

Compliance with Rules and Contacting Contest Winners

Finalists and the Contest Winners must comply with all terms and conditions of the Official Rules, and winning is contingent upon fulfilling all applicable requirements. Awards may be subject to Federal income taxes, and the contest sponsors will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

General Conditions

The Sponsors reserve the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at the sponsors' sole discretion. Participation in this Challenge constitutes a contestant's full and unconditional agreement to abide by the Challenge's Official Rules, available at www.healthyyoungamerica.org.

Authority: 15 U.S.C. 3719.

Dated: August 16, 2013.

Dori Salcido,

Assistant Secretary for Public Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Financial Resources, Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AM, Office of the Assistant Secretary for Financial Resources (ASFR), as last amended at 76 FR 19774-19776 dated April 8, 2011; 75 FR 369-370, dated January 5, 2010; 74 FR 57679-57682, dated November 9, 2009; and 71 FR 38884-88, dated July 10, 2006, as follows:

B. Under Section AM.20 Functions, make the following changes:

1. Under paragraph D, "Office of Finance (AMS)," delete in its entirety and replace with the following:

D. Chapter AMS, Office of Finance (AMS)

Section AMS.00 Mission: The Office of Finance is headed by the Deputy Assistant Secretary for Finance, who is also the Deputy Chief Financial Officer. The mission of the Office of Finance is to provide financial accountability and

enhance program integrity through leadership, oversight, collaboration, and innovation.

Section AMS.10 Organization. The Office of Finance (OF) is headed by the Deputy Assistant Secretary for Finance (DASF), who is also the Deputy Chief Financial Officer and reports to the Assistant Secretary for Financial Resources/Chief Financial Officer (CFO). The office includes the following:

- Immediate Office (AMS)
- Office of Financial Policy and Reporting (AMS1)
- Office of Financial Systems Policy and Oversight (AMS2)
- Office of Program Integrity Coordination (AMS3)

Section AMS.20 Functions:

1. *Immediate Office (AMS).* The Immediate Office is responsible for support and coordination of the Office of Finance components in their management of the areas listed in section AMS.00 Mission above, including the following functions: (1) Coordinates strategic planning for the HHS CFO community and the Office of Finance; (2) Serves as the liaison with internal and external stakeholders regarding financial management matters; (3) Provides operational support for the Office of Finance and; (4) Advises the ASFR/CFO regarding financial management matters affecting the Department.

2. *Office of Financial Policy and Reporting (AMS1).* The Office of Financial Policy and Reporting (OFPR) is responsible for financial management policy and standards, internal controls, statutory financial reports and audits and other managerial reports. The Division includes:

- Division of Financial Management Policy (AMS11)
- Division of Financial Statements and Audit (AMS12)
- Division of Financial Reporting and Analysis (AMS13)
- Division of Accounting Standardization and Monitoring (AMS14)

The functions of each OFPR division include:

a. *Division of Financial Management Policy (AMS11).* The Division:

(1) Leads the Department's efforts to establish and maintain proper internal controls and ensures that requirements are met under OMB Circular A-123, "Management's Responsibility for Internal Control" and the Federal Managers' Financial Integrity Act (FMFIA);

(2) Coordinates with the OPDIVs in the preparation of the corrective action

plan (CAP), which is submitted annually to OMB and reflects the material weaknesses and reportable conditions from the annual CFO audit and the FMFIA report;

(3) Recommends, develops, and promulgates Department-wide policies, procedures, and standards for financial management areas including OMB, GAO, Treasury, Federal Accounting Standards Advisory Board (FASAB), and other agency guidance related to government-wide accounting policy and standards, cash management, credit management, debt management, payment and disbursement activities and functions, and budget execution accounting;

(4) Provides support to the OPDIV CFOs for financial planning and improvement initiatives;

(5) Serves as principal staff advisor on financial management policy matters to the DASF;

(6) Manages the Departmental process for the development of the required annual report on the audited financial statements; and

(7) Maintains a system for tracking and improving cash and credit management and debt collection performance throughout the Department.

b. *Division of Financial Statements and Audit (AMS12).* The Division:

(1) Oversees the preparation and submission of consolidated financial statements for the Department based upon the OMB and Treasury submission schedules;

(2) Acts as the principal liaison with the OIG in planning the annual financial statement audit strategy under the CFO Act and the 1994 amendments under the Government Management Reform Act (GMRA);

