



Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of the General Counsel, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: This document revises and restates the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC). Issuance of this Statement of Organization rescinds all prior Statements of Organization.

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SUPPLEMENTARY INFORMATION: The Office of the Secretary (OS) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC), should now read as follows:

Section I. Mission

The General Counsel is responsible for providing all legal services and advice to the Secretary, Deputy Secretary, and all subordinate organizational components of the Department, which legal advice, to the maximum extent permitted under Executive Order 14215 (Feb. 18, 2025), shall be binding on the Department unless overturned by the Secretary. Under direction of the General Counsel, the Office of the General Counsel (OGC) serves as the sole officially designated source of legal advice and services to the Department's operating and staff divisions (except the OIG) to ensure that all the operating and staff divisions receive uniform advice. OIG is authorized to have its own Office of the Counsel to the Inspector General (OCIG) with respect to matters solely within the OIG's jurisdiction. See 62 FR 30859 (June 5, 1997).

Section II. Organization and Leadership

The Office of the General Counsel, under the supervision of the General Counsel, consists of the Immediate Office and Divisions. OGC may maintain satellite offices as duty locations for attorneys and staff assigned to one or more Divisions. Satellite offices are not separate organizational components of OGC.

Subsection A. The Immediate Office of the General Counsel

1. The Immediate Office of the General Counsel

The Immediate Office of the General Counsel consists of the General Counsel, his or her executive assistant(s), a Principal Deputy General Counsel, such other Deputy General Counsel as the Secretary deems appropriate and

appoints, such other Special Assistant Deputy General Counsel, Senior Counsel, Counsel, Senior Advisors and attorneys and staff as the General Counsel deems appropriate, the Office of Legal Resources (OLR), and the Legislation Section (GCL).

- a. The General Counsel. The General Counsel is the chief legal officer of the Department and is directly responsible to the Secretary.
- b. Principal Deputy General Counsel. The Principal Deputy General Counsel is the second-ranking legal officer of the Department and is usually a non-career inferior officer appointed by the Secretary and is directly responsible to the General Counsel and the Secretary.
- c. Deputy General Counsel. The Deputy General Counsel report to the General Counsel and each shall be responsible for overseeing such substantive legal areas and corresponding OGC portfolios as designated by the General Counsel. Deputy General Counsel may be assigned oversight of one or more portfolios within the Office of the General Counsel. In addition, certain Deputy General Counsel may generally be responsible for OGC management and operations, oversight of OLR, and such litigation, substantive, or programmatic portfolios and other duties as determined by the General Counsel. For performance evaluation purposes, it is OGC's policy that, when feasible, a career Deputy General Counsel will be assigned to serve as the rating official for all career Associate General Counsel, Chief Counsel, the OLR Director, and any career Senior Counsel or Senior Advisor.
- d. Chief Legal Officer for the Centers for Medicare & Medicaid Services (CMS). The Chief Legal Officer for CMS is a Deputy General Counsel and is the principal legal officer for CMS and reports to the General Counsel. The Chief Legal Officer is responsible for overseeing the provision of legal services to CMS. The Chief Legal Officer shall be responsible for such substantive, litigation, programmatic, management, and other legal matters relating to CMS as determined by the General Counsel.
- e. Chief Counsel, Food and Drug Administration. The Chief Counsel of the Food and Drug Administration (FDA) is an Associate General Counsel, serves as the principal legal officer for FDA, and reports to the General Counsel. The Chief Counsel heads the Office of the Chief Counsel, also known as the Food and Drug Division of the Office of the General Counsel. Consistent with 21 CFR 5.1105, the Office of the Chief Counsel is administratively within the Office of the Commissioner of Food and Drugs but is part of the Office of the General Counsel. Subject to the direction of the General Counsel, the Chief Counsel oversees the provision of legal services to FDA and performs the functions assigned to the Chief Counsel under applicable law, including designating and supervising Office of the General Counsel attorneys who represent FDA components or advise the Commissioner in administrative proceedings, consistent with applicable separation-of-functions requirements.
- f. Special Assistant Deputy General Counsel. The General Counsel may designate one or more attorneys to act as a special assistant and to carry

the title Special Assistant Deputy General Counsel. Any Special Assistant Deputy General Counsel shall report directly to the General Counsel or to such Deputy General Counsel as the General Counsel may designate.

