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Advanced Research Projects Agency for Health (ARPA-H): Congressional Action and Selected Policy Issues

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Through FY2022 appropriations (P.L. 117-103), Congress provided \$1 billion to the Department of Health and Human Services (HHS) to establish the Advanced Research Projects Agency for Health (ARPA-H). The law provided funding to a new ARPA-H account at HHS, available until September 30, 2024, and allowed the HHS Secretary to place the new agency anywhere within the department within 30 days of enactment. On March 30, 2022, HHS Secretary Xavier Becerra submitted a notice to the appropriations committees that ARPA-H is to reside within the National Institutes of Health (NIH), while the ARPA-H Director is to report directly to the HHS Secretary.

The Biden Administration originally proposed ARPA-H as part of the President’s FY2022 budget request for the NIH. The budget request sought \$6.5 billion for ARPA-H over three years to “drive transformational health research innovation and speed medical breakthroughs by tackling ambitious challenges requiring large-scale, sustained, and cross-sector coordination.” As proposed by the Biden Administration, the initial focus of ARPA-H would have included building platforms and capabilities to try to deliver cures for diseases such as cancer, Alzheimer’s disease, and diabetes.

Absent additional legislation, the FY2022 appropriation gives HHS considerable flexibility to design and structure the new agency. As proposed by the Biden Administration, ARPA-H is modelled after other “ARPAs,” especially the Defense Advanced Research Projects Agency (DARPA) and the Advanced Research Projects Agency-Energy (ARPA-E). The “ARPA model” involves an organizational structure designed to be flat and nimble, staffed by tenure-limited program managers with a high degree of autonomy to select and fund research projects using a milestone-based contract approach. In contrast, NIH relies predominantly on the scientific peer review process to award most of its funding. Some evidence suggests that this investigator-driven and consensus-based process is less likely to fund transformative or “high-risk, high-reward” projects. Supporters of the proposal argue that high-risk, high-reward biomedical research may lead to health breakthroughs on a faster timeline and is critical to ensuring U.S. competitiveness and addressing societal challenges.

Several bills are being considered in the 117th Congress that would codify and further delineate ARPA-H’s goals, structure, placement, activities, and authorities. A Senate proposal, S. 3819, was incorporated into the PREVENT Pandemics Act (S. 3799), in an amendment in the nature of a substitute, and ordered to be reported by the Senate Committee on Health, Education, Labor, and Pensions (HELP) on March 15, 2022. Meanwhile, the Advanced Research Projects Agency for Health Act (H.R. 5585) passed the House on June 22, 2022. As Congress continues its deliberations on ARPA-H, several policy debates remain. Such debates include (1) where to place ARPA-H within the federal government and how to facilitate its independence and autonomy, (2) what the appropriate goals are for ARPA-H and how to prevent its activities and programs from duplicating the efforts of other federal agencies and the private sector, and (3) what the appropriate current and future appropriations levels are for ARPA-H.

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Introduction

The federal government has long invested in biomedical science through the National Institutes of Health (NIH). This investment has been credited with contributing to advances in treating disease and providing medical care, increasing life expectancy, and preventing millions of deaths. For much of its history, NIH has focused in large part on supporting basic research: research that explores the fundamental mechanisms of biology and behavior. Such research facilitates scientific knowledge that informs medical advances. Traditionally, the private sector, such as the biopharmaceutical industry, has largely taken on the role of supporting research and development (R&D) activities aimed at bringing new technologies and products to market, such as pharmaceutical drugs.¹

In recent years, legislation such as the 21st Century Cures Act (P.L. 114-255) and the provisions establishing the National Center for Advancing Translational Sciences (NCATS)² have expanded NIH's role in biomedical innovation, that is, research efforts aimed at driving new paradigms and potentially breakthrough science and technologies.³ The Biden Administration continued this trend by proposing a new Advanced Research Projects Agency for Health (ARPA-H) at NIH in its FY2022 budget request.⁴

In March 2022, Congress adopted the ARPA-H proposal in the Consolidated Appropriations Act, 2022 (P.L. 117-103), which provided \$1 billion to a new Department of Health and Human Services (HHS) account to establish ARPA-H (in Division H, Labor, HHS, Education, and Related Agencies Appropriations Act, LHHS). Both chambers are considering bills that would codify ARPA-H and define its goals, scope, placement, activities, and authorities (e.g., H.R. 5585 and S. 3819). Subsequently, S. 3819 was incorporated into the PREVENT Pandemics Act (S. 3799) as amended and ordered to be reported by the Senate Committee on Health, Education, Labor, and Pensions (HELP) on March 15, 2022. The House passed H.R. 5585 on June 22, 2022.

