SUMMARY

The Department of Health (DOH), Office of Inspector General conducted an audit of internal controls over drugs in county health department (CHD) dental clinics. Our audit results are based upon a sampling of various dental clinics within nine CHDs. Selected CHDs included Broward, Dixie, Gilchrist, Indian River, Jackson, Jefferson, Palm Beach, Taylor, and Washington counties. We reviewed selected controls as of the date of our visit. (For visit dates to each CHD please see EXHIBIT A).

The purpose of our audit was to determine whether controls are sufficient for the proper accounting of drugs in dental clinics at selected CHDs. We also wanted to determine whether drugs in dental clinics at selected CHDs are securely stored.

To accomplish our objectives, we reviewed applicable law, rules, policy, and procedures. We visited 16 dental clinics at nine CHDs that we judgmentally selected. We interviewed appropriate personnel at Headquarters and the CHDs. We evaluated risks and selected internal controls to determine whether the controls were in place and working effectively.

The audit was conducted in conformance with International Standards for the Professional Practice of Internal Auditing, issued by the Institute of Internal Auditors (January 2009), as provided by Section 20.055(5)(a), Florida Statutes, and as recommended by Quality Standards for Audits by Offices of Inspector General (Principles and Standards for Offices of Inspectors General, Association of Inspectors General, 2004 Revision).

In general, we found that there were an insufficient number of controls over the inventory and security of drugs in the dental clinics that would mitigate the risk of loss. Although our findings are based on the results of our examination at the selected CHD dental clinics, our general approach was to include recommendations in this report that should be reviewed and responded to by the Public Health Dental Program Office (Program Office). We included a chart to summarize the prevalence of identified control weaknesses at the dental clinics we examined (See EXHIBIT A). Since sufficient documentation was not available, we relied on CHD dental staff to inform us of the types of drugs maintained in their inventory. The clinics we visited generally reported having only local anesthetics, Nitrous Oxide, and antibiotics. We did not count quantities and did not tie inventories to purchasing records. While it was not the focus of our audit, nothing came to our attention to indicate that any drugs were unaccounted.
The following issues were identified and should receive additional review and corrective action by management:

- Dental clinics we visited did not implement DOH's policies and procedures for the proper accounting of drugs.
- Drugs in nine of 16 dental clinics were not stored in a secure manner.
- Five of 16 CHD dental clinics we visited used Nitrous Oxide which was not on DOH's State Formulary.
- Two Broward CHD dental clinics were operating in non-DOH facilities without current written contracts.

INTRODUCTION

Section 20.055, Florida Statutes, charges DOH’s Office of Inspector General responsibility to provide a central point for coordination of activities that promote accountability, integrity, and efficiency in government. Audits are conducted to review and evaluate internal controls necessary to ensure the fiscal accountability of DOH.

This audit was included in the Office of Inspector General’s Three Year Audit Plan beginning 2010-2011, which is the result of an annual risk-assessment.

Audit fieldwork took place August through September 2010 at DOH headquarters in Tallahassee, as well as at each of the CHD dental clinics included in this examination. The audit was conducted by Office of the Inspector General audit staff Mark H. Boehmer, Certified Public Accountant, Senior Management Analyst II, Lead Auditor, under the supervision of Michael J. Bennett, Certified Internal Auditor, Director of Auditing.

BACKGROUND

The dental program was established in 1936 to oversee the provision of dental services in the state. The Program Office has four primary functions: 1) provide statewide policy direction related to oral health issues; 2) promote and administer oral health education and preventive dental programs; 3) collect and analyze data on oral health; and 4) support the provision of direct dental care services through the CHDs and other public and private organizations.

Section 154.01(2)(c), Florida Statutes, authorizes DOH to provide dental services. The Florida legislature established the Public Health Dental Program Act in Section 381.0052, Florida Statutes, authorizing DOH to implement a comprehensive dental program to include diagnostic, basic restorative, surgical, pulpal therapy, prophylaxis, and limited prosthetic services.

FINDINGS, RECOMMENDATIONS, AND MANAGEMENT’S RESPONSES AND CORRECTIVE ACTION PLANS

The following findings and recommendations address issues that should receive additional review by management.

Finding 1 – Dental clinics we visited did not implement DOH’s policies and procedures for the proper accounting of drugs.

DOH’s Bureau of Statewide Pharmaceutical Services has established policies and procedures for all DOH entities that procure, store, administer, dispense, issue, or otherwise distribute prescription or over-the-counter (OTC) drugs, including vaccines to CHD patients.
Without adequate controls over inventories, drugs utilized by dental clinics could be inappropriately used or stolen.

