

II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19182 Filed 9–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

AGENCY: Office of the Assistant Secretary for Financial Resources (ASFR), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is making several updates within the Office of the Assistant Secretary for Financial Resources (AM), the Immediate Office (AMM), the Office of Budget (AML), the Office of Finance (AMS), the Office of Grants (AMU), and the Office of Acquisitions (AMX), to better align office titles with office activities and to clearly delineate ASFR's portfolio across its five components.

FOR FURTHER INFORMATION CONTACT:

Christine Jones, Deputy Assistant Secretary for Operations and Management, Office of the Assistant Secretary for Financial Resources, Hubert H. Humphrey Building, 200

Independence Ave. SW, Room 514–G, Washington, DC 20201, (202) 690–7542.

SUPPLEMENTARY INFORMATION: Part A (Office of the Secretary), Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AML, Office of Budget, as last amended at 74 FR 150 (39327) dated July 30, 2009; at Chapter AM, ASFR, as last amended at 74 FR 215 dated November 9, 2009; at Chapter AMS, Office of Finance, as last amended at 81 FR 88249, dated December 7, 2016; at Chapter AMX, Office of Acquisitions, as last amended at 84 FR 20154, dated May 8, 2019; at Chapter AMU, Office of Grants, as last amended 85 FR 81935, dated December 17, 2020; and at Chapter AMM, Immediate Office, as last amended at 86 FR 6354, dated January 21, 2021.

This notice realigns the Grants Quality Service Management Office (Grants QSMO) from the Immediate Office (AMM) to the Office of Grants (AMU); and compiles the responsibilities of ASFR into one **Federal Register** notice. All notices above are superseded by the following changes:

(1) Chapter AM, Office of the Assistant Secretary for Financial Resources

Section AM.00 Mission: The mission of the Office of the Assistant Secretary for Financial Resources is to advise the Secretary on all aspects of budget, grants, financial management, acquisitions, and Enterprise Risk Management and to provide direction for these activities throughout HHS.

Section AM.10 Organization: The Office of the Assistant Secretary for Financial Resources is headed by the Assistant Secretary for Financial Resources, who reports to the Secretary, and accomplishes its work through its component offices:

- Immediate Office (AMM)
- Office of Budget (AML)
- Office of Finance (AMS)
- Office of Grants (AMU)
- Office of Acquisitions (AMX)

Section AM.20 Functions: The Assistant Secretary for Financial Resources has several formal and informal roles, including Chief Financial Officer (CFO), Chief Performance Improvement Officer (PIO), Chief Acquisition Officer (CAO), HHS audit follow-up official, and lead official for budget and Department-wide grants policy. The Assistant Secretary is also a close advisor to the Secretary on policy issues.

(2) Chapter AMM, Immediate Office

Section AMM.00 Mission: The Immediate Office is responsible for support, operations, and coordination required to execute the mission of the Office of the Assistant Secretary for Financial Resources (ASFR) and the implementation of HHS's Enterprise Risk Management (ERM) capabilities. The Immediate Office also leads strategic and workforce development initiatives across ASFR.

Section AMM.10 Organization: The Immediate Office is headed by the Deputy Assistant Secretary for Operations and Management, who reports to the Assistant Secretary for Financial Resources, and includes the following:

- Division of Administrative Operations (AMM1)
- Division of Enterprise Risk Management (AMM2)

Section AMM.20 Functions:

1. Division of Administrative Operations (AMM1): The Division:

- (a) Provides operational support for the ASFR.
- (b) Coordinates administrative and operational issues across ASFR.
- (c) Serves as the liaison with internal and external stakeholders regarding operational matters.
- (d) Leads activities that enhance ASFR's management and operations.