- g. Senior Counsel, Special Counsel, Counsel, or Senior Advisor to the General Counsel: Senior Counsel, Special Counsel, Counsel, or Senior Advisor to the General Counsel perform such duties as may be assigned to them by the General Counsel, Principal Deputy General Counsel, or Deputy General Counsel.

2. Order of Succession

- a. General Counsel Vacancy. In the event of a “vacancy” in the position of General Counsel as a result of death, resignation, or an inability to perform the functions and duties of the office, the Principal Deputy General Counsel shall serve as the Acting General Counsel as dictated by the Federal Vacancies Reform Act of 1998, 5 U.S.C. § 3345 *et seq.*, unless the President designates another Acting General Counsel pursuant to the Act.
- b. Principal Deputy General Counsel Vacancy. In the event of vacancies in offices of both the General Counsel and the Principal Deputy General Counsel, the Deputy General Counsel with the greatest seniority in that position shall perform the functions of or serve as the Acting General Counsel as dictated by the Federal Vacancies Reform Act of 1998, unless the President designates another Acting General Counsel pursuant to the Act.

3. The Office of Legal Resources, Immediate Office of the General Counsel

The Office of Legal Resources (OLR) shall be headed by a Director, who is responsible for providing personnel, budget, correspondence, and information technology support to the Office of the General Counsel as well as providing legal information law services through the Law Library. The Office of Legal Resources includes six branches, each headed by a Director or Manager:

- a. Budget
- b. Correspondence
- c. Human Capital Services
- d. Information Technology
- e. Legal Information
- f. Procurement, Policy and Planning

4. The Legislation Section, Immediate Office of the General Counsel.

The Legislation Section is a component of the Immediate Office. The Section shall be headed by a Senior Counsel for Legislation, who reports to the General Counsel through such Deputy General Counsel as the General Counsel may designate.

Subsection B. Divisions

Each OGC Division is under the general supervision of the General Counsel. Each OGC Division head reports directly to the designated Deputy General Counsel on substantive legal matters, litigation strategy, and other matters as directed by the General Counsel. There are 11 divisions in the Office of the General Counsel:

1. The Advanced Research Projects Agency for Health (ARPA–H) Division shall be headed by a Chief Counsel/Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel.
2. The Centers for Medicare & Medicaid Services Division (CMSD) shall be headed by an Associate General Counsel, who reports to the General Counsel through the Chief Legal Officer for CMS. The Division consists of four groups, each headed by at least one Deputy Associate General Counsel, and a Principal Deputy Associate General Counsel, reporting to the Associate General Counsel:
 - a. Litigation Group
 - b. Program Review Group
 - c. Program Integrity Group
 - d. Program Enforcement Group

The Associate General Counsel may designate supervisory attorneys to report to the Deputy Associate General Counsel as appropriate.

3. The Children, Families, and Aging Division (CFAD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel.

CFAD also includes a Deputy Associate General Counsel, who reports to the Associate General Counsel. The Associate General Counsel may designate supervisory attorneys to report to the Deputy Associate General Counsel as appropriate.
4. The Civil Rights and Health Information Privacy Division (CPD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel who reports to the Associate General Counsel:
 - a. Civil Rights Branch
 - b. Health Information Privacy Branch
5. The Ethics Division (ETH) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:
 - a. Ethics Advice and Policy Branch
 - b. Ethics Program Administration Branch

The Associate General Counsel and Deputy Associate General Counsel for Ethics Advice and Policy simultaneously serve by secretarial delegation as the

Department's Designated Agency Ethics Official and Alternate Designated Agency Ethics Official, respectively.

