

**Key Provisions for Academic Medicine in the
Consolidated Appropriations Act, 2023 (H.R. 2617)
December 22, 2022**

This document prepared by the Association of Academic Medical Colleges Office of Government Relations (AAMC OGR) summarizes key provisions of the [Consolidated Appropriations Act, 2023](#), that are of interest to academic medicine. This package, referred to as the omnibus, includes nearly \$1.7 trillion in fiscal year (FY) 2023 discretionary government funding for all 12 annual spending bills, as well as a host of other provisions, including a number related to health care. After prolonged negotiations, the Senate reached a bipartisan agreement on various procedural issues and passed the \$1.7 trillion spending package by a vote of 68 – 29 on Dec. 22. The legislation now moves to the House for consideration where it is also expected to pass. The Biden Administration issued a [Statement of Administration Policy](#) expressing support for the omnibus and the President’s intent to sign.

Upon its release, AAMC President and CEO David J. Skorton, MD, and Chief Public Policy Officer Danielle Turnipseed, JD, issued a [Dec. 20 statement](#) expressing appreciation for the bipartisan efforts to provide crucial investments to support the work of academic medicine to improve the health of patients, families, and communities and urging Congress to pass the package.

For ease of reference, this document is ordered by Division consistent with the legislation.

Division B: Commerce Justice Science (CJS) Appropriations

National Science Foundation (NSF)

According to the [Senate-prepared summary](#), the bill provides a total of \$9.9 billion for the NSF through the CJS appropriations provisions as well as through supplemental funding. The funding total would represent an increase of \$1.04 billion (12%) over the comparable FY 2022 funding level, and includes specific funding for the implementation of the CHIPS and Science Act (referred to as the Research and Development, Competition, and Innovation Act). Additional details about the NSF funding level are available in the Commerce, Justice, Science [joint explanatory statement](#).

Division H: Labor, Health and Human Services (HHS), and Education Appropriations

According to the House-prepared Labor-HHS-Education [summary](#) and [joint explanatory statement](#), the bill would provide a total of \$226.8 billion for the Departments of Labor, Health and Human Services (HHS), and Education, including \$120.7 billion in base discretionary funding for HHS, an increase of \$9.9 billion (8.9%) over the comparable FY 2022 funding level. In the introduction, the joint explanatory statement states that “unless otherwise noted, the language set forth in [House Report 117-403](#) carries the same weight as language included in this explanatory statement and should be complied with unless specifically addressed to the contrary in this explanatory statement.”

National Institutes of Health (NIH) & Other Research-related Provisions

The bill provides a total of \$47.459 billion for the NIH in FY 2023, an increase of \$2.5 billion (5.6%) above the FY 2022 enacted level, [as supported by](#) the AAMC and its convened Ad Hoc Group for Medical Research. This funding level includes the full \$1.1 billion provided to the NIH in FY 2023 through the Innovation Account in the 21st Century Cures Act.

The bill retains the salary cap at Executive Level II of the federal pay scale. The bill also includes increases for the NIH Clinical and Translational Science Awards (CTSA) program (\$629.6, an increase of \$22.9 million) and the Institutional Development Award (IDeA) program (\$426 million,

an increase of \$15.6 million), among other increases. The bill notes that none of the funds provided “may be used to support any activity conducted by, or associated with, the Wuhan Institute of Virology.”

The joint explanatory statement includes language on several research-related issues.

- *Collection and Reporting of Animal Research Numbers and Agency Funding.* The explanatory statement reiterates the requested plan “to improve the accuracy and transparency of collected data on the use of animals in NIH-funded research,” including a draft form for the annual collection of this data.
- *Foreign government influence.* As in FY 2022, the bill includes \$2.5 million to the NIH Office of Extramural Research to “expeditiously complete foreign influence investigations.”
- *Regional Biocontainment Laboratories.* The agreement directs \$52 million within the NIH National Institute of Allergy and Infectious Diseases (NIAID) to be evenly divided among the 12 regional biocontainment labs to support research, train new researchers, maintain a skilled BSL-3 workforce, and establish best practices for BSL-3 facilities.
- *Biomedical Research Facilities.* The bill provides \$80 million within the NIH Office of the Director for grants to public and/or non-profit entities to “expand, remodel, renovate, or alter” existing research facilities, an increase of \$10 million above the FY 2022 level.
- *Increasing Diversity in Biomedical Research.* Under the National Institute of General Medical Sciences, the explanatory statement notes a \$10 million increase for programs like the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program and the Minority Access to Research Careers undergraduate programs.