2. Division of Enterprise Risk Management (ERM) (AMM2): The Division:

- (a) Coordinates across HHS to establish, and communicate, and sustain HHS's ERM vision, culture, strategy, and framework.
- (b) Designs, implements, and matures an ERM capability across HHS, including governance and community management.
- (c) Develops and shares tools, guidance, and best practices regarding ERM.
- (d) Provides technical assistance and direction to HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs) on implementing ERM.
- (e) Facilitates strategic initiatives across HHS's risk portfolio of existing and emerging risks and opportunities, including guiding updates of the agency's risk profile, and management's prioritization of risks and opportunities.
- (f) Leads the Department's efforts to meet the ERM requirements in OMB Circular A–123, "Management's Responsibility for Enterprise Risk Management and Internal Control."
- (g) Prepares reports, briefings, and makes recommendations to senior HHS leadership, OPDIVs, STAFFDIVs and other stakeholders on ERM related activities.

(h) Leads activities that enhance HHS implementation and integration of ERM into business operations.

(3) Chapter AML, Office of Budget

Section AML.00 Mission: The Office of Budget provides advice and support to the Secretary and the ASFR on matters pertaining to the formulation of the HHS and President's Budget. The Office of Budget manages the performance budget and provides program assessment and performance reporting, along with presentation of budgets and budget-related legislation to the Office of Management and Budget (OMB), the public, media, and Congressional committees. The Office of Budget provides resolution of issues arising from the execution of final appropriations. The Office of Budget manages HHS apportionment activities, which provide funding to the HHS OPDIVs and STAFFDIVs. The Office of Budget coordinates, oversees, and convenes resource managers and financial accountability officials within the Office of the Secretary to update, share, and implement related HHS-wide policies, procedures, operations, rules, regulations, recommendations, and priorities. The Office of Budget coordinates and prepares guidelines for reprogramming execution, transfers between accounts, and other crosscutting funding methods and provides recommendations in managing and processing crosscutting funding proposals.

Section AML.10 Organization: The Office of Budget is headed by the Deputy Assistant Secretary for Budget, who reports to the Assistant Secretary for Financial Resources, and includes the following:

- Division of Discretionary Programs (AML1)
- Division of Health Benefits and Income Support (AML3)
- Division of Budget Policy, Execution, and Review (AML4)
- Division of the Office of the Secretary Budget (AML5)

Section AML.20 Functions:

1. Division of Discretionary Programs (AML1): The Division:

(a) Provides analytical services and assistance to the Secretary, the Assistant Secretary for Financial Resources, and Department OPDIV heads in their budgetary management of the Department's principal discretionary social services, health, and science programs.

(b) Reviews budgets and related requests for resources and analyzes plans and proposals for new or alternative legislation.

(c) Analyzes proposed regulations, reorganizations, or program initiatives to determine their policy, resource, and management implications.

(d) Proposes recommendations on draft regulations, proposed legislation, and reorganization proposals.

(e) Proposes budget options and policy initiatives, as necessary, to achieve program objectives established by the Secretary.

(f) Assists in the development of strategies for the presentation of the budget to the Office of Management and Budget and the Congress and develops materials for key Departmental officials who testify at hearings before these bodies.

(g) Provides guidance to OPDIVs and STAFFDIVs in the formulation of their budgets.

(h) Conducts special reviews and analyses to examine assigned OPDIV program operations and management effectiveness.

(i) Assists in the development of performance plans, reports, and program assessments under the Government Performance and Results Modernization Act (GPRAMA).

(j) Assists in the presentation of the Department's budget to the public by developing material for use by Departmental officials, and reviews press statements and other public documents for consistency with approved budgets and plans.

2. Division of Health Benefits and Income Support (AML3): The Division:

(a) Provides analytical services and assistance to the Secretary, the Assistant Secretary for Financial Resources, and the Department OPDIV heads in the budgetary management of the Department's programs including Medicare, Medicaid, Family Support Payments and other entitlements in support of children and families.

(b) Reviews budget and related requests for resources; analyzes plans and proposals for new legislation, regulations, or program initiatives to determine their resource, policy, and management implications; proposes recommendations to the Deputy Assistant Secretary for Budget on budget requests, draft regulations, proposed legislation, and reorganization proposals.

(c) Assists the Secretary, the Assistant Secretary for Financial Resources, and the OPDIV heads in evaluating programs and budgetary proposals by developing reliable cost projections for legislative and planning proposals and ensuring that proposals are consistent with approved plans and policies.

