

**DEPARTMENT OF HEALTH**

Prescription Drug Monitoring Program



Sherrill F. Norman, CPA  
Auditor General

## State Surgeon General and State Health Officer

The Department of Health is established by Section 20.43, Florida Statutes. The head of the Department is the State Surgeon General and State Health Officer who is appointed by the Governor and subject to confirmation by the Senate. During the period of our audit, the following individuals served as the State Surgeon General and State Health Officer:

Dr. Celeste Philip	From May 18, 2016 Interim, March 11, 2016, through May 17, 2016
Dr. John H. Armstrong	Through March 10, 2016

The team leader was E. Annette Green, CPA, and the audit was supervised by Lisa Norman, CPA.

Please address inquiries regarding this report to Lisa Norman, CPA, Audit Manager, by e-mail at [lisanorman@aud.state.fl.us](mailto:lisanorman@aud.state.fl.us) or by telephone at (850) 412-2831.

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# DEPARTMENT OF HEALTH

## Prescription Drug Monitoring Program

### **SUMMARY**

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This operational audit of the Department of Health (Department) focused on the Department's administration of the Prescription Drug Monitoring Program and contract management. Our audit disclosed the following:

**Finding 1:** The Department did not make or obtain an independent and periodic assessment of the effectiveness of relevant service organization controls for the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E-FORCSE<sup>®</sup>) system.

**Finding 2:** Enhancements to available E-FORCSE<sup>®</sup> system data and Department procedures were needed to effectively assess whether pharmacies and dispensing practitioners reported controlled substance dispensing information to the E-FORCSE<sup>®</sup> system within the time frame prescribed by State law.

### **BACKGROUND**

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According to State law,<sup>1</sup> the purpose of the Department of Health (Department) is to protect and promote the health of all residents and visitors in the State. In 2009, the Legislature established the State's Prescription Drug Monitoring Program (Program) in State law<sup>2</sup> and specified that, by December 1, 2010, the Department was to design and establish a comprehensive electronic database system to collect controlled substance<sup>3</sup> prescription information from pharmacies and dispensing health care practitioners and provide prescription information to pharmacies, health care practitioners, certain law enforcement and regulatory agencies, and others as authorized by State law. Pursuant to State law,<sup>4</sup> the Department contracted with a service organization to implement the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E-FORCSE<sup>®</sup>) system. The E-FORCSE<sup>®</sup> system captures information specific to each prescribed controlled substance dispensing transaction, such as the name, date of birth, and address of the individual who received the dispensed drug; the name and address of the prescriber and dispenser; the prescription date and dispensing date; and the drug name, quantity dispensed, days of supply, and authorized number of refills.

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<sup>1</sup> Section 20.43(1), Florida Statutes.

<sup>2</sup> Chapter 2009-198, Laws of Florida, enacted as Section 893.055, Florida Statutes.

<sup>3</sup> Pursuant to Section 893.055(1)(b), Florida Statutes, controlled substances include the controlled substances listed in Schedules II, III, or IV outlined in Section 893.03, Florida Statutes.

<sup>4</sup> Section 893.055(2)(a), Florida Statutes.

## ***FINDINGS AND RECOMMENDATIONS***

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### **Finding 1: Service Organization Controls**

The Department contracted with a service organization to implement, operate, and maintain the E-FORCSE<sup>®</sup> system to capture information specific to each prescribed controlled substance. The contractual agreements between the Department and the service organization required the secure collection, storage, and reporting of required data and secure access to E-FORCSE<sup>®</sup> system data. As the Department relies on the E-FORCSE<sup>®</sup> system, and the sensitive and confidential information contained therein,<sup>5</sup> to administer the Program, it is incumbent upon the Department to take steps to reasonably ensure the integrity, reliability, and security of E-FORCSE<sup>®</sup> system data. Such steps may include requiring the service organization to provide a service auditor's report<sup>6</sup> on the effectiveness of the controls established by the organization for the E-FORCSE<sup>®</sup> system or, alternatively, Department staff to monitor the effectiveness of relevant service organization controls.

