Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RISK ASSESSMENT OF FOOD AND DRUG ADMINISTRATION'S PURCHASE CARD PROGRAM

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief
Date: September 2020
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Risk Assessment of Food and Drug Administration's Purchase Card Program

Why OIG Did This Audit

The Government Charge Card Abuse Prevention Act of 2012 (Charge Card Act), P.L. No. 112-194, requires OIGs to conduct annual risk assessments of agency purchase card programs. OIGs must report to the heads of their agencies on the results of their analyses by January 31 of each year.

We used the risk areas of the Committee of Sponsoring Organizations of the Treadway Commission's (COSO's) Enterprise Risk Management-Integrated Framework and the Office of Management and Budget (OMB) Compliance Standards to assess the Food and Drug Administration's (FDA's) ability to manage internal controls and risk in its purchase card program.

Our objective was to analyze the risk of illegal, improper, or erroneous purchases in the FDA purchase card program and to determine whether FDA has designed and implemented controls and strategies to mitigate these potential risks.

How OIG Did This Audit

We interviewed FDA management, performed purchase transactions testing, reviewed documents, and evaluated FDA's responses to an OIG questionnaire. Based on this review, we used the COSO framework and the OMB Compliance Standards to identify 6 risk areas and 56 sub-risk areas.

What OIG Found

FDA generally designed and implemented controls and strategies to mitigate the potential risks of illegal, improper, or erroneous purchases in its purchase card program. Within the 6 risk areas related to FDA's purchase card program, we identified 56 sub-risk areas and assessed 50 as low risk and 6 as moderate risk. Overall, we assessed the FDA purchase card program as low risk.

RISK	SUB-RISK
Governance and Culture	11 - Low
Strategy and Objective Setting	2 - Low
Performance	10 - Low, 2 - Moderate
Review and Revision	3 - Low
Information, Communication and Reporting	7 - Low, 1 - Moderate
OMB Compliance Standards	17 - Low, 3 - Moderate

Level of Risk: Low Moderate High Critical

What OIG Recommends

This report contains no recommendations.

The full report can be found at https://oig.hhs.gov/oas/reports/region4/41906234.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Government Charge Card Abuse Prevention Act of 2012 (Charge Card Act), P.L. No. 112-194, requires Offices of Inspectors General (OIGs) to conduct annual risk assessments of agency purchase card programs; which include convenience checks,[1] combined integrated card programs, and travel card programs; to analyze the risks of illegal, improper, and erroneous purchases and payments. OIGs must report to the heads of their agencies on the results of their analyses by January 31 of each year.

Under the provisions of the Charge Card Act, we performed a risk assessment of HHS's charge card program for Federal fiscal year (FY) 2013 and identified the Food and Drug Administration (FDA)[2] as having a moderate risk of inappropriate travel card and purchase card transactions. The Charge Card Act requires that OIGs use risk assessments in determining the necessary scope, frequency, and number of IG audits or reviews of these programs. This report contains the results of our current FDA purchase card assessment.

OBJECTIVE

Our objective was to analyze the risk of illegal, improper, or erroneous purchases in the FDA purchase card program and to determine whether FDA has designed and implemented controls and strategies to mitigate these potential risks.

BACKGROUND

Food and Drug Administration

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

To accomplish its mission, FDA participates in the HHS Purchase Card Program. FDA uses government purchase cards to buy equipment, supplies, and services. During FY 2018, FDA had 826 holders of purchase cards.

[1] Convenience checks are used in the purchase card program to make purchases from merchants that do not accept purchase cards.

[2] FDA is one of the eleven operating divisions within HHS.

Federal Government Purchase Card Program

The General Services Administration (GSA) SmartPay Program is the world's largest commercial payment solution program, providing services to more than 560 Federal agencies, organizations, and Native American tribal governments.