(d) Coordinates the preparation of budget estimates and forecasts of

resources required to support the programs and operations of the Department.

(e) Reviews reprogramming requests and recommends appropriate action to the Deputy Assistant Secretary for Budget.

(f) Provides guidance in budget formulation for the appropriate OPDIV.

(g) Conducts special management reviews and analyses and develops management options to ensure efficient and effective program operations and to encourage management improvements.

(h) Proposes budget options and policy initiatives, as necessary, to achieve program objectives established by the Secretary.

(i) Assists in the development of strategies for presentation of the budget to the Office of Management and Budget and the Congress and develops materials for key Department officials who testify at hearings before these bodies.

(j) Assists in the development of performance plans, reports, and program assessments under the GPRAMA.

(k) Manages the overall allocation of Health Care Fraud and Abuse Control (HCFAC) funds.

3. Division of Budget Policy, Execution and Review (AML4): The Division:

(a) Directs the formulation and presentation of the HHS budget by developing and promulgating to the OPDIVs and others the policies, procedures, guidance, and schedules for preparing budget submissions.

(b) Coordinates the presentation of the Department's budget and performance plan to Congress including preparation and submission of justifications, reports, significant items, and crosscutting materials; preparation of the Secretary's testimony before the Appropriations Committees; and coordination of transcripts, questions for the record, and other hearing materials.

(c) Provides advice and analysis to support Department-wide budget decision-making.

(d) Maintains active communication with Department budget officers with regard to budget events and activities with OMB, GAO, Congress and other parties.

(e) Manages a computerized budget information system reflecting HHS-wide data and coordinates OPDIV input into this system.

(f) Provides direct staff support to the Secretary in preparation for appropriation hearings and other budget-related presentations and briefings.

(g) Actively communicates with the Budget and Appropriations Committees in the Congress and provides intelligence and analyses of budget decisions to senior HHS staff and the OPDIVs.

(h) Prepares guidelines for determining funding levels under continuing resolutions.

(i) Coordinates preparation of guidelines governing reprogrammings, transfers between accounts, and other crosscutting funding methods; provides recommendations and staff support in managing and processing crosscutting funding proposals.

(j) Analyzes and prepares reports on HHS performance in managing Full Time Equivalent (FTE) levels and in implementing FTE policy and provides expert advice on Department-wide staffing.

(k) Provides leadership and direction in the Department-wide review, analysis and appraisal of financial elements of program execution and the development and execution of policies related to efficient allocation, expenditure and control of funds.

(l) Coordinates and tracks outlay projections: (1) To assist OMB in the continuing effort to monitor spending and to thereby improve the management of the Government's overall cash and debt operations; and (2) in support of formulation of the budget, including the maintenance of HHS ceiling controls and the development of outlay estimates shown in the President's Budget for controllable programs.

(m) Promulgates Departmental spending policies, especially in the event of Continuing Resolutions and possible suspension of operations due to the failure of the Congress to enact appropriations on time and works with agency budget officers and the OMB in formulating agency funding and contingency staffing plans.

(n) Maintains a system of Department-wide budget execution, including the management and control of the apportionment of funds in accordance with the requirements of the Anti-Deficiency Act and OMB regulations; and requests and monitors the receipt of Treasury warrants.

(o) Serves as principal staff advisor to the ASFR on all matters involving budget execution.

(p) Acts as liaison on behalf of HHS with OMB, the Treasury Department, the Congressional Budget Office, and other agencies on matters involving budget execution.

(q) Responsible for the development and maintenance of a system of financial information which involves the collection, organization, and

maintenance of financial data in electronic form as well as the development of reporting mechanisms for making the financial information useful and available for decision making.

(r) Represents the Department in government-wide activities to implement the development and implementation of performance measures and budget-related performance planning policies, requirements and processes. Manages program performance assessment activities.

(s) Provides special management review services for selected activities.

(t) Manages the formulation, execution, and balances of the Nonrecurring Expenses Fund.

(u) Monitoring compliance with the GPRA Modernization Act and other related legislation and guidance.