6. The Food and Drug Division (FDD) —also known as the Office of the Chief Counsel—is headed by the Chief Counsel identified in II.A.1.d. The Division consists of two branches, each of which is headed by one or more Deputy Associate General Counsel who report to the Chief Counsel:
 - a. Litigation Branch
 - b. Program Review Branch
7. The General Law Division (GLD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel, as well as Assistant Deputy Associate General Counsel selected by the Associate General Counsel to provide oversight and supervision of Sections within the Division:
 - a. Claims and Employment Law Branch
 - b. Procurement, Fiscal, and Information Law Branch
8. The Disease Prevention and Health Information Technology Division (DPTD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division may also have a designated Deputy Associate General Counsel. The Division consists of four sections, each reporting to the Associate General Counsel:
 - a. Global Affairs Section
 - b. Health Information Technology Section
 - c. Preparedness and Response Section
 - d. Public and Environmental Health Section

The General Counsel may designate an attorney from this Division to serve as the primary and responsible legal advisor to the Director of the Centers for Disease Control and Prevention (CDC), who may be designated the Chief Legal Officer for the CDC.

9. The Public Health Division (PHD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division consists of three branches, each of which is headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:
 - a. Indian Health Service (IHS) Branch
 - b. National Institutes of Health (NIH) Branch
 - c. Public Health and Science Branch
10. The National Complex Litigation and Investigations Division (NCLID) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division shall also have a

designated Deputy Associate General Counsel for E-Discovery, who reports to the Associate General Counsel.

11. The Unaccompanied Alien Children Legal Representation Division (UACLRD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division operates as a legal service provider for unaccompanied alien children. The Division shall be separate and distinct from the Children, Families, and Aging Division and shall not provide legal advice or representation to the Administration for Children and Families or the Office of Refugee Resettlement with respect to matters in which the Division provides legal advice, counsel, or representation to an unaccompanied alien child. The Associate General Counsel may designate supervisory attorneys to provide oversight and supervision of attorneys and staff within the Division, as appropriate.

Subsection C. Satellite Offices

The General Counsel may establish satellite offices at locations designated by the General Counsel. Attorneys and staff assigned to a satellite office remain assigned to their respective Divisions and subject to the operational, professional, and substantive supervision of the General Counsel through applicable Division leadership and designated Deputy General Counsel.

The General Counsel may designate a senior attorney as a Managing Counsel at a satellite office to provide limited, site-specific administrative oversight, including oversight of facilities, space, security, and other shared administrative matters. Such designation does not confer authority to assign or direct legal work, supervise or evaluate personnel, establish litigation or legal positions, or otherwise exercise operational, professional, or substantive oversight, except pursuant to a separate written delegation.

Section III. Functions

Subsection A. The General Counsel and the Office of the General Counsel

1. The General Counsel. The General Counsel is authorized to promulgate such directives and issue such legal opinions as may be necessary to carry out the responsibilities of the Office. The General Counsel, directly or through attorneys in the Office of the General Counsel, undertakes the following activities unless an applicable statute provides otherwise or the General Counsel has delegated the responsibility elsewhere:
 - a. Furnishes all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, and units of the Department in connection with the operations and administration of the Department and its programs, unless otherwise expressly delegated by statute to another agency or official.
 - b. Furnishes legal services and advice on such other matters as may be submitted by the Secretary, the Deputy Secretary, any other senior leaders, and other persons authorized by the Secretary to request such

service or advice.

- c. Represents the Department in all litigation when such direct representation is not precluded by law, and in other cases, supervises the conduct of such litigation.
- d. Acts as the Department's representative in communicating with the Department of Justice, including all United States Attorneys, on all civil and criminal matters.
- e. Acts as the Department's representative in communicating with Office of White House Counsel and the Offices of General Counsel for any other Department or Agency.
- f. Authorizes indemnification of Department employees, as appropriate, pursuant to 45 CFR part 36.
- g. Oversees the Department's legal review of proposed Federal legislation and prescribes Department-wide procedures for routing and reviewing legislative materials.
- h. Supervises all legal activities of the Department and its operating and staff divisions, except with respect to certain matters within the jurisdiction of the OIG.
- i. Ensures that no one in the Department, other than those in OGC or expressly authorized by the General Counsel to do so, provides any legal advice to anyone in the Department that implies that they are functioning as a departmental lawyer.
- j. Issues all Advisory Opinions except those relating to the Anti-Kickback Act (SSA 1128B(b)), the Anti-Inducement Act (SSA 1128A(a)(5)), and the Ethics in Patient Referral Act of 1989.