Our examination of Department contractual agreements with the service organization disclosed that the agreements did not include a provision requiring the service organization to provide a service auditor's report, nor had the Department requested or received such a report. In addition, our audit procedures disclosed that the Department had not monitored the effectiveness of relevant service organization controls. For example, we found that, while the contractual agreements specified that level 2 background screenings<sup>7</sup> were to be performed on all service organization employees who were to work with the E-FORCSE<sup>®</sup> system and that the organization's employees were to satisfy minimum work experience requirements, ranging from 1 to 5 years depending on the employee's assigned job duties, the Department had not verified that the required background screenings had been performed or that the service organization employed staff who satisfied the work experience requirements. In response to our audit inquiry, Department management indicated that they had requested the service organization to conduct background screenings on the employees and return the results to the Department and also submit documentation of employee qualifications to the Department for review.

Absent an evaluation of relevant service organization controls, Department management has reduced assurance that relevant internal controls supporting the operation and maintenance of the E-FORCSE<sup>®</sup> system are in place and functioning properly.

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<sup>5</sup> Pursuant to Section 893.0551, Florida Statutes, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, United States Drug Enforcement Administration number, and any other unique identifying information or number of a patient or patient's agent, health care practitioner, dispenser, employee of a practitioner who is acting on behalf of and at the discretion of a practitioner, pharmacist, or pharmacy, included in the E-FORCSE<sup>®</sup> system, is confidential and exempt from public inspection.

<sup>6</sup> A service auditor's report, as described by the American Institute of Certified Public Accountants, Statement on Standards for Attestation Engagements No. 16, *Reporting Controls at a Service Organization*, provides information and auditor conclusions related to a service organization's controls. Service organizations make service auditor's reports available to user organizations to provide assurances related to the effectiveness of the service organization's relevant internal controls.

<sup>7</sup> As defined in Section 435.04, Florida Statutes, level 2 background screenings include, but need not be limited to, fingerprinting for Statewide criminal history records checks through the Department of Law Enforcement, national criminal history records checks through the Federal Bureau of Investigation, and may include local criminal records checks through local law enforcement agencies.

**Recommendation:** Because of the critical and sensitive and confidential nature of E-FORCSE<sup>®</sup> system data, we recommend that Department management make or obtain an independent and periodic assessment of the service organization's relevant internal controls. Such an assessment should include examination of documentation evidencing that service organization employees met contractual requirements related to background screenings and work experience.

## **Finding 2: Statutory Reporting Requirement**

State law<sup>8</sup> requires that, each time a controlled substance is dispensed to an individual, the pharmacy or dispensing health care practitioner is to report the event in the E-FORCSE<sup>®</sup> system as soon as possible, but no more than 7 days after the controlled substance is dispensed, unless an extension is approved by the Department. Compliance with the statutory reporting requirement is critical to the Department's ability to effectively administer the Program and further the Program's goal of providing timely information to pharmacists, health care practitioners, and other E-FORCSE<sup>®</sup> system information users.<sup>9</sup>

When pharmacies and dispensing practitioners electronically report dispensing transaction information to the E-FORCSE<sup>®</sup> system, the system captures information such as the dispenser name and the number of dispensing transactions included in the uploaded file. Department procedures permitted multiple dispenser reports to be uploaded to the E-FORCSE<sup>®</sup> system as part of the same file. For example, chain pharmacies were permitted to upload to the E-FORCSE<sup>®</sup> system one file, containing controlled substance dispensing information for all pharmacies licensed in the State. If a pharmacy or dispensing practitioner did not have any dispensing transactions to report for a preceding 7-day period, the Department required the pharmacy or health care practitioner to complete a *Report Zero Activity* form in the E-FORCSE<sup>®</sup> system.

As part of our audit, we performed inquiries of Department management and analyzed E-FORCSE<sup>®</sup> system data for the period July 2014 through January 2016 to determine whether the Department appropriately assessed whether pharmacies and dispensing practitioners reported dispensing transaction information to the E-FORCSE<sup>®</sup> system within the time frame prescribed by State law. Our audit procedures disclosed that, to effectively evaluate dispenser compliance with statutory reporting requirements, enhancements to available E-FORCSE<sup>®</sup> system data and Department procedures for determining the timeliness of the information reported to the E-FORCSE<sup>®</sup> system were needed. Specifically, we noted that:

- The E-FORCSE<sup>®</sup> system did not capture the date uploaded for each dispensing transaction in a manner that would permit a reliable assessment of the number of days that elapsed between the date a controlled substance was dispensed and the date the dispensing information was reported to the E-FORCSE<sup>®</sup> system.
- The Department evaluated compliance with the statutory reporting requirement based on the number of times each month a dispenser uploaded dispensing records to the E-FORCSE<sup>®</sup> system. Dispensers who uploaded dispensing records four or more times in a month were

<sup>8</sup> Section 893.055(4), Florida Statutes.