The Ad Hoc Group, convened by the AAMC, [issued a press statement](#) in response to the release of the omnibus text, applauding appropriators for including an eighth-straight year of bipartisan funding growth in the agency, and urging all lawmakers to “work quickly to pass the omnibus.”

Advanced Research Projects Agency for Health (ARPA-H)

The omnibus provides \$1.5 billion for the Advanced Research Projects Agency for Health (ARPA-H) through FY 2025 (\$500 million, or a 50% increase over FY 2022) through the HHS Office of the Secretary in FY 2023. As in FY 2022, the Secretary would have the authority to transfer the funding to NIH or another HHS agency within 30 days of the bill’s enactment. The bill also includes authorizing language for ARPA-H to be established separately within the NIH (additional detail below).

Centers for Disease Control and Prevention (CDC)

The omnibus provides a program level of \$9.22 billion for CDC, including funds provided by the Prevention and Public Health Fund, an increase of \$760 million (8.9%) above the FY 2022 program level. Within the total, the bill includes \$175 million for public health data modernization, a \$75 million increase (75%) above the FY 2022 enacted level.

The Racial and Ethnic Approaches to Community Health (REACH) program receives \$68.9 million, a \$3 million (4.6%) increase over FY 2022 levels. The bill provides a flat \$8 million for the CDC Social Determinants of Health Pilot Program in FY 2023, which will provide grants to state, local, territorial, or tribal jurisdictions to support the development of Social Determinants of Health Accelerator Plans.

The omnibus package also makes significant investments in improving maternal health, including \$108 million, an increase of \$25 million (30.1%) above the FY 2022 enacted level, for the Safe Motherhood/Infant Health program.

The bill also includes \$40 million, a \$5 million (14.3%) increase over FY 2022 for the Advanced Molecular Detection program.

Agency for Healthcare Research and Quality (AHRQ)

The spending bill provides \$373.5 million for AHRQ, an increase of \$23.1 million (6.6%) above the FY 2022 spending level.

Gun Violence Prevention Research

For a fourth year in a row, the legislation includes dedicated funding for firearm injury and mortality prevention research, with \$12.5 million for the CDC and \$12.5 million for the NIH, the same funding levels as FY 2022.

Health Resources and Services Administration (HRSA)

The legislation provides \$879.8 million for the Title VII Health Professions and Title VIII Nursing workforce development programs in FY 2023, a \$60.6 million (12%) increase above FY 2022 comparable levels. Despite proposed funding in both the House and Senate FY 2023 draft spending bills, the Preventing Burnout in the Health Workforce program, authorized by Dr. Lorna Breen Health Care Provider Protection Act (P.L. 117-105), did not receive any discretionary funding in the omnibus package. Out of the total, \$28.4 million (a \$4 million or 16% increase) was set aside for the Centers of Excellence, and \$2.3 million (a \$1.08 million or 88% increase) for the Faculty Loan Repayment Program. For a more detailed breakdown of the Title VII/VIII FY 2023 funding levels by program, please refer to the [HPNEC funding table](#).

The bill also includes funding for the following HRSA workforce programs:

- \$385 million for the Children's Hospitals Graduate Medical Education program (a \$10 million or 2.7% increase over FY 2022).
- \$125.6 million for the National Health Service Corps (NHSC) discretionary appropriation (a \$4 million or 3.28% increase). The NHSC receives the majority of its support through a mandatory funding mechanism.
- \$12.5 million for the Rural Residency Program (a \$2 million or 19% increase).