2. The Legislation Section (GCL). The Legislation Section:

- a. Drafts all proposed legislation originating in the Department, reviews specifications for such proposed legislation, and reviews all proposed Federal legislation submitted to the Department or any constituent unit of the Department for comment.
- b. Prepares or reviews reports and letters to congressional committees, the Office of Management and Budget, and others concerning proposed Federal legislation.
- c. Reviews proposed testimony of Department officials before congressional committees relating to proposed Federal legislation.
- d. Acts as the Department's liaison with the Office of Management and Budget on legislative matters.

- e. Prescribes procedures governing the routing and review within the Department of all materials relating to proposed Federal legislation, including all such materials received by any constituent unit of the Department.

Subsection B. Functions and Responsibilities of the OGC Divisions

The Divisions within OGC provide legal counsel to their clients, as described below, subject to the professional supervision and control of the General Counsel and the designated Deputy General Counsel.

1. The Advanced Research Projects Agency for Health (ARPA–H) Division. The ARPA–H Division provides legal services to ARPA–H.
2. Centers for Medicare & Medicaid Services Division (CMSD). CMSD provides legal services to the Centers for Medicare & Medicaid Services (CMS), the Office of Medicare Hearings and Appeals (OMHA) and the Departmental Appeals Board (DAB). CMSD also represents CMS in connection with certain administrative and judicial proceedings involving programs administered by CMS, provides legal guidance for programs administered by CMS, and reviews proposed and final regulations and Federal Register notices prepared by CMS. CMSD acts as the primary liaison to the Department of Justice and other federal departments for programs administered by CMS.
3. Children, Families, and Aging Division (CFAD). CFAD provides legal services to the Administration for Children and Families and its various agencies, including the Office of Refugee Resettlement and Administration for Community Living. In addition, the Division advises the Department on initiatives authorized by the Indian Employment, Training, and Related Services Demonstration Act of 2017.
4. Civil Rights and Health Information Privacy Division (CPD). CPD provides legal services to the Office for Civil Rights (OCR) and advises on the implementation and enforcement of civil rights laws, conscience and religious freedom laws, and health information privacy laws, including e.g., the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR part 2. CPD does not defend claims filed by HHS employees.
5. Ethics Division (ETH). ETH administers and oversees Department-wide implementation of comprehensive government ethics program requirements under the Ethics in Government Act of 1978 as amended, Executive Order 12731, and implementing regulations at 5 CFR part 2638. This includes providing legal advice, training, and policy instruction and guidance consistent with core ethics program elements, including conflict of interest, impartiality, financial disclosure, outside activities, political activity, lobbying, pre-clearance ethics agreements, gifts, and travel payments from non-federal sources.

ETH also communicates on matters related to government ethics with the Office of Counsel to the President, the Office of Government Ethics, the Office of Special Counsel, the Office of Inspector General, Special Investigations Unit, the Department of Justice, the Office of Personnel Management, and the General Services Administration.

In addition, ETH develops component-specific conduct regulations and implementing procedures.

