

**SUPPLEMENTARY INFORMATION:** On September 24, 2020, the Department issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs on its website. The proposals were issued consistent with FDA's authorities under sections 801 and 804 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 381, 384. The Department is issuing this Notice to include revised versions of these proposals in the **Federal Register**.

Dated: January 13, 2021.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions, and Delegations of Authority

Part R (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (60 FR 56605, as amended November 6, 1995; as last amended at 85 FR 34210-34212 dated June 3, 2020) is amended to reorganize sections of the Office of the Administrator, the Federal Office of Rural Health Policy, the Healthcare Systems Bureau, the Maternal and Child Health Bureau, and the Bureau of Primary Health Care.

Key functional changes include establishing the Office of Special Health Initiatives, the Office of Provider Support, and the Office for the Advancement of Telehealth within the Office of the Administrator; abolishing the Healthcare Systems Bureau; and renaming two Offices within the Bureau of Primary Health Care to increase attention and focus on Health Center Program compliance and funding oversight.

This reorganization establishes, updates, realigns, and/or deletes the organization, functions, and delegation of authority for the (1) Office of the Administrator (RA); (2) Office of Special Health Initiatives (RA4); (3) Office for the Advancement of Telehealth (RA3); (4) Federal Office of Rural Health Policy (RH); (5) Office of Provider Support (RD); (6) Healthcare Systems Bureau (RR); (7) Bureau of Primary Health Care (RC); and (8) Maternal and Child Health Bureau (RM).

#### Chapter RA—Office of the Administrator

##### Section RA.10 Organization

Delete the organization for the Office of the Administrator (RA) in its entirety and replace with the following:

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Communications (RA6);
- (3) Office of Legislation (RAE);
- (4) Office of Planning, Analysis and Evaluation (RA5);
  - Office of Policy Analysis (RA53);
  - Office of Research and Evaluation (RA56);
  - Office of External Engagement (RA57);
  - Office of Performance and Quality Measurement (RA58);
  - Office of Strategic Initiatives (RA59);
- (5) Office of Civil Rights, Diversity and Inclusion (RA2);
- (6) Office for the Advancement of Telehealth (RA3);
- (7) Office of Special Health Initiatives (RA4);
  - Office of Pharmacy Affairs (RA41);
  - Office of Global Health (RA42);
  - Division of Global Health (RA421);
- and
  - Division of Injury Compensation Programs (RA43).
- (8) Office of Health Equity (RAB); and
- (9) Office of Women's Health (RAW).

##### Section RA.20 Function

Delete the functional statement for Immediate Office of the Administrator (RA) and replace; delete the functional statements for the Office of Global Health (RAI), and replace with the Office of Special Health Initiatives (RA4); and add the functional statement for the Office for the Advancement of Telehealth (RA3).

#### Immediate Office of the Administrator (RA)

The Immediate Office of the Administrator for the Health Resources and Services Administration (HRSA) leads and directs programs and activities of the agency and advises the Office of the Secretary of Health and Human Services on policy matters concerning them. Specifically, the Immediate Office of the Administrator: (1) Provides consultation and assistance to senior agency officials and others on clinical, health care delivery, and health workforce issues; (2) serves as the agency's focal point on efforts to strengthen the practice of public health as it pertains to the HRSA mission; (3) establishes and maintains communication with health organizations in the public and private

sectors; (4) coordinates the agency's policy development, data strategy, evaluation and research planning processes; (5) manages the legislative analysis and engagement for the agency; (6) administers HRSA's equal opportunity and civil rights activities; (7) provides overall leadership, direction, coordination and planning in support of the agency's special health initiatives; (8) manages programs to advance the use of telehealth and coordination of health information technology; (9) manages HRSA's global health issues; (10) leads HRSA's efforts to improve the health, wellness, and safety of women and girls through policy, programming and outreach/education; (11) provides leadership and policy development in the administration of the 340B Drug Pricing Program; (12) oversees efforts to address the special needs of minority and disadvantaged populations, including coordination of tribal activities for HRSA; (13) provides cross-cutting leadership on HRSA's behavioral health and oral health programs; and (14) administers the National Vaccine Injury Compensation Program.

