

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**Ron DeSantis**

Governor

Scott A. Rivkees, MD

State Surgeon General

Vision: To be the Healthiest State in the Nation

September 1, 2020

Scott A. Rivkees, MD
State Surgeon General
4052 Bald Cypress Way
Tallahassee, Florida 32399

Dear Dr. Rivkees:

Pursuant to Section 20.055(6)(h), Florida Statutes, our office is to update you on the status of corrective actions taken since March 13, 2020 when the Office of the Auditor General published its Report Number 2020-154, *Food Service Establishment Licensing and Inspections and Prior Audit Follow-Up*.

Six months after publication, management reports some of the corrective action plans made in response to recommendations from the Office of the Auditor General have been completed. Three corrective actions have been completed and five are still in progress. We will conduct another follow-up in six months regarding the remaining corrective actions still in progress.

If I may answer any questions, please let me know.

Sincerely,

Michael J. Bennett, CIA, CGAP, CIG
Inspector General

MJB/akm
Enclosure

cc: Melinda M. Miguel, Chief Inspector General, Executive Office of the Governor
Lisa Norman, Office of the Auditor General
Kathy DuBose, Staff Director, Joint Legislative Auditing Committee
Courtney F. Coppola, Chief of Staff
Shamari Roberson, DrPH, MPH, Deputy Secretary for Health
Mike Mason, Operations Director
Michele Tallent, Deputy Secretary for Operations

Status of Corrective Action Plans



Report Number: 2020-154
Report Title: Department of Health, Food Service Establishment Licensing and Inspections and Prior Audit Follow-Up
Report Date: March 13, 2020
Status As Of: September 1, 2020

No.	Finding	Recommendation	Corrective Action Plan	Status of Corrective Action Plan
1	Department of Health (Department, DOH) records did not evidence that food service establishment licenses were issued prior to the commencement of operations and some county health departments (CHDs) utilized license application forms that did not require all the information specified by the Department's application.	(1.1) We recommend that Department management establish procedures to track the commencement date for newly licensed food service establishments.	<p>(1.1) The Bureau of Environmental Health follows the legal interpretation that the act of the initial inspection and permitting is our permission to the food service establishment that they may commence food service. Sanitation certificates contain an Issued Date, which is the date that the new establishment received an inspection with a satisfactory result. The establishment may commence business on the date that the sanitation certificate is issued, as the establishment has been found to have satisfied the statutory and rule requirements. It should also be noted that there is communication between the CHD and the establishment from the time that the application is received to the time that the sanitation certificate is issued. Upon receipt of the application, a plan review and construction site visits will follow. Should a facility be found conducting food service activities prior to issuance of the sanitation certificate, enforcement proceedings would begin. Chapter F of DOH Manual (DOHM) 150-4, <i>Environmental Health Program</i>, provides the process for issuance of a sanitation certificate for newly licensed food service establishments.</p> <p>Each CHD maintains individual internal processes for tracking each step of the permitting process, assuring timely issuance of sanitation certificates prior to the food establishment commencing operation. The audit revealed one sanitation certificate that was issued by default due to a break in the process when the responsible employee left employment. This CHD immediately revised their process to prevent this situation from repeating itself.</p>	<p>(1.1) Previously closed.</p> <p>Management previously accepted any associated risk.</p>

