

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Strategic Programs

Office of Program and Strategic Analysis

Effective Date: October 9, 2020

1. Office of Program and Strategic Analysis (DCDKA).

- A. Directs the long-range planning processes – including strategic, resource, and program planning-and coordinates with the Office of the Commissioner and Department of Health and Human Services long-range planning based on analysis.
- B. Assists and consults with components in development and implementation of proposals related to key strategic initiatives and priorities.
- C. Evaluates the impact of operations and policies on external stakeholders, including patients, consumers, health care providers, regulated industry and other constituents.
- D. Develops analytics approached and conducts analyses for special evaluation studies to inform Center strategy, operations, and policies.
- E. Participates in and supports Food and Drug Administration user fee negotiations and implementation of those agreements.

2. Program Evaluation and Implementation Staff (DCDKA1).

- A. Conducts program evaluation studies on Center initiatives, including designing evaluation frameworks, developing data to improve effectiveness and efficiency.
- B. Provides project management and other technical services to facilitates or coordinate implementation of significant initiatives and to improve the efficiency and effectiveness of resources and key business processes.

- C. Conducts a wide range of qualitative and quantitative analyses to answer key questions of operations, and inform internal strategy and decision-making, as well as Center strategy with respect to the external stakeholder environment.
- D. Evaluates impact of external factors (e.g. industry behavior, proposed legislation) on Center programs. Recommends new initiatives or change in existing programs and priorities.
- E. Facilitates and coordinates development of strategic and operational plans throughout the Center.

3. Economics Staff (DCDKA2).

- A. Serves as the subject matter expert in evaluating economic research that impacts the Center and communicates to Center leadership the implications of the research.
- B. Conducts cost-benefit analyses, budget impact analyses, operations research, and value analyses to help senior managers evaluate the value, costs, impacts to budget, and return on investment associated with proposed or existing actions, practices, operations, procedures, or policies.
- C. Identifies the underlying economic principles that cause and drive policies and external actions and evaluates how these principles are expected to impact various stakeholder groups and public health.
- D. Uses modern visualization and programming methods to make data, and the information it contains, easy to access, use, and understand for the Center and Center leadership.
- E. Uses modern data science methods to automate the collection, organization, presentation, and communication of data to the Center and Center leadership.
- F. Conducts modern statistical and machine learning methods to predict the outcome(s) associated with proposed policies and external actions taken by stakeholders.
- G. Uses economics theory and quantitative analytics to assess the populations a policy might affect, how the policy might change their outcomes, whether the policy could cause any unintended consequences, and to identify alternate courses of action or policy options for management consideration.

4. Analytics and Data Services Staff (DCDKA3).

- A. Conducts qualitative and quantitative analyses applying techniques, such as risk analysis and modeling, statistical modeling, data mining, and machine

learning to support Center for Drug Evaluation and Research's (CDER) senior management in their decision making.

- B. Provides program performance analysis and report for various CDER user fee programs.
- C. Serves as the primary reporting source for all reporting on new drugs, biologics, biosimilars, and generic drug review programs and processes.
- D. Determines Center reporting requirements as regulations, policies, and program commitments change.
- E. Coordinates program and performance data and information requests from external public stakeholders (e.g. for Congressional reports, General Accounting Office and Office of Inspector General studies).

5. Lean Management Staff (DCKA4).

- A. Serves as the coordinator and focal point for process improvement and organizational change management.
- B. Provides consultation on application of process improvement concepts and methodologies in the Center.
- C. Conducts operational and management analyses on cross-cutting internal processes, recommending business process improvements as appropriate to improve the efficiency of operations.
- D. Provides organizational change management support to cross-cutting internal initiatives.
- E. Provides project management and other technical services to direct and/or coordinate implementation of significant business process initiatives.
- F. Facilitates and coordinates development of strategic and operational plans ranging from Office/Division level through Center level.

6. Resource Capacity Planning Staff (DCKA5).

- A. Serves as the coordinator and focal point for resource capacity planning and its interfaces with budget planning, execution, and relevant financial analyses for medical product user fee programs that impact CDER.
- B. Provides resource capacity planning analysis to human drug user fee and non-user fee program stakeholders to inform resource requests and allocation decision in all organizational components.

- C. Develops and executes relevant methodologies and decision criteria to support resource utilization and demand estimation as well as resource allocation recommendations.
- D. Supports calculation of adjustments to user fees and operating reserves for various user fee programs per statutory requirements.
- E. Provides estimates of fee-paying units in support annual user fee setting.
- F. Produces analytics content for annual user fee financial reports, five-year plans and other financial or resource-related work products.
- G. Oversees and manages operational and communications aspect of activity-based time reporting within CDER.
- H. Establishes standards for use of capacity planning and time report data and supports utilization of such data in support of operations, such as planning, budget and finance, and resource decision making.

7. Decision Support and Analysis Staff (DCKA6).

- A. Serves as subject matter expert for developing and incorporating decision analysis tools, methods and approaches to support, structure, and effectively communicate Center's drug regulatory decision-making, including but not limited to benefit-risk assessment, uncertainty assessment, patient elicitation methods, and other decision framing approached.
- B. Serves as the coordinator and focal point for Center to facilitates the advancement, operationalization, and use of structured benefit-risk assessment into regulatory, including but not limited to associated with user fee programs and other Center-led initiatives.
- C. Provides direct decision support and consultation to review teams and signatory authorities to support challenging regulatory decisions, utilizing facilitative approaches coupled with appropriate decision analysis tools and methods.

8. Authority and Effective Date.

The functional statements for the Office of Program and Strategic Analysis were approved by the Commissioner of Food and Drugs and effective on October 9, 2020.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Strategic Programs
Office of Programs and Strategic Analysis**

Office of
Programs & Strategic Analysis

Program Evaluation & Implementation Staff
Economics Staff
Analytics & Data Services Staff
Lean Management Staff
Resource Capacity Planning Staff
Decision Support & Analysis Staff (DCDKA)

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, Office of Program & Strategic Analysis organization structure depicting all the organizational structures reporting to the Director:

Office of Program & Strategic Analysis (DCDKA).

These organizations report to the Office of Program & Strategic Analysis:

Program Evaluation & Implementation Staff

Economics Staff

Analytics and Data Services Staff

Lean Management Staff

Resource Capacity Planning Staff

Decision Support & Analysis Staff