#### Office for the Advancement of Telehealth (RA3)

The Office for the Advancement of Telehealth (1) ensures successful dissemination of appropriate information technology advances, such as telehealth or electronic health records systems; (2) monitors the health information technology policy and activities of other HHS components for useful application in rural areas; (3) provides overall direction and leadership over the management of programs to advance the use of telehealth and coordination of health information technology; and (4) serves as the operational focal point for coordinating and advancing the use of telehealth technologies across all of HRSA's programs including, but not limited to, the provision of health care at a distance (telemedicine), distance based learning to improve the knowledge of agency grantees and others, and improved information dissemination to both consumers and providers about the latest developments in telemedicine.

The Office for the Advancement of Telehealth carries out the following functions: (1) Develops and coordinates telehealth network and telehealth resource centers grant programs; (2) provides professional assistance and support in developing telehealth initiatives; and (3) administers grant programs to promulgate and evaluate the use of appropriate telehealth

technologies among HRSA grantees and others.

#### **Office of Special Health Initiatives (RA4)**

##### *Office of the Director (RA4)*

The Office of Special Health Initiatives (OSHI) provides a crosscutting focal point for HRSA to deliver on population health and Secretarial priorities, especially those that may be more clinical in nature. Specifically, OSHI (1) coordinates and collaborates with components in the Department of Health and Human Services (HHS) that align with the work of OSHI; (2) serves as the principal advisor within HRSA on global health issues; (3) provides agency-wide leadership and policy development in the administration of the 340B Drug Pricing Program to promote access to clinically and cost effective pharmacy services to the country's most vulnerable patient populations; (4) serves as the lead on behavioral health issues that span HRSA; (5) provides cross-cutting leadership on HRSA oral health programs; and (6) directs and administers the National Vaccine Injury Compensation Program.

##### *Office of Pharmacy Affairs (RA41)*

The Office of Pharmacy Affairs promotes access to clinical and cost effective pharmacy services to enable participating entities to stretch scarce federal resources in order to serve more patients, expand their services, or offer additional services. Specifically, the Office of Pharmacy Affairs: (1) Manages the 340B Drug Pricing Program involvement of pharmaceutical manufacturers that participate in the Medicaid program, through Pharmaceutical Pricing Agreements; (2) maintains a publicly accessible database of participating covered entities, sites, and contract pharmacies; (3) publishes guidelines/regulations to assist in the understanding and participation in the 340B Program; (4) maintains a Prime Vendor Program to increase the value of the 340B Program; (5) provides technical assistance to Program stakeholders to support their appropriate and best use of the 340B Program; (6) fosters mutually productive relationships with federal and private sector partners; (7) provides a national platform for the coordination and development of leading practices for pharmacy services; (8) promotes comprehensive and efficient pharmacy management application and systems use to ensure safe and effective medication use; (9) manages quality improvement activities; and (10)

promotes program integrity compliance and improvement activities.

##### *Office of Global Health (RA42)*

The Office of Global Health provides expertise and advises HRSA on global health issues. Specifically, the Office of Global Health: (1) Provides leadership, coordination, and advancement of global health programs relating to sustainable health systems for vulnerable and at-risk populations; (2) provides leadership within HRSA for the support of global health and coordinates policy development with the HHS Office of Global Affairs, other departmental agencies, bilateral/multilateral organizations, and other international organizations and partners; (3) monitors HRSA's border health activities and investments, in partnership with HRSA's Office of Regional Operations, to promote collaboration and improve health care access to those living along the U.S. borders, such as the U.S.-Mexico border and the U.S. Affiliated Pacific Islands; (4) provides management and oversight of international programs aimed at improving quality and innovation in human resources for health, health workforce recruitment, education, retention, and applied research systems; (5) supports and conducts programs associated with the international migration and recruitment of health personnel, foreign, and immigrant health workers; (6) provides support for the agency's international travel and the Department of State's International Visitors Leadership Program; and (7) provides national leadership, including serving as the Deputy Principal representative and providing support to the HRSA Administrator, implements training, and systems strengthening functions of the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief (PEPFAR).

