

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**RISK ASSESSMENT OF THE FOOD AND
DRUG ADMINISTRATION'S TRAVEL CARD
PROGRAM**

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**May 2021
A-04-19-06235**

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: May 2021

Report No. A-04-19-06235



Why OIG 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 travel card programs. OIGs must report to the Office of Management and Budget (OMB) 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) Enterprise Risk Management-Integrated Framework and OMB Compliance Standards to assess the Food and Drug Administration's (FDA's) ability to manage internal controls and risk in its travel card program.

Our objective was to analyze the risk of illegal, improper, or erroneous purchases in the FDA travel 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 travel 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 46 sub-risk areas.

Risk Assessment of the Food and Drug Administration's Travel Card Program

What OIG Found

FDA generally designed and implemented controls and strategies to mitigate the potential risks of illegal, improper, or erroneous purchases in its travel card program. Within the 6 risk areas related to the FDA travel card program, we identified 46 sub-risk areas and assessed 38 as low risk and 8 as moderate risk. Overall, we assessed the FDA travel card program as low risk.

RISK	SUB-RISK
Governance and Culture	■ 11 - Low
Strategy and Objective Setting	■ 1 - Low
Performance	■ 4 - Low ■ 4 - Moderate
Review and Revision	■ 2 - Low ■ 2 - Moderate
Information, Communication and Reporting	■ 6 - Low
OMB Compliance Standards	■ 14 - Low ■ 2 - Moderate

Level of Risk: ■ Low ■ Moderate ■ High ■ Critical

What OIG Recommends

This report contains no recommendations.

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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 Office of Management and Budget (OMB) 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. To meet the Charge Card Act requirements, we review each HHS Operating Division on a cyclical basis and are now conducting a new risk assessment of FDA to identify whether the overall risk level has changed since our prior review. The Charge Card Act requires that OIGs use risk assessments in determining the necessary scope, frequency, and number of Inspector General (IG) audits or reviews of these programs. This report contains the results of our current FDA travel card assessment.

OBJECTIVE

Our objective was to analyze the risk of illegal, improper, or erroneous purchases in the FDA travel 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.

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.

To accomplish this mission, FDA participates in the HHS Travel Card Program. FDA uses government travel cards for purchases of travel-related services or products such as rental cars and hotel rooms. During FY 2018, FDA had 6,014 travel card holders.

Federal Government Travel 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 travel card holders can pay for travel and travel-related expenses with their GSA SmartPay travel card.

Agencies using the GSA SmartPay travel 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 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's)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 travel card program for FY 2018.⁶ To assess HHS's ability to manage internal controls and risk in its travel 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 travel card programs. In this report, we refer to the matrix as "OMB Compliance Standards."

We interviewed FDA management, performed travel 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 was the most recent data at the time we began our annual risk assessment. We therefore examined procedures and analyzed travel 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 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.
3. **Performance** – decentralized operations, past failures, inherent risk, technology usage, technology processes, risk assessment, corrective action plans, and risk response (control activities).
4. **Review and Revision** – risk management evaluation, travel card need, ongoing monitoring results (management considerations), and recurring monitoring.
5. **Information, Communication, and Reporting** – information infrastructure, program effectiveness, raw data conversions, data availability, management communication, and management involvement.
6. **OMB Compliance Standards** – segregation of duties; transactions authorized; transaction classifications; records access; cardholder records; rebates; training; cardholder policies; credit worthiness; employee separation; split payments; IG Audits; adverse personnel actions (guidelines); and, for centrally billed accounts (CBAs), payment authority, disputed charges, and airline refunds.

Using the principles established in COSO’s ERM and the OMB Compliance Standards, we then conducted a 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 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.

⁸ Our risk appetite for travel card programs is low. Therefore, if we rate an agency 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.

Appendix A contains our scope and methodology.

RESULTS OF AUDIT

Within the 6 risk areas related to the FDA travel card program, we identified 46 sub-risk areas and assessed 38 as low risk and 8 as moderate risk. (See the table below.) Overall, we assessed the FDA travel 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 travel card program. We included a detailed assessment of the sub-risk areas in a table at Appendix B.