Preparedness

The omnibus provides \$305 million for the Hospital Preparedness Program (HPP) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), an increase of \$9.5 million (3.2%) over the FY 2022 level. Within the HPP total, the bill provides \$7.5 million for the National Emerging Special Pathogens Training and Education Center (NETEC), an increase of \$1 million (15%). The HPP total also includes \$21 million (flat funding) for the Regional Emerging Special Pathogen Treatment Centers (RESPTCs). The agreement also provides \$9.2 million for academic centers for public health preparedness.

Department of Education

The agreement includes \$50 million for planning and implementation grants designed to promote transformational investments in research infrastructure at four-year historically Black colleges and

universities (HBCUs), tribal colleges and universities (TCUs), or minority-serving institutions (MSIs), either alone or as the lead entity in consortia.

The bill makes additional investments in HBCUs, TCUs, and MSIs to institutional capacity and student support including \$100.8 million for the Strengthening Historically Black Graduate Institutions Program (a \$7.7 million or 8.3% increase).

Division J: Military Construction & Veterans Affairs Appropriations

Department of Veterans Affairs (VA)

According to the Senate Appropriations Committee-prepared [summary](#), the legislation includes \$135.2 billion in nondefense discretionary funding for the VA and military construction, an increase of \$34 billion above the fiscal year 2022 level, a 34% increase. The Military Construction, VA, and Related Agencies joint explanatory statement is [here](#).

VA Medical Services

The bill provides an additional \$216 million for VA Medical Services for FY 2023 beyond the \$70.3 billion provided as advanced appropriations for FY 2023 in the FY 2022 spending bill. FY 2023 funding for VA Medical Services represents a \$11.7 billion (19.8%) increase over the comparable FY 2022 spending level. The bill also provides \$74 billion in FY 2024 advanced appropriations.

VA Medical Community Care

The bill provides an additional investment of \$4.3 billion in FY 2023 funding, in addition to \$24.2 billion provided in the prior year's appropriation, for a \$5 billion (21.5%) increase in FY 2023 over the comparable FY 2022 spending level. The bill also provides \$33 billion in FY 2024 advanced appropriations.

VA Medical and Prosthetic Research Program

The bill provides a total of \$916 million for the VA research program in FY 2023, a \$34 million (3.9%) increase above the FY 2022 funding level.

The [joint explanatory statement](#) includes text on the following issues:

- *Animal Research.* Congress continues to limit research on dogs, cats, and non-human primates and directs VA to report to Congress on alternatives to animal models that were considered and why they were not chosen for specific research projects.
- *Access to Clinical Oncology Trials.* The report directs the VA to allocate at least \$10 million to support partnerships with National Cancer Institute-designated comprehensive cancer centers to improve veterans' access to clinical trials.

Division O – Extenders and Technical Corrections

Title III – Immigration Extensions

Sec. 304 - The omnibus includes a clean extension of the Conrad 30 J-1 visa waiver program through FY 2023. Sens. Klobuchar and Collins and Reps. Schneider and Bacon led Dear Colleague Letters to include the Conrad State 30 and Physician Access Reauthorization Act (S. 1810, H.R. 3541) into the year-end package. This program is of no cost to taxpayers.

Title X – Budgetary Effects

Sec. 1001 – Provides a two-year delay of Statutory Pay-As-You-Go Act (PAYGO) 4% Medicare sequester, avoiding \$38 billion in Medicare provider cuts. The AAMC supported and asked for the delay of this cut, as it impacts the financial viability of faculty physician practices and threatens the access of Medicare patients to their providers.

Division U: Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022

Chapter 4, Subtitle G – Research Matters (p. 2482, VIPER Act)

- Also included in the omnibus is text of the AAMC-endorsed VA Infrastructure Powers Exceptional Research (VIPER) Act of 2021, which will improve the functionality and efficiency of the VA Medical and Prosthetic Research program while also ensuring continuity of existing research affiliations in light of updated guidance from the VA that would impact outside salary support for VA researchers.