We selected four procedures in DOH policy that would assist in the proper accounting of drugs in the dental clinics. We asked staff at the dental clinics we visited for specific documentation to support those procedures. Our examination revealed the following:

**There was no documentation of current inventory levels in CHD dental clinics.**

Section 499.0121(6)(c), *Florida Statutes*, requires that all establishments at which prescription drugs are stored or handled keep records as are necessary for the protection of the public health. “Records..., must be readily available for authorized inspection.”

A prescription drug is defined in Section 499.003(42), *Florida Statutes*, as, "a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (45), or subsection (52)".

DOH Policy (DOHP) 395-1-08, *Statewide Pharmaceutical Services Policies and Procedures for CHDs* (pharmaceutical policy) requires that, "All CHDs shall establish and maintain a system, either in electronic or manual form, to provide accurate audit trails for all pharmaceuticals ordered, received, inventoried, and distributed by the CHDs."

Staff at all dental clinics we visited reported that documentation of orders placed is maintained. However, no dental clinic was able to provide documentation of current inventory levels of anesthesia and other drugs that we observed.

**Periodic inventory counts were not being performed by CHD dental clinics.**

In October 2007, the State Surgeon General issued a written directive to all CHDs that was, "intended to expand to all CHDs with medication rooms that receive State Pharmacy drugs. Therefore, all CHDs with medication rooms should initiate a review of procedures to ensure immediate compliance with the requirements of DOHP 150-1-01 and the additional requirements that are attached to this directive”. DOHP 150-1-01 was subsequently revised and renumbered as DOHP 395-1-08.

Specific to non-controlled substance drug inventory management, the State Surgeon General directed, "To monitor for diversion of noncontrolled or "program" medication, the CHD pharmacist, physician or designee will conduct quarterly inventories of selected medication to compare and reconcile with pharmacy, physician or nurse issuance inventory and dispensing/administration records."

This directive was subsequently incorporated into the pharmaceutical policy that assigns this responsibility to the, “CHD Business Manager and physician, whose license and/or DEA registration permits drugs to be stored/administered, or designee,” to conduct quarterly inventories.

The pharmaceutical policy requires that, "Pharmaceuticals administered, dispensed, issued, or otherwise distributed to CHD clients will be entered into the appropriate pharmaceutical record form and the quantity disbursed reduced from the CHD's pharmaceutical inventory in order to maintain an accurate perpetual inventory balance."
CHD dental staff at the 16 dental clinics we visited explained that no quarterly inventory counts were performed. Some dental clinics reported taking an inventory at fiscal year end (June 30) for state financial statement valuation purposes.

No CHD dental clinic had a formally-established stock control level for reordering.

The pharmaceutical policy stipulates that, "Each CHD must establish a stock control level for each medication carried in inventory."

CHD dental staff at the 16 dental clinics we visited explained there was no formally-established stock control level for reordering each medication carried in inventory. Staff at most of the dental clinics we visited reported that a reorder is placed when only two or three boxes remain in inventory.

No CHD dental clinic reported maintaining a log that documents each time a drug is removed from the primary drug storage area.

DOH’s pharmaceutical policy requires that, "manual or electronic inventory control procedures must contain sufficient documentation to enable the CHD to track a drug from its initial order through its receipt and final disposition. Issue documents or invoices, record cards, transfer documents, accurate medical record entries, and careful attention to maintaining administration logs are all essential to a complete audit trail."

None of the 16 dental clinics we visited maintained a log to document each time a drug is removed from the primary drug storage area. Most dentists explained this type of documentation is recorded in each patient’s medical record.

While it is necessary to record this information in the patient’s medical record, without some type of record that is maintained for each drug it is impossible to track a drug from its initial order through its receipt and final disposition.

RECOMMENDATION:
We recommend the Public Health Dental Program Office assist CHDs implement DOH’s Statewide Pharmaceutical Services Policies and Procedures for County Health Departments regarding the appropriate inventorying of drugs that address, at a minimum, the issues noted in this finding.

An alternative may include the Public Health Dental Program Office developing statewide policies and procedures regarding the inventorying of drugs that specifically apply to CHD dental clinics.

MANAGEMENT’S RESPONSE AND CORRECTIVE ACTION PLAN:
We concur. We will develop a DOH Technical Assistance Guideline (TAG) document to serve as a resource for assisting CHD dental directors and dental managers in complying with applicable policies and procedures contained in DOHP 395-1-08, Statewide Pharmaceutical Services Policies and Procedures for County Health Departments and applicable law contained in Section 499.0121(6)(c), and other sections of Florida Statutes regarding the inventorying and recordkeeping of prescription drugs.

