

OIG INITIAL FOLLOW-UP: AUDITOR GENERAL OPERATIONAL AUDIT DIVISION OF DRUGS, DEVICES, AND COSMETICS AG’S Report Number: 2026-007 AG’S Report Date: July 24, 2026 OIG Project Number: G-2526BPR-024					
No.	Division/Finding(s)	Auditor General’s Recommendation(s)	Previous Management Response(s)/ Proposed Corrective Actions	Status Update(s)/Anticipated Completion Date and Contact	OIG’s Assessment: OPEN/CLOSED
1	<u>Division of Drugs, Devices, and Cosmetics</u> CONTROLLED SUBSTANCE OVERSIGHT 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.	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.	<u>Initial Response dated July 24, 2025-Division of Drugs, Devices and Cosmetics</u> 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 20th 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.	<u>Status as of December 11, 2025:</u> a) The Department completed this process on July 17, 2025. b) The Department began this process on July 21, 2025, and has continued each month thereafter. The Department intends to continue this process in perpetuity. c) The Department began this process in August 2025 and has continued each month thereafter. The Department intends to continue this process in perpetuity. Furthermore, the Department has developed a standardized form to extend CSR cross referencing to out-of-state permittees. d) The Department began this process on June 21, 2025, and has continued each month thereafter. The Department intends to continue this process in perpetuity. Furthermore, the Department has developed a standardized form that is filled out by purchasing entities to establish the purchasing	CLOSED – The Division of Drugs, Devices and Cosmetics (DDC) submitted supporting documents to our office for review and evaluation. a) DDC documented their efforts to identify registrants in the CSR system with DEA numbers in July of 2025 and again in October of 2025. DDC also documented the mass email listings and noted their efforts to identify and notify licensees of their obligations under section 499.0121(14), F.S. DDC’s efforts are sufficient in identifying and notifying entities of their obligation. b) DDC also explained how it identifies entities that have failed to report, and the corrective action taken for entities that have not complied. Additionally, the Division provided a copy of their Policy 4.1, <i>Monthly Controlled Substance Procedures</i>, which

		• 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.	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.	entity's practice and therefore clinical needs. e) There remain no DDC employees with a known conflict of interest. DDC will continue to timely submit conflict of interest and outside employment forms to the Department's chief ethics officer each fiscal year.	was consistent with DDC's response. c) Our office requested a sample of the November 2025 monthly inspection reports for five inspectors. We noted that each inspector had one CSR reporter and that there was documentation of cross reference of CSR reports against the distribution record and an investigative report documented in at least one of the inspections. As such our office determined that DDC's corrective action is sufficient and continued monitoring is not required. d) The Division provided supporting documentation of the last two randomly audited CSR reports and methodology used to determine inconsistencies. Our office found the Division's efforts to be sufficient to close this audit recommendation and finding. e) The Division provided an explanation that DDC employees do not have any known conflicts of interest. Our office determined no other action was warranted for this audit recommendation and finding.
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2	<u>Division of Technology</u> CHANGE MANAGEMENT CONTROLLS 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	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.	<u>Initial Response dated July 24, 2025-Division of Technology</u> The Division concurs with the finding and will ensure established change control processes are followed.	<u>Status as of December 11, 2025:</u> The division has an established change control process and is ensuring all change requests follow the process which is initiated by submitting a change request through the ticketing system followed by levels of approval prior to implementation.	CLOSED – The Division of Technology (Technology) provided a copy of the <i>IT-102 Change Management Procedure</i>, which identifies the steps to document, track, manage and report all of DBPR's change requests assigned to Technology. Technology also provided the change request form and evidence of the associated ticket and approval within the ticketing system. These highlight the flow of the ticket through the change management process and the final approval by the requestor. Technology further noted that this information is also routinely covered during the Production Control meetings with the Knowledge Champions. Our office notes the ticketing system process is consistent with procedures documented in Technology's <i>IT-102 Change Management Procedure</i>. Our office confirmed this process during a Production

					Control meeting with the Knowledge Champions that there were discussions on change management request. Based on our review of the documentation our office notes the corrective actions implemented by the Division of Technology are sufficient and monitoring is no longer required. The finding is therefore closed.
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3	<u>Division of Technology</u> CSR SYSTEM SECURITY CONTROLS – USER AUTHENTICATION 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.	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.	<u>Initial Response dated July 24, 2025-Division of Technology</u> We acknowledge the recommendation from the auditors and are in the process of implementing a long-term solution.	<u>Status as of December 11, 2025:</u> The Department has submitted an updated Operational Work Plan to the OPB for the CSR system cloud modernization initiative. Upon approval of this plan, the Department will proceed with requesting a budget amendment to initiate the project. Implementation of enhanced security controls is included as a key component of the planned project activities.	OPEN – Our office reviewed the status update provided by the Technology. Based on our review, our office has determined that we will continue to monitor the corrective action for this audit finding and recommendation.

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4	<u>Division of Technology</u> INFORMATION SECURITY MANAGER 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.	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.	<u>Initial Response dated July 24, 2025-Division of Technology</u> 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.	<u>Status as of December 11, 2025:</u> The ISM meets weekly with the Secretary on cybersecurity and compliance matters.	CLOSED – Our office reviewed a copy of the ISM's scheduled meetings with the Secretary. Our review indicates that the screenshot evidences the ISM's weekly meetings with the Secretary. Based on our review, our office determined that continued monitoring of this finding is no longer warranted. The documentation provided by the division of Technology is sufficient to close this audit finding and recommendation.

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5	<u>Division of Administration and Financial Management</u> PURCHASING CARD CONTROLS Department controls for promptly canceling purchasing cards upon a cardholder's separation from Department employment need improvement.	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	<u>Initial Response dated July 24, 2025-Division of Administration and Financial Management</u> 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.	<u>Status as of December 11, 2025:</u> Enhanced procedures are in place to assist in the timely cancellation of purchasing cards for separated employees. Supervisors are reminded to use the Separation Checklist, which includes instructions for purchasing cards. The Purchasing Card Administrator cancels purchasing cards when she is notified of a separating employee and uses the biweekly separation report to check that any cards for separated employees have been canceled. Additionally, the Purchasing Card Administrator now conducts a quarterly review of all cardholders to determine if a purchasing card is still needed by all employees who have active purchasing card accounts.	CLOSED – Our office reviewed documentation submitted by the Division of Administration and Financial Management (AFM). Our review notes that AFM has enhanced processes, although it has not documented them yet. AFM also submitted a copy of the separation checklist, which requires that supervisors retrieve P-Card from employee email the P-Card Administrator. An email of the separated employee report was provided for review in which our office notes that the P-Card Administrator and the Chief of Finance and Accounting are identified in the distribution list. Additionally, as part of the supporting documentation demonstrating its internal controls, AFM submitted a copy of the initial email provided by the P-Card Administrator to the Division of Alcoholic Beverages and Tobacco (AB&T). The documentation consists of an email sent in August 2025 requesting that AB&T division managers

					indicate whether a P-Card was still needed for their respective employees. Based on our review, our office notes AFM has initiated proper controls in place consistent with the Auditor General's findings and recommendations.
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