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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Advanced Research Projects Agency for Health

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) has modified its structure. This notice announces the establishment of the Advanced Research Projects Agency for Health (or ARPA-H).

DATES: This reorganization was approved by the Secretary of Health and Human Services and takes effect May 24, 2022.

SUPPLEMENTARY INFORMATION: Part N, National Institutes of Health, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) (May 27, 1975 at 40 FR 22859, as amended most recently on November 3, 2004 at 69 FR 64081, and redesignated from Part HN as Part N on November 9, 1995 at 60 FR 56605, is amended as set forth below to implement ARPA-H.

Section N, *Organization and Functions* is amended as follows:

(1) Under *Grants Management Branch (NW83, formerly HNW83)* insert the following:

Advanced Research Projects Agency for Health (NY, formerly HNY). 1) Provides leadership for high-risk, high-reward biomedical and health research to speed application and implementation of health breakthroughs equitably. 2) Creates, supports, and manages programs to catalyze the development of transformative, evidenced-based, use-driven capabilities, platforms, and technologies in a range of biomedical and health research areas. 3) Facilitates partnerships and collaboration among government, academia, industry, and other sectors to accelerate the translation of innovation into meaningful and measurable benefits for the nation. 4) Converts use-driven research into tangible, sustainable solutions for patients.

Acquisition and Contracting Office (NY2, formerly HNY2). 1) Advises the ARPA-H Director and staff on acquisition and contract and grant financial advisory services. 2) Develops/implements ARPA-H policies, provides oversight, and manages the operational components in the areas of acquisition and contracts management, including other transactions. 3) Manages and conducts a comprehensive program of all research and development contracting, non-research and development contracting, ARPA-H support contracting, and commercial item acquisitions using simplified acquisition procedures, GSA Federal Supply Schedule acquisitions and simplified acquisitions. 4) Provides advice and assistance regarding all phases of the acquisition cycle from planning to closeout with the purpose of accomplishing all acquisitions needed for the scientific mission and all related acquisitions required by its customers.

Comptroller's Office (NY3, formerly HNY3). 1) Directs ARPA-H-wide budget policy, planning, analysis, formulation, and presentation, in collaboration with HHS Office of the Assistant Secretary for Financial Resources and NIH Office of Budget. 2) Manages the ARPA-H appropriated budget, including reprogramming and coordination of the use of the Director's Discretionary Fund and transfer authority. 3) Advises the ARPA-H Director and staff and provides leadership and direction for budgetary matters and financial management activities. 4) Develops policies and instructions for central services budget preparation and presentation. 5) Administers allocation of funds and manages a system of fund and budgetary controls. 6) Provides an ARPA-H manpower resource control system designed to allocate resources. 7) Provides, develops, and maintains an ARPA-H Management Account Structure. 8) Directs planning and implementation of ARPA-H fiscal systems and procedures, in coordination with NIH and/or HHS fiscal systems and procedures, and provides accounting services to all ARPA-H components. 9) Supports the Office of Acquisition and Contracting (OAC) in the development of policies and procedures pertaining to grants and contracts.

Engagement and Communications Office (NY4, formerly HNY4). 1) Plans and directs activities to communicate information about ARPA-H programs and accomplishments to the general public, scientific community, patients and patient groups, professional societies and organizations, and public advocacy groups. 2) Advises the Director of ARPA-H on effective communications strategies. 3) Represents the Director of ARPA-H in relations with media, scientific publications, and other public stakeholder groups. 4) Coordinates communications policy, strategy, and activities, including Freedom of Information Act requests, with the NIH Office of Communications and Public Liaison. 5) Leads internal and external engagement activities and outreach efforts to develop, build, and improve ARPA-H relationships with stakeholders. 6) Develops and implements initiatives to collect feedback and gain support of ARPA-H research initiatives. 7) Collaborates with the ARPA-H Office of Legislative and Congressional Affairs on a range of external advocacy initiatives in furtherance of ARPA-H's mission. 8) Creates and publishes public and agency information resources including regular publications in a variety of formats. 9) Fosters participation in and promotion of ARPA-H activities. 10) Maintains resources for ARPA-H special events, recruitment initiatives and other public-facing activities.

Legislative and Governmental Affairs Office (NY5, formerly HNY5). 1) Advises the ARPA-H Director and staff on the full range of legislative and intragovernmental issues, and provides leadership and direction for ARPA-H legislative analysis, development, and liaison. 2) Identifies, analyzes, and reports on legislative developments relevant to ARPA-H programs and activities and the national biomedical and health research effort. 3) Monitors new legislative proposals and their progress through the legislative process, including changes in the statutory base of ARPA-H activities, and develops and coordinates technical assistance. 4) Assesses, monitors, and manages the ARPA-H relationship with the ARPA-H Congressional

Authorizing and Appropriations Committees, as well as other agencies across the federal government, and takes necessary action to facilitate improvements in these relationships. 5) Provides coordination on ARPA-H legislative matters with the NIH, HHS, Congress, Federal Agencies, and other non-Federal national and international organizations. 6) Coordinates the preparation of testimony or statements for ARPA-H leadership before congressional committees or other groups. 7) Develops responses to Congressional requests, develops responses to report language, and special reports, staff documents, or other materials concerning ARPA-H interests, activities, and relationships.