Anticipated completion date: February 4, 2011
**FINDING 2** – Drugs in nine of 16 dental clinics were not stored in a secure manner.

We examined how drugs were stored in each of the dental clinics visited. Our examination revealed the following:

*Local anesthetics were not in a sufficiently controlled environment in nine of 16 clinics inspected.*

Section 499.0121(1)(b), *Florida Statutes*, requires that, "An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must, ...have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions."

A prescription drug is defined by Section 499.003(42), *Florida Statutes*, as, "a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described in Section 503(b) of the Federal Food, Drug, and Cosmetic Act or Section 465.003(8), s. 499.007(13), or Subsection (11), Subsection (45), or Subsection (52) ".

Seven dental clinics securely stored local anesthetics and other drugs in locked cabinets or behind doors with combination locks used at all times.

However, local anesthetics were not in a sufficiently controlled environment in nine of 16 clinics inspected. Some of these dental clinics had cabinets with locks, but the locks were not used. Some dental clinics used rolling carts to store their main inventory (example at Figure 1). Others used cabinets with magnetic latches, but no locks. All of these storage areas could be compromised by unauthorized personnel.

*Six of 16 CHD dental clinics did not have an authorized custodian of keys to dental drug storage areas.*

The pharmaceutical policy stipulates that, "Drugs must be separated and not combined with other commodities in the storage area."

We additionally found that at Children’s Diagnostic and Treatment Center, Fort Lauderdale, CHD dental staff stored food in a refrigerator with drug supplies (See Figure 2).
controls over Drugs in CHD Dental Clinics

permits drugs to be stored/administered, will determine the minimum number of keys, swipe cards, or access codes entrusted to staff personnel for the purpose of gaining entry to the drug storage area. The limitations should not be so stringent as to impede the normal workflow, but also should not be so all-inclusive that drug accountability and responsibility are endangered or impaired. The names of all individuals permitted access to the drug storage area will be documented on a CHD memorandum of record, authorized by the CHD Administrator/Director. This memorandum will be updated as necessary and must be maintained in the official records of the CHD.”

Additionally, "Access to the drug storage areas must be restricted to personnel authorized to handle drugs or by an authorized city, county, state or federal employee operating within the scope of his/her duties."

Six of 16 CHD dental clinics did not have an authorized custodian of keys to dental drug storage areas.

RECOMMENDATION:
We recommend the Public Health Dental Program Office assist CHDs implement DOH’s Statewide Pharmaceutical Services Policies and Procedures for County Health Departments regarding the appropriate security of drugs in dental clinics that address, at a minimum, the issues noted in this finding.

An alternative may include the Public Health Dental Program Office developing statewide policies and procedures regarding the security of drugs that specifically apply to CHD dental clinics.

MANAGEMENT’S RESPONSE AND CORRECTIVE ACTION PLAN:
We concur. We will develop a DOH TAG to serve as a resource for assisting CHD dental directors and dental managers in complying with applicable policies and procedures contained in DOHP 395-1-08, Statewide Pharmaceutical Services Policies and Procedures for County Health Departments and applicable law contained in Section 499.0121(1-3), Florida Statutes, regarding security and storage of pharmaceuticals.

Anticipated completion date:
February 4, 2011

FINDING 3 – Five of 16 CHD dental clinics we visited used Nitrous Oxide which was not on DOH’s State Formulary.

The State Surgeon General directed in 1997 that, "all CHD drug formularies will be sent to the DOH Central Pharmacy and reviewed," by DOH’s Pharmacy and Therapeutics (P&T) Committee. This requirement was incorporated into the pharmaceutical policy. "The P&T Committee will certify that all drugs provide appropriate, consistent and equitable drug therapy meeting the clinical needs of Floridians in an effective, efficient, and fiscally responsible manner. The P&T Committee will review and certify formularies on a monthly or as required basis. Drugs must be listed on an approved formulary in order for a CHD to order or procure same."

Five of 16 dental clinics we visited used Nitrous Oxide, which was not on the approved State Formulary. Of the dental clinics we visited, Fort Lauderdale Health Center-Fort Lauderdale; North Regional Health Center-Pediatric Clinic, Pompano Beach; Indian River; Jackson; and Washington CHD clinics used Nitrous Oxide. Neither the Program Office nor any CHD had submitted a request to DOH’s P&T Committee to review Nitrous Oxide.
Oxide to certify that it provides appropriate, consistent, and equitable drug therapy to meet clinical needs.

