

SMG 1117A.1

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Effective Date: December 14, 2018

1. Office of Operations (DCN).

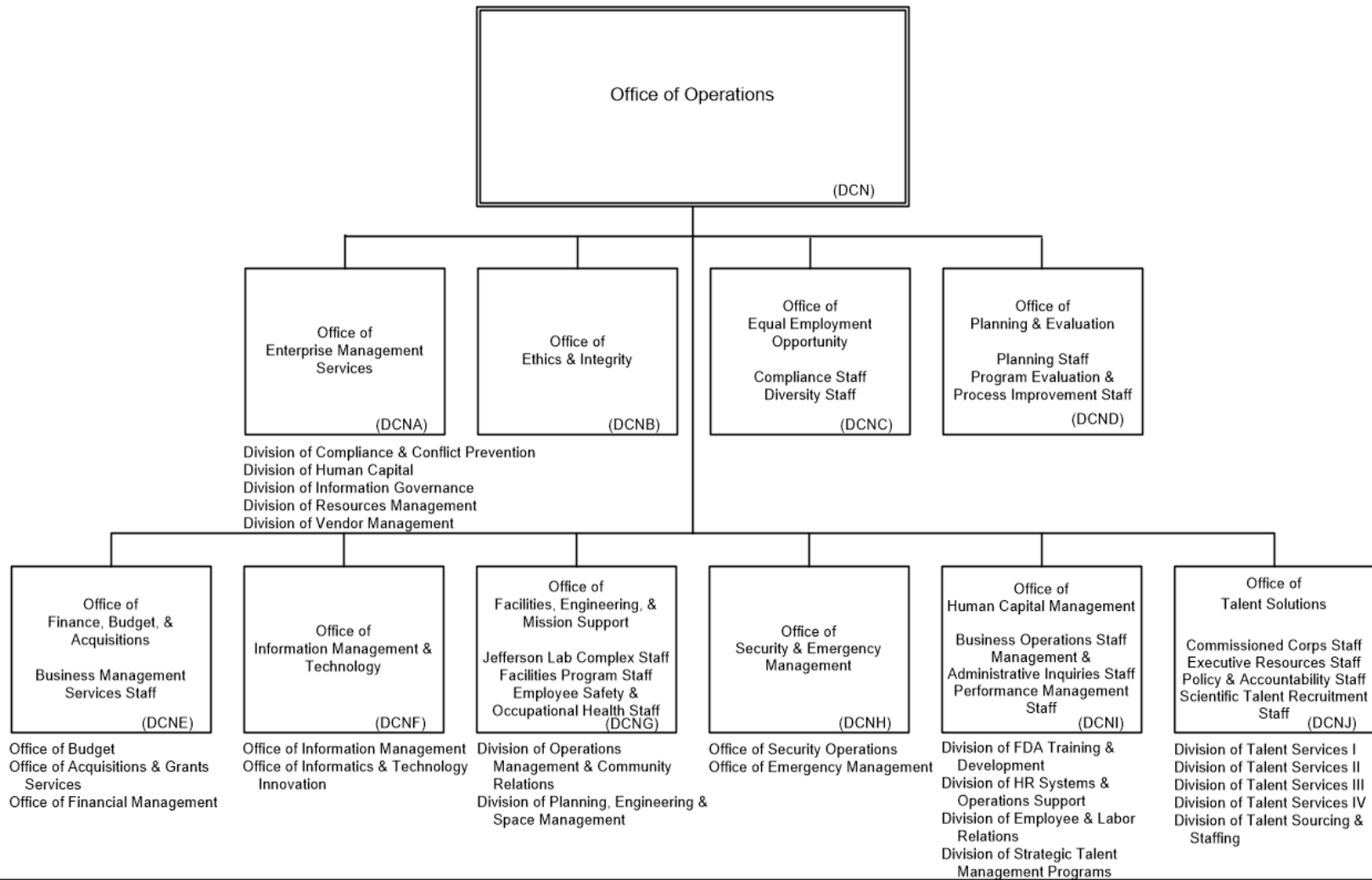
- A. Provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations to ensure the timely and effective implementation and high-quality delivery of services across the Food and Drug Administration (FDA), its Centers and Offices.
- B. Advises and assists the Commissioner, Deputy Commissioners, and other key officials on various administrative management and business activities.
- C. Chairs all FDA user fee programs which oversee financial management and provide financial management support.
- D. Participates in international initiatives to ensure FDA's capability and readiness to work with foreign counterparts in responding to international emergencies involving or impacting FDA-regulated products and to share information with international counterparts during such emergencies.
- E. Plans, directs, and coordinates a comprehensive financial management program for the FDA that encompasses the areas of automated financial systems, fiscal accounting, voucher audit, and financial reporting. Issues periodic reports regarding the status of the FDA's financial management and develops financial inputs for programs and financial plans.
- F. Provides leadership and direction regarding all aspects of a variety of management programs including organization management, delegations of authority, environmental and safety management, and programs related to ethics and conflict of interest matters.
- G. Plans, organizes and carries out annual and multi-year budgeting in support of FDA's public health mission and programs.