Table: Risk Assessment of the FDA Travel Card Program

RISK	SUB-RISK
Governance and Culture	■ 11 - Low
Strategy and Objective Setting	■ 1 - Low
Performance	■ 4 - Low ■ 4 - Moderate
Review and Revision	■ 2 - Low ■ 2 - Moderate
Information, Communication and Reporting	■ 6 - Low
OMB Compliance Standards	■ 14 - Low ■ 2 - 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, and organizational structure. Some examples of how FDA lowered related risks were:

- FDA required travel card holders to sign the HHS Zero Tolerance Policy.⁹

⁹ The HHS Zero Tolerance Policy strictly prohibited the misuse of travel charge cards and identified specific prohibited card uses.

- FDA had its own policies and procedures manual, which it followed in addition to the HHS Travel Policy.
- FDA had clearly defined responsibilities for each travel related position.

STRATEGY AND OBJECTIVE SETTING

“Strategy and Objective-Setting” works together with ERM in the strategic-planning process. Ideally, business objectives put strategy into practice and shape the entity’s day-to-day operations and priorities.

We assessed as low risk the sub-risk area “Management Responsiveness” within the “Strategy and Objective-Setting” component because FDA mitigates risk by performing internal reviews and followups on control deficiencies and creating corrective action plans (CAPs).

For example, FDA is in the process of following up on 2 deficiencies addressed in its FY 2017 CAP:

- One center in FDA did not have a standardized process to ensure that travel cardholders completed refresher training every 3 years.
- ATM access was not always removed after a restricted¹⁰ cardholder’s need expired.

FDA did not have corrective actions for these deficiencies in place at the time of our review because the target date for correction was after our assessment in FY 2020. This followup process should ensure that FDA management gives priority to identifying and addressing deficiencies.

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.

¹⁰ Any individual with a Fair Isaac Corporation (FICO) credit score below 660, or who refuses to permit a credit score check, will be issued a restricted travel charge card. A restricted travel charge card will have a lower credit limit than the HHS standard credit limit and will have no ATM withdrawal capability. However, a restricted cardholder may submit a request with justification to temporarily increase the ATM advance limit or request ATM access on a case-by-case basis to meet the needs of the cardholder’s travel.

Of the eight sub-risk areas within the “Performance” component, we assessed four as moderate risk and four as low risk.

We assessed as moderate risk the sub-risk areas “Inherent Risk” and “Technology Usage” because our transaction testing of 50 transactions identified 18 transactions in which a more detailed review would have identified errors in voucher documentation.

For example, in one transaction we tested, a traveler’s return flight landed at 12:35 a.m. Because the flight landed after midnight, the travel system charged the hotel per diem by default, even though the traveler incurred no hotel expense; however, neither the traveler nor the reviewer removed the extra hotel per diem charge. In another transaction we tested, the traveler claimed ATM fees that were higher than the actual ATM fee amounts.

We also assessed as moderate risk the sub-risk areas “CAPs” and “Risk Response” because the transition of the travel card vendor from JPMorgan Chase to Citibank caused delays responding to risk. During this transition, FDA could not access monitoring systems that the travel card vendor typically makes available. Even though mitigation was not possible during this transitional period, the risk was present at the time of our assessment.

We assessed the remaining four sub-risk areas as low risk. Some examples of how FDA lowered related risks were:

- FDA regularly used available technology, such as IntelliLink¹¹ and PaymentNet,¹² to track the number and type of travel card misuse.
- An FDA internal review identified issues, related deficiencies, and recommendations for management to track. The internal review included the status of remediation for each issue. At the time of our risk assessment, FDA planned to follow up on the outstanding recommendations.

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.

¹¹ Visa IntelliLink Spend Management (IntelliLink) is a complete reporting and expense management solution for organizations that use Visa card products. With IntelliLink, you can easily access a cardholder’s expenses, view spending patterns, and analyze transaction details.

¹² PaymentNet, JPMorgan Chase’s web-based program, provides a convenient method of querying information and transaction detail for purchasing activity on each travel charge card, allocating transactions to one or more funds, and accessing monthly statements on the first working day of each new month.

Of the four sub-risk areas within the “Review and Revision” component, we assessed two as low risk and two as moderate risk. The two moderate sub-risk areas were “Ongoing Monitoring Results” and “Recurring Monitoring.” We assessed these sub-risk areas as moderate risk because our transaction tests found instances in which a more detailed review would have identified errors in voucher documentation. For example, a traveler submitted double the mileage costs on a voucher but attached documentation for the correct mileage costs.

