findings disclosed in the Auditor General Operational Audit of Department of Corrections Pharmaceutical Contracts by describing corrective actions taken by TYA Pharmaceuticals. However, as the findings in that audit report (No. 2005-037) pertained to Department deficiencies, the Department is responsible for corrective actions, including ensuring that TYA Pharmaceuticals is responsive to applicable deficiencies as well.

¹ As required by the amended contract, TYA Pharmaceuticals' General Counsel reported to the Department in correspondence dated October 3, 2005, rebates of \$62.15 for the quarter ended September 30, 2005.

Source: *Terry Yon & Associates, Inc. (DBA TYA Pharmaceuticals) Financial Statements, December 31, 2004, With Independent Auditor's Report Thereon.*

APPENDIX B

MANAGEMENT RESPONSE

FLORIDA
DEPARTMENT of
CORRECTIONS*Equal Opportunity Employer*2601 Blair Stone Road • Tallahassee, FL 32399-2500
Phone: (850) 488-7480Governor
JEB BUSHSecretary
JAMES V. CROSBY, JR.<http://www.dc.state.fl.us>
Fax: (850) 922-2848

December 30, 2005

Mr. William O. Monroe, CPA
Auditor General
G74 Claude Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1450

RE: Preliminary and Tentative Audit Findings, Department of Corrections
Pharmaceutical Contracts and Follow-up on Audit No. 2005-037 for the period
March 2004 through June 2005 and selected actions taken through November
30, 2005

Dear Mr. Monroe:

We have reviewed the preliminary and tentative findings and recommendations included with your letter dated December 1, 2005, regarding your operational audit of the department's pharmaceutical contracts. As you are aware, this audit report was conducted as a follow-up to the Pharmaceutical Contracts Operational Audit Report (No. 2005-037, dated September 2004). Pursuant to Section 11.45 (4) (d), Florida Statutes, our response to the follow-up audit is attached.

The prior report disclosed deficiencies related to the department's pharmaceutical repackaging contract with TYA Pharmaceuticals. Please note that the department has implemented all of the recommendations made by the Auditor General in that report. Appropriate changes were made to the contract and the management of the contract including:

- Implementation of a pharmacy ordering procedure specific to this contract addressing the ordering and receipting of pharmaceuticals
- Implementation of contract monitoring procedures specific to the prior audit findings and additional contract manager training
- A performance measure requiring timely filling of pharmacy orders.
- A requirement that the vendor timely notify the department of inspections or audits by Federal and/or State oversight agencies
- A requirement that appropriate licenses and registrations are maintained by the vendor with appropriate copies to be timely submitted

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Mr. William O. Monroe
December 30, 2005
Page Two

Findings in your current follow-up audit of the repackaging contract (C 2116) note that:

- Although the date of receipt was shown on each order reviewed, the time of receipt on one order was not shown
- Pharmacy staff had not been given instruction regarding the monitoring of the performance measure introduced in response to the original audit
- The respective contract number was not shown on invoices submitted by the vendor
- The financial and compliance report required by the contract was not submitted by the vendor until November 2005

These deficiencies do not support or indicate that the department did not proactively address the recommendations in the original audit. Unfortunately, even where the department has implemented appropriate procedures, in contracts involving a significant number of individual service transactions (i.e., numerous daily pharmacy deliveries or significant receipting and approval, etc.) paperwork deficiencies do occur. The deficiencies noted indicate a need on the department's behalf, to strengthen internal controls in regard to contract management; which the department has done and will continue to do. I do not believe that these deficiencies demonstrate an intentional failure on anyone's behalf to follow established procedures in the performance of contract-related duties – this is more a matter of oversight and ineffectiveness. While this in no way minimizes the significance of the findings and recommendations in the preliminary and tentative audit findings– it does put them into an appropriate perspective - that the department did take the findings and recommendations of the Audit Report No. 2005-037 very seriously and did implement appropriate, comprehensive and effective corrective action in implementing those recommendations. The department needs to better ensure that staff is carrying out these directives.

