

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

FOR FURTHER INFORMATION CONTACT:

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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 a General Counsel, consists of:

1. Immediate Office
2. Divisions
3. Regional Offices

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, and the Office of Legal Resources (OLR).

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.

i. Chief Counsel for Food, Research, and Drugs. One Deputy General Counsel will be appointed as the Chief Counsel for Food, Research, and Drugs and will be responsible for supervising the Associate General Counsel, and their staff, who provide legal services to the National Institutes of Health and the Food and Drug Administration.

ii. 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.

d. Senior Counsel, Special Counsel, Counsel, or Senior Advisor to the General Counsel: Senior Counsel, Special Counsel, Counsel, or Senior Advisors to the General Counsel perform such duties as may be assigned to them by the General Counsel, Principal Deputy General Counsel, Deputy General Counsel, or Chief Counsel for Food, Research, and Drugs.

2. Order of Succession

a. General Counsel Vacancy. In the event of the General Counsel's absence, or 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 act in the General Counsel's stead, or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.*

b. Principal Deputy General Counsel Vacancy. In the event of the absence of or 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 Vacancies Reform Act of 1998.

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

The Office of Legal Resources 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

Subsection B. Divisions

Each OGC Division is under the general supervision of the General Counsel. Each OGC office head reports directly to the designated Deputy General Counsel on substantive legal matters, litigation strategy, and other matters as directed by the General Counsel. The OGC office heads who provide legal services to the National Institutes of Health and the Food and Drug Administration will report directly

to the Chief Counsel for Food, Research, and Drugs. There are ten 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 a designated Deputy General Counsel. The Division consists of three groups each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

- a. Litigation Group
- b. Program Review Group
- c. Program Integrity 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, Privacy, and Technology Division (CRD) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The Division will be responsible for providing legal advice on all civil rights, health policy, privacy, and related policy and enforcement matters in the Department, with the exception of defending claims filed by employees of HHS. The Division consists of two groups, each headed by a Deputy Associate General Counsel who reports to the Associate General Counsel:

- a. Civil Rights Branch
- b. Health Information Privacy and Technology 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) shall be headed by a Chief Counsel who shall be an Associate General Counsel and who shall report directly to the Chief Counsel for Food, Research, and Drugs in the Immediate Office of the General Counsel. The Division consists of two branches, each of which is headed by one or more Deputy Associate General Counsel who report to the Associate General 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 Legislation Division (GCL) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel.

9. The Public Health Division (Ph.D.) shall be headed by an Associate General Counsel, who reports to the General Counsel through a designated Deputy General Counsel or the Chief Counsel for Food, Research, and Drugs. The Division consists of four 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. Centers for Disease Control and Prevention Branch
- c. National Institutes of Health Branch
- d. 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.

Subsection C. Regional Offices

Each OGC Regional Office is under the general supervision of the General Counsel. Each OGC office 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 four OGC regional offices:

1. OGC Region 1—Philadelphia shall be headed by a Chief Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The office has a Deputy Chief Counsel, who reports to the Chief Counsel.

2. OGC Region 2—Atlanta shall be headed by a Chief Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The office consists of two branches, each of which is headed by a Deputy Chief Counsel reporting to the Chief Counsel:

- a. HHR Branch (Administration for Children and Families (ACF) and Centers for Medicare & Medicaid Services (CMS) Program Advice and Litigation)
- b. General Law Branch (Personnel and Contract Advice and Litigation)

3. OGC Region 3—Kansas City shall be headed by a Chief Counsel, who reports to the General Counsel through a designated Deputy General Counsel.

4. OGC Region 4—Denver shall be headed by a Chief Counsel, who reports to the General Counsel through a designated Deputy General Counsel. The office has a Deputy Chief Counsel, who reports to the Chief Counsel.

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. Provides legal review of all proposals for Federal legislation originating within the Department, as well as all proposed Federal legislation submitted to the Department or to any operating division of the Department for comment; as appropriate, prepares or reviews reports and letters to congressional committees, the Office of Management and Budget, and others on proposed Federal legislation; and prescribes procedures to govern the routing and review, within the Department, of material relating to proposed Federal legislation.