We assessed the remaining two sub-risk areas as low risk. Some examples of how FDA lowered related risks were:

- FDA performed periodic reviews to determine whether each cardholder still needs their card.
- FDA actively monitored and followed up on instances of significant misuse or abuse.

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.

We assessed as low risk all six sub-risk areas that we identified within the “Information, Communications, and Reporting” component. These areas primarily related to technology. Some examples of how FDA lowered related risks were:

- FDA used available technology, such as PaymentNet and Intellilink, to obtain, distribute, and monitor information regarding cardholder activity.
- FDA’s senior personnel used email to communicate policy changes to employees.

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 16 sub-risk areas that we identified in the “OMB Compliance Standards” component, we assessed 2 as moderate risk and 14 as low risk.

We assessed as moderate risk the sub-risk area “Training” because not all of the training dates for travel card holders were documented in PaymentNet and, therefore, not quickly accessible.

Finally, we assessed as moderate risk the sub-risk area “Airline Refunds” because FDA allowed a traveler to submit a voucher without a final airline receipt. When flight changes are not

reflected in the ConcurGov¹³ system, the traveler could be reimbursed more than the actual expense. After we identified this inappropriate payment, FDA stated that it would conduct voucher testing as a followup.

The 14 sub-risk areas we assessed as low risk primarily related to employee responsibilities. Some examples of how FDA lowered related risks were:

- FDA clearly defined responsibilities that did not allow for any individual to control all key aspects of a transaction.
- FDA only issued travel cards to employees who:
 - were determined to be credit worthy,
 - completed required training, and
 - completed required forms including a signed HHS Traveler Agreement.

CONCLUSION

Within the 6 risk areas related to the FDA travel card program, we identified 46 sub-risk areas and assessed 38 as low risk and 8 as moderate risk. Even though we assessed eight 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 travel card program. Overall, we assessed the FDA travel card program as low risk. Therefore, this report contains no recommendations.

¹³ ConcurGov is the HHS-wide travel system.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We performed a risk assessment of HHS's travel card program for FY 2018. To assess HHS's ability to manage internal controls and risk for its travel 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 46 sub-risk areas.

Using the principles established in COSO's ERM and the OMB Compliance Matrix, we conducted a 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 travel cards and travel card transaction testing.

We performed our audit from April 2019 to March 2021.

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 travel cards and reviewed FDA's policies;
- reviewed the results of FDA's internal monitoring of its travel card program;
- conducted limited travel 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 controls and strategies for identified risks; and
- discussed the results with FDA officials.

We provided FDA with a draft report on March 26, 2021, 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 RISK AND SUB-RISK AREAS

Level of Risk: ■ Low ■ Moderate ■ High ■ Critical

RISK	Governance and Culture	Strategy and Objective Setting	Performance	Review and Revision	Information, Communication and Reporting	OMB Compliance Standards
SUB-RISK	<ul style="list-style-type: none"> ■ Human Resource Practices ■ Workplace Ethics ■ Employee Behavior ■ Orientation ■ Ethics Reporting ■ Availability of Policies ■ Reinforce Policies ■ Communication Channels ■ Whistleblower ■ Knowledge & Skills ■ Organizational Structure 	<ul style="list-style-type: none"> ■ Management Responsiveness 	<ul style="list-style-type: none"> ■ Decentralized Operations ■ Past Failures ■ Technology Processes ■ Risk Assessment ■ Inherent Risk ■ Technology Usage ■ Corrective Action Plans ■ Risk Response (Control Activities) 	<ul style="list-style-type: none"> ■ Risk Management Evaluation ■ Travel Card Need ■ Ongoing Monitoring Results (Management Considerations) ■ Recurring Monitoring 	<ul style="list-style-type: none"> ■ Information Infrastructure ■ Program Effectiveness ■ Raw Data Conversions ■ Data Availability ■ Management Communication ■ Management Involvement 	<ul style="list-style-type: none"> ■ Segregation of Duties ■ Transactions Authorized ■ Transaction Classification ■ Records Access ■ Cardholder Record ■ Rebates ■ Cardholder Policies ■ Credit Worthiness ■ Employee Separation ■ Split Payments ■ Adverse Personnel Action (Guidelines) ■ CBA Payment Authority ■ CBA Disputed Charges ■ IG Audit ■ Training ■ CBA Airline Refunds