To ensure that the management of both the repackaging contract (C2116) and the pill-splitting contract (C2197) is improved, I have implemented the following steps: first, I have directed my Inspector General to provide a written response within six months to me regarding this audit and the status of any corrective action taken; secondly, the Inspector General will implement a system whereby his staff will request an update from the contract manager of all other audited contracts regarding implementation of recommended corrective action; and thirdly, I have created a Contract Management Assistance Section tasked with statewide contract management training which will assist the Contract Manager in this case, in recognizing contract management issues and in more closely monitoring these contracts to ensure that TYA and Associates is providing services in accordance with the terms of the contracts.

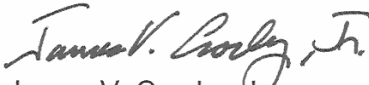
APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Mr. William O. Monroe
December 30, 2005
Page Three

I appreciate the recommendations and constructive comments provided by your staff. As stated above, the department's response and proposed corrective action to the preliminary and tentative findings is attached. If further information is needed, please contact Mr. Gerald H. Abdul-Wasi, our Inspector General, at (850) 410-4302.

Sincerely,


James V. Crosby, Jr.
Secretary

Attachments

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

**FLORIDA DEPARTMENT OF CORRECTIONS
RESPONSE TO PRELIMINARY AND TENTATIVE AUDIT FINDINGS,
PHARMACEUTICAL CONTRACTS AND FOLLOW-UP ON AUDIT NO. 2005-037
FOR THE PERIOD MARCH 2004 THROUGH JUNE 2005 AND SELECTED ACTIONS
TAKEN THROUGH NOVEMBER 30, 2005**

Finding No. 1: The Department did not utilize a competitive process for selecting TYA Pharmaceuticals as the vendor for the pill-splitting Contract (No.2197) with a 71-month term and an expected cost of \$12 million. In addition, the Deputy Assistant Secretary of Health Services Administration (who has since resigned) had a prior financial relationship with TYA Pharmaceuticals and participated in the decision to contract with TYA Pharmaceuticals for the service. Also, two documents used by the Department to ensure that proper contracting processes are utilized were not adequately completed.

Recommendation: To ensure that the contracting process is fair and that the contract provides the best value for the State, we recommend that the Department utilize the competitive procurement process set forth in State law for the procurement of all medication and pharmaceutical services. The Department should ensure that there is no appearance of or opportunity for favoritism and that all significant factors considered during the procurement process are adequately documented. We also recommend that, prior to entering into future contracts for services the Department completes a valid comparison of the cost of the service if performed by Department staff with the cost of acquiring the service from a vendor.

Response:

1) The process for the procurement of commodities and services is delineated in Chapter 287, Florida Statutes. Section 287.057(5) of that chapter excludes certain contractual services from the competitive procurement process including "...health services which involves examination, diagnosis, treatment, prevention, medical consultation, or administration". The department utilized this part of the procurement process set forth in state law to select TYA Pharmaceuticals to provide pill-splitting services.

The halving of medications, i.e. pill splitting, is a unique service. Pursuant to federal Food and Drug Agency (FDA) rules and regulations, halved tablets cannot be repackaged and per Florida Pharmacy rules can only be issued by way of a prescription; pill-splitting is therefore a pharmaceutical service. Although the statutory language does not specifically mention pharmaceutical services, the department does consider that these services fall under the umbrella of health services and as such qualify to be exempt from the competitive procurement process.

Proviso language enacted during the 2005 Legislative Session requires the department to solicit competitive bids for pharmaceutical repackaging services. In consideration of this directive and in an effort to ensure that the department is indeed getting the best value for the State, the department decided to issue an Invitation to Bid (ITB) for the pill-splitting contract as well. Accordingly, and as noted in the preliminary and tentative findings by the Auditor General, TYA and Associates was notified by letter dated July 22, 2005 of the department's intent. Both bids have been issued and new competitively procured contracts will be in place by July 1, 2006.