4. Division of the Office of the Secretary Budget (AML5): The Division:

(a) Reviews and analyzes the budgets of the STAFFDIVS funded by the General Departmental Management (GDM), Medicare Hearings and Appeals (MHA), Office of Inspector General (OIG), Office of the National Coordinator (ONC), Office for Civil Rights (OCR), and Public Health Social Services Emergency Fund (PHSSEF) appropriations. Prepares special analyses of these budgets for use in decision-making, particularly for evaluating capacity and determining if alternative approaches are feasible.

(b) Monitors Congressional appropriations hearings in which the GDM STAFFDIVS, OIG and OCR are participants.

(c) Reviews budgets and related requests for resources and analyzes plans and proposals for new or alternative legislation.

(d) Analyzes proposed regulations, reorganizations, or program initiatives to determine their policy, resource, and management implications.

(e) Proposes recommendations on draft regulations, proposed legislation, and reorganization proposals.

(f) Proposes budget options and policy initiatives as necessary to achieve program objectives established by the Secretary.

(g) Assists in the development of strategies for the presentation of the budget to the OMB and the Congress and develops materials for key Departmental officials who testify at hearings before these bodies.

(h) Provides guidance to STAFFDIVS in the formulation and execution of their budgets.

(i) Conducts special reviews and analyses to examine assigned

STAFFDIV program operations and management effectiveness.

(j) Provides staff assistance to the Secretary, the ASFR, the Service and Supply Funds (SSF) Board of Directors, OPDIV Budget Officers and STAFFDIV Heads in the budgetary and financial management of the SSF.

(k) Provides for budget policy management and financial integrity of the SSF in the provision of Departmental common use administrative services.

(l) Assists in the planning and preparation of the SSF budget for presentation to the SSF Board, the OMB, and Congress.

(m) Provides budget policy and technical support to the Program Support Center Director (and other activity managers) on all SSF activities.

(n) Directs and provides technical guidance to SSF activity managers in preparing annual budgets.

(o) Directs and provides technical guidance to SSF accountants in preparing annual financial statements. Assists in the planning and preparation of these statements for presentation to the SSF Board, auditors, and the Office of Management and Budget.

(p) Establishes Department policy in receiving and responding to Inspector General reports and audits.

(q) Prepares apportionment requests for the SSF.

(r) Provides Chief Financial Officer (CFO) certification on Office of the Secretary Quarterly and Annual Financial Statements.

(s) Provides oversight of the HHS OS OPDIV travel program that consists of 17 OS STAFFDIVS in assuring that processes are followed as described in the Federal Travel Regulation and manages the performance and execution of travel authorizations, vouchers, Individual Billed Accounts and Centrally Billed Accounts.

4. Chapter AMS, Office of Finance
Section AMS.00 Mission: The Office of Finance leads the HHS financial management community through responsible stewardship, financial accountability, collaboration and innovation, and enhanced program integrity.

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

- Immediate Office of Finance (AMS)
- Office of Financial Policy and Reporting (AMS1)

- Office of Financial Systems Policy and Oversight (AMS2)
- Office of Program Audit Coordination (AMS3)

Section AMS.20 Functions:

1. Immediate Office of Finance

(AMS): The Office:

(a) Advises the ASFR/CFO on all aspects of financial management matters affecting the Department including policy, workforce, and technology topics.

(b) Provides executive leadership, professional training, and strategic direction to the HHS CFO community to meet the CFO Act requirements.

(c) Leads strategic planning for the HHS CFO community and the Office of Finance.

(d) Serves as the liaison on financial management matters with internal and external stakeholders such as OMB, US Department of the Treasury (Treasury), and other Federal and non-Federal organizations.

(e) Leads the Department's efforts to meet the HHS-wide annual assessment of internal controls and develops the Department's annual assurance statement according to requirements in OMB Circular A-123, "Management's Responsibility for Enterprise Risk Management and Internal Control."

(f) Provides administrative and operational support for the Office of Finance.

(g) Leads workforce development initiatives for the Office of Finance.

(h) Leads other activities that enhance the Office of Finance's management and operations.

