

**DEPARTMENT OF BUSINESS AND  
PROFESSIONAL REGULATION**

Controlled Substance Oversight  
and Selected Administrative Activities



Sherrill F. Norman, CPA  
Auditor General

## **Secretary of the Department of Business and Professional Regulation**

The Department of Business and Professional Regulation is established by Section 20.165, Florida Statutes. The head of the Department is the Secretary who is appointed by the Governor and subject to confirmation by the Senate. Melanie S. Griffin served as Department Secretary during period of our audit.

The Auditor General conducts audits of government 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.

The team leader was Adam Bravard, CPA, and the audit was supervised by David Cain, CPA.

Please address inquiries regarding this report to Christi Alexander, CPA, Audit Manager, by e-mail at [christialexander@aud.state.fl.us](mailto:christialexander@aud.state.fl.us) or by telephone at (850) 412-2786.

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# DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

## Controlled Substance Oversight and Selected Administrative Activities

### **SUMMARY**

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This operational audit of the Department of Business and Professional Regulation (Department) focused on controlled substance oversight and selected administrative activities. Our audit disclosed the following:

#### **Controlled Substance Oversight**

**Finding 1:** Department oversight of entities engaged in the wholesale distribution of controlled substances within the State was not sufficient to ensure entity compliance with State law or the adequate protection of the public health, safety, and welfare.

#### **Information Technology Controls**

**Finding 2:** Department change management controls need improvement to ensure that all Controlled Substance Reporting (CSR) System program code changes are managed by, and do not bypass, the Department's change management process.

**Finding 3:** Certain security controls related to CSR System user authentication need improvement to ensure the confidentiality, integrity, and availability of Department data and information technology (IT) resources.

**Finding 4:** The designation of the Deputy Chief Information Officer as the Department's Information Security Manager (ISM) did not promote an appropriate separation of duties between daily IT operations and the assessment and oversight of cybersecurity program controls.

#### **Selected Administrative Activities**

**Finding 5:** Department controls for promptly canceling purchasing cards upon a cardholder's separation from Department employment need improvement.

### **BACKGROUND**

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The Department of Business and Professional Regulation (Department) was created and organized consistent with State law<sup>1</sup> to license and regulate businesses and professionals operating in the State. The Department operates through 11 divisions to carry out the Department's varied responsibilities, including safeguarding citizens of the State from injury due to the use of adulterated, contaminated, or misbranded drugs, drug ingredients, and cosmetics by administering the provisions of the Florida Drug and Cosmetic Act.<sup>2</sup> For the 2023-24 fiscal year, the Legislature appropriated approximately \$172 million to the Department and funded 1,560.25 positions.<sup>3</sup>

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<sup>1</sup> Section 20.165, Florida Statutes.

<sup>2</sup> Chapter 499, Florida Statutes.

<sup>3</sup> Chapter 2023-239, Laws of Florida.

## **FINDINGS AND RECOMMENDATIONS**





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### CONTROLLED SUBSTANCE OVERSIGHT

The Federal Controlled Substances Act (CSA) regulates certain drugs and other substances, whether medical or recreational, legally or illicitly distributed, that are found to pose a risk of abuse and dependence. The CSA simultaneously aims to protect the public from the dangers of controlled substances diverted into or produced for the illicit market while ensuring that patients have access to pharmaceutical controlled substances for legitimate purposes. To accomplish these goals, the CSA imposes two overlapping legal schemes: (1) registration provisions that require individuals and entities working with controlled substances to register with the Drug Enforcement Administration (DEA), take steps to prevent diversion and misuse of controlled substances, and report certain information to regulators; and (2) trafficking provisions that establish penalties for the production, distribution, and possession of controlled substances outside the legitimate scope of the registration system.

As depicted in Chart 1, the CSA establishes five categories of controlled substances, known as Schedules I through V, based on the substances medical utility and potential for abuse and dependence. Substances considered to present the greatest risk to the public health and safety are subject to the most stringent controls and sanctions. A lower Schedule number corresponds to greater restrictions, so substances in Schedule I are subject to the strictest controls, while substances in Schedule V are subject to the least stringent controls. Notably, because substances in Schedule I have no accepted medical use, it is only legal to produce, dispense, and possess those substances in the context of Federally approved scientific studies.