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		<p>(1.2) We also recommend that Department management ensure that license applications utilized by the CHDs capture all the information required by the Department's Application.</p>	<p>(1.2) This recommendation is different from the previous recommendation as it pertains to the application and not the issuance of the sanitation application. The environmental health directors from the two CHDs identified as to not using the correct application will be reminded not to modify the application, and will be sent the current original application form for use. Chapter F of the DOHM 150-4, <i>Environmental Health Program</i>, has been revised to include language prohibiting modification to the application form. The Bureau of Environmental Health currently conducts programmatic evaluations of the Food Safety and Sanitation Program in each CHD every four years. The file review subcomponent of the evaluation includes a measure to review the file application for ten randomly selected facilities to ensure the application is completed in its entirety. When a CHD is found not complying with this requirement, it is documented on the evaluation as a deficiency requiring correction.</p>	<p>(1.2) Completed.</p> <p>Orange and Pinellas CHDs were identified as altering the applications. These CHDs corrected this error September 2018 with the implementation of the revised rule chapter and corresponding documents. In addition, a memorandum was sent to all CHDs reminding them that they must not alter the application form.</p>
2	<p>The Department did not always inspect food service establishments in accordance with the Department's established inspection frequency and sometimes did not timely conduct reinspections of establishments.</p>	<p>(2.1) We recommend that Department management ensure that food service establishments are inspected in accordance with established inspection frequencies and scheduled reinspection dates.</p>	<p>(2.1) The Bureau of Environmental Health's Chief has implemented sending a monthly quota report to the CHD health officers/administrators and environmental health directors to ensure they are aware of their inspection status in each program, including the Food Safety and Sanitation Program. When identified triggers are observed, the Bureau of Environmental Health's Chief or their designee will reach out to the CHD to determine the cause of a lag in completing the required inspections. This monthly report is meant to generate conversation between the health officers/administrators and environmental health directors regarding the status of the programs, identify resource issues, and bring awareness to the situation.</p> <p>In addition, the Food Safety and Sanitation Program is evaluated quadrennially, and includes a measurement pertaining to the completion of required routine inspections. When a CHD is found not complying with this requirement, it is documented on the evaluation as a deficiency requiring correction.</p>	<p>(2.1) Previously completed.</p>

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		<p>(2.2) We also recommend that Department management ensure that Department records evidence the reason for and date of any changed reinspection dates.</p>	<p>(2.2) Chapter F of DOHM 150-4, <i>Environmental Health Program</i>, contains the procedure for documenting a change of date when a reinspection is rescheduled. The procedure does not require the reinspection date to be changed in the “Initial Food Service Inspection Report” as this document may not be edited after the customer has signed the form. Instead, the procedure directs staff to place documentation in the hard copy or electronic file, indicating the new date and reason for the change of date. No later than April 1, 2020, the Bureau of Environmental Health will send a memorandum to the CHDs reminding them of this procedure.</p> <p>In addition, during the file review portion of the quadrennial evaluation of the Food Safety and Sanitation Program, reinspections are reviewed to ensure that they are performed on the date originally stated on the initial inspection report or that there is documentation in the file indicating the change of date and the reason for the change. When a CHD is found not complying with this requirement, it is documented on the evaluation as a deficiency requiring correction.</p> <p>The Food Safety and Sanitation Program has scheduled six regional consistency meetings beginning April 29, 2020 and ending December 9, 2020 for CHD inspection and supervisory staff with food program duties. The agenda for these meetings will include review of the procedure for reinspection.</p>	<p>2.2) In progress.</p> <p>CHDs are actively involved with response to the COVID-19 pandemic. The pandemic has delayed scheduling of consistency meetings. These meetings will no longer be regional as they will be held virtually with each individual county. These meetings are currently being scheduled.</p> <p><i>Anticipated Completion Date: December 31, 2020</i></p>