GSA SmartPay enables authorized government employees to make purchases on behalf of the Federal Government in support of their organization's mission. Government account holders use the program to pay for items such as commercial goods and services.

Agencies using the GSA SmartPay card must establish procedures for use and control of the card that are consistent with Federal law and the terms and conditions of the current GSA SmartPay contract.

Federal Requirements

The Charge Card Act and Office of Management and Budget (OMB) Memorandum M-13-21, "Implementation of the Government Charge Card Abuse Prevention Act of 2012," require executive-branch agencies (agencies) to be aware of charge-card-related audit findings and to ensure that the findings are promptly resolved after completion of an audit.

The Charge Card Act also requires agencies to establish and maintain safeguards and internal controls for the charge card program.[3] The charge card program includes purchase, travel, integrated,[4] and centrally billed government credit cards.

Federal agencies are required to comply with regulations and OMB guidance governing Federal grants. OMB Circular No. A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, updated July 15, 2016, provides guidance to Federal managers and defines management's responsibilities for enterprise risk management (ERM) and internal control. The circular emphasizes the need to integrate and coordinate risk management and strong and effective internal controls into existing business activities and as an integral part of managing an agency.

OMB Circular No. A-123 also establishes an assessment framework based on the Government Accountability Office's *Standards for Internal Control in the Federal Government* (The Green

[3] Section 2(a) of the Charge Card Act, P.L. 112–194 (enacted Oct. 5, 2012).

[4] An integrated card is a combination of two or more business lines on a single card (e.g., purchase and travel).

Book) and Committee of Sponsoring Organizations of the Treadway Commission's (COSO)[5] *Enterprise Risk Management—Integrating with Strategy and Performance* (June 2017) that managers must integrate into risk management and internal control functions.

Enterprise Risk Management

COSO developed ERM. ERM consists of five interrelated components that are derived from the way management runs an organization:

- Governance and Culture;
- Strategy and Objective-Setting;
- Performance;
- Review and Revision; and
- Information, Communication, and Reporting.

ERM provides a common language, concepts, and principles that facilitate targeting the riskiest organizations and transactions to audit, study, and investigate.

HOW WE CONDUCTED THIS AUDIT

We performed a risk assessment of HHS's charge card program for FY 2018.[6] To assess HHS's ability to manage internal controls and risk in its charge card program, we used ERM. We applied standards derived from the OMB Compliance Matrix,[7] which were designed to assist agencies in evaluating control risks within the charge card programs. In this report, we refer to the matrix as "OMB Compliance Standards."

We interviewed FDA management, performed purchase transactions testing, reviewed documents, and evaluated FDA's responses to an OIG questionnaire.

[5] COSO is a joint initiative of five private sector organizations dedicated to providing leadership through the development of frameworks and guidance on ERM, internal controls, and fraud deterrence designed to improve organizational performance and governance and to reduce the extent of fraud in organizations. The most recent version of the framework was updated June 2017.

[6] FY 2018 had the most recent data at the time we began our annual risk assessment. We therefore examined procedures and analyzed purchase card transactions for that FY.

[7] OMB Memorandum M-13-21 encourages agencies to use the Compliance Summary Matrix. The compliance matrix is designed to assist agencies in employing an effective charge card internal control program that is in balance with the need to maintain card flexibility and ease of use in support of agency mission activities.

We used the five ERM components and the OMB Compliance Standards as areas of risk for a total of six risk areas. Within those 6 risk areas, we identified a total of 56 sub-risk areas (as listed below):

1. **Governance and Culture** – human resource practices, workplace ethics, employee behavior, orientation, ethics reporting, availability of policies, reinforce policies, communication channels, whistleblower, knowledge and skills, and organizational structure.

2. **Strategy and Objective-Setting** – management responsiveness and risk tolerances.

3. **Performance** – incident identification, decentralized operations, past failures, inherent risk, technology usage, technology processes, risk assessment, risk response, corrective action plans, risk response (control activities), identifying misuse, and reliance on contractors.