2. Office of Financial Policy and Reporting (AMS1): The Office:

(a) Is responsible for financial management policy and standards, internal controls over reporting, statutory financial reports and audits, and other managerial reports.

(b) Advises the Deputy Assistant Secretary for Finance on all aspects of financial management policy and reporting matters affecting the Department including statutory and managerial financial reports, financial reporting standards, OMB and Treasury transparency initiatives, proper accounting treatment, and accounting standardization.

(c) Reviews and interprets OMB, U.S. Government Accountability Office (GAO), Treasury, and Federal Accounting Standards Advisory Board (FASAB) guidance and requirements related to government-wide accounting policies and standards.

(d) Recommends, develops, and promulgates Department-wide policies, procedures, and standards for financial

management areas including OMB, GAO, Treasury, FASAB, and other agency guidance related to government-wide accounting policies and standards, cash management, credit management, debt management, payment and disbursement activities and functions, and budget execution accounting.

(e) Serves as the principal liaison with the OIG in planning the annual financial statement audit strategy under the CFO Act, as amended.

(f) Leads the Departmental process for the development of the required annual report on HHS's audited financial statements; collaborates with the OPDIVs and STAFFDIVs on the preparation of the Department's agency financial report, and coordinates with OPDIVs and STAFFDIVs to ensure timely audit deliverables.

(g) Reviews and analyzes OPDIVs' financial statements and key reconciliations and oversees the preparation and submission of consolidated Department financial statements as required by OMB and Treasury.

(h) Oversees the design, preparation, review, analysis, and submission of financial management reports for the Department, as required by legislation, regulation, OMB, Treasury, GAO, Congress, and other stakeholders.

(i) Leads the Department's efforts to establish and maintain proper internal control over reporting and ensures that requirements are met under Appendix A, OMB Circular A-123, "Management's Responsibility for Enterprise Risk Management and Internal Control."

(j) Assures OPDIVs' reporting is in accordance with internal control and reporting standards from OMB, GAO, Treasury, FASAB, and the HHS Accounting Treatment Manual (ATM).

(k) Coordinates with the OPDIVs in the preparation of corrective action plans (CAP) and oversees the mitigations of risks contributing to material weaknesses, significant deficiencies, and other reportable conditions from the annual CFO Act audit.

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

(m) Serves as the liaison with OMB, Treasury, authoritative Federal agencies, intragovernmental groups, and other agencies on standard general ledger compliance matters, accounting, financial policy, and reporting issues.

(n) Collaborates with system owners and financial management offices to facilitate standardized enterprise-wide

solutions within the financial accounting reporting systems.

(o) Collaborates with the Office of Financial Systems Policy and Oversight to ensure financial system conformity with the Department's Accounting Treatment Manual (ATM) and related data standards.

(p) Provides advice and assistance to OPDIVs and STAFFDIVs on proper accounting treatments in accordance with the Department's ATM and on financial reporting and related fiscal matters.

(q) Oversees the strategic planning and maintenance of the Department-wide ATM consistent with Federal accounting concepts, standards, and HHS financial management policies.

(r) Introduces uniform business rules and data standards required to support new financial reporting requirements.

(s) Provides support to the OPDIV CFOs for financial planning and improvement initiatives.

(t) Aligns business goals with IT services, products, software, and infrastructure, identifying opportunities for process improvements through business process reengineering and automation.

3. Office of Financial Systems Policy and Oversight (AMS2): The Office:

(a) Is responsible for overseeing and managing the Department-wide financial systems.

(b) Advises the Deputy Assistant Secretary for Finance on all aspects of financial systems matters affecting the Department including strategic direction for financial management systems, innovative solutions, and workforce development.

(c) Establishes, facilitates, and supports a governance framework for Department-wide financial management.

(d) Serves as the liaison on financial systems matters with internal and external stakeholders such as OMB, Treasury, and other Federal and non-Federal organizations.

(e) Develops and promulgates policies, directives, and guidance for Department-wide financial management systems and ensures compliance.