- H. Advises the Commissioner and other key FDA officials on administrative management and budget matters for components within the Office of the Commissioner (OC). Provides advice and guidance with regard to formulation and development of administrative management policies, procedures, and controls.
- I. Provides management direction and leadership for acquisitions, grants, cooperative agreements, technology transfers, and interagency agreements.
- J. Provides advice and assistance to the Commissioner and senior management officials on FDA Operations. Establishes and oversees implementation of the FDA information management policy and governance, procedures and processes to ensure the FDA is in compliance with the Clinger/Cohen Act.
- K. Establishes, directs and leads FDA level programs and all strategic aspects of information management including: information technology (IT) shared services, telecommunications, crisis management and security operations, strategic planning, capital planning and investment control, and enterprise architecture.
- L. Provides oversight and advises on management of emergency and crisis management policies and programs including strategic oversight of emergency exercises, overseeing and evaluating emergency and crisis situations, and security operations.
- M. Provides continued program effectiveness and technical expertise in support for various programs within the Office of Operations.
- N. Provides assessments on the effectiveness of the organizational components programs (e.g. policies and procedures, regulations and guidance documents) based on information/feedback received from both inside and outside the Office's regarding to any trends or consistent problems and makes recommendations for change or improvement.

2. Authority and Effective Date.

The functional statements for the Office of Operations were approved by the Secretary for Health and Human Services, and effective on December 14, 2018.

**Department of Health and Human Services
 Food and Drug Administration
 Office of Operations**



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The following header reflects the organizational hierarchy.
Department of Health and Human Services
Food and Drug Administration
Office of Operations

The following is the Food and Drug Administration, Office of Operations organizational structure depicting the organizations reporting to the Chief Operating Officer.

The organizations below report to the Office of Operations (DCN)

Office of Enterprise Management Services (DCNA)

Office of Ethics and Integrity (DCNB)

Office of Equal Employment Opportunity (DCNC)

Office of Planning and Evaluation (DCND)

Office of Finance, Budget, and Acquisitions (DCNE)

Office of Information Management and Technology (DCNF)

Office of Facilities Engineering and Mission Support Services (DCNG)

Office of Security and Emergency Management (DCNH)

Office of Human Capital Management (DCNI)

Office of Talent Solutions (DCNJ)

The organizations below report to the Office of Enterprise Management Services (DCNA)

Division of Compliance and Conflict Prevention

Division of Human Capital

Division of Information Governance

Division of Resources Management

Division of Vendor Management

The organizations below report to the Office of Equal Employment Opportunity (DCNC)

Compliance Staff

Diversity Staff

The organizations below report to the Office of Planning and Evaluation (DCND)
Planning Staff
Program Evaluation and Process Improvement Staff

The organizations below report to the Office of Finance, Budget, and Acquisitions
Business Management Services Staff
Office of Budget
Office of Acquisitions & Grants Services
Office of Financial Management

The organizations below report to the Office of Information Management and
Technology (DCNF)
Office of Information Management (DCNFA)
Office of Informatics & Technology Innovation (DCNFB)

The organizations below report to the Office of Facilities Engineering and Mission
Support Services (DCNG)
Jefferson Lab Complex Staff
Facilities Program Staff
Employee Safety and Occupational Health Staff
Division of Operations Management and Community Relations
Division of Planning, Engineering and Space Management

The organizations below report to the Office of Security and Emergency Management
(DCNH)
Office of Security Operations
Office of Emergency Management

The organizations below report to the Office of Human Capital Management (DCNI)
Business Operations Staff
Management and Administrative Inquiries Staff
Performance Management Staff
Division of FDA Training and Development
Division of HR Systems and Operations Support
Division of Employee and Labor Relations
Division of Strategic Talent Management Programs

The organizations below report to the Office of Talent Solutions (DCNJ)
Commissioned Corps Staff
Executive Resources Staff
Policy and Accountability Staff
Scientific Talent Recruitment Staff
Division of Talent Services I
Division of Talent Services II
Division of Talent Services III

Division of Talent Services IV
Division of Talent Sourcing and Staffing

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