**Chart 1  
CSA Scheduling Criteria**

	 ABUSE POTENTIAL	 MEDICAL USE	 SAFETY/DEPENDENCE	 EXAMPLES
<b>SCHEDULE I</b>	<b>High</b>	⊗ Not currently accepted	Lack of accepted safety for use of the substance under medical supervision	Marijuana, heroin, lysergic acid diethylamide (LSD), 3, 4 methylenedioxymethamphetamine (MDMA), peyote
<b>SCHEDULE II</b>	<b>High</b>	✓ Currently accepted	Abuse may lead to severe psychological or physical dependence	Cocaine, methamphetamine, oxycodone, fentanyl, Adderall
<b>SCHEDULE III</b>	<b>Less than the substances in Schedules I and II</b>	✓ Currently accepted	Abuse may lead to moderate or low physical dependence or high psychological dependence	Ketamine, anabolic steroids, testosterone, Tylenol with codeine
<b>SCHEDULE IV</b>	<b>Low potential</b> for abuse relative to the substances in Schedule III	✓ Currently accepted	Abuse may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III	Xanax, Valium, Ambien
<b>SCHEDULE V</b>	<b>Low potential</b> for abuse relative to the substances in Schedule IV	✓ Currently accepted	Abuse may lead to limited physical dependence or psychological dependence relative to the substances in Schedule IV	Cough medicines with codeine, certain antidiarrheal medicines, FDA-approved drugs containing the marijuana extract cannabidiol (CBD)

Source: Congressional Research Service Report No. R45948.

The DEA is the Federal agency primarily responsible for implementing and enforcing the CSA. The CSA establishes distribution controls to prevent the misuse of substances deemed to pose a potential danger to the public welfare. Most substances subject to the CSA are also subject to other Federal or state regulations, including the Federal Food, Drug, and Cosmetic (FD&C) Act. The FD&C Act is a consumer protection statute that seeks to prevent harm to consumers who obtain drugs (and other public health products) through commercial channels. Any person or organization that produces, distributes, or otherwise works with prescription drugs that are also controlled substances must comply with the requirements of both the CSA and the FD&C Act. State controlled substance laws often mirror Federal law and are relatively uniform across jurisdictions because almost all states have adopted a version of the Uniform Controlled Substances Act.

At the State level, the Department's Division of Drugs, Devices, and Cosmetics (Division) is responsible for regulating and enforcing State law<sup>4</sup> and rules<sup>5</sup> related to manufacturing and distributing drugs, devices, and cosmetics. Division responsibilities include requiring the submittal and maintenance of prescription drug distribution records and monitoring purchasing levels for levels that are inconsistent with the purchasing entity's clinical needs for controlled substances. In general, entities involved in the wholesale and distribution of prescription drugs in the State are to apply to the Division for a license by submitting an application, paying applicable fees, having a designated representative pass a written

<sup>4</sup> Chapter 499, Florida Statutes, Florida Drug and Cosmetic Act.

<sup>5</sup> Department Rules, Chapter 61N-1, Florida Administrative Code.

examination, providing proof of financial responsibility and liability insurance, designating a manager with certain qualifications, and licensees are to comply with all State and Federal laws and regulations and undergo regular inspections to ensure compliance. For the 2023-24 fiscal year, the Division was appropriated approximately \$2.6 million and authorized 27.50 full-time equivalent (FTE) positions, including 10 FTE positions assigned as drug inspectors.

### **Finding 1: Division Oversight Over Controlled Substances**

Pursuant to State law,<sup>6</sup> a wholesale distributor that deals in controlled substances is to register with the DEA and simultaneously notify and provide the Department its DEA number. Wholesale distributors must allow the Department and authorized Federal, State, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.<sup>7</sup>

Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor (entity) in performing its due diligence must:<sup>8</sup>

- Establish and maintain policies and procedures to credential physicians licensed under State law<sup>9</sup> and pharmacies that purchase or otherwise receive from an entity controlled substances listed in Schedule II or Schedule III as provided in Section 893.03, Florida Statutes. Specifically, the entity is to maintain records of such credentialing and make the records available to the Department upon request. The credentialing must, at a minimum, include: a determination of the clinical nature of the receiving entity and any specialty practice area, a review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor, and a determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.
- Take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify transactions that are suspicious in nature. More specifically, an entity is to establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions, as well as assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, an entity may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the entity's policies and procedures. An entity must report to the Department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law.