<sup>9</sup> Section 893.055(7)(c), Florida Statutes, specifies that certain users, such as a law enforcement agency during an active investigation regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances, are not permitted direct access to the E-FORCSE<sup>®</sup> system, but may request through the Department information from the E-FORCSE<sup>®</sup> system.

considered to be in compliance. However, the effectiveness of this evaluation mechanism is limited, as it presumes that each upload occurs approximately every 7 days and only includes dispensing transactions from the 7-day period preceding the upload.

In response to our audit inquiry, Department management indicated that it would not be practical to modify the E-FORCSE® system to capture the date each dispensing transaction was reported. However, absent an effective method to compare the date a controlled substance is dispensed to an individual to the date the dispensing transaction is reported to the E-FORCSE® system, the Department's ability to ensure that timely information regarding the dispensation of controlled substances is available to pharmacists, health care practitioners, and other E-FORCSE® system information users, is diminished.

**Recommendation: We recommend that Department management work with the E-FORCSE® system contractor to establish a method to effectively and accurately assess whether pharmacies and dispensing practitioners report to the E-FORCSE® system in accordance with the time frame prescribed by State law each time a controlled substance is dispensed to an individual.**

## **OBJECTIVES, SCOPE, AND METHODOLOGY**

The Auditor General conducts operational audits of governmental entities to provide the Legislature, Florida's citizens, public entity management, and other stakeholders unbiased, timely, and relevant information for use in promoting government accountability and stewardship and improving government operations.

We conducted this operational audit from February 2016 through July 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

This operational audit of the Department of Health (Department) focused on the administration of the Prescription Drug Monitoring Program (Program) and contract management. The overall objectives of the audit were:

- To evaluate management's performance in establishing and maintaining internal controls, including controls designed to prevent and detect fraud, waste, and abuse, and in administering assigned responsibilities in accordance with applicable laws, administrative rules, contracts, grant agreements, and guidelines.
- To examine internal controls designed and placed in operation to promote and encourage the achievement of management's control objectives in the categories of compliance, economic and efficient operations, the reliability of records and reports, and the safeguarding of assets, and identify weaknesses in those internal controls.
- To identify statutory and fiscal changes that may be recommended to the Legislature pursuant to Section 11.45(7)(h), Florida Statutes.

This audit was designed to identify, for those programs, activities, or functions included within the scope of the audit, deficiencies in management's internal controls, instances of noncompliance with applicable governing laws, rules, or contracts, and instances of inefficient or ineffective operational policies, procedures, or practices. The focus of this audit was to identify problems so that they may be corrected

in such a way as to improve government accountability and efficiency and the stewardship of management. Professional judgment has been used in determining significance and audit risk and in selecting the particular transactions, legal compliance matters, records, and controls considered.

As described in more detail below, for those programs, activities, and functions included within the scope of our audit, our audit work included, but was not limited to, communicating to management and those charged with governance the scope, objectives, timing, overall methodology, and reporting of our audit; obtaining an understanding of the program, activity, or function; exercising professional judgment in considering significance and audit risk in the design and execution of the research, interviews, tests, analyses, and other procedures included in the audit methodology; obtaining reasonable assurance of the overall sufficiency and appropriateness of the evidence gathered in support of our audit's findings and conclusions; and reporting on the results of the audit as required by governing laws and auditing standards.

Our audit included the selection and examination of transactions and records. Unless otherwise indicated in this report, these transactions and records were not selected with the intent of statistically projecting the results, although we have presented for perspective, where practicable, information concerning relevant population value or size and quantifications relative to the items selected for examination.

An audit by its nature, does not include a review of all records and actions of agency management, staff, and vendors, and as a consequence, cannot be relied upon to identify all instances of noncompliance, fraud, abuse, or inefficiency.