Division FF: Health and Human Services: Health Extenders and Strengthening Public Health Act of 2022

Title I – Restoring Hope for Mental Health and Well-Being

Subtitle A – Mental Health and Crisis Care Needs

Chapter 2 – Into the Light for Maternal Mental Health and Substance Use Disorders

Sec. 1111 – Reauthorizes the Screening and Treatment for Maternal Mental Health and Substance Use Disorder program, which provides grants for states to establish, improve, or maintain programs that aim to improve the detection and treatment of perinatal behavioral health conditions. Authorizes \$24 million annually for FY 2023 through FY 2028.

Sec. 1112 – Establishes a national maternal mental health hotline to provide information, brief intervention, and resources to individuals affected by or at risk for perinatal mood disorders. Authorizes \$10 million annually for FY 2023 through FY 2028.

Sec. 1113 – Directs the HHS Secretary to convene a task force examining federal strategies to improve access to maternal mental health care.

Subtitle B – Substance Use Disorder Prevention, Treatment, and Recovery Services

Chapter 5 – Timely Treatment for Opioid Use Disorder

Sec. 1251 – Directs the Assistant Secretary for Mental Health and Substance Use to conduct a study within 180 days regarding the impact of opioid treatment program (OTP) flexibilities provided during the COVID-19 public health emergency.

Sec. 1252 – Changes federal opioid treatment standards to allow an OTP to operate one or more mobile units to dispense medications at locations other than the registrant's primary place of business under the same registration (as opposed to separately registering each mobile unit). Eliminates the requirement that an individual be addicted to opioids for at least one year prior to being eligible for admittance to an OTP.

Chapter 6 – Additional Provisions Relating to Addiction Treatment

Sec. 1262 – Eliminates the requirement that a health care provider apply for a separate waiver through the Drug Enforcement Administration (DEA) prior to dispensing certain narcotic drugs (e.g., buprenorphine) for the purposes of maintenance or detoxification treatment. This language was originally included in the AAMC-endorsed Mainstreaming Addiction Treatment (MAT) Act ([S. 445/H.R. 1384](#)).

Sec. 1263 – Requires physicians and other prescribers of controlled substances to complete eight hours of training on the treatment and management of opioid and substance use disorders. This language was originally included in the Medication Access and Training Expansion (MATE) Act ([H.R. 2067](#)).

Subtitle C – Access to Mental Health Care and Coverage**Chapter 1 – Improving Uptake and Patient Access to Integrated Care Services**

Sec. 1301 – Reauthorizes a program that allows HHS to award grants to states that partner with a community program, health center, or primary care practice to implement and evaluate integrated behavioral health models. Authorizes incentive payments for practices that implement the Collaborative Care Model (CoCM).

Chapter 2 – Helping Enable Access to Lifesaving Services

Sec. 1311 – Reauthorizes multiple programs to strengthen the behavioral health workforce, including the Mental and Behavioral Health Workforce Education and Training grant program, reauthorized as a HRSA Title VII grant program through FY 2027 at \$50 million annually.

Sec. 1312 – Reauthorizes the Minority Fellowship Program through FY 2027 at \$25 million annually.

Title IV– Medicare Provisions**Subtitle B – Other Expiring Medicare Provisions**

Sec. 4111 – Extends the incentive payment for participation in eligible alternative payment models (APMs) at 3.5% to 2025.

Sec. 4112 – Adjusts the Medicare Physician Fee Schedule (PFS) conversion factor cuts, scheduled to be nearly 4.5% in 2023, to 2.5% in 2023 and 1.25% in 2024.

Sec. 4113 – Extends key Medicare COVID-19 telehealth waivers through Dec. 31, 2024, in the following ways:

- Removes geographic requirements and expands originating sites for telehealth services.
- Allows qualified occupational therapists, physical therapists, speech language pathologists, and audiologists to provide telehealth services.
- Allows federally qualified health centers and rural health clinics to continue to be reimbursed for telehealth services as distant site providers.
- Delays the implementation of the in-person requirements for Medicare tele-mental health services.
- Allows Medicare beneficiaries to continue to receive audio-only telehealth visits.