##### *Division of Global Programs (RA421)*

The Division of Global HIV/AIDS Program provides national leadership, implements training, and systems strengthening functions of the Global HIV/AIDS Program as part of PEPFAR. This includes strengthening health systems for delivery of prevention, care and treatment services for people with HIV/AIDS in PEPFAR-funded countries and providing management and oversight of international programs aimed at improving quality and innovation in health professions education and training. The Division shares lessons learned from both the domestic and Global HIV/AIDS Programs grant recipient community.

The Division of Global HIV/AIDS Program provides leadership in improving care, treatment, and support services for people with HIV/AIDS outside of the United States and its territories. Specifically, the Division: (1) In coordination with the Department of State's Office of the Global AIDS Coordinator, plans, develops, implements, evaluates, and coordinates the activities of the clinical assessment system strengthening; (2) provides guidance and expertise to funded programs; (3) develops funding opportunity announcements and program guidance documents; (4) conducts on-site program reviews and reviews of pertinent and required reports, and activities to assess compliance with program policies and country priorities; (5) in conjunction with other division, bureau, and agency entities, assists in the planning and implementation of priority HIV activities such as workgroups, meetings, and evaluation projects; (6) collaborates with other federal agencies and in-country partners in the implementation of the PEPFAR program, and (7) provides management and oversight of international programs aimed at improving quality and innovation in health professions education, retention, training, faculty development, and applied research systems.

##### *Division of Injury Compensation Programs (RA43)*

The Division of Injury Compensation Programs, on behalf of the Secretary of HHS, administers and implements all statutory and charter authorities related to the operations of the National Vaccine Injury Compensation Program, the Countermeasures Injury Compensation Program, and the HHS Medical Review Claims Panel by: (1) Evaluating claims for compensation filed under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program through medical review and assessment of compensability for all complete claims; (2) processing awards for compensation made under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program; (3) promulgating regulations to develop and revise Vaccine and Countermeasures Injury Tables; (4) providing professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV) and the Medical Claims Review Panel; (5) maintaining responsibility for activities related to the ACCV including the development of policy, regulations, budget formulation, and legislation; the development and

renewal of its charter and action memoranda to the Secretary; and the analysis of its findings and proposals; (6) developing and maintaining all automated information systems necessary for program implementation; (7) developing and disseminating program information; (8) maintaining a working relationship with the Department of Justice (DOJ) and the U.S. Court of Federal Claims through the DOJ, in the administration and operation of the National Vaccine Injury Compensation Program; (9) providing management, direction, budgetary oversight, coordination, and logistical support for the Medical Expert Panel, as well as Clinical Reviewer contracts; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine and Countermeasures Injury Tables, in coordination with the Office of the General Counsel; (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; (12) providing submission of special reports to the Secretary of HHS, the Office of Management and Budget, Congress, and other governmental bodies; and (13) providing guidance in using the results and decisions of the Medical Claims Review Panel to HHS Operating Divisions to improve the quality of health care in its facilities and by its practitioners.

#### Chapter RH—Federal Office of Rural Health Policy

##### Section RH.10 Organization

Delete the organization for the Federal Office of Rural Health Policy (RH) in its entirety and replace with the following:

The Federal Office of Rural Health Policy (RH) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Federal Office of Rural Health Policy includes the following components:

- (1) Office of the Associate Administrator (RH);
- (2) Hospital State Division (RH1);
- (3) Community-Based Division (RH2);
- (4) Policy Research Division (RH5);
- (5) Administrative Operations Division (RH6); and
- (6) Rural Strategic Initiatives Division (RH7).

