March 31, 2022

Joseph A. Ladapo, MD, PhD
State Surgeon General
4052 Bald Cypress Way, Bin A-00
Tallahassee, Florida 32399

Dear Dr. Ladapo:

Enclosed is our internal audit report # A-2122-006, *Follow-up Audit of County Health Departments' Ordering and Shipping Clients' Lab Work.* The report provides an independent evaluation of the current processes used by county health departments to prepare and ship specimens for testing to the Bureau of Public Health Laboratories.

The audit was conducted by Ashlea K. Mincy, CIGA, Assistant Director of Auditing, and supervised by Mark H. Boehmer, CPA, Director of Auditing.

Management agreed with the findings identified in the report. We will provide you a status update in six months detailing the progress management has made toward addressing the proposed corrective actions included in Appendix A of the report.

If you wish to discuss the report, 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, CPA, Office of the Auditor General
Kenneth A. Scheppke, MD, FAEMS, Deputy Secretary for Health
Mark Lander, Interim Deputy Secretary for County Health Systems
Mike Mason, Assistant Deputy Secretary for Health
Mark H. Boehmer, CPA, Director of Auditing

FLORIDA DEPARTMENT OF HEALTH
OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF COUNTY HEALTH DEPARTMENTS' ORDERING AND SHIPPING CLIENTS' LAB WORK

Report # A-2122-006 • March 31, 2022

Purpose of this project:
Following a series of lost shipments of laboratory (lab) specimens from county health departments (CHDs) to the Department of Health's (Department, DOH) laboratories, the Office of Inspector General (OIG) initiated this project to verify whether corrective action plans from the OIG's Audit #A-1718DOH-020, *County Health Departments' Ordering and Shipping of Clients' Lab Work,* published on December 7, 2018, had been implemented and were having a positive impact on improving processes used by CHDs and other entities to prepare and ship lab specimens for testing.

What we examined:
We reviewed the corrective actions implemented after the issuance of the prior audit report and observed the opening of lab specimens on January 11, 2022, at the Department's Jacksonville Laboratory (Laboratory).

Summary of results:
While the corrective actions implemented successfully corrected four of the seven issues identified during our prior audit, we identified the following issues that management should continue to address.

- CHDs included unnecessary Personally Identifiable Information (PII) and Protected Health Information (PHI) in shipments to the Laboratory.
- Some packages of lab specimens were not properly identified with UN 3373 labels.
- Lab specimens were not consistently shipped.

Additional details follow below. Management's response to the issues noted in this report may be found in **Appendix A**.

BACKGROUND

The Bureau of Public Health Laboratories (BPHL), pursuant to Section 381.0202(1), Florida Statutes, provides clinical and environmental lab services to the 67 counties for the protection of public health, with labs in Jacksonville, Miami, and Tampa.

CHDs' use of the Department's *Health Management System* (HMS) includes client registration, scheduling, care coordination, electronic lab test ordering, and test results. Each client's electronic medical record is maintained in HMS. The electronic lab test ordering and results function (e-Lab) in HMS was procured from Change Healthcare Solutions, LLC (vendor). With proper use of the e-Lab function, an ordering provider electronically creates, modifies, and submits lab orders when a need for microbiological and chemical analyses is identified.

The e-Lab creates an electronic requisition form and a specimen container label with corresponding barcodes. The label is to be affixed to the specimen container. The creation of requisitions and labels in e-Lab, and affixing the label to the specimen reduces the need for clients' PHI in shipments to the Laboratories. There is no need for additional documentation in the shipment. The shipment would not include discernable client PII or PHI, should it be opened by someone other than authorized Laboratory staff. Upon receipt at the Laboratories, the barcode located on the label is scanned, providing staff access to the electronic order. Once lab testing is complete, providers can then access test results in e-Lab.

DETAILED RESULTS AND RECOMMENDATIONS

Criteria for the detailed results below, unless otherwise stated, include:

- All PII contained in the Department's records relating to an individual's personal health services is confidential. - Section 119.0712(1), Florida Statutes.
- The identity of a person upon whom a HIV test has been performed is confidential. - Section 381.004(2)(f), Florida Statutes.
- Personal information is defined as an individual's first name or first initial and last name in combination with data elements that include any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnoses by a health care professional; or an individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual. - Section 501.171(1)(g), Florida Statutes.
- The Department defines PHI as health information that contains information such that an individual person can be identified as the subject of that information. – DOH Policy (DOHP) 50-24-19, *Health Record Policy*.

Our audit identified the following opportunities to improve effectiveness and efficiencies in operations:

1. CHDs included unnecessary PHI in shipments to the Laboratory.

- Our testing identified some instances where shipments sent from CHDs to the Laboratory continue to include manifests and/or hard copies of the requisition forms in addition to the specimen containers' labels. The information on the manifests and requisitions included client name, age, date of birth, gender, address, phone number, insurance information, and test type.
- Including the client name, date of birth, and test description increases the likelihood that clients PHI will be disclosed in the event of a shipment being lost, damaged, or misdelivered. Also, the information listed above plus the clients' addresses, phone numbers, insurance information, etc. could be used to commit identity theft.

We recommend the Office of County Health Systems implement additional efforts to promote CHDs use only labels with barcodes when shipping specimens to the Laboratories, except where paperwork, such as manifests and/or requisitions, is required.