4. **Review and Revision** – risk management evaluation, ongoing monitoring results (management considerations), and recurring monitoring.

5. **Information, Communication, and Reporting** – infrastructure, raw data conversion, timely information, levels of information, data availability, management communication, management involvement, and historical data.

6. **OMB Compliance Standards** – segregation of duties, transactions authorized, transaction classification, records access, document controls, cardholder record, training, cardholder policies, employee separation, adverse personnel action (guidelines), safeguarding assets, convenience checks, reconciling, disputed charges, records retention, purchase card need, cost recovery, penalties, summary of violations, and summary of personnel adverse actions.

Using the principles established in COSO's ERM and the OMB Compliance Standards, we then conducted a high-level risk assessment of the areas that we identified and assigned a level of risk (low, moderate, high, or critical) to each sub-risk area based on our review of documents and responses from FDA.[8]

We conducted this performance audit 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

[8] Our risk appetite for charge card programs is low. Therefore, if we rate a risk area as low risk, our response is to accept the risk and take no further action. However, if we rate an agency as higher risk, we respond in the following ways: (1) if moderate risk, we conduct a followup risk assessment; (2) if high risk, we conduct an audit; or (3) if critical risk, we notify our Office of Investigations concerning the possibility of fraud and request immediate action.

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.

Appendix A contains our audit scope and methodology.

RESULTS OF AUDIT

Within the 6 risk areas related to FDA's purchase card program, we identified 56 sub-risk areas and assessed 50 as low risk and 6 as moderate risk. (See the table below.) Overall, we assessed the FDA purchase card program as low risk. FDA generally designed and implemented controls and strategies to mitigate the potential risks of illegal, improper, or erroneous purchases in its purchase card program. We included a detailed assessment of the sub-risk areas in a table at Appendix B.

Table: Risk Assessment of FDA's Purchase Card Program

RISK	SUB-RISK
Governance and Culture	11 - Low
Strategy and Objective Setting	2 - Low
Performance	10 - Low, 2 - Moderate
Review and Revision	3 - Low
Information, Communication and Reporting	7 - Low, 1 - Moderate
OMB Compliance Standards	17 - Low, 3 - Moderate

Level of Risk: Low Moderate High Critical

GOVERNANCE AND CULTURE

"Governance" sets the organization's tone, reinforcing the importance of, and establishing oversight responsibilities for, ERM. "Culture" pertains to ethical values, desired behaviors, and understanding of risk in the entity.

We assessed as low risk all 11 sub-risk areas that we identified within the governance and culture component, such as workplace ethics, availability of policies, knowledge and skills, and organizational structure. Some examples of how FDA reduced related risks to a low level were:

- FDA emphasized ethical use of the purchase card during compliance reviews and in training documents.

- FDA employed people with the necessary knowledge and skills to identify improper purchases.

- FDA defined key areas of responsibility in its organizational structure and clearly communicated purchase card policies and procedures to employees.

STRATEGY AND OBJECTIVE-SETTING

"Strategy and Objective-Setting" works together with ERM in the strategic-planning process. Business objectives put strategy into practice while serving as a basis for identifying, assessing, and responding to risk.

We assessed as low risk the two sub-risk areas that we identified within the strategy and objective-setting component, namely, management responsiveness and risk tolerances. FDA reduced its related risk to a low level. In response to our prior risk assessment of FDA's charge card programs, management instituted onsite audits of charge cards and high-risk transactions at each of FDA's centers. Based on these onsite audits, we reduced the Strategy and Objective-Setting rating from moderate to low risk, and this contributed to our reduction of FDA's overall risk from moderate to low.

PERFORMANCE

The "Performance" component includes identifying and assessing risks that may impact the achievement of strategy and business objectives. Risks should be prioritized by severity in the context of risk appetite. The organization then selects risk responses and takes a portfolio view of the amount of risk it has assumed. The results of this process are reported to key risk stakeholders.