- Continues flexibility for hospices to use virtual visits to meet the face-to-face visit requirement for recertification for eligibility for the hospice benefit.
- Requires the HHS Secretary to complete a study on telehealth and Medicare program integrity with an interim report due on Oct. 1, 2024, and a final report due on April 1, 2026.

Sec. 4114 – Provides a one-year delay of Clinical Laboratory Fee Schedule payment cuts and data reporting requirements until Jan. 1, 2024.

Subtitle C – Medicare Mental Health Provisions

Sec. 4122 – Provides 200 new, Medicare-supported graduate medical education (GME) slots in 2026 with 100 specifically designated for psychiatry and psychiatry subspecialties and no restrictions on the remaining positions. AAMC led and championed this provision. The following categories of teaching hospitals will each receive 10% of the slots: rural teaching hospitals, teaching hospitals over their current GME caps, teaching hospitals in states with new medical schools or branch campuses, and teaching hospitals serving Health Professional Shortage Areas (HPSAs).

Sec. 4123 – Beginning January 1, 2024, establishes a 50% payment increase under the Medicare Physician Fee Schedule (PFS) for crisis services furnished by a mobile crisis unit or in other non-office settings (HCPCS codes 90839 and 90840). Requires the HHS Secretary to provide education and outreach with respect to the ability of health care providers to bill for crisis services under the PFS. Directs the HHS Secretary to provide education regarding the ability of auxiliary personnel, including peer support specialists, to furnish crisis services and behavioral health integration services.

Sec. 4124 – Beginning January 1, 2024, revises Medicare’s partial hospitalization benefit to provide coverage for intensive outpatient services.

Sec. 4125 – Directs HHS to begin collecting data necessary to revise the Medicare prospective payment system for inpatient psychiatric hospitals and psychiatric units.

Sec. 4126 – Adds a new exemption to the Stark Law to allow hospitals and other health care organizations to provide evidence-based physician wellness programs.

Sec. 4128 – Directs HHS to conduct outreach to physicians and other health care providers regarding the availability of behavioral health integration services as a covered benefit under Medicare. Requires a report to Congress on the methods used for provider outreach and the number of Medicare beneficiaries who were provided with behavioral health integration services.

Sec. 4129 – Requires HHS to conduct outreach to physicians and other health care providers regarding the inclusion of services furnished by an opioid treatment program (OTP) as a covered benefit under Medicare.

Subtitle D – Other Medicare Provisions

Sec. 4140 – Extends the AAMC-supported Acute Hospital Care at Home program waiver until Dec. 31, 2024.

TITLE V – Medicaid and CHIP Provisions
Subtitle B – Medicaid and CHIP Coverage

Sec. 5111 – Extends funding for the Children’s Health Insurance Program (CHIP) for two years, through FY 2029.

Sec. 5112 – Requires states to provide children under the age of 19 with continuous coverage under Medicaid or CHIP, effective January 1, 2024.

Sec. 5113 – Permanently extends the American Rescue Plan provision that created a state plan option to extend postpartum Medicaid coverage up to one year.

Sec. 5131 – Sunsets the Families First Coronavirus Response Act’s enhanced Medicaid funding and continuous coverage requirement on April 1, 2023. Allows states to begin the process of initiating redeterminations for Medicaid eligibility over a period of at least 12 months. Provides states with enhancing Medicaid funding for April 1, 2023, through Dec. 31, 2023, subject to meeting certain requirements, including updating beneficiaries’ contact information and using more than one modality to contact beneficiaries in the case of returned mail. Establishes public reporting requirements for all states during the redetermination period and provides additional enforcement mechanisms for the Centers for Medicare and Medicaid Services during this period.