(f) Oversees, manages, and operates Department-wide financial systems as per the CFO Act of 1990, Federal Financial Management Improvement Act (FFMIA) of 1996, Federal Managers Financial Integrity Act (FMFIA) of 1982, and other federal requirements.

(g) Facilitates the annual Department-wide financial systems Audit in accordance with GAO's Financial Information System Controls Audit Manual (FISCAM).

(h) Assesses Department-wide financial management systems for compliance with FFMA requirements, security, and internal controls and includes the evaluation results in the Department's annual assurance statement.

(i) Provides executive leadership to plan and implement innovative solutions using Business Intelligence & Data Analytics, Artificial Intelligence, and other technologies to achieve efficiencies, reduce costs, improve quality, and improve reporting and analytical capabilities for financial management.

4. Office of Program Audit Coordination (AMS3): The Office:

(a) Serves as the central point of contact for coordinating program audit support through payment accuracy and audit resolution activities across the Department.

(b) Advises the Deputy Assistant Secretary for Finance on all aspects of payment integrity-related matters affecting the Department and serves as the liaison with internal and external stakeholders, OMB, and other Federal and non-Federal entities.

(c) Leads the Department-wide efforts to implement the Payment Integrity Information Act of 2019, and payment integrity-related Executive Orders and other regulatory requirements.

(d) Provides leadership, guidance, training, and support to both HHS and non-HHS single audit stakeholders to ensure compliance with the Uniform Guidance (2 CFR part 200).

(e) Serves as ASFR's audit liaison for Government Accountability Office (GAO) engagements and serves as HHS' Office of Inspector General (OIG) audit liaison.

(f) Oversees the development, implementation, change management, and overall operations of enterprise-wide audit tracking and analytics systems.

(g) Performs analysis using grant- and audit-related data to advance the use of such data and evidence in HHS programs' management.

5. Chapter AMU, Office of Grants.

Section AMU.00 Mission: The Office of Grants provides Department-wide leadership, guidance, and oversight for HHS' grants management policies, practices, systems, and workforce development activities. The Office of Grants provides technical assistance to the Department's OPDIVs and STAFFDIVs, assesses the effectiveness of the grants programs and processes; develops pertinent HHS-wide regulatory guidance, policies, and performance standards; maintains and reports Departmental grant/financial assistance

award information; and conducts special Departmental improvement initiatives related to grants. The Office of Grants fosters collaboration, innovation, and accountability in the administration and management of the grant functions throughout the Department. The Office of Grants provides input for coordinated Department positions on proposed legislation and Government regulations specific to grant-related matters. The Office of Grants is responsible for carrying out HHS's responsibilities as the lead standards setting agency, per the Grant Reporting Efficiency and Agreements Transparency (GREAT) Act and as designated by OMB, to set government-wide data requirements for all federal grant-making agencies. The Office of Grants also manages Federal shared service initiatives, such as *Grants.gov* and GrantSolutions. The Office of Grants represents HHS to the OMB, GAO, other Federal agencies, and Congress in matters of Departmental grant policies and management.

Section AMU.10 Organization: The Office of Grants is headed by the Deputy Assistant Secretary for Grants, also the Department's Senior Grants Management Official, who reports to the Assistant Secretary for Financial Resources, and includes the following:

- Immediate Office of Grants (AMU)
- Division of Policy Oversight Effectiveness and Training (AMU1)
- Division of Information and Solutions (AMU2)

Section AMU.20 Functions:

1. Immediate Office of Grants (AMU): The Office:

- (a) Assists in the management and administration of the Office's functions
- (b) Facilitates and coordinates government wide initiatives and activities on behalf of the HHS and Federal grant community, as appropriate.

2. Division of Policy Oversight Effectiveness and Training (AMU1): The Division:

- (a) Formulates, oversees, and evaluates Department-wide implementation of grants policies governing the award and management of grants throughout HHS, in support of existing laws, regulations, and OMB Circulars.

(b) Develops and implements HHS grants management regulations and publishes new policies and modifications in the HHS Grants Policy Directives (GPDs), including all directives necessary to implement new intergovernmental and HHS policies.

(c) Maintains a program of continuous improvement initiatives that promote

effective and efficient grant and program management practices across the Department.