##### Section RH.20 Function

Delete the functional statement for the Office of the Associate Administrator and replace with the following:

#### Federal Office of Rural Health Policy

##### *Office of the Associate Administrator (RH)*

The Federal Office of Rural Health Policy (FORHP) is responsible for the overall leadership and management of the Office. FORHP serves as a focal point within HHS for rural health-related issues and as a principal source of advice to the Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the nation's rural areas. FORHP provides leadership within HHS and with stakeholders in providing information and counsel related to access to, and financing and quality of, health care to rural populations. Specifically, the Office of the Associate Administrator (1) Provides staff support to the National Advisory Committee on Rural Health and Human Services; (2) stimulates and coordinates interaction on rural health activities and programs in the agency, Department and with other federal agencies; (3) directs and oversees the development and implementation of a research agenda that supports delivery of health services in rural areas; (4) provides overall direction and leadership over the management of nationwide community-based rural health grants programs; (5) provides overall direction and leadership over the management of a program of state grants which supports collaboration within state offices of rural health; (6) provides overall direction and leadership over the Office's administrative and management functions; and (7) provides overall direction and leadership over the Office's new rural health program initiatives created as a result of agency, Department and/or administrative priorities.

#### Chapter RD—Office of Provider Support

##### Chapter RD.00 Mission

The Office of Provider Support ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the U.S. to prevent, prepare for and respond to coronavirus disease 2019 (COVID-19).

##### Section RD.10 Organization

Establish the Office of Provider Support organization as follows:

The Office of Provider Support (RD) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Office of Provider Support includes the following components:

- (1) Office of the Associate Administrator (RD);

- (2) Division of Provider Support (RD1);
- (3) Division of Customer Support (RD2); and
- (4) Division of Data Analytics and Program Integrity (RD3).

##### Section RD. Function

Establish the function of the Office of Provider Support (RD) as follows:

##### Office of Provider Support (RD)

The Office of Provider Support ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the U.S. to prevent, prepare for and respond to coronavirus. The Office reimburses health care providers for health care related expenses or lost revenues attributable to coronavirus and to provides claims reimbursement for health care entities for COVID-19 testing and treatment for uninsured individuals.

##### *Office of the Associate Administrator (RD)*

The Office of the Associate Administrator provides overall leadership, direction, coordination, and planning in support of the programs designed to make payments to health care providers for expenses and lost revenue related to COVID-19 and to reimburse health care entities' claims for COVID-19 testing and/or treatment of uninsured individuals, helping to ensure a sustained, robust health care system. The Office guides and directs the development of policy priorities for the allocation of payments and claims reimbursements and ensures the proper management of programs. Specifically, the Office of the Associate Administrator: (1) Provides overall direction and leadership over the management of funds to reimburse health care providers for expenses and lost revenue related to COVID-19; (2) provides overall direction and leadership over the management of funds dedicated specifically for the testing and treatment of the uninsured individuals with possible or actual cases of COVID-19; (3) directs data collection and analysis in support of program execution; (4) provides oversight of an audit protocol and plan that monitors proper execution of funds; (5) ensures compliance with regulations and limits risk through establishment and maintenance of a system of internal controls; (6) maintains effective relationships within HRSA and with other federal and nonfederal agencies, state, and local governments, and other public and private organizations associated with the response to COVID-

19; (7) plans, directs, coordinates, and evaluates the Office's administrative and management functions, e.g., budget, personnel, procurements, delegations of authority, and responsibilities related to the awarding of program funds; (8) represents the Office, agency, and federal government, as designated, with other federal and non-federal agencies, state and local governments, and other public and private organizations concerned with the response to COVID-19 and the resiliency of the national healthcare systems; and (9) coordinates, reviews, and provides clearance of correspondence and official documents entering and leaving the Office.