6. Food and Drug Division (FDD). FDD acts as the legal advisor to the Commissioner of Food and Drugs and provides legal services to the Food and Drug Administration (FDA). This includes representing the FDA in connection with judicial and administrative proceedings involving programs administered by the FDA, providing legal advice and policy guidance for programs administered by the FDA, and reviewing proposed and final regulations and Federal Register notices prepared by FDA. FDD acts as the Department and FDA's primary liaison to the Department of Justice and other federal departments for programs administered by FDA; all criminal prosecutions, investigations, and civil matters may be referred to the Department of Justice only through or in consultation with the Chief Counsel, appropriate Deputy General Counsel or the General Counsel.
7. General Law Division (GLD). GLD provides advice and representation with respect to laws and regulations that are applicable Government-wide including laws and regulations that govern business management activities and administrative operations such as procurement, contracting, personnel, budget, appropriations, federal real property, employment, information disclosure and privacy (but not health information privacy) and federal tort claims. In addition, the Associate General Counsel for GLD acts as the Department Claims Officer unless otherwise determined by the Secretary.
8. National Complex Litigation and Investigations Division (NCLID). NCLID provides legal services to all agencies and offices within the Department, as directed by the General Counsel. NCLID provides legal services in connection with complex litigation or anticipated complex litigation by or against the Department. Such litigation may include cases for which other OGC divisions request NCLID participation, cases spanning multiple OGC divisions, or cases outside the scope of other OGC divisions. NCLID administers the OGC-wide E-discovery program and coordinates the use of E-discovery technology with agencies and offices within the Department. NCLID will also conduct internal investigations at the request of the Secretary, Deputy Secretary, or the General Counsel.
9. The Disease Prevention and Health Information Technology Division (DPTD) provides legal services to the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), the Office of the National Coordinator for Health Information Technology (ONC), and the Administration for Strategic Preparedness and Response (ASPR). DPTD also provides legal services to the Office of Global Affairs (OGA) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE).

The Public and Environmental Health Section provides legal services to CDC and ATSDR concerning public-health, disease-control, quarantine and isolation, emergency-response, environmental-health, occupational safety and worker health, and hazardous-substance authorities.

The Health Information Technology Section advises ONC concerning its authorities under the HITECH Act, the 21st Century Cures Act, the Public Health Service Act, and related statutes.

The Global Affairs Section advises OGA and the CDC's Global Health Center concerning global health, international public health engagement and activities, and such additional functions in the international space as may be assigned by the General Counsel.

The Preparedness and Response Section advises ASPR concerning emergency preparedness and response authorities; public-health emergency declarations and waivers; the Public Readiness and Emergency Preparedness Act; medical countermeasures; the Biomedical Advanced Research and Development Authority; and the Strategic National Stockpile.

10. Public Health Division (PHD). PHD provides legal services to all Public Health Service agencies and programs not otherwise assigned to another OGC Division, including, but not limited to (i) the Office of the Assistant Secretary for Health, and its various programs, including the Office of the Surgeon General and the Commissioned Corps of the U.S. Public Health Service; (ii) the Office of the Secretary's Office of Minority Health; (iii) the National Institutes of Health; (iv) the Health Resources and Services Administration; (v) the Indian Health Service; (vi) the Agency for Healthcare Research and Quality; and (vii) the Substance Abuse and Mental Health Services Administration.
11. Unaccompanied Alien Children Legal Representation Division (UACLRD). UACLRD provides direct legal services to unaccompanied alien children (UAC). Attorneys within UACLRD provide direct legal advice and counsel to UAC; provide introductory legal orientation concerning immigration proceedings and applicable processes, rights, and responsibilities; and represent individual UAC as counsel in immigration proceedings, including by entering appearances on behalf of UAC before immigration courts and other appropriate immigration adjudicatory bodies. UACLRD attorneys may provide such representation throughout the course of an individual UAC's immigration proceedings, as appropriate.

UACLRD performs these functions independently of the Children, Families, and Aging Division, the Administration for Children and Families, and the Office of Refugee Resettlement. UACLRD does not provide legal advice or representation to those entities with respect to matters in which UACLRD represents an individual UAC. The Division may coordinate with other OGC components and appropriate Federal entities as necessary to carry out its responsibilities, consistent with its professional responsibilities to the UAC whom its attorneys represent.

Robert F. Kennedy, Jr.

Secretary,

U.S. Health and Human Services.

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