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3	Department controls for food service establishment complaint investigations need enhancement to ensure that all complaints are recorded in the Department's Environmental Health Database (EHD), complaint investigation activities are documented in accordance with Department policies and procedures, and investigations are timely conducted.	(3.1) We recommend that Department management work with the CHDs to ensure that the EHD includes all food service establishment complaint investigations and such investigations are documented and timely conducted in accordance with Department policies and procedures.	(3.1) The procedure for handling complaints is found in Chapters F and Y of DOHM 150-4, <i>Environmental Health Program</i> . These chapters have been revised to assure clarity regarding the procedure for recording the details of the complaint investigation. No later than April 1, 2020, the Bureau of Environmental Health will send a memorandum to the CHDs reminding them of this procedure. The Food Safety and Sanitation Program has scheduled six regional consistency meetings beginning April 29, 2020 and ending December 9, 2020 for CHD inspection and supervisory staff with food program duties. The agenda for these meetings will include training about all aspects of complaint investigations.	(3.1) In progress. CHDs are actively involved with response to the COVID-19 pandemic. The pandemic has delayed scheduling of consistency meetings. These meetings will no longer be regional as they will be held virtually with each individual county. These meetings are currently being scheduled. <i>Anticipated Completion Date: December 31, 2020</i>
		(3.2) We also recommend that Department management revise Department policies and procedures to ensure investigators are aware of the requirement to document all complaint investigation activities on a <i>Complaint Investigation Record</i> form.	(3.2) The procedure for handling complaints is found in Chapters F and Y of DOHM 150-4, <i>Environmental Health Program</i> . These chapters have been revised to assure clarity regarding the procedure for recording the details of the complaint investigation. The DOHM 150-4, <i>Environmental Health Program</i> , is currently being revised and must undergo internal review prior to being approved for implementation.	(3.2) In progress. Completion of this corrective action has been delayed due to the Bureau's involvement with the pandemic. <i>Anticipated Completion Date: December 31, 2020</i>
4	Bureau of Public Health Pharmacy (Bureau) pharmaceutical inventory management controls continue to need improvement.	We recommend that Bureau management ensure that Bureau records are appropriately adjusted for the results of physical inventory counts and adequately evidence the investigation of noted differences and reason for inventory record adjustments to drug quantities.	Effective immediately, all physical inventory (on-hand shelf) counts conducted in the Bureau will be performed using the two-count methodology, which is composed of two specified teams conducting the counts. After the first physical count is completed, the count teams will compare the count results to identify discrepancies between the two physical count numbers. The count teams will then physically recount the products with discrepancies until one confirmed shelf count number is determined. The confirmed physical shelf count will then be compared to the product quantity as recorded in the related systems to determine discrepancies between the physical counts and the system records.	In progress. The following procedures have been implemented: <ul style="list-style-type: none"> • All physical inventory (on-hand shelf) counts conducted in the bureau are performed using the two-count methodology. • All physical inventory discrepancies were reconciled using the investigative methodology, the revised recording and reporting process, and the revised adjustment justification criteria. • A Variance Report format was developed and incorporated with the revised management review and approval process with signatures.

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			<p>All discrepancies must be investigated for cause and the research actions included as a part of the justification for adjustment.</p> <p>If discrepancies remain after investigation, Bureau staff are to adjust the inventory quantities in the related systems (QS/1 dispensing and the Pharmaceutical Forms System (PFS)). To record the adjustment, the existing Inventory Report produced from each system will be enhanced to include an area for the adjustment justification to be documented for each item. The justification must include the following information:</p> <ul style="list-style-type: none"> • Date of the adjustment; • Suspected cause of the discrepancy; • Investigative steps taken to determine the cause of the discrepancy; • Total amount of the quantity adjustment done in the systems; • Dollar amount (+, -) of the adjustment. <p>After each monthly inventory, a copy of the final inventory report that reflects discrepancies will be developed for management review and submitted within five working days from the conclusion of the inventory. The delegated management position will then acknowledge the inventory report by signature and maintain the documentation on-site for audit purposes.</p> <p>Actions to be completed to enhance the inventory process will be as follows: The existing physical inventory Internal Operating Procedures (IOP) 058-016, <i>Issuance-Bulk-Logistics</i>; and IOP 064-016, <i>Central Pharmacy</i> will be revised to reflect the procedures listed above;</p> <ul style="list-style-type: none"> • A format will be developed for the management review report (Variance Report); and • The existing systems inventory report will be revised to allow for comprehensive information related to the adjustments. 	<p>There is one outstanding action that has not been completed by June 30, 2020:</p> <ul style="list-style-type: none"> • The existing physical inventory IOPs (058-016: Issuance-Bulk-Logistics; 064-016: Central Pharmacy) have not been revised to reflect the procedures listed above as of this reporting date. These IOPs will be completed by the revised Completion Date listed below. <p>NOTE: Inventories for February through March 2020 were conducted under the new procedures. The physical inventory count schedule was interrupted by the COVID response during the months of April-May 2020. A year-end inventory count was conducted in June to comply with fiscal year-end reporting and for insurance projections for the upcoming fiscal year. The physical inventory count schedule will be resurrected in the new fiscal year (July 2020).</p> <p><i>Anticipated Completion Date: October 31, 2020</i></p>