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Two

2). No one individual can enter into a contract with a vendor on behalf of the department. Once the respective program office initiates a request for a contract, the request is subject to a detailed review process by all levels of the organization culminating in the Office of the Secretary. This process is designed to carefully weigh the proposed contract's benefit to the state, the potential impact on public safety and additional expense/revenue to the department. The presence of a signature at each level of review indicates that in the opinion of the signer, the contract is in the best interests of the department and the state of Florida. However, the department recognizes the concerns raised regarding the prior financial relationship that the Deputy Assistant Secretary for Health Services Administration had with TYA and Associates. If such a situation should arise in the future, the department will document the action taken to exclude the individual from the contract approval process and so mitigate the increased risk of the appearance of or opportunity for favoritism.

3) With regard to the two documents that were not adequately completed, they are respectively the Conflict of Interest Questionnaire that is executed by the contract manager prior to execution of the contract, and the Department of Corrections' Health Services Pre-Contract Check List, an internal work document utilized by the Office of Health Services (OHS) to track steps to be taken by that office as part of the contracting process. The audit notes that the Conflict of Interest Questionnaire did not have a contract number or vendor name filled-in and that the Pre-Contract Check List was not completed.

It is not uncommon for the Conflict of Interest Questionnaire to be signed and submitted to the Bureau of Procurement & Supply, and placed into the bureau's working file, without a contract number. This document is filled out as part of the Request for Contractual Services process and is routinely signed by the program office (contract manager) and submitted before a contract number is assigned by the Bureau of Procurement & Supply. The contract number is only added when the contract is finalized for review and approval. The proposed vendor's name is required to be filled-in when the form is submitted to the Bureau of Procurement & Supply; however, the contract manager mistakenly filled-in the type of service rather than the proposed vendor's name. Even though the vendor's name was not present, the form was attached to several documents that identified the proposed vendor as Terry Yon & Associates. The contract number and the name of the vendor have since been added and the form is complete.

The Department of Corrections' Health Services Pre-Contract Check List is an internal work document utilized by OHS for tracking purposes. It is a tool that assists the contract manager and other OHS personnel in ensuring that documents that must be submitted for issuance of a contract are completed. This is not a form that is required by any purchasing procedure or rule and is for internal purposes only. Failure to complete sections of the form does not mean that the item has not been addressed or completed for contracting purposes. Even though various sections were not completed, Contract C2197 contains a Scope, Rates, Term, and identification of the Payee as well as other information referenced in the audit as not completed on the check list. Although this is a check list and planning tool only, the document was returned to OHS and has been completed and signed.

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Three

4) The department concurs with the recommendation that a valid comparison of the cost of the service if performed by department staff be made with the cost of acquiring the service from a vendor. It should be noted that in determining whether to privately contract for the provision of any contractual service, the department does consider the following:

- whether the service could more cost-effectively be performed by department staff or is beyond the department's expertise;
- whether the service can be provided in a manner that meets or exceeds the department's service-delivery;
- whether the service provides a cost benefit for taxpayers and is in the best interests of the state; and
- whether the service, as proposed by the private entity, will meet the department's needs and standards.

However, although this criterion was informally considered and discussed the department agrees that they should be formally addressed and documented before entering into any large-scale contract for the provision of services.

Finding No. 2: The Department was unable to provide records related to the employment of the Deputy Assistant Secretary of Health Services Administration who had a prior financial relationship with TYA Pharmaceuticals.

Recommendation: As the employment application contains important information that should be retained, we recommend that the Department's Inspector General consider reviewing the Department's Personnel Office records requirements and procedures, including any situations that may allow documents not to be obtained or retained.

Response: The department concurs with this recommendation.

Finding No. 3: Contrary to the terms of the pill-splitting Contract (No.C2197), the Department was not provided the information necessary to perform background checks for some TYA Pharmaceutical's employees prior to the individuals being hired or assigned to work under the contract.

Recommendation: We recommend that the Department more closely monitor and enforce specific contract requirements regarding TYA Pharmaceutical's employee background checks and fingerprinting.