*Division of Policy and Program Operations (RD1)*

The Division of Policy and Program Operations is the focal point for the policy development, program operations, and communications operations for Office programs. Specifically, the Division of Policy and Program Operations: (1) Works with the contractor to ensure effective and efficient program operations; (2) leads and coordinates the analysis, development, and drafting of policies impacting Office programs; (3) analyzes issues arising from legislation, budget proposals, regulatory actions and other program or policy actions; (4) works collaboratively with other components within HRSA and HHS, and with other federal agencies, state and local governments, and public and private organizations on issues affecting Office programs and policies; (5) keeps Congress apprised of programs and activities as necessary; (6) links Office programs to HRSA-wide policy development, analyses, and evaluation as applicable; (7) serves as a key point of contact to coordinate, review and clear congressional, Executive Branch and other stakeholder group inquiries in conjunction with the agency and the Department; (8) serves as a key point of contact to coordinate activities related to congressional inquiries, and other stakeholder groups in conjunction with the agency and Department; and (9) assumes special projects or takes the lead on certain issues as tasked by the Office's leadership.

*Division of Customer Support (RD2)*

The Division of Customer Support serves as the organizational focal point for the Office's centralized, comprehensive customer service function to support recipients or potential recipients of program funds. The Division provides responses to provider inquiries that arrive at the Office through a variety of channels

including providers, health delivery entities, stakeholders, Congress, and others.

*Division of Data Analytics and Program Integrity (RD3)*

The Division of Data Analytics and Program Integrity is responsible for the collection, management, and analysis of the data needed for the Provider Relief Fund and COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration of the Uninsured Program, and for ensuring the overall integrity of the programs and payments made. Specifically, the Division of Data Analytics and Program Integrity: (1) Maintains data and analytic capabilities to inform policy decisions and to support Office functions; (2) develops and manages Office data strategy; and (3) develops and manages Office program and payment integrity strategy.

Chapter RC—Bureau of Primary Health Care

Section RC.10 Organization

Delete the organization for the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

The Bureau of Primary Health Care (RC) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Bureau of Primary Health Care (RC) includes the following components:

- (1) Office of the Associate Administrator (RC);
- (2) Division of Workforce Management (RC2);
- (3) Division of National Hansen's Disease Program (RC4);
- (4) Office of Strategic Business Operations (RCA);
- (5) Office of Health Center Investment Oversight (RCC);
- (6) Office of Health Center Program Monitoring (RCF);
- (7) Office of Policy and Program Development (RCH); and
- (8) Office of Quality Improvement (RCK).

Section RC.20 Function

Delete the functional statement for the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

**Bureau of Primary Health Care**

*Office of the Associate Administrator (RC)*

Provides overall leadership, direction, coordination, and planning in support of BPHC programs. Specifically, the Office of the Associate Administrator:

(1) Establishes program goals, objectives, and priorities, and provides oversight to their execution; (2) plans, directs, coordinates, supports, and evaluates bureau wide management activities; (3) maintains effective relationships within HRSA and with other HHS organizations, other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations; and (4) manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service (PHS) Act.

Division of Workforce Management (RC2)

The Division of Workforce Management plans, directs, and coordinates bureau-wide administrative management activities and serves as the organizational focus for bureau workforce staff development and evaluation efforts in support of organizational goals and objectives. Specifically, the Division of Workforce Management: (1) Serves as the Bureau of Primary Health Care's principal source for administrative and management advice, analysis, and assistance; (2) provides strategic guidance and coordinates personnel activities for the bureau, including the allocation of personnel resources; (3) develops policies and procedures for internal operations, interpreting and implementing management policies, procedures and systems; (4) develops and coordinates bureau program and administrative delegations of authority activities; (5) provides guidance to the bureau on financial management activities; (6) provides bureau-wide support services such as continuity of operations and emergency planning, procurement planning and coordination, supply management, equipment utilization, workforce planning, printing, property management, space management, and management reports; (7) plans and implements strategies for development of staff and succession planning; and (8) coordinates bureau administrative management and workforce activities with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations, as appropriate.