Of the 12 sub-risk areas that we identified in the "Performance" component, we assessed 2 as moderate risk and 10 as low risk.

We assessed as moderate risk the sub-risk area "Decentralized Operations" because Approving Officials (AO) did not increase surveillance of cardholder transactions when the AO was not at the same location as the cardholder. The HHS Purchase Card Program Guide (Program Guide) recommends an increased oversight of transactions for cardholders that are geographically separated. Also, FDA did not review all new AOs or cardholders within 90 days of their appointments to identify procedural errors or misuse. The Program Guide recommends a review of new AOs and cardholders within 90 days as a risk reduction method.

We assessed as moderate risk the sub-risk area "Technology Processes" because our transaction testing indicated that FDA made some common errors that it did not identify, even though its processes for identifying improper or potentially fraudulent purchases were systemic and ongoing. Examples of those errors were sales tax paid (Federal agencies are exempt from sales tax) and missing AO approval documentation.

The 10 sub-risk areas that we assessed as low risk primarily related to identifying and responding to risk and the use of technology and contractors. Some examples of how FDA reduced related risks to a low level were:

- FDA conducted annual assessments of internal controls to support its Agency Assurance Statement (OMB Circular A-123 report) and implemented an enhanced Purchase Card Audit plan in FY 17.

- FDA's Office of Acquisitions and Grants Services (OAGS), as part of its internal control assessment, conducted comprehensive, annual onsite audits of each Center/Office and issued an audit report for each center. In addition, OAGS provided a corrective action plan (CAP) to each center and tracked the status of the CAP until resolved.

- FDA used the Visa Intellilink Compliance Management[9] module to search for potentially fraudulent, improper, and abusive practices.

REVIEW AND REVISION

By "reviewing" the performance of entities within an organization, the organization considers how well the ERM components function over time and what "revisions" are needed as changes occur.

We assessed as low risk all three sub-risk areas that we identified within the review and revision component. These areas primarily related to risk management and monitoring. Some examples of how FDA reduced related risks to a low level were:

- FDA developed a process narrative report that explains the proper management of the purchase card. This process narrative report supports its statement of management assurance, which states that FDA evaluated its internal controls and met the requirements of OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. This process narrative report summarizes the steps taken in each comprehensive assessment of internal controls that FDA conducted at individual centers. As a part of the individual assessments, FDA used transaction testing and data mining to identify risk areas such as potential split transactions and blocked merchants.

- FDA used effective, ongoing monitoring techniques to detect card misuse and took action against cardholders and AO's that didn't adhere to purchase card guidelines. FDA provided the most recent results of this monitoring in its Annual Report of Program Performance, which described instances of cardholders not maintaining adequate documentation and failing to purchase items from required sources.

[9] This application helps to identify and document instances of card misuse, abuse, or potential fraud.

- Management was responsive to the results of ongoing monitoring and was diligent in logging and tracking the status of CAPs as they were resolved. For instance, some CAPs required additional training, which FDA provided and verified that all necessary employees completed by obtaining their training certificates.

INFORMATION, COMMUNICATION, AND REPORTING

ERM requires a continual process of obtaining and sharing necessary information from both internal and external sources, which flows up, down, and across the organization.

Of the eight sub-risk areas that we identified in the "Information, Communication, and Reporting" component, we assessed one as moderate risk and seven as low risk. The one sub-risk area that we assessed as moderate was "Timely Information."

We assessed as moderate risk the sub-risk area "Timely Information" because FDA relies on a manual onsite audit[10] for its oversight of the program. While these onsite audits provide a comprehensive examination of the purchasing card program, they were not fully completed at the time of our assessment. FDA is aware of this limitation.