Response: During the start-up phase of the pill-splitting contract the vendor did fail to notify the department of the individuals who would be working so that appropriate background checks could be performed. However, this was actually discovered during a routine monitoring of the contract by the contract manager on March 24th, 2005 and the vendor was officially notified of the issue in a letter dated March 28th 2005. Accordingly, the background checks were immediately completed and all personnel employed by the vendor were appropriately cleared.

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Four

The department acknowledges that although the contract does require fingerprinting of vendor employees prior to employment, none have been requested. This requirement is no longer deemed to be necessary and a contract amendment will be processed to delete this requirement from the contract. It is the department's opinion that background checks are sufficient to ensure that prospective TYA employees are appropriately screened prior to employment.

Finding No. 4: Department records and procedures were not sufficient to ensure that pharmaceutical orders were properly approved, accurately priced, and filled within the time periods prescribed in the Contracts (Nos. C2116 and C2197).

Recommendation: We again recommend that the Department ensure that documentation containing the required order information including time, date, and appropriate signatures is maintained. The Department should also ensure that expenditures are adequately supported. In addition, the responsibilities for preparing and authorizing orders and accepting and approving orders as received should be separated to the extent possible.

Response: In response to the audit of Contract C2116 conducted in September 2004, the department did implement additional policies and procedures regarding the ordering, receiving, and signing for pharmaceutical orders; As noted in the cover letter, all the invoices and support documentation reviewed in conjunction with the pharmaceutical-repackaging contract (C2116) had the appropriate date stamp of receipt; however, one did not have the time of receipt noted. The contract has been amended to specifically address this issue.

The department acknowledges the issues regarding the pill-splitting contract (C2197). These occurred during the start-up of the contract and have been addressed. The department's four pharmacy managers do need to be more vigilant in analyzing the documentation to ensure that the terms of the contract are being met and to ensure this does happen the following changes have been made:

Each pharmacy manager will combine all orders sent to the vendor's pharmacy site in a twenty four (24) hour period (from 1:01 PM the previous day to 1 PM the current day). They will have a pharmacy technician count all orders placed and so note on an attached cover sheet. All orders are to be signed, dated, and timed. Any issues relating to the placed order are to be noted on the cover sheet. When each order is received pharmacy staff is to ensure it agrees with the order placed. Any discrepancies are to be reported to the vendor immediately via telephone and email with a copy to the contract manager. The vendor shall respond to the notification of discrepancy via email with a copy to the contract manager. Such correspondence will assist the contract manager in determining appropriate compliance with the contract. The department will add the following department check list to the document analysis process to more accurately ensure appropriate, correct, and timely documentation:

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Five

1. Are ordering and receiving function separated?
 2. Are all appropriate signatures on all ordering, faxed, and receiving documents?
 3. Are all ordering, faxed, and receiving documents dated and timed?
 4. Are all orders faxed to the vendor received?
 5. Were any extra prescriptions received from the vendor that could not be accounted for?
 6. Are all medication credit return logs properly completed?
 7. Are all medications logs for credit returns properly signed, dated, and timed?
- Each pharmacy manager or their designee will be responsible for ascertaining all required information and that the responsibilities for ordering and receiving are separated every week
 - If all items are correct, the check list will be so noted and signed
 - If any items are incorrect then the checklist will be so noted and signed. The staff responsible for the errors will be notified and appropriate corrective action implemented. Repeated problems will result in disciplinary action as determined by departmental policy.
 - The department's Director of Pharmacy will monitor this process quarterly at each pharmacy. Each Pharmacy Manager that fails to check the above weekly will be disciplined according to department policy.

Finding No. 5: The Department had not established procedures to effectively measure TYA Pharmaceutical's performance in timely filling and delivering pharmaceutical orders as stipulated in the performance measure in the Contracts (Nos.C2116 and C2197).

Recommendation: We recommend that the Department implement procedures for evaluating and documenting TYA Pharmaceutical's performance related to the timely filling and delivering of pharmaceutical orders. This documentation should be retained for use in enforcing the liquidated damages provisions of the contracts when warranted.