(3) Reviews and interprets OMB, GAO, Treasury and Federal Accounting Standards Advisory Board (FASAB) guidance related to government "wide" accounting policy and standards and develops the Department's policy for implementation of reporting requirements. Assures that policies and procedures are in accordance with internal control and reporting standards of financial management activities;

(4) Provides financial statement review and analyses for the OPDIV and Department consolidated financial statements. Monitors OPDIV and accounting center key reconciliations;

(5) Provides advice and assistance to OPDIVs and STAFFDIVs on financial accounting, reporting and related fiscal matters, and advises the DASF on such matters as they relate to financial reporting; and

(6) Acts as the liaison with OMB, Treasury, and other agencies on accounting, financial policy and fiscal matters related to financial reporting, including Treasury's intergovernmental groups.

c. *Division of Financial Reporting and Analysis (AMS13)*. The Division:

(1) Oversees the design, preparation, and submission of financial management reports for the Department, as required by legislation, regulations, OMB requests, and Congressional requests;

(2) Provides review and analysis of financial management reports for senior management, OMB, Congress, and other stakeholders;

(3) Reviews and interprets OMB, GAO, Treasury, and FASAB guidance related to financial management reporting requirements or data requests that are in addition to the consolidated financial statements;

(4) Supports the maintenance and operation of Department databases, and reporting tools for audited financial statements and other management reporting;

(5) Provides guidance, advice and assistance to OPDIVs and STAFFDIVs on new reporting and related fiscal matters; and

(6) Serves as principal advisor to the DASF as it relates to new required financial reports and management reporting.

d. *Division of Accounting Standardization and Monitoring (AMS14)*. The Division:

(1) Establishes the planning, implementation and oversight process for the Departmental accounting treatment standardization and monitoring;

(2) Ensures the development and implementation of accounting standards in accordance with policy for the consistent development and implementation of accounting systems;

(3) Monitors the accounting center, OPDIV, and Department's financial system change management to ensure accounting standardization and compliance with Federal accounting concepts, standards, and HHS financial management policies;

(4) Provides advice and serves as the focal point with OMB, Treasury and other Federal agencies on standard general ledger compliance matters;

(5) Develops uniform business rules and data standards to support new financial system implementations and reporting requirements; and

(6) Advises the DASF on financial systems related matters, in collaboration with the Office of Financial Systems Policy and Oversight.

3. *Office of Financial Systems Policy and Oversight (AMS2)*. The Office of Financial Systems Policy and Oversight (OFSPPO) is responsible for overseeing the management of Department-wide financial systems. The Office includes:

○ Division of Financial Systems (AMS21)

○ Division of Systems Policy and Compliance (AMS22)

○ Division of Planning, Governance, and Strategic Direction (AMS23)

The functions of each OFSPPO

Division include:

a. *Division of Financial Systems (AMS21)*. The Division:

(1) Oversees the planning, design, development, implementation and maintenance of the Department-wide financial systems, including the three major core accounting systems (the Healthcare Integrated General Ledger Accounting System (HIGLAS) at the Centers for Medicare & Medicaid Services (CMS), National Institutes of Health Business System (NBS), and the Unified Financial Management System (UFMS) for the rest of the Department), a Consolidated Financial Reporting System (CFRS) and a Financial Business Intelligence System (FBIS);

(2) Oversees, coordinates and performs the project planning, execution, and monitoring activities for enhancing the Department-wide financial systems environment;

(3) Ensures that the Department's financial systems comply with applicable Federal and Departmental policies and procedures;

(4) Collaborates with other business domains and ensures that the integration with mixed financial systems is secure and reliable; and

(5) Coordinates the resolution of security vulnerabilities and audit findings identified in the financial systems.

b. *Division of Systems Policy and Compliance (AMS22)*. The Division:

(1) Develops policies for Department-wide financial management systems including core financial systems and the financial portion of the mixed systems;

(2) Oversees compliance with Federal and Departmental policies and procedures for financial systems and information technology;

(3) Monitors the Department's compliance with the Federal Financial Management Improvement Act of 1996 (FFMIA) and Section 4 of the Federal Managers' Financial Integrity Act;

(4) Administers a data integrity and quality control program to ensure compliance with applicable Federal directives, Departmental financial systems policy and automated financial

data exchange requirements, including the establishment of Department-wide financial definitions and data structures;

(5) Provides advice and serves as the focal point with OMB, Treasury and other Federal agencies on financial systems compliance matters; and