In conducting our audit we:

- Reviewed applicable laws, rules, Department policies and procedures, and other guidelines, and interviewed Department personnel to gain an understanding of the Program and Department contract management.
- Performed inquiries of Department personnel and inspected documents and records to determine whether Department management had adequately designed and implemented controls, including policies and procedures, for the Program and Department contract management.
- Compared Program requirements specified in Section 893.055, Florida Statutes, to Department Rules, Chapter 64K-1, Florida Administrative Code, to determine whether Department rules contained sufficient provisions to administer and implement the requirements of Section 893.055, Florida Statutes.
- Obtained an understanding of selected information technology (IT) controls for the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E-FORCSE<sup>®</sup>) system, assessed the risks related to those controls, evaluated whether selected IT application controls were in place, and tested the effectiveness of the controls.
- From the population of 35 payment transactions, totaling \$523,479, made by the Department to the E-FORCSE<sup>®</sup> system service organization during the period July 2014 through February 2016, examined Department records for 5 payment transactions, totaling \$113,514, to determine whether the Department verified that contract deliverables had been appropriately satisfied prior to payment.
- Performed inquiries of Department management and examined contractual agreements between the Department and the E-FORCSE<sup>®</sup> system service organization for the period July 2014 through January 2016 to determine whether the Department had obtained and reviewed a service

auditor's report on the effectiveness of the controls established by the organization for the E-FORCSE® system.

- Reviewed Department policies and procedures, examined Department records related to the design and implementation of the E-FORCSE® system, and analyzed E-FORCSE® system data for 3 selected weeks during the period July 2014 through January 2016, to determine whether the Department had adequately designed and implemented controls related to collecting and reporting controlled substance dispensing information in accordance with State law and Federal regulations.
- Performed inquiries of Department personnel and examined Department records to assess the effectiveness of Department controls related to the development of Program performance measures and whether the Department timely and accurately reported performance measure information to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 2015, as required by Section 893.055(8), Florida Statutes.
- From the population of approximately 57 million records uploaded to the E-FORCSE® system during the period July 2014 through January 2016, analyzed E-FORCSE® system data related to 60 unique system numbers representing individuals to whom controlled substances were dispensed during 3 selected weeks (20 individuals for each week) during the period July 2014 through January 2016, to determine whether the E-FORCSE® system records included the information required by Section 893.055, Florida Statutes.
- Examined Department records and performed inquiries of Department personnel related to four Program employee teleworking agreements to determine whether the Department had adequately designed and implemented controls for the teleworking agreements to ensure compliance with Section 110.171, Florida Statutes.
- Evaluated the provisions included in the Department's contract with the direct support organization, the Florida PDMP Foundation, Inc. (Foundation), established pursuant to Section 893.055(11), Florida Statutes, to determine whether the contract contained the elements required by Section 893.055(11)(d), Florida Statutes.
- Examined Department records related to Foundation activities to determine whether the Department had evaluated Foundation compliance with State law, including obtaining an independent financial audit in accordance with Sections 215.981 and 893.055(11)(i), Florida Statutes.
- Examined training records for 36 of the 170 Department contract managers for the period July 1, 2014, through January 27, 2016, to determine whether the contract managers completed the training required by the Department and State law in contracts and grant management.
- Examined Department records for 45 contracts, totaling \$190,434,839, from the population of 572 contracts, totaling \$457,282,832, renewed or executed during the period July 2014 through January 2016, to determine whether the Department complied with applicable laws, rules, regulations, Department procedures, and other guidelines for contract procurement and awards.
- From the population of 98,435 contract payment transactions, totaling \$373,426,068, made by the Department during the period July 2014 through January 2016, examined Department records related to 40 contract payment transactions, totaling \$365,280, to determine whether the payments were appropriately authorized, supported, and reviewed, paid only after receipt of contractual deliverables, and accurately recorded in Department accounting records.
- Examined Department records for 45 contracts, totaling \$190,434,839, from the population of 572 contracts, totaling \$457,282,832, renewed or executed during the period July 2014 through January 2016, to determine whether Department records evidenced that contract terms were monitored, monitoring tools were completed, monitoring reports were timely provided to the

contractors and reflected issues identified during monitoring, and the Department had timely followed up on all issues identified in the monitoring reports.