Response: As noted in the preliminary and tentative findings, the department has added a performance measure to the contract to ensure the timely filling and delivering of pharmaceutical orders. However, the pharmacy managers have not been provided written instructions on how to document and report compliance with the measure. This is not to say that such documentation was not being done - pharmacy managers have been orally instructed regarding sending documentation via email to the contract manager regarding items missing from orders and whether orders are received in a timely manner. However, they have not been provided written instructions on when to report, who to report to, and how to report these issues. Accordingly, the department concurs with the recommendation and will issue appropriate instructions to assist staff in documenting performance. All reported incidents will be placed in the contract file and also forwarded to the vendor for any responses relating to extenuating or mitigating circumstances. All of the vendor's responses will also be placed in the contract file.

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Six

All pharmacy sites will also be mailed copies of each contract, (C2116 and C2197) as well as amendments to the contracts. The pharmacies will be required to note via email that they have received the contracts and associated amendments. The contracts are kept on file at each pharmacy will become part of the quarterly monitoring process. Failure to have the contracts and associated amendments on file will result in appropriate discipline according to department policy.

Finding No. 6: The Department did not always record contract payments to the applicable pharmaceutical contract in Department accounting records, limiting the Department's decision-making and monitoring abilities (Nos.C2116 and C2197).

Recommendation: We recommend the Department take appropriate measures to ensure that payments are properly charged to the correct contract in the Department's accounting records. Such measures should include enforcing the invoicing provisions of Contract No.C2116 and amending Contract No.C2197 to require TYA Pharmaceuticals to include the contract number on applicable invoices.

Response: The department concurs with this recommendation. The accounting records have been updated to reflect the correct contract number. The contract manager will initiate the recommended amendment to the contract and will ensure that the vendor complies with the provisions of the contract requiring them to place contract numbers on the invoices.

Finding No. 7: Although required by the repackaging contracts (most recently by Contract No.C2116), the Department did not obtain an annual financial reporting package from TYA Pharmaceuticals until November 2005 (for the year ending December 31, 2004). The provision of an annual financial and compliance audit to the Department has been a contract condition in repackaging contracts between the Department and TYA Pharmaceuticals since January 1998.

Recommendation: The Department should continue to monitor the timely submission of the contractually required audit reports by TYA Pharmaceuticals. Once obtained, the Department should review the reports for any reportable conditions, related-party transactions, or instances of noncompliance and utilize this information during contract monitoring and when negotiating future contracts.

Response: The department concurs with this recommendation. A letter will be sent to the vendor's contract representative outlining the timelines required by each contract. The contract manager will distribute the financial and compliance audit report to all appropriate parties which will be reviewed accordingly.

APPENDIX B

MANAGEMENT RESPONSE (CONTINUED)

Response to Preliminary and Tentative Findings
Page Seven

Finding No. 8: Contrary to the terms of repackaging Contract No. 2116, TYA Pharmaceuticals did not notify the Contract Manager in writing within seven days of receiving a Department of Health Inspection Report.

Recommendation: We recommend the Department take the necessary actions to ensure that TYA Pharmaceuticals notifies the Contract Manager in writing within seven days of any complaint filed, investigation made, warning letters, or inspection reports issued or any disciplinary actions imposed and include a copy of any related documentation with the notification. In addition, the Contract Manager should evaluate the sufficiency of TYA Pharmaceutical's planned corrective actions and then ascertain whether those actions sufficiently resolved the noted deficiencies. The Contract Manager should also ensure that all documentation is properly dated and retained in the Contract File.

Response: The Department of Health inspection conducted on June 28th 2005 was of the vendor's pharmacy site from where the pill-splitting services of Contract C2197 are provided, not from where the repackaging services of Contract C2116 are provided. Unlike Contract C2116, Contract C2197 does not require the vendor to notify the department of such visits. However, as noted in the preliminary and tentative findings, the vendor did provide a copy of the respective inspection report the day of the monthly audit of the contract. Regardless, the reporting requirements should be the same in both contracts and a contract amendment to Contract C2197, adding the vendor reporting requirements will be processed accordingly.