(6) Collaborates with the HHS Office of the Chief Information Officer (OCIO) and ensures that the financial systems environment is secure and reliable and complies with IT policies and procedures.

c. *Division of Planning, Governance, and Strategic Direction (AMS23)*. The Division:

(1) Develops strategic plans to manage, enhance and support Department-wide financial systems environment;

(2) Develops and provides strategic advice on the future of Department-wide financial systems;

(3) Establishes, manages and operates governance framework for Department-wide financial system;

(4) Manages the IT portfolio and investment functions throughout the Capital Planning & Investment Control Lifecycle (CPIC) lifecycle for Department's financial systems;

(5) Establishes and manages acquisition vehicles for Department-wide financial systems;

(6) Oversees and monitors Department-wide and Operating Division specific accounting and financial management system investments; and

(7) Advises the DASF on financial systems related matters, in collaboration with the Office of Financial Policy and Reporting.

4. *Office of Program Integrity Coordination (AMS3)*. The Office of Program Integrity Coordination (OPIC) serves as the central point of contact for coordinating program integrity, payment accuracy and audit resolution activities across the Department. The Office includes:

○ Division of Program Integrity Integration and Oversight (AMS31)

○ Division of Analytics, Research and Evaluation (AMS32)

○ Division of Payment Accuracy Improvement (AMS33)

○ Division of Audit Resolution (AMS34)

The functions of each Division include:

a. *Division of Program Integrity Integration and Oversight (AMS31)*. The Division:

(1) Identifies opportunities and works across HHS to integrate program integrity into business operations;

(2) Coordinates, develops, and/or provides program integrity related communications, outreach, and training;

(3) Oversees, monitors, and follows-up on program integrity risk assessments;

(4) Develops tools and guidance regarding program integrity and provides technical assistance and direction to HHS Divisions on enhancing program integrity;

(5) Shares program integrity related best practices and other activities that improve program integrity;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders on program integrity related activities; and

(7) Leads other activities that enhance HHS program integrity and integrate it into business operations.

b. *Division of Analytics, Research and Evaluation (AMS32)*. The Division:

(1) Provides support for the Department's program integrity governance structure;

(2) Analyzes, evaluates, coordinates, tracks, and provides quality control/quality assurance on program integrity related information;

(3) Identifies evidenced-based program integrity practices and leverages results to recommend solutions to program integrity challenges;

(4) Develops communication resources to facilitate program integrity outreach;

(5) Develops and leverages innovative approaches, using innovative tools and technology, to enhance HHS program integrity;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders on program integrity analytics and solutions; and

(7) Leads other activities that enhance program integrity related analytics and problem solving.

c. *Division of Payment Accuracy Improvement (AMS33)*. The Division:

(1) Implements the Improper Payments Information Act of 2002, the Improper Payments Elimination and Recovery Act of 2010, the Improper Payments Elimination and Recovery Improvement Act of 2012, and improper payment related Executive Orders and other regulatory requirements;

(2) Provides analysis of high risk programs and coordinates error rate measurements and improvements for high risk programs;

(3) Coordinates efforts among HHS Divisions to recapture improper payments;

(4) Identifies and shares best practices on addressing improper payments with

HHS leadership, HHS Divisions, OMB, and other agencies;

(5) Participates in inter-agency and HHS workgroups to address improper payments;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, OMB and other stakeholders on improper payment initiatives; and

(7) Leads other activities that support improving payment accuracy.

d. *Division of Audit Resolution (AMS34)*. The Division:

(1) Reviews, resolves, and coordinates, where necessary, the audit findings of grantees affecting the programs of more than one HHS Division or Federal agency;

(2) Coordinates and provides technical assistance to grantees and HHS Divisions on all aspects of audit resolution in an effort to reduce the number and significance of audit findings;

(3) Works with HHS' Single Audit Coordinator to streamline and enhance the efficiency of the audit resolution process;

(4) Establishes and monitors Department policies regarding audit resolution, as required by OMB Circular A-50 and other OMB or regulatory guidance;

(5) Prepares the Management Report on Final Action for the Department's annual Agency Financial Report;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders regarding audit resolution activities; and

(7) Leads other activities that support and advance audit resolution.

Dated: August 15, 2013.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0150]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by September 23, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0670. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims—(OMB Control Number 0910-0670)—Extension

This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. The guidance encourages applicants to