Title II – Preparing For And Responding To Existing Viruses, Emerging New Threats, And Pandemics (PREVENTS) Act

The end-of-year omnibus includes many provisions of the HELP Committee-approved PREVENT Pandemics Act ([S. 3799](#)). Of note, the omnibus includes:

Subtitle A – Strengthening Federal and State Preparedness

Chapter 1 – Federal Leadership and Accountability

Sec. 2101 – 2102 – Requires Senate confirmation of the CDC director (beginning Jan. 20, 2025), outlines specific authorities of the director, and establishes an advisory committee to the director. Under Sec. 2101, the director is responsible for submitting the CDC Strategic Plan that facilitates coordination with private sector agencies; state, local, and Tribal health departments; other public sector entities; and other offices and agencies under HHS.

Sec. 2104 – Establishes the White House Office of Pandemic Preparedness and Response Policy, and the authorities of its director, who will be appointed by the President. The director is also responsible for submitting a preparedness outlook report and convening an interdepartmental working group that will evaluate national biosecurity and pandemic preparedness.

Chapter 2 – State and Local Readiness

Sec. 2113 – Reauthorizes the trauma care program to improve and coordinate trauma care and emergency medical services during a public health emergency. Grants to improve trauma care in rural areas and for trauma centers (Level I, II, and III) are also included in this section.

Subtitle B – Improving Public Health Preparedness and Response Capacity

Chapter 1 – Improving Public Health Emergency Responses

Sec. 2201 - Allows for HHS to award grants, contracts, or cooperative agreements for evidence-based projects that address factors related to improving health outcomes, including but not limited to, developing networks that increase the capacity of eligible entities to address these factors. (Note that the section was originally titled “Addressing social determinants of health and improving health outcomes” in the PREVENT Pandemics Act.)

Chapter 2 – Improving State, Local, and Tribal Public Health Data

Sec. 2211 – Aims to modernize state, local, and tribal biosurveillance capabilities, including but not limited to: integrating and updating existing public health data systems and HHS networks; integrating laboratory and public health data systems and capabilities to support rapid and accurate lab test results; improving data collection, reporting, and dissemination; and the electronic exchange of health information between states and health provider and facilities.

Sec. 2212 – Includes text of the Tracking Pathogens Act ([S. 3534](#)) which requires directors of federal agencies to expand activities related to advanced molecular detection and genomic sequencing of pathogens, including through partnerships with academic institutions.

Sec. 2213 – Includes provisions to improve information sharing and availability of public health data by requiring the Office of the National Coordinator for Health Information Technology (ONCHIT) to assess laboratory information standards, including standards for electronic ordering and reporting of laboratory test results, and supports information sharing through data use agreements for public health emergencies as directed by the HHS Secretary. (Note that this section is similar to Sec. 213. of the PREVENT Pandemics Act.)

Sec. 2214 – Includes provisions that enhance the prediction, modeling, and forecasting of disease outbreaks and potential PHEs, and other epidemic forecasting and outbreak analytics capabilities and activities through collaboration with academic institutions and other federal agencies.

Chapter 3 – Revitalizing the Public Health Workforce

Sec. 2221 and 2222 – Establishes the Bio-Preparedness Workforce Pilot Program to provide loan repayment for certain health professionals, and reauthorizes a grant program to promote positive health behaviors and outcomes for medically underserved communities. The Bio-Preparedness Workforce Pilot Program and public health loan repayment program will be included under the HRSA Title VII programs in FY 2023.

Chapter 4 – Enhancing Public Health Preparedness and Response

Sec. 2231 – Allows the CDC to award grants, contracts, or cooperative agreements to institutions of higher education to establish Centers for Public Health Preparedness and Response.

Subtitle C – Accelerating Research and Countermeasure Discovery

Chapter 1 – Fostering Research and Development and Improving Coordination

Sec. 2301 – Requires NIH’s National Institute of Allergy and Infectious Diseases (NIAID) to collaborate with ASPR and BARDA to establish or continue a multidisciplinary research program to advance preclinical development of antivirals and other viral medical countermeasures to address pathogens of pandemic concern. This would include grants, contracts, or cooperative agreements to public or private entities.