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.

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).

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 the 477 initiative authorized by the Indian Employment, Training, and Related Services Demonstration Act of 2017.

4. Civil Rights, Privacy, and Emerging Technology Division (CRD). CRD provides legal services for the Office for Civil Rights (OCR) and provides advice with respect to the enforcement of civil rights laws, conscience statutes, the Health Insurance and Portability and Accountability Act of 1996 (Social Security Act § 1171 *et seq.*), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the rules implementing them with respect of HHS-funded programs and activities. CRD also provides legal services to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC). CRD 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.

8. Legislation Division (GCL). GCL:

- Drafts all proposed legislation originating in the Department, reviews specifications for such proposed legislation, and reviews all proposed legislation submitted to the Department or to any constituent unit of the Department for comment.

- Prepares or reviews reports and letters to congressional committees, the Office of Management and Budget, and others on proposed legislation.

- Reviews proposed testimony of Department officials before congressional committees relating to pending or proposed legislation.

- Acts as Department liaison with the Office of Management and Budget on legislative matters.

- Prescribes procedures to govern the routing and review, within the Department, of material relating to proposed federal legislation.

9. National Complex Litigation and Investigation 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 or regional offices request NCLID participation, cases spanning multiple OGC divisions or regional offices, or cases outside the scope of other OGC divisions or regional offices. 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 General Counsel.

10. Public Health Division (Ph.D.). Ph.D. provides legal services to all Public Health Service agencies (except to FDA) and their programs, including the Office of the Surgeon General and the Commissioned Corps of the U.S. Public Health Service. The represented Public Health Service agencies include, but are not limited to: (i) the Office of the Assistant Secretary for Health, and its various programs; (ii) the Office of the Secretary's Office of Minority Health; (iii) the Centers for Disease Control and Prevention; (iv) the National Institutes of Health; (v) the Health Resources and Services Administration; (vi) the Indian Health Service; (vii) the Substance Abuse and Mental Health Services Administration; (viii) the Agency for Healthcare Research and Quality, (ix) the Administration for Strategic Preparedness and Response, and (x) the Agency for Toxic Substances and Disease Registry.

Subsection C. Functions and Responsibilities of the OGC Regional Offices

There are four OGC Regional Offices, each led by a Chief Counsel. Regional offices within OGC provide a full range of legal services, subject to the professional supervision and direction of the General Counsel and the designated Deputy General Counsel. This includes providing legal advice and representation in administrative and judicial litigation regarding programs operated by the Centers for Medicare and Medicaid Services, the Administration for Children and Families, the Administration for Community Living, and Public Health Service agencies including the Indian Health Service, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Centers for Disease Control and

Prevention; and providing legal advice and representation in administrative and judicial litigation relating to business management activities and administrative operations, such as employment and labor relations, information disclosure and privacy, federal tort claims, and suspensions, disallowances, and other recoveries of payments made under HHS programs, of HHS components operating in their regions.

The HHS regional offices are located in the following cities and cover all states and territories of the United States, as well as three independent states in the Pacific.

1. OGC Region 1—Philadelphia.
2. OGC Region 2—Atlanta.
3. OGC Region 3—Kansas City (MO).
4. OGC Region 4—Denver.

Robert F. Kennedy, Jr.,

Secretary, U.S. Health and Human Services.

[FR Doc. 2025-04130 Filed 3-13-25; 8:45 am]

BILLING CODE 4150-26-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Disease Control and Applied Immunology.

Date: April 8, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ekaterina Mikhailovna Nestorovich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-1367, ekaterina.nestorovich@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Adaptive and Innate Immunity.

Date: April 8, 2025.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Mechanisms of Autoimmunity.

Date: April 9, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lisa Ann Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2582, lisa.lewis3@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Applied Immunology and Disease Control.

Date: April 10, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irene Ramos Lopez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-4891, irene.ramoslopez@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: HIV/AIDS Biological.

Date: April 11, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805-P, Bethesda, MD 20892, (301) 435-0000, drammehbs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Immunity and Host Defense.

Date: April 16, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.