State law<sup>10</sup> also requires each entity, manufacturer, or repackager that engages in the wholesale distribution of controlled substances within the State to submit a report of all transactions (receipts and distributions of controlled substances listed in Schedule II through Schedule V) to the Department by the 20th of each month. If the entity, manufacturer, or repackager does not have any controlled substance

<sup>6</sup> Section 499.0121(10)(b), Florida Statutes.

<sup>7</sup> Section 499.0121(10)(a), Florida Statutes.





<sup>8</sup> Section 499.0121(15), Florida Statutes.

<sup>9</sup> Chapters 458, 459, 461, or 466, Florida Statutes.

<sup>10</sup> Section 499.0121(14), Florida Statutes.

transactions for the month, they still must report to the Department that no transactions occurred in the period. The Department must share the reported data with the Department of Law Enforcement (DLE) and, upon request, with local law enforcement agencies. The Department must monitor purchasing activity to identify purchasing levels that are inconsistent with the purchasing entity's, manufacturer's, or repackager's clinical needs and the DLE is to investigate such purchasing levels to determine whether violations of State law occurred.<sup>11</sup> All monthly reports are to be submitted to the Department via the Division's Controlled Substance Reporting (CSR) System, which is to serve as the State's data repository for all entities engaged in the wholesale distribution of controlled substances, for all controlled substance transactions, and include the data elements required by State law and depicted in Chart 2.

## Chart 2 Monthly Controlled Substance Reporting Data Requirements

	<p>The Federal DEA registration number of the wholesale distributing location and the entity to which the drugs are distributed or from which the drugs are received.</p>
	<p>The transaction code that indicates the type of transaction.</p>
<p><b>NDC</b></p>	<p>The National Drug Code identifier of the product and the quantity distributed or received.</p>
	<p>The DEA Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.</p>
	<p>The date of the transaction.</p>

Source: Section 499.0121(14), Florida Statutes.

As part of our audit, we interviewed Division management, evaluated Division processes, examined Division records for 21 of the 206 entities, manufacturers, and repackagers listed in the CSR System as of April 26, 2024, and examined inspection reports for 2 of the 19 entities inspected during the period July 2022 through December 2023. Our audit procedures found that Division oversight of entities engaged in the wholesale distribution of controlled substances within the State was not sufficient to ensure entity, manufacturer, and repackager compliance with State law or the adequate protection of the public health, safety, and welfare. Specifically, we found that the Division had not:

- Maintained a complete and accurate registry of entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances within the State. Specifically, the Division had not established a process to identify all entities, manufacturers, and repackagers required to report to the State and be subject to regulation, nor to ensure that Division records for such entities, manufacturers, and repackagers were accurate or complete. According to

<sup>11</sup> Section 499.0121(14)(f), Florida Statutes.

Department management, while migrating data from the Division's legacy controlled substance reporting system to the CSR System in February 2023, Department programming staff purged 1,151 entities, manufacturers, and repackagers listed in the legacy system as engaged in the wholesale distribution of controlled substances, going from a total of 1,357 such entities to 206 such entities. Department management indicated that the entities, manufacturers, and repackagers were purged due to extended periods of reporting inactivity. Notwithstanding, Division records did not evidence either the criteria or the specific basis for removing the entities, manufacturers, and repackagers from the system, or that the Division had followed up with the entities, manufacturers, and repackagers who had not reported to determine the appropriateness of the purge. As the Division is tasked with ensuring that all entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances appropriately report to the State and are subject to regulation, including disciplinary action against those who fail to comply with applicable requirements, the absence of records demonstrating the propriety of the purge erodes confidence in the information necessary to execute the Division's statutory responsibilities.