2. *Some packages of lab specimens were not properly identified with UN 3373 labels.*

- 49 CFR 172.400 requires packages that contain hazardous materials, including infectious substances, be affixed with labels specified for the material. This identifies to handlers the package contains a Category B infectious substance, which could be either a diagnostic, clinical specimen, or biological substance.
- 49 CFR 173.199 requires shipments containing Category B infectious substances to be labeled on the outside of the package with a UN 3373 label. This CFR also requires persons who ship such specimens to receive "General Awareness" hazardous materials training and "Infectious Substances" training. Those who prepare and ship specimens fitting the criteria for UN 3373 are required to know the requirements for proper transport.
- Packages we inspected from three CHDs did not include the required UN 3373 label on the outside of the package.
- The Department is subject to monetary penalties for failing to properly ship specimens without required labels. 49 CFR 107.329 explains each person who knowingly violates a requirement of Federal hazardous material transportation law is liable for a civil penalty up to $84,425 per violation. The penalty can be up to $196,992 per violation if the result is a serious illness.

We recommend the Office of County Health Systems implement additional efforts to promote requirements that CHDs properly label shipments of lab specimens, in accordance with 49 CFR 173.199.

3. *Lab specimens were not consistently shipped.*

- 49 CFR 173.199 requires Category B infectious substances to be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. The secondary packaging must be secured in rigid outer packaging with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging. Absorbent material must be placed between the primary receptacle and secondary packaging when the substance is a liquid. The absorbent material must be of sufficient quantity to absorb entire contents of the primary receptacles and not compromise the integrity of the cushioning material or the outer packaging. The triple packaging must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. The triple packaging must be capable of successfully passing the drop tests at a height of at least 1.2 meters (3.94 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging.
- Packages we inspected from two CHDs did not include absorbent material between the primary receptacle and secondary packaging.
- Specific specimens must be shipped at 2-8°Celsius on gel ice packs, to ensure the integrity of the test specimen. Packages from two CHDs required to be shipped at a specific temperature were not packaged in a cooler with gel ice packs.

We recommend BPHL, in collaboration with the Office of County Health Systems, implement additional efforts to train all CHD employees responsible for packaging and shipping of Category B infectious disease specimens to ensure consistency.

SUPPLEMENTAL INFORMATION

Section 20.055, Florida Statutes, charges the Department's OIG with responsibility to provide a central point for coordination of activities that promote accountability, integrity, and efficiency in government.

Ashlea K. Mincy, CIGA, Assistant Director of Auditing, conducted the audit under the supervision of Mark H. Boehmer, CPA, Director of Auditing.

Our methodology included reviewing applicable law, rule, policy, and operational procedures; inspecting shipments of specimens; and interviewing management and staff.

This audit was conducted in conformance with *International Standards for the Professional Practice of Internal Auditing*, issued by the Institute of Internal Auditors, as provided by section 20.055(6)(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).

We want to thank management and staff in the Department's Bureau of Public Health Laboratories for the information and documentation they provided, and for their cooperation throughout the project.

Copies of all final reports are available on our website at **www.FloridaHealth.gov** **(search: internal audit)**. If you have questions or comments, please contact us by the following means:

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4052 Bald Cypress Way, Bin A03, Tallahassee, FL 32399

Email:
inspectorgeneral@flhealth.gov

Phone:
850-245-4141

APPENDIX A: MANAGEMENT RESPONSE

	Recommendation	Management Response
1	*We recommend the Office of County Health Systems implement additional efforts to promote county health departments (CHDs) use only labels with barcodes when shipping specimens to the Laboratories, except where paperwork, such as manifests and/or requisitions, is required.*	We concur. The Bureau of Public Health Laboratories (BPHL) will provide training to county health departments that specifically addresses the issues identified in the Office of Inspector General (OIG) report. This training will be available beginning in May 2022. The training will be a PowerPoint presentation that can be offered via teams or in person. *Contact:* Susanna Crowe / Valerie Shipley *Anticipated Completion Date:* May 31, 2022
2	*We recommend the Office of County Health Systems implement additional efforts to promote requirements that CHDs properly label shipments of lab specimens, in accordance with 49 CFR 173.199.*	We concur. BPHL will provide training to CHDs that specifically addresses the issues identified in the OIG report. This training will be available beginning in May 2022. The training will be a PowerPoint presentation that can be offered via teams or in person. In addition, BPHL will continue to invite CHD staff to attend in person, packaging and shipping training which covers both category A and category B shipping requirements. It is anticipated that the next cycle of training will begin in late spring, 2022 (the presentation is currently being routed for approval). *Contact:* Susanna Crowe / Valerie Shipley *Anticipated Completion Date:* June 20, 2022
3	*We recommend BPHL, in collaboration with the Office of County Health Systems, implement additional efforts to train all CHD employees responsible for packaging and shipping of Category B infectious disease specimens to ensure consistency.*	We concur. BPHL will provide training to CHDs that specifically addresses the issues identified in the OIG report. This training will be available beginning in May 2022. The training will be a PowerPoint presentation that can be offered via teams or in person. In addition, BPHL will continue to invite CHD staff to attend in person, packaging and shipping training which covers both category A and category B shipping requirements. It is anticipated that the next cycle of training will begin in late spring, 2022 (the presentation is currently being routed for approval). *Contact:* Susanna Crowe / Valerie Shipley *Anticipated Completion Date:* June 20, 2022