RECOMMENDATIONS:
We recommend the Public Health Dental Program Office submit a request to DOH’s P&T Committee to review Nitrous Oxide for possible certification and addition to the State Formulary.

We also recommend the Public Health Dental Program Office survey all CHD dental clinics or obtain an inventory of all drugs used in all CHD dental clinics and submit one request on behalf of all CHD dental clinics to ensure all drugs used in DOH’s dental clinics have been submitted to DOH’s P&T Committee for their review and possible approval to DOH’s State Formulary.

MANAGEMENT’S RESPONSE AND CORRECTIVE ACTION PLAN:
3a – We concur. We completed formal requests to add both medical nitrous oxide and medical oxygen to the State Formulary. A meeting of the DOH P&T Committee convened on Tuesday, November 30, 2010. During that meeting, Committee members voted in favor of adding medical nitrous oxide and medical oxygen to the State Formulary.

Anticipated completion date: December 10, 2010

3b – We concur. We will survey CHD dental directors and dental managers regarding the use and dispensing of all medical drugs in their dental clinical facilities; use this information to complete an inventory of all medical drugs used or dispensed in CHD dental clinics for the treatment and prevention of oral diseases and conditions; submit requests to add such medicinal drugs to the State Formulary, as appropriate; and advise CHD dental directors and managers of how to access the State Formulary.

Anticipated completion date: February 25, 2011

FINDING 4 – Two Broward CHD dental clinics were operating in non-DOH facilities without current written contracts.

Broward CHD operates eight dental clinics. We determined the Broward CHD was operating in two non-DOH facilities we visited without current written contracts.

Broward CHD has maintained a dental clinic at Children's Diagnostic and Treatment Center, 1401 South Federal Highway, Fort Lauderdale, with Broward CHD providing one dentist, one dental assistant and one secretary specialist to provide dental care services to HIV exposed and/or infected children, youth and adult females since May 2005. The written agreement covering these services ended May 2006.

Broward CHD has also maintained a dental clinic on the campus of Broward College, Davie, since June 2008 without a written agreement. The arrangement began as a grant from Health Foundation of South Florida, in June 2008. Broward CHD explained the grant has been extended, but there was no documentation to support such an extension. The grant document did not discuss many of the elements necessary to protect DOH, including liability.

According to guidelines from DOH’s Office of General Counsel, “DOH uses Memorandums of Agreement (MOAs) on a limited basis to formalize its contractual relationships with outside vendors.” However, MOAs may only be used if the agreement does not involve DOH expenditure or compensation to the entity for services performed.
RECOMMENDATION:
We recommend Broward CHD develop, execute, and maintain written agreements with the respective vendors where and so long as it operates dental clinics in non-DOH facilities. These agreements should discuss the terms and conditions of the intended contractual arrangement.

MANAGEMENT’S RESPONSE AND CORRECTIVE ACTION PLAN:
We concur. The project with Broward College expires November 2010. Therefore a new contract is not necessary. A new contract with Children’s Diagnostic and Treatment Center has been executed and is currently in place.

The contract manager will include dental contracts in the list of all Broward CHD contracts compiled and distributed on a monthly basis (and posted to a shared folder) to ensure that the list is complete and that all contracts are identified.

Anticipated completion date:
November 22, 2010
The chart below is intended to quickly identify and summarize the prevalence of control weaknesses that we identified and which are explained in Findings 1 and 2 in the body of this report. Findings 3 and 4 are not included in this chart.

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<th>Facility</th>
<th>Date of Visit</th>
<th>No documentation of current inventory levels</th>
<th>No periodic inventory counts</th>
<th>No formally-established stock control level</th>
<th>No log maintained to document each time a drug is removed from drug cabinet</th>
<th>Drugs were not in a sufficiently controlled environment</th>
<th>No authorized key custodian to dental drug storage areas</th>
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<td>Sept. 7, 2010</td>
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* - Control weakness identified.
REPORT DISTRIBUTION

Pursuant to Section 20.055(5)(b), Florida Statutes, this report is a public record as defined by Section 119.011(12), Florida Statutes.

CLOSING COMMENTS

We would like to thank management and staff of the Public Health Dental Program Office, the Bureau of Statewide Pharmaceutical Services, and the Office of General Counsel for their cooperation and assistance to us during the course of this audit.

We particularly appreciate the cooperation and valued assistance of CHD management and their dental clinic staff for helping us during our on-site visits and subsequent follow-up.