- Established a mechanism, including policies and procedures, to effectively track and evidence Division efforts to inspect entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances.
- Established a mechanism to ensure that monthly reports were timely and appropriately submitted by the entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances and reviewed the reports to ensure all applicable information was submitted in accordance with State law.
- Acted against entities, manufacturers, and repackagers who failed to comply with controlled substance reporting requirements.
- Monitored or identified controlled substance purchasing levels that were inconsistent with purchasing entity clinical needs.
- Ensured that Division inspectors were independent of entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances.

Additionally, for the 42 monthly reports required to be submitted to the Division by the 21 tested entities, manufacturers, and repackagers, we found that:

- 27 reports were filed 68 days to 428 days (an average of 146 days) late.
- Reports for 5 entities were not received for 1 of the 2 months tested.
- For 2 entities, a DEA Form 222 number or Controlled Substance Ordering System Identifier was not included for 22,888 Schedule II transactions reported for October 2022 and May 2023.

Also, Division records for the 2 tested inspections did not evidence efforts to monitor the entities':

- Physician and pharmacy credentialing.
- Measures to identify orders exceeding 7,500-unit doses of any one controlled substance in a month and assessment of such orders for reasonableness.
- Reporting of regulated transactions involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance indicating that a listed chemical will be used in violation of the law.

For one of the two entities, we also noted that Division records did not evidence efforts to monitor the entity's procedures for identifying suspicious orders and preventing suspicious transactions. In response

to our audit inquiry, Division management indicated that the Division had not established a process to effectively monitor for these compliance items.

Effective oversight and monitoring evaluates whether State law is being met and identifies problems as early as possible so that corrective actions may be promptly initiated. Absent adequate controls, including a mechanism to track all entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances, the Department has less assurance that the public health is safeguarded from the misuse of controlled substances deemed to pose a potential danger to the public welfare.

**Recommendation: We recommend that Division management ensure that Division controls for the oversight of entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances sufficiently safeguard the public health, safety, and welfare. Specifically, we recommend that Division management:**

- **Maintain a complete and accurate registry of each entity, manufacturer, and repackager engaged in the wholesale distribution of controlled substances within the State.**
- **Establish a mechanism, including policies and procedures, to track and evidence the monitoring of each entity, manufacturer, and repackager engaged in the wholesale distribution of controlled substances for compliance with applicable requirements of State law.**
- **Ensure that each entity, manufacturer, and repackager engaged in the wholesale distribution of controlled substances timely submits complete monthly reports in accordance with State law.**
- **Review monthly reports and take appropriate action against entities, manufacturers, and repackagers who fail to comply with controlled substance reporting requirements.**
- **Monitor entity physician and pharmacy credentialing and entity measures to identify controlled substance purchasing levels that are inconsistent with purchasing entity clinical needs or are otherwise unreasonable, suspicious, or a possible violation of law.**
- **Ensure that Division records evidence that inspectors are independent of entities, manufacturers, and repackagers engaged in the wholesale distribution of controlled substances.**

#### INFORMATION TECHNOLOGY CONTROLS

State law<sup>12</sup> requires State agencies to establish cybersecurity controls to ensure the security of agency data, information, and information technology (IT) resources. Additionally, Department of Management Services (DMS) rules<sup>13</sup> establish minimum cybersecurity standards for ensuring the confidentiality, integrity, and availability of State agency data, information, and IT resources.

#### **Finding 2: Change Management Controls**

To promote effective change management over IT resources, DMS rules<sup>14</sup> require State agencies to establish a change control process to manage upgrades and modifications to existing IT resources. Effective change management controls ensure that changes (program or functionality) follow a change

<sup>12</sup> Section 282.318(4), Florida Statutes.

<sup>13</sup> DMS Rules, Chapter 60GG-2, Florida Administrative Code.

<sup>14</sup> DMS Rule 60GG-2.003(5)(c), Florida Administrative Code.

management process that provides for an appropriate separation of duties and ensures that changes are appropriately authorized, reviewed and tested, approved, and moved to production.