(d) Leads Departmental efforts to enhance the knowledge and skills of Departmental employees with grant management and grant program related responsibilities.

(e) Represents the Department and serves as liaison in interagency grants policy and management activities; maintains working relationships with OMB, U.S. General Services Administration (GSA), GAO and other Federal agencies to coordinate and assist in the development of proposed legislation and policy.

(f) Leads the Grants Quality Service Management and Data Standards functions with responsibility for creating and managing a government-wide marketplace offering federal agencies modern IT solutions and services to support their grants missions; advising agencies and OMB on federal grants IT investments; and driving the implementation of grants data standards.

3. The Division of Information and Solutions (AMU2): The Division:

(a) Develops, manages, and operates major, grant-shared services and solution offerings for HHS, as directed by the Secretary of HHS or delegated authority.

(b) Manages DATA act reporting for the Department's grant transactions and provides technical assistance to HHS STAFFDIVs and OPDIVs to promote data integrity.

(c) Coordinates initiatives that require cross-Departmental system development or enhancement of grant management or adjacent systems to meet Departmental goals or to comply with government wide grants policy requirements.

6. Chapter AMX, Office of Acquisitions

Section AMX.00 Mission: The Office of Acquisitions provides leadership, guidance, and oversight to constituent organizations, and coordinates long and short-range planning for HHS' acquisition practices, systems, and workforce. The Office of Acquisitions provides technical assistance to the Department's OPDIVs and STAFFDIVs; evaluates effectiveness of the acquisition programs and processes; develops pertinent HHS-wide regulatory guidance, policies, and performance standards; maintains Departmental contract award information; and conducts special Departmental initiatives related to acquisitions. The Office of Acquisitions provides input for coordinated Department positions on proposed legislation and Government regulations specific to acquisition

related matters, processes suspension and debarment cases, and manages activities associated with the training, development, and certification of—and strategic planning for—the Department’s acquisition workforce.

Section AMX.10 Organization: The Office of Acquisitions is headed by the Deputy Assistant Secretary for Acquisitions, also the Department’s Senior Procurement Executive (SPE) and Suspension and Debarment Official (SDO), who reports to the Assistant Secretary for Financial Resources, and includes the following:

- Immediate Office (AMX)
- Division of Strategic Programs and Business Systems (AMX1)
- Division of Acquisition Policy, Legislation, Oversight & Workforce (AMX2)
- Office of Small and Disadvantaged Business Utilization (The Office of Acquisitions provides administrative support to the Director, who reports directly to the Deputy Secretary) (AMX3)
- Office of Recipient Integrity and Compliance (AMX4)

Section AMV.20 Functions:

1. Immediate Office of Acquisitions (AMX): The Office:

(a) Provides strategic planning, execution, oversight, and management.

(b) Provides acquisition system performance measurement and management.

(c) Leads customer engagement and communications efforts.

(d) Provides SPE industry engagement support.

(e) Provides budget planning and tracking.

(f) Serves as human resources liaison (recruitment, security processing & onboarding support, timekeeper, and performance management support).

(g) Provides executive administrative support and travel support.

(h) Provides equipment inventory and support.

(i) Leads employee engagement.

(j) Manages executive correspondence.

(k) Conducts small purchases.

2. The Division of Strategic Programs and Business Systems. (AMX1): The Office:

(a) Serves as the System Owner for the HHS Consolidated Acquisition Solution (HCAS) and develops Department-wide standards that include acquisition system policies and guidance.

(b) Manages contract data quality and analytics initiatives.

(c) Works with the other divisions within the Office of Acquisitions to develop innovative processes and tools

acquiring, adopting, tailoring, and sharing best practices for use by the HHS acquisition workforce.

(d) Leads and implements the Department’s Category Management Program, designed to increase acquisition efficiency, enhance mission performance, increase spend under management, and incorporate innovative approaches, solutions, and products to meet enterprise requirements.

(e) Manages the Government Purchase Card Program and develops pertinent HHS-wide regulatory guidance, policies, and procedures; maintains department wide spend and refund data, among other statistical data on the card program; conducts internal audits to assess the program’s implementation risk.