Sec. 2303 – Allows HHS to contract with public and private entities toward rapid development of diagnostic tests in a public health response, and requires HHS to develop policies and procedures related to public and private entities accessing specimens of pathogens to support the development of tests.

Chapter 2 – Improving Biosafety and Biosecurity

Sec. 2312 – Requires the White House Office of Science and Technology Policy (OSTP) director to develop a strategy for the maintenance and coordination of BSL-3 and -4 laboratories owned by the federal government or established with federal funding.

Section 2314 – Directs HHS to conduct or support research to improve the safe conduct of biomedical research involving pathogens of pandemic potential or select agents.

Section 2315 – Directs OSTP to review and conduct oversight on existing federal policies regarding federally-funded research that may involve the “creation, transfer, or use of enhanced pathogens of pandemic potential.” Beginning within 60 days of enactment, HHS cannot fund research conducted in a laboratory in a “country of concern” involving pathogens of pandemic potential.

Chapter 3 – Preventing Undue Foreign Influence in Biomedical Research

Section 2321 – Requires NIH grantees to disclose participation in foreign talent recruitment programs.

Section 2322 – Requires the HHS Secretary to develop a risk framework for the conduct of NIH-funded research involving human genomic information that considers any associated national security risks. HHS is required to implement controls related to the risk framework, and update related human genomic data access and sharing policies.

Section 2324 – Requires the HHS Secretary to consult with federal national security and intelligence agencies as well as research institutions and advocacy groups to identify opportunities and strategies to address national security threats to biomedical research and intellectual property, as well as identify emerging federally-funded research areas of interest for foreign adversaries.

Chapter 4 – Advanced Research Projects Agency-Health (ARPA-H)

This chapter includes authorizing language for ARPA-H, including its establishment within the NIH. The bill authorizes no more than eight program offices, with no fewer than two-thirds dedicated to supporting research and development activities. The HHS Secretary may exempt ARPA-H from certain NIH policies and requirements, and must publish a notice in the Federal Register describing the policies from which ARPA-H will be exempt. The ARPA-H director will serve a four-year term

and may be reappointed for a second consecutive term. Regarding location, the bill prohibits ARPA-H from being located on existing NIH campuses, and requires the agency to have offices or facilities in at least three geographic areas. Program managers will be appointed by the director for 3-year terms with the ability for one consecutive reappointment. The director is required to provide a strategic plan to Congressional authorizing committees not later than one year after enactment of the law. The bill authorizes \$500 million per year for FY 2024 through FY 2028 for the agency.

Subtitle D – Modernizing and Strengthening the Supply Chain for Vital Medical Products

Sec. 2401 – 2409 – Addresses warm base manufacturing and the Strategic National Stockpile (SNS) including supply chain considerations, maintenance and use of the SNS, authority for the HHS to sell excess products, and a pilot program for grants to support State-based strategic stockpiles.

Title III – Food and Drug Administration

Subtitle F – Cross-Cutting Provisions

Chapter 1 – Clinical Trial Diversity and Modernization

This chapter combines text from Title V – Improving Diversity in Clinical Studies from the House-passed Food and Drug Amendments of 2022 ([H.R. 7667](#)) and Title V – Enhancing Development and Combating Shortages of Medical Products of the HELP Committee-approved PREVENT Pandemics Act ([S. 3799](#)). This chapter requires certain trial sponsors to include diversity action plans in their trial design as well as a requirement for the FDA to issue guidance on these action plans. The FDA is also required to convene one or more public workshops to solicit input on increasing diversity in clinical trial enrollment. The omnibus also includes language requiring FDA to issue guidance regarding decentralized clinical trials and opportunities to modernize clinical trials, including utilization of digital health technologies.

Other Provisions

VALID Act

Of note, the omnibus does not include the VALID Act or language which would have authorized FDA regulation of laboratory-developed tests in a manner that likely would have had detrimental impacts on academic medicine and patient care delivery. The lack of VALID Act provisions is a result of this community's work to educate lawmakers about academic clinical labs unique role in patient care delivery and coordination at academic medical centers.