To evaluate the appropriateness of Department change management controls for the CSR System, we requested from the Department a system-generated list of all program code changes implemented into production during the period February 2023 through December 2023. However, due to system limitations, the Department was unable to provide a system-generated list of all CSR System program code changes implemented into production. Instead, Department management indicated that the Department relies on policies and procedures that restrict specified staff from implementing CSR System program changes that have not been approved in the ticketing system. Notwithstanding, without a system-generated list of program changes implemented into the production environment and a reconciliation of the list of program changes to the ticketing system that ensures that all implemented changes were properly tested and approved, Department management has limited assurance that unauthorized changes were not implemented.

Absent effective change management controls to ensure that all program code changes are properly authorized, reviewed and tested, approved, and moved to production, the risk that unauthorized program code changes may be implemented into the CSR System production environment is increased.

**Recommendation:** We recommend that Department management enhance change management controls to ensure that all CSR System program code changes are managed by, and do not bypass, the Department’s change management process.

### Finding 3: CSR System Security Controls – User Authentication

Security controls are intended to protect the confidentiality, integrity, and availability of data and IT resources. Our audit disclosed that certain security controls related to CSR System user authentication need improvement. We are not disclosing specific details of the issues in this report to avoid the possibility of compromising Department data and related IT resources. However, we have notified appropriate Department management of the specific issues.

Without appropriate security controls related to CSR System user authentication, the risk is increased that the confidentiality, integrity, and availability of Department data and related IT resources may be compromised.

**Recommendation:** We recommend that Department management improve certain security controls related to CSR System user authentication to ensure the confidentiality, integrity, and availability of Department data and related IT resources.

### Finding 4: Information Security Manager

State law<sup>15</sup> requires each State agency head to designate an Information Security Manager (ISM) to administer the agency’s cybersecurity program and, for information security duty purposes, the ISM is to report directly to the agency head. Best practices provide that organizational placement of the ISM outside the line of authority of those responsible for the Department’s daily IT operations is essential to

<sup>15</sup> Section 282.318(4)(a), Florida Statutes.

ensuring an appropriate separation of duties between daily IT operations and the assessment and oversight of cybersecurity program controls.

We evaluated the Department's designation of an ISM and found that, while the Deputy Chief Information Officer (CIO) served as the ISM and indicated that she was able to report directly to the Department Secretary for information security duty purposes, if needed, organizationally, the ISM reported to the Department's Chief Information Officer (CIO) who was responsible for the Department's daily IT operations. In response to our audit inquiry, Department management indicated that they believed the Deputy CIO serving as the ISM was appropriate.

Appropriate organizational placement promotes the independence of the ISM function and accountability for the administration of the Department's cybersecurity program.

**Recommendation: To promote the independent assessment and oversight of cybersecurity program controls, we recommend that Department management ensure that the Department's designated ISM is organizationally separated from the Department's daily IT operations.**

#### SELECTED ADMINISTRATIVE ACTIVITIES

As part of our audit, we evaluated selected Department administrative activities and controls, including those related to purchasing cards.

#### **Finding 5: Purchasing Card Controls**

As a participant in the State's purchasing card program, the Department is responsible for implementing key controls, including procedures for timely canceling purchasing cards upon a cardholder's separation from Department employment. The Department's *Purchasing Card Plan* (Plan) specified that, on or before the cardholder's separation from Department employment, the Department's Purchasing Card Administrator (PCA) was to be notified and that the PCA was to cancel the purchasing card. As of January 3, 2024, the Department had 499 active purchasing cards and purchasing card charges totaled \$1,785,182 during the period July 2022 through December 2023.

To determine whether the Department timely canceled purchasing cards upon an employee's separation from Department employment, we examined Department records for the purchasing cards assigned to 110 employees who separated from Department employment during the period July 2022 through December 2023. Our examination disclosed that 51 employee purchasing cards were canceled 1 to 284 days (an average of 70 days) after the employees' separation dates, while 3 employee purchasing cards had not been canceled as of December 31, 2023, although 52, 381, and 422 days had elapsed since the employees left Department employment.<sup>16</sup> According to Department management, the purchasing cards were not timely canceled due to delays in notifying the PCA of the employment separations and the Department waiting on purchasing card charges to clear the account.