Division of National Hansen's Disease Program (RC4)

The National Hansen's Disease Program, in accordance with regulations

and the PHS Act, Sec. 320 as amended by Public Law 105–78, Sec. 211, (1) provides care and treatment for persons with Hansen’s Disease (leprosy), including managing a national short-term and outpatient health care delivery program providing specialized services to persons with Hansen’s Disease; (2) conducts and promotes the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen’s disease and other mycobacterial diseases and complications related to such diseases; (3) conducts training in the diagnosis and management of Hansen’s disease and related complications; (4) provides education and training to staff from the outpatient Hansen’s Disease Clinics and to private physicians; (5) operates and oversees the National Hansen’s Disease Museum and Cemetery; (6) consults on the coordination of activities within HRSA and HHS and with other federal agencies, state, and local governments, and other public and private organizations involved in Hansen’s Disease activities; (7) manages a network of contracted outpatient clinics providing care to persons with Hansen’s Disease; and (8) manages and coordinates the National Hansen’s Disease Program’s administrative and operational activities with HRSA and HHS, other federal agencies, state and local governments; and other public and private organizations involved in Hansen’s Disease activities.

*Office of Strategic Business Operations (RCA)*

The Office of Strategic Business Operations serves as the organizational focus for the development of the Bureau of Primary Health Care external affairs, organizational data development and analysis, and management information systems to meet the goals and objectives of the bureau. Specifically, the Office of Strategic Business Operations: (1) Serves as the bureau’s focal point for communication and program information dissemination; (2) serves as the bureau’s Executive Secretariat and focal point for records management policies and guidance; (3) leads strategic data analytics for bureau operations; (4) monitors bureau activities in relation to HRSA and HHS Strategic Plans; (5) serves as the bureau focal point for the design and implementation of management information systems to assist and improve program performance and internal operations; and (6) consults and coordinates bureau external affairs, business analytics, and information systems with other

components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations.

*Office of Health Center Investment Oversight (RCC)*

The Office of Health Center Investment Oversight oversees the Bureau of Primary Health Care’s primary health care service delivery programs, including initiatives focused on special populations and associated activities within all HHS Regions. Specifically, the Office of Health Center Investment Oversight: (1) Oversees bureau primary health care service delivery programs for compliance with funding requirements; (2) monitors the performance of bureau primary health care service delivery programs, making programmatic recommendations and providing assistance to improve performance, where appropriate; (3) reviews findings, analyzes data, and provides recommendations through periodic and episodic grantee funding progress assessments; and (4) provides consultation to and coordinates activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in the implementation of bureau primary health care service delivery programs.

*Office of Health Center Program Monitoring (RCF)*

The Office of Health Center Program Monitoring oversees the Bureau of Primary Health Care’s primary health care service delivery programs, including those focused on special populations, and associated activities within all HHS Regions. Specifically, the Office of Health Center Program Monitoring: (1) Oversees bureau primary health care service delivery programs for compliance with program requirements; (2) provides assistance on program-related statutory/regulatory policy and program requirements; (3) reviews findings, analyzes data, and provides recommendations through periodic and episodic grantee compliance assessments; and (4) provides consultation to and coordinates activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in the implementation of bureau primary health care service delivery programs.

*Office of Policy and Program Development (RCH)*

The Office of Policy and Program Development serves as the

organizational focus for the development of the Bureau of Primary Health Care programs and policies. Specifically, the Office of Policy and Program Development: (1) Leads and monitors the strategic development of primary care programs, including health centers, special population programs, and other health systems; (2) provides assistance to communities, community-based organizations, and bureau programs related to the development and expansion of primary care; (3) develops bureau capital programs and oversees loan guarantee programs, including the awarding of new grants under section 1610(b) of the PHS Act, under the Health Care and Other Facilities grant program, and under the Patient Protection and Affordable Care Act, Public Law 111–148; (4) leads and coordinates the analysis, development, and drafting of budget and policy impacting bureau programs; (5) provides support to the National Advisory Council on Migrant Health; (6) performs environmental scanning on issues that affect bureau programs; and (7) consults and coordinates with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations on issues affecting bureau programs and policies.