Strategic Resources Office (NY6, formerly HNY6). 1) Advises the ARPA-H Director and staff on all phases of ARPA-H-wide administration and management. 2) Provides leadership and direction to all aspects of ARPA-H management. 3) Oversees the management of functions in the areas of personnel management, management policy, management assessment, and logistics management, IT support, safety, space and facility management, property, support services, and security operations. 4) Coordinates with and serves as a liaison to the relevant NIH offices to provide a high-level of service to ARPA-H staff.

Treatment Innovation Office (NY7, formerly HNY7). 1) Furthers development of novel and innovative therapeutics or other interventions to manage, treat, or cure diseases and conditions. 2) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to disease or condition management therapies. 3) Responds to requests for information on highly technical matters and matters of public policy related to therapeutics and treatment interventions.

Health Equity, Dissemination, and Implementation Office (NY8, formerly HNY8). 1) Advances programs that concentrate on promoting health equity, access to care, and ethical

aspects of science and technology development. 2) Undertakes projects and initiatives to address and lessen health disparities and inequities in biomedical and health research within the United States and abroad. 3) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to health equity, inclusion, recruitment, enrollment, and retention, access to care, and ethical aspects of science and technology development, as well dissemination and implementation of those research advances into real-world settings and clinical practice. 4) Responds to requests for information on highly technical matters and matters of scientific and public policy related to health equity, inclusion, recruitment, enrollment, and retention, access to care, and ethical aspects of science and technology development, as well dissemination and implementation of those research advances into real-world settings and clinical practice.

Health Data Office (NY9, formerly HNY9). 1) Focuses on thoughtful approaches to revolutionizing how scientific and health data and information technology are collected, organized, integrated, and used. 2) Develops strategies to assemble interdisciplinary teams to fuse mathematical approaches and biomedical research creating massive datasets that are carefully annotated, made widely available, allow for integration across programs, and are sensitive to issues of subject consent, personal privacy, and unintended biases that are crucial for addressing the most significant biomedical problems faced by society. 3) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to health data and information technology. 4) Responds to requests for information on highly technical matters and matters of scientific and public policy related to health data and information technology.

Health Promotion and Disease Detection Office (NYA, formerly HNYA). 1) Advances approaches, interventions, and technologies that further the overall health and wellness of

Americans and prevent diseases. 2) Promotes innovation in tools, technologies, processes, or other approaches that enhance early detection of diseases. 3) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to health promotion and disease detection. 4) Responds to requests for information on highly technical matters and matters of public policy related to health promotion and disease detection.

Health Resources and Policies Office (NYB, formerly HNYB). 1) Advances progress in confronting challenges to the overall ecosystem of biomedical and health research, whether they be processes, policies, or models, to enable acceleration of advances. 2) Applies scientific and engineering principles to solve challenges that delay the delivery of technologies, interventions, or other approaches to the patient. 3) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to health resources and policy. 4) Responds to requests for information on highly technical matters and matters of scientific and public policy related to health resources and policy.

Systems Technology Office (NYC, formerly HNYC). 1) Focuses on those systems that impact health – from physiologic systems (e.g., immune) to the healthcare system and everything in between. 2) Speeds progress in the integration of systems, including and especially technological approaches to doing so. 3) Advises the ARPA-H Director on matters concerning ARPA-H-sponsored research activities related to health systems technology. 4) Responds to requests for information on highly technical matters and matters of scientific and public policy related to health systems technology.

Equity and Inclusion Office (NYD, formerly HNYD). 1) Coordinates, facilitates, and supports programs to ensure equity, diversity, and inclusion in all aspects of ARPA-H's work. 2) Provides strategic and programmatic leadership for ARPA-H's efforts to reduce health

disparities and foster health equity in biomedical research. 3) Evaluates ARPA-H's progress towards achieving greater diversity and health equity in biomedical and health research. 4) Promotes ARPA-H efforts to build a diverse cohort of collaborators, staff, performers, and others.

Strategic Planning, Evaluation, and Analytics Office (NYE, formerly HNYE). 1) Oversees ARPA-H-wide planning, evaluation, and analysis/analytic activities. 2) Advises ARPA-H leadership and staff on all aspects of strategic planning, reporting, and operational effectiveness for ARPA-H activities. 3) Provides leadership and guidance to ARPA-H's business community in the development and oversight of a strategic administrative management plan, goals, organizational effectiveness and business analytics. 4) Oversees the development of analytic and evaluation strategies to drive greater efficiency and effectiveness in administrative and programmatic operations.

Innovation and Entrepreneurship Office (NYF, formerly HNYF). 1) Inspires innovation and creativity throughout ARPA-H, including stimulating the culture of innovation, ideation, and dynamic thinking and leveraging design research and design thinking. 2) Promotes practical strategies to provide resources for programs and projects to incorporate and implement transition principles to inform innovation in overall ARPA-H commercialization strategies. 3) Serves as the ARPA-H focal point for the management of all Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program activities, and implementation of pertinent legislation, rules and regulations and associated matters related to the SBIR/STTR Program. 4) Proposes and implements innovative strategies to promote the commercialization of innovative high impact technologies including research tools, medical devices, and therapeutics throughout the program development and management lifecycle. 5) Assesses the commercial potential of ARPA-H technology priorities and provides guidance

on how best to structure programs, projects, and goals for successful transition.

DELEGATIONS OF AUTHORITY: All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this amendment and are consistent with this amendment shall continue in effect, pending further redelegation.

Dated: May 24, 2022.

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Xavier Becerra

Secretary

U.S. Department of Health and Human Services

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