<sup>16</sup> Subsequently, Department management reported canceling 1 of the 3 cards on May 30, 2024, and the other 2 cards on June 25, 2025.

Although our audit tests did not disclose any charges incurred subsequent to the 54 cardholders' separation from Department employment, prompt cancellation of purchasing cards upon a cardholder's separation from Department employment reduces the risk that unauthorized charges will occur.

**Recommendation: We recommend that Department management strengthen employment separation procedures to ensure that purchasing cards are promptly canceled upon a cardholder's separation from Department employment.**

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

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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 2024 through September 2024 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 Business and Professional Regulation (Department) focused on controlled substance oversight and selected administrative activities. For those areas, the 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 responsibilities in accordance with applicable laws, administrative rules, contracts, grant agreements, and other guidelines.
- Examine internal controls designed and placed into 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.
- 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 internal controls significant to our audit objectives; 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; identifying and evaluating internal

controls significant to our audit objectives; 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, waste, abuse, or inefficiency.

In conducting our audit, we:

- Reviewed applicable laws and interviewed Department personnel to obtain an understanding of Department processes and responsibilities related to controlled substance oversight.
- Inquired of Department management regarding whether the Department made any expenditures or entered into any contracts under the authority granted by an applicable state of emergency during the period July 2022 through December 2023. From the population of ten emergency expenditures made by the Department during the period July 2022 through December 2023, totaling \$267,553, we examined Department records for four selected expenditures, totaling \$121,603, to determine whether the expenditures appeared reasonable and necessary given the nature of the declared state of emergency and the statutory responsibilities of the Department.
- Obtained an understanding of selected Department information technology (IT) controls, assessed the risks related to those controls, evaluated whether selected general IT controls for the Controlled Substance Reporting (CSR) System were in place, and tested the effectiveness of the selected controls.
- From the population of 206 prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, retail pharmacy drug wholesale distributors (entities), manufacturers, and repackagers that engaged in the wholesale distribution of controlled substances and were listed in the CSR System as of April 26, 2024, examined Department records for 21 selected entities, manufacturers, or repackagers for the months of October 2022 and May 2023 to determine whether the entities, manufacturers, and repackagers submitted distribution reports to the CSR System in accordance with State law.
- From the population of 19 entity inspections performed by the Division during the period July 2022 through December 2023, examined Division records for 2 selected inspections to determine whether the Division ensured that entities complied with State law.
- Observed, documented, and evaluated the effectiveness of selected Department processes and procedures for:
  - Cash and revenue management.
  - The assignment and use of motor vehicles. As of December 31, 2023, the Department was responsible for 589 active motor vehicles with related acquisition costs totaling \$10,602,206.
  - The administration of purchasing cards in accordance with applicable guidelines. As of December 31, 2023, the Department had 499 active purchasing cards.

- The administration of Department travel in accordance with State law and other applicable guidelines. During the period July 2022 through December 2023, Department travel expenditures totaled \$1,930,090.
- The administration of the requirements of the Florida Single Audit Act. During the period July 2022 through December 2023, the Department provided State financial assistance totaling \$6,214,314 to five non-State recipients.
- 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.

A handwritten signature in blue ink that reads "Sherrill F. Norman". The signature is written in a cursive style with a large initial 'S'.

Sherrill F. Norman, CPA  
Auditor General

# MANAGEMENT'S RESPONSE

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Ron DeSantis, Governor  
Melanie S. Griffin, Secretary

July 24, 2025

Sherrill F. Norman  
Auditor General  
G74 Claude Pepper Building  
111 West Madison Street  
Tallahassee, FL 32399-450

Dear Auditor General Norman,

In accordance with Section 11.45(4)(d), Florida Statutes, I have enclosed our response to the preliminary and tentative audit findings and recommendations included in your operational audit of the Department of Business and Professional Regulation, Controlled Substance Oversight and Selected Administrative Activities.