*Office of Quality Improvement (RCK)*

The Office of Quality Improvement serves as the organizational focus for program quality including clinical and operational quality improvement, patient safety and risk management, data reporting, and program evaluation. Specifically, the Office of Quality Improvement: (1) Provides leadership for implementing bureau clinical quality improvement strategies/initiatives, including health information technology; (2) oversees the bureau’s Federal Tort Claims Act medical malpractice liability programs, reviewing risk management and patient safety activities to improve policies and programs for primary health care services, including clinical information systems; (3) leads and coordinates the bureau’s national and state technical assistance/programs and activities, including those focused on special populations; (4) identifies, provides assistance, and supports bureau programs around quality improvement and performance reporting activities; (5) oversees bureau programs related to health information technology and quality improvement; (6) serves as the bureau’s focal point for the design and implementation of program evaluations and research; (7) coordinates and supports emergency preparedness and

response for bureau programs; and (8) coordinates bureau/quality improvement and performance reporting activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations.

#### Chapter RM—Maternal and Child Health Bureau

##### Section RM.20 Function

Delete the functional statement for the Division of Child, Adolescent and Family Health (RM3) and replace with the following:

#### *Division of Child, Adolescent and Family Health (RM3)*

The Division of Child, Adolescent and Family Health provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, young adults and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community-based, and culturally competent systems of care for such populations. Specifically, the Division: (1) Administers a program which supports the development of systems of care and services for children, adolescents, young adults, and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children, adolescents, young adults, and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with the Maternal and Child Health Bureau Divisions and Offices in promoting program objectives and the mission of the bureau; (5) serves as the focal point within the bureau in implementing programmatic statutory requirements for state programs for children, adolescents, young adults, and their families; (6) provides consultation and technical assistance to state programs for children, adolescents, young adults, and their families and to local communities, consistent with a bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) provides liaison with public, private,

professional and voluntary organizations on programs designed to improve services for children, adolescents, young adults, and their families; (8) carries out a national program supporting Child Death Review systems; (9) carries out a national program on school health activities; (10) carries out a national program designed to improve the provision of emergency medical services for children; (11) administers the Poison Control Program; (12) carries out a national program designed to improve the provision of oral health services for children; (13) carries out a national program on injury prevention for children and adolescents; (14) coordinates within this agency and with other federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated state-based systems of care for children, adolescents, young adults, and their families; (15) disseminates information on preventive health services and advances in the care and treatment of children, adolescents, young adults, and their families; (16) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, young adults, and their families; and (17) administers funds and other resources for grants, contracts, and cooperative agreements.

#### Chapter RR—Healthcare Systems Bureau

##### Section RR.10 Organization

Delete the organization for the Healthcare Systems Bureau (RR) in its entirety.

##### Section R.30, Delegation of Authority

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed, provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

**Authority:** 44 U.S.C. 3101

Dated: January 14, 2021.

**Alex M Azar II,**

*Secretary, Department of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Statement of Organization, Functions, and Delegations of Authority

January 7, 2021.

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

**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), to reflect, among other things, OGC participation in the Inter-Agency False Claims Act Working Group and re-allocation of responsibilities concerning certain requests under the Freedom of Information Act. Issuance of this Statement of Organization rescinds all prior Statements of Organization.

**SUPPLEMENTARY INFORMATION:** The Office of the Secretary (OS)'s 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 Mission of the Office of the General Counsel and the General Counsel, who is the special advisor to the Secretary on legal matters, is to provide all legal services and advice to the Secretary, Deputy Secretary, and all subordinate organizational components of the Department.

Section II. Organization. The Office of the General Counsel, under the supervision of a General Counsel, consists of:

1. The General Counsel and Immediate Office of the General Counsel
2. Divisions in the Office of the General Counsel
3. Ten 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 shall consist of the General Counsel, his or her executive assistant, a Principal Deputy General Counsel, such other Deputy General Counsel, both non-career and career, as the Secretary deems appropriate and appoints, Associate and Assistant Deputy General Counsel, Senior Counsel, and such other attorneys and assistants 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