

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 Medical Policy

Effective Date: December 14, 2018

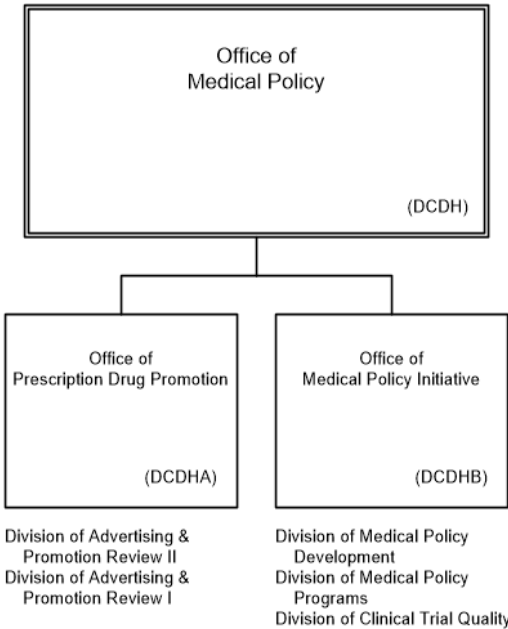
1. Office of Medical Policy (DCDH).

- A. Provides Center oversight (scientific and regulatory) and leadership in the development of medical policy, procedures, and policy initiatives pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, post market surveillance processes, and the science and efficiency of clinical trials.
- B. Provides scientific and regulatory leadership in ensuring accurate and effective communication of medical information to healthcare professionals and patients in compliance with applicable regulations.
- C. Foster an interdisciplinary approach to medical policy development, implementation, and coordination through collaboration with other disciplines, program areas, Food and Drug Administration Centers, and stakeholders in a manner that enhances integration of evolving science and policy into drug development, regulatory review, and post-market surveillance processes.
- D. Provides guidance and policy development regarding prescription promotion and reviews prescription drug advertising and promotional labeling to ensure that the information contained in these materials is not false or misleading.

2. Authority and Effective Date.

The functional statements for the Office of Medical Policy 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
Center for Drug Evaluation and Research
Office of Medical Policy**



Staff Manual Guide 1266.1
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Medical Policy organization structure depicting all the organizational structures reporting to the Director.

Office of Medical Policy (DCDH).

These organizations report to the Office of Medical Policy:
Office of Prescription Drugs Promotion (DCDHA)
Division of Advertising & Promotion Review II (DCDHAB)
Division of Advertising & Promotion Review I (DCDHAC)
Office of Medical Policy Initiative (DCDHB)
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Trial Quality (DCDHBC)