

SMG 1118A.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Policy, Legislation and International Affairs

Effective Date: December 14, 2018

1. Office of Policy, Legislation and International Affairs (DCO).

- A. Advises the Commissioner and other key Food and Drug Administration (FDA) officials on matters relating to FDA policy, regulations development, legislative issues, and international affairs.
- B. Provides strategic policy direction, legislative interactions, and data-driven analysis for FDA to more effectively and efficiently protect and promote public health.
- C. Conducts economic analyses and special studies.
- D. Manages the Government Accountability Office (GAO) and Office of the Inspector General (OIG) studies and interactions on behalf of the FDA.
- E. Oversees significant and cross-cutting policy and engages in strategic problem solving.
- F. Serves as FDA's focal point for the coordination, oversight, and processing of regulations, guidance and other policy documents.
- G. Provides executive oversight, strategic leadership, and policy direction to FDA's international efforts, including global information sharing, development of international standards, trade relations, and international organizational relationship building.
- H. Serves as executive oversight for all legislative liaison activities.

2. Intergovernmental Affairs Staff (DCO1)

- A. Coordinates strategically across FDA Headquarters, Centers and Offices to respond to inquiries from States and to engage in proactive outreach to States on critical FDA policy issues.
- B. Develops collaborative relationships with policy making State and Tribal partners to ensure engagement and representation on FDA policy issues.
- C. Collaboratively engage in proactive outreach to policy making state partners on important cross-cutting FDA policy issues as well as facilitate resolution to concerns around policy issues.

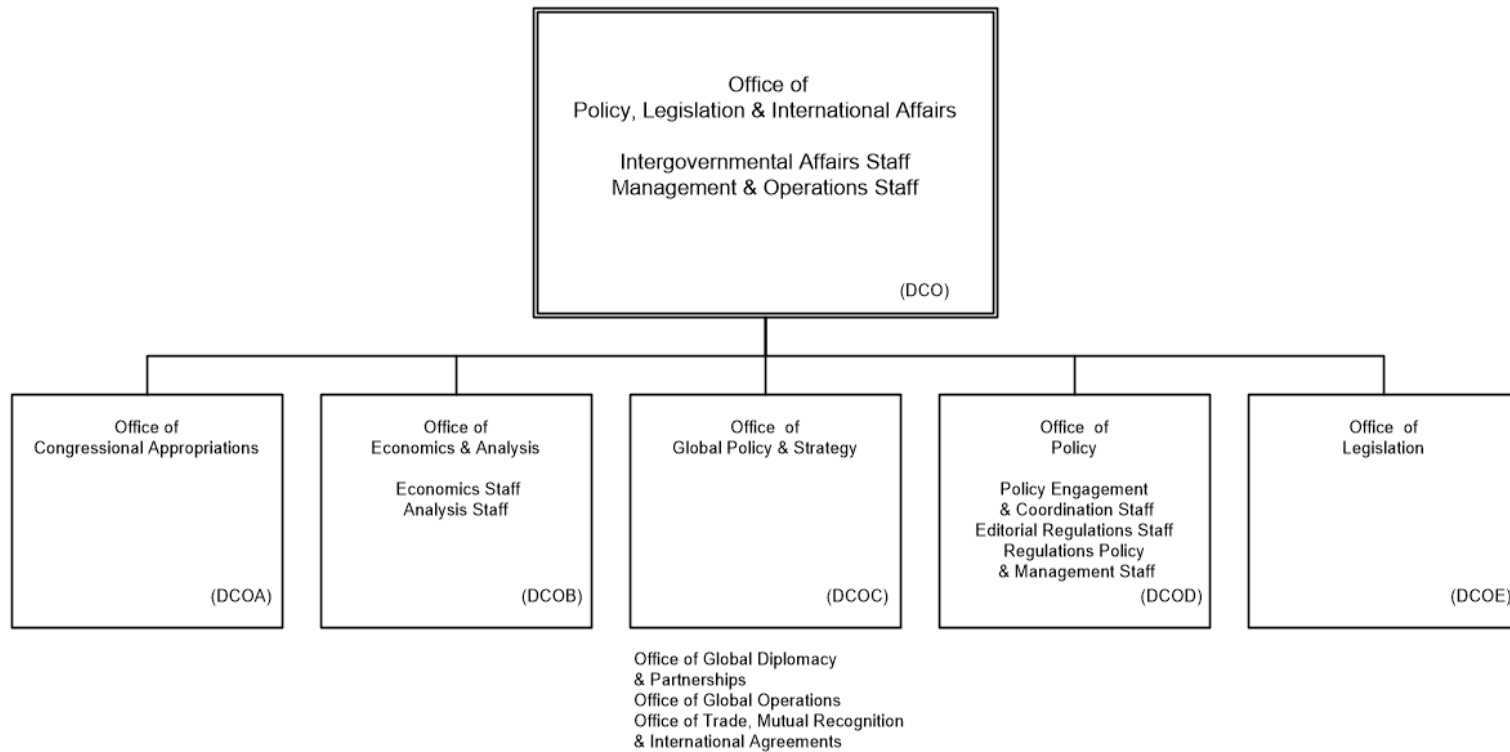
3. Management and Operations Staff (DCO2)

- A. Provides overall guidance and leadership on cross-cutting resource and strategic management activities including budget execution, formulation, internal controls and process improvement as well as other management analysis needs.
- B. Coordinates and delivers a wide range of administrative services to the Office including human capital, budgetary, information technology, and program management activities. Serves as liaison on human capital and performance management initiatives.
- C. Conducts special projects and assignments in support of the office's priorities and management initiatives.

4. Authority and Effective Date.

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

**Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Policy, Legislation and International Affairs**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Policy, Legislation and International Affairs organization structure depicting all the organizational structures reporting to the Deputy Commissioner.

These organizations report to the Office of Policy, Legislation and International Affairs (DCO):

- Intergovernmental Affairs Staff
- Management and Operations Staff
- Office of Congressional Appropriations (DCOA)
- Office of Economics and Analysis (DCOB)
- Office of Global Policy and Strategy (DCOC)
- Office of Legislation (DCOD)
- Office of Policy (DCOE)

These organizations report to the Office of Economics and Analysis (DCOB):

- Economics Staff
- Analysis Staff

These organizations report to the Office of Global Policy and Strategy (DCOC):

- Office of Global Diplomacy and Partnerships
- Office of Global Operations
- Office of Trade, Mutual Recognition, and International Agreements

These organizations report to the Office of Policy (DCOE):

- Policy Engagement and Coordination Staff
- Regulations Policy and Management Staff

- Editorial Regulations Section

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