- Analyzed the number and dollar value of contracts assigned to the 170 Department contract managers for the period July 1, 2014, through January 27, 2016, to determine the reasonableness of the number of contracts assigned to each contract manager.
- Reviewed applicable laws, rules, and other State guidelines to obtain an understanding of the legal framework governing Department operations.
- Observed, documented, and evaluated the effectiveness of selected Department processes and procedures for:
  - The assignment and use of motor vehicles. As of January 2016, the Department was responsible for 405 motor vehicles with related acquisition costs totaling \$10,629,445.
  - The management of tangible personal property. During the period July 2014 through January 2016, the Department acquired tangible personal property totaling \$6,232,964.
- Communicated on an interim basis with applicable officials to ensure the timely resolution of issues involving controls and noncompliance.
- Performed various other auditing procedures, including analytical procedures, as necessary, to accomplish the objectives of the audit.
- Prepared and submitted for management response the findings and recommendations that are included in this report and which describe the matters requiring corrective actions. Management's response is included in this report under the heading **MANAGEMENT'S RESPONSE**.

## **AUTHORITY**

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Section 11.45, Florida Statutes, requires that the Auditor General conduct an operational audit of each State agency on a periodic basis. 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.



Sherrill F. Norman, CPA  
Auditor General

# MANAGEMENT'S RESPONSE

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**Mission:**

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



**Vision:** To be the **Healthiest State** in the Nation

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**Rick Scott**  
Governor

**Celeste Philip, MD, MPH**  
Surgeon General and Secretary

December 15, 2016

Ms. Sherrill F. Norman, CPA  
Auditor General  
Room G74, Claude Pepper Building  
111 West Madison Street  
Tallahassee, FL 32399-1450

Dear Ms. Norman:

We are pleased to respond to the preliminary and tentative audit findings and recommendations concerning the Office of the Auditor General's operational audit of the *Department of Health Prescription Drug Monitoring Program*. Our response to the findings, as required by Section 11.45(4)(d), *Florida Statutes*, is enclosed.

We appreciate the efforts of you and your staff in assisting to improve our operations and information systems. Please contact our Inspector General, James D. Boyd, by calling (850) 245-4141, should you have any questions.

Sincerely,

Celeste Philip, MD, MPH  
Surgeon General and Secretary

CP/mhb  
Enclosure

cc: James D. Boyd, CPA, MBA, Inspector General  
Michele Tallent, Deputy Secretary for Administration

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*Preliminary and Tentative Findings*

Report Number: To be determined  
 Report Title: Prescription Drug Monitoring Program  
 Report Date: To be determined

No.	Finding	Recommendation	Management Response	Corrective Action Plan
1.	<p>The Department of Health (Department) did not make or obtain an independent and periodic assessment of the effectiveness of relevant service organization controls for the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E-FORCSE®) system.</p>	<p>Because of the critical and sensitive and confidential nature of E-FORCSE® system data, we recommend that Department management make or obtain an independent and periodic assessment of the service organization's relevant internal controls. Such an assessment should include examination of documentation evidencing that service organization employees met contractual requirements related to background screenings and work experience.</p>	<p>We concur.</p>	<p><b>In Progress.</b>          Projected Completion Date – January 31, 2017</p> <p>The Department will amend the contract with its service organization to require current and any future service organizations to provide the results of an annual independent assessment of the service organization's relevant internal controls. The contract will also be amended to include statement of work deliverables that require service organizations to quarterly provide documentation evidencing that the service organization's employees meet contractual requirements related to background screenings and work experience.</p>
2.	<p>Enhancements to available E-FORCSE® system data and Department procedures were needed to effectively assess whether pharmacies and dispensing practitioners reported controlled substance dispensing information to the E-FORCSE® system within the timeframe prescribed by State law.</p>	<p>We recommend that Department management work with the E-FORCSE® system contractor to establish a method to effectively and accurately assess whether pharmacies and dispensing practitioners report to the E-FORCSE® system in accordance with the timeframe prescribed by State law each time a controlled substance is dispensed to an individual.</p>	<p>We concur.</p>	<p><b>In Progress.</b>          Projected Completion Date – January 31, 2017</p> <p>The Department will modify its statement of work to require the service organization to implement an enhancement to the E-FORCSE® system, which will allow staff to effectively and accurately assess whether dispensers are reporting to the E-FORCSE® database in accordance with the timeframe prescribed by State law.</p>