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5	As similarly noted in prior audit reports, most recently in our report No. 2016-087, the Bureau did not maintain complete and accurate records of drugs returned from the CHDs.	We again recommend that Bureau management maintain complete and accurate records of all drugs returned from the CHDs and work with CHD staff to use the Pharmaceutical Forms System (PFS) to properly document the return of all prescription drugs to the Central Pharmacy and warehouse in accordance with established procedures.	<p>During the period of the original audit, Return Merchandise Approval (RMA) forms were not housed in the PFS and the bureau recorded returns on Excel spreadsheets titled as Pharmacy Return Logs. Since 2016, a Quarantine Module has been added to the PFS which includes the only approved RMA forms to be used for product return. The system also acts as the Pharmacy Return Log and a reporting module for returned drugs is being developed.</p> <p>Per revised IOP 044-016, <i>Quarantine and Disposition of Pharmaceuticals</i>, all returned quarantine drugs must have a RMA form accompanying and included with the shipped boxes. The RMA form must be entered in PFS by the returning entity. All product received without the RMA form will be declined for receipt or returned to the sending entity. These steps to return quarantine product have been and continue to be discussed on the monthly Statewide Pharmaceutical conference calls.</p> <p>The RMA procedure is also referenced in the revised Department Procedure 395-1-19, <i>Public Health Pharmacy Policy and Procedures</i>.</p> <p>Actions to be completed to enhance the quarantine drug return process is as follows:</p> <ul style="list-style-type: none"> • Develop a PFS training module for users to access for proper procedures on quarantine drug return; • Continue to discuss the process on the Statewide Pharmaceutical conference call; and • Review and if necessary, enhance the PFS reporting module to produce periodic reports of quarantine returned drugs for management review. 	<p>Completed.</p> <p>The following procedures have been implemented:</p> <ul style="list-style-type: none"> • A training module has been developed and posted on the PFS website for users to access for proper procedures on quarantine drug return. • The issue is a recurring, as needed talking point on the CHD Statewide Pharmaceutical conference call to continue the discussion and emphasis on the proper process for return of quarantine product. • Periodic reports related to RMA submissions and quarantine reverse distribution are available on-demand from the respective providers.

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6	Department controls for timely removing user access privileges to Department information technology applications continue to need improvement.	We again recommend that Department management strengthen controls to ensure that access privileges are timely removed upon a user's separation from employment.	<p>The Health Management Systems (HMS) has been modified to support Single Sign-On (SSO) and uses Azure Active Directory for authentication. For systems that have deployed SSO, deactivation takes place in Azure Active Directory (Azure AD). Once a user is deactivated in Azure AD, they can no longer access the information systems that have deployed SSO.</p> <p>Users are deactivated in Azure Active Directory by three basic means:</p> <ol style="list-style-type: none"> 1. A separated employee goes through the off-boarding process in the new Florida Department of Health Human Resources System (FLHealthDeskHR) which was deployed in the spring of 2019. The new FLHealthDeskHR automatically deactivates the user. 2. For more instant deactivation, any supervisor/manager can deactivate an employee/contractor under them by accessing the Profile Manager application from InsideFLHealth. Their direct reports are listed, and the option for deactivation is presented. Deactivation can be immediate, or it can be scheduled out a few days in advance. 3. Request through a service ticket to Information Technology (IT), and IT will take appropriate action. <p>Once deactivation takes place, any information system that utilizes Azure AD for authentication will no longer be available to the deactivated user.</p> <p>For information systems that do not employ SSO, it is the responsibility of the supervisor or manager to ensure the separated users are properly deactivated by ensuring the application's user administrator goes into the system and flags the user appropriately.</p>	<p>In progress.</p> <p>This corrective action was in the planning stage when placed on hold March 2020 as a result of COVID 19. Office of Information Technology (OIT) staff was temporarily reassigned to implement systems to support Department staff assigned to telework. A new virtual private network system and rapid expansion of virtual desktop infrastructure and remote workstation capabilities were undertaken to assist CHDs, divisions and offices transition staff and functions to meet this new and emerging threat. OIT has transitioned back to normal operations since July 2020.</p> <p>The Department's Triennial Risk Assessment determined that several of the policies referenced in this audit are in the process of being updated. These policies will be updated to reflect the recommendations put forth in Finding 6. Moving forward efforts will focus on the creation of an initial awareness campaign that will be designed and executed, annual training material will be added to existing recurring training requirements for management, and a Management Guide for performing information system user access reviews will be developed and made available.</p> <p><i>Anticipated Completion Date: December 31, 2020</i></p>

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			Information about how to deactivate a separated user in Azure AD, and information about policy requirements to deactivate users in information systems that have not employed SSO, will be added to existing recurring training requirements for management, and a Management Guide for performing information system user access reviews will be developed and made available.	