(f) Oversees contract performance through the Contractor Performance Assessment Reporting System (CPARS) and Federal Awardee Performance and Integrity Information System (FAPIIS).

(g) Leads industry engagement through its Industry Liaison function.

3. The Division of Acquisition Policy, Legislation, Oversight & Workforce (AMX2): The Office:

(a) Provides leadership in acquisitions through regulations and policy development and implementation and workforce planning, development, and training.

(b) Formulates Department-wide acquisition policies and procedures governing acquisition activities, including publishing and maintaining the HHS Acquisition Regulation (HHSAR), and providing advice and technical assistance on matters related to HHS acquisition programs.

(c) Participates in government-wide acquisition rulemaking through the Civilian Agency Acquisition Council.

(d) Manages workforce development initiatives for the Department’s acquisition workforce.

(e) Provides oversight of the implementation of acquisition regulations and policies by the Department’s OPDIVs and STAFFDIVs to ensure consistent policy interpretation and application.

(f) Provides advice, oversight and support regarding operational acquisition and business practices and issues and conducts procurement management reviews and promotes consistent and standardized business practices.

(g) Serves as the Department’s liaison relating to acquisition issues for OMB, Congress, GAO and the OIG.

(h) Acts as the Department’s Task Order Ombudsman and Advocate for Competition.

4. The Office of Recipient Integrity and Compliance (AMX3): The Office:

(a) Provides leadership, guidance, and oversight of the Department’s suspension and debarment program, and coordinates long and short-range planning for HHS’ suspension and debarment efforts.

(b) Provides technical assistance to the Department’s OPDIVs and STAFFDIVs; evaluates effectiveness of the programs and processes; develops pertinent HHS-wide regulatory guidance, and policies; maintains Departmental suspension and debarment information; and conducts special Departmental initiatives related to recipient integrity.

5. Office of Small & Disadvantaged Business Utilization (AMX4): The Office:

(a) Is headed by a Director who reports directly to the Deputy Secretary and is administratively supported by the Office of Acquisitions.

(b) Advocates for the use of small and socioeconomic businesses as Federal contractors pursuant to Public Law 95–507 and has responsibility within the Department for policy, plans, and oversight to execute the functions under Sections 8 & 15 (k) of the Small Business Act.

(c) Provides leadership, policy, guidance, and supervision, as well as coordinating short- and long-range strategic planning to assure that small business vendors have a fair opportunity to compete for and are awarded prime and subcontracts with the Department.

(d) Provides small business technical assistance to the Department’s OPDIVs and STAFFDIVs; reviews and evaluates planned procurements to ensure that small and socioeconomic businesses are given thorough consideration; evaluates effectiveness of the small business programs and processes; develops pertinent HHS-wide policies, guidance, and performance standards; drafts Federal government and Departmental small business reports; and conducts special Departmental initiatives related to small and socioeconomic business concerns.

(e) Manages the development and implementation of appropriate small business vendor engagement activities that promote the utilization of small and socioeconomic business within the HHS acquisition portfolio as prime and subcontractors.

Delegations of Authority. Pending further redelegation, directives or orders made by the Secretary or the ASFR, all delegations and redelegations of authority made to officials and employees of affected organizational

components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Cheryl R. Campbell,

Assistant Secretary for Administration.

[FR Doc. 2023–19165 Filed 9–5–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Study Section.

Date: October 27, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 827–8231, luis.dettin@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 30, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19155 Filed 9–5–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group, Developmental Biology Study Section.

Date: October 20, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, (301) 451–0000, jolanta.topczewska@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 30, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19153 Filed 9–5–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Learning, Memory, Language, Communication and Related Neuroscience.

Date: October 4–5, 2023.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Eileen Marie Moore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8928, eileen.moore@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special topics: Noninvasive Neuromodulation and Neuroimaging Technologies.

Date: October 5–6, 2023.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pablo M Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, pablo.blazquezgamez@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 30, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19152 Filed 9–5–23; 8:45 am]

BILLING CODE 4140–01–P