The seven sub-risk areas that we assessed as low risk primarily related to the availability and accuracy of data, and the effectiveness of management's communication and involvement. Some examples of how FDA reduced related risks to a low level were:

- FDA used JP Morgan Chase (PaymentNet) to reconcile purchases, and PaymentNet data was available in real time.

- FDA used reports and statistical data taken from Visa Intellilink from prior FYs and/or performance periods to analyze trends, anomalies, and actual card use. This information was regularly used to determine samples for annual onsite reviews.

- FDA regularly communicated policies and procedures, standards, and workplace ethics for its purchase card program.

OMB COMPLIANCE STANDARDS

The OMB Compliance Standards are designed to assist agencies in employing an effective charge card internal control program that is in balance with the need to maintain card flexibility and ease of use in support of agency mission activities.

Of the 20 sub-risk areas that we identified in the "OMB Compliance Standards" component, we assessed 3 as moderate risk and 17 as low risk.

[10] FDA used a risk-based approach to select a sample of cardholders, as well as tested multiple areas of internal controls.

We assessed as moderate risk the sub-risk area "Transactions Authorized" because our transaction tests found instances in which proper AO approval did not occur until after a purchase was made.

We also assessed as moderate risk the sub-risk area "Cardholder Record" because the total number of cardholders that FDA identified was not supported by the documentation we received.

Finally, we assessed as moderate risk the sub-risk area "Training" because cardholders paid sales tax in some of our transaction tests, even though cardholders received training on the exemption of sales tax.

The 17 sub-risk areas that we assessed as low risk primarily related to "segregation of duties" and "reconciling." Some examples of how FDA reduced related risks to a low level were:

- Key management controls included segregation of duties so that a participant in the purchase card program was not permitted to serve in two or more roles, such as purchaser and AO, for the same transaction. OAGS were responsible for enforcing this control.

- FDA had controls in place to verify that transactions were properly recorded and reconciled and that purchase cards were invalidated when an employee separated from the agency.

- FDA clearly communicated penalties for misuse of the purchase card including card cancellation, termination of employment, fines and/or imprisonment, civil judgements, and salary offsets. FDA also maintained a record of violations and adverse personnel actions.

CONCLUSION

Within the 6 risk areas related to FDA's purchase card program, we identified 56 sub-risk areas and assessed 50 as low risk and 6 as moderate risk. Even though we assessed six sub-risk areas as moderate risk, FDA developed various controls and strategies that are designed to mitigate the potential risks of illegal, improper, or erroneous purchases in its purchase card program. Therefore, this report contains no recommendations.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We performed a risk assessment of HHS's charge card program for FY 2018. To assess HHS's ability to manage internal controls and risk for its charge card program, we used ERM developed by COSO. We applied the COSO framework and standard from the OMB Compliance Matrix to identify 6 risk areas and 56 sub-risk areas.

Using the principles established in COSO's ERM and the OMB Compliance Matrix, we conducted a high-level risk assessment of the areas that we identified and assigned a level of risk (low, moderate, high, or critical) to each sub-risk area based on our review of documents and responses from FDA.

We focused our review on FDA's internal controls, including policies and procedures, related to purchase cards and purchase transaction testing.

We performed our fieldwork at FDA in Beltsville, Maryland.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, policies, and guidance;
- developed a risk assessment questionnaire, reviewed FDA's responses, and analyzed these responses in the context of the COSO framework;
- held discussions with FDA officials about purchase cards and reviewed FDA's policies;
- reviewed the results of FDA's internal monitoring of its purchase card program;
- conducted purchase card transaction testing to verify the effectiveness of internal controls;
- conducted a risk assessment of the risk areas and sub-risk areas that we identified and assigned a level of risk to each sub-risk area;
- assessed mitigating processes and strategies for identified risks; and
- discussed the results with FDA officials.

We provided FDA with a draft audit report on August 26, 2020, for review. FDA elected not to provide any written comments.

We conducted this performance audit 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.

APPENDIX B: FDA's RISK AND SUB-RISK AREAS