We appreciate the time, energy, and dedication put forth by your staff, as well as your continuing efforts to improve the operations of state government.

If you have any questions, please contact Rodney J. MacKinnon, Inspector General, at 850-717-1576.

Sincerely,

Melanie S. Griffin

cc: Jared Ochs, Chief of Staff  
Emilie Oglesby, Deputy Secretary of Business Regulation  
Anthony Coniglio, Director of the Division of Drugs, Devices, and Cosmetics  
Joseph Martin, Chief Information Officer  
Sally Huggins, Director of Administration



**Finding 1:**

Department oversight of entities engaged in the wholesale distribution of controlled substances within the State was not sufficient to ensure entity compliance with State law or the adequate protection of the public health, safety, and welfare.

**Finding 1 Response:**

The Department accepts this finding and has taken the following remedial actions since the audit period that addresses these finding and recommendations:

- a) The Department has cross referenced its licensing database against the CSR userbase to identify all licensees with associated DEA numbers. Licensees with DEA numbers that are not in the CSR system will be notified of their obligations under section 499.0121(14), F.S., to register with CSR and report all distributions and receipts of controlled substances.
- b) The Department has developed a process by which it is anticipated that, beginning July 21, 2025, and continuing each month thereafter, CSR reporters that have failed to report by the 20<sup>th</sup> of the month will be identified and referred to DDC’s compliance team by the CSR administrator for investigation.
- c) The Department has developed a process by which it is anticipated that, beginning August 1, 2025, DDC compliance team supervisors will ensure that each inspector’s monthly inspections include at least one CSR reporter. These inspections will include a cross reference of CSR reports against distribution records to identify possible omissions and/or inaccuracies.
- d) The Department has developed a process by which, beginning June 21, 2025, CSR reports are randomly audited to identify purchases inconsistent with the needs of purchasing entities. Purchasing entities are evaluated for practice area(s) to identify inconsistent purchasing trends.
- e) There are currently no DDC employees with a known conflict of interest. DDC has proactively acted to timely review and submit to the Department’s chief ethics officer all outside employment requests and conflict of interest forms for DDC employees beginning with the 2024-2025 fiscal year. Moving forward, this process will continue.

**Finding 2:**

Department change management controls need improvement to ensure that all Controlled Substance Reporting (CSR) System program code changes are managed by, and do not bypass, the Department’s change management process.

**Finding 2 Response:**

The Division concurs with the finding and will ensure established change control processes are followed.

**Finding 3:**

Certain security controls related to CSR System user authentication need improvement to ensure the confidentiality, integrity, and availability of Department data and information technology (IT) resources.

**Finding 3 Response:**

We acknowledge the recommendation from the auditors and are in the process of implementing a long-term solution.

**Finding 4:**

The designation of the Deputy Chief Information Officer as the Department's Information Security Manager (ISM) did not promote an appropriate separation of duties between daily IT operations and the assessment and oversight of cybersecurity program controls.

**Finding 4 Response:**

While the Deputy Chief Information Officer also serves as the agency's Information Security Manager (ISM), this structure is common amongst state agencies and is permissible. The designation reflects the individual's deep knowledge of the agency's IT environment and ensures cybersecurity oversight remains closely aligned with executive leadership priorities.

To ensure appropriate governance and mitigate any potential conflict of interest, the ISM reports weekly, directly to the agency head, cybersecurity risks, strategy, and compliance matters. Additionally, compensating controls including internal audits and periodic independent security and risk assessments are performed to ensure objective oversight of the cybersecurity program.

**Finding 5:**

Department controls for promptly canceling purchasing cards upon a cardholder's separation from Department employment need improvement.

**Finding 5 Response:**

The Department concurs with the finding and recommendation and has already implemented enhanced procedures to ensure that purchasing cards are canceled timely. A Separation Checklist, provided through the Office of Human Resources, now includes specific instructions on the process that must be followed to cancel an employee's purchasing card upon separation from the Department. Additionally, the DBPR Purchasing Card Administrator and Bureau Chief of Finance and Accounting has been added to the Separation Report distribution list, which is reviewed to further support the timely cancellation of purchasing cards.