The ARPA-H proposal responds to concerns by some in the scientific and patient advocacy communities that traditional funding processes are too risk averse—supporting incremental advances over high-risk, high-reward, or potentially transformative research.⁵ Support for high-risk, high-reward research is considered an important element in developing breakthrough technologies that address societal challenges, including health-related challenges, and in

¹ For more information on NIH and the process of pharmaceutical drug development, see CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Judith A. Johnson and Kavya Sekar; and CRS Infographic IG10013, *The Pharmaceutical Drug Development Process*, by Agata Bodie and Kavya Sekar.

² NCATS was established by the Consolidated Appropriations Act, 2012 (P.L. 112-74).

³ The NIH defines *innovation* as “something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies.” NIH peer review criteria also uses the following criteria to evaluate innovation in a research proposal: “Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?” See <https://grants.nih.gov/grants/peer/critiques/rpg.htm>.

⁴ White House, Office of Science and Technology Policy, “Advanced Research Projects Agency for Health (ARPA-H),” <https://www.whitehouse.gov/ostp/advanced-research-projects-agency-for-health-arpa-h/>.

⁵ For example, see Suzanne Wright Foundation, “HARPA: Health Advanced Research Projects Agency,” <https://www.harpa.org/>; and Bhaven N. Sampat, and Robert Cook-Deegan, “An ARPA for Health Research?,” *Milbank Quarterly*, <https://www.milbank.org/quarterly/opinions/an-arpa-for-health-research/>.

maintaining the economic competitiveness of the United States.⁶ In addition, the recent rapid development of safe and effective Coronavirus Disease 2019 (COVID-19) vaccines based on novel technologies such as messenger RNA (mRNA), built partly upon investments by the Defense Advanced Research Projects Agency (DARPA), has spurred increased interest in the usefulness and value of the “ARPA model” or other innovative approaches for biomedical research in general.⁷

This report provides an overview of ARPA-H as proposed by the Biden Administration, outlines congressional action as of the date of the report, and discusses selected policy issues still under debate as Congress considers legislation that would explicitly authorize ARPA-H. The **Appendix** provides a side-by-side comparison of key provisions in the legislative proposals that would codify ARPA-H.

Overview of the Biden Administration’s ARPA-H Proposal

The Biden Administration laid out its vision for the proposed ARPA-H in NIH’s FY2022 budget request. Administration officials also published an ARPA-H concept paper and an article in *Science* magazine, authored by then-NIH Director Francis Collins, then-director of the White House Office of Science and Technology Policy (OSTP) Eric Lander, and others, both of which laid out a more detailed vision and justification for the proposed agency.⁸ According to the proposal, ARPA-H would be modeled after the Defense Advanced Research Projects Agency (DARPA), which is part of the Department of Defense (DOD), and would contain several “ARPA model” characteristics, including a flat organizational structure designed to be nimble and staffed by tenure-limited program managers with a high degree of autonomy to select and fund projects using a milestone-based contract approach.⁹ NIH, in contrast, generally funds most of its research through the scientific peer review process—a committee-based review process to evaluate scientific investigator-driven research proposals for funding.¹⁰ Some data suggests that this investigator-driven and consensus-based process may not adequately fund “high-risk, high-reward” projects,¹¹ a term often associated with projects that have high potential for meeting

⁶ Organization for Economic Cooperation and Development (OECD), *Effective Policies to Foster High-Risk/High-Reward Research*, OECD Science, Technology, and Industry Policy Papers, No. 112, May 2021, <https://read.oecd.org/10.1787/06913b3b-en?format=pdf>.

⁷ CRS Insight IN11446, *DARPA’s Pandemic-Related Programs*, by Marcy E. Gallo; and Chiara Franzoni, Paula Stephan, and Reinilde Veugelers, “Funding Risky Research,” National Bureau of Economic Research Working Paper, June 2021.

⁸ NIH, *Congressional Justification: FY2022*, May 28, 2021, <https://officeofbudget.od.nih.gov/pdfs/FY22/br/2022%20CJ%20Overview%20Volume%20May%2028.pdf>, pp. 1-11; White House, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper*, <https://www.whitehouse.gov/wp-content/uploads/2021/06/ARPA-H-Concept-Paper.pdf>; NIH, “Lander, Collins Set Forth a Vision for ARPA-H,” press release, June 22, 2021, <https://www.nih.gov/news-events/news-releases/lander-collins-set-forth-vision-arpa-h>; and Francis S. Collins et al., “ARPA-H: Accelerating Biomedical Breakthroughs,” *Science*, vol. 373, no. 6551 (July 9, 2021).

⁹ For more information on DARPA, see CRS Report R45088, *Defense Advanced Research Projects Agency: Overview and Issues for Congress*, by Marcy E. Gallo.

¹⁰ See “Peer Review Process for Extramural Funding” in CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Judith A. Johnson and Kavya Sekar.

¹¹ Chiara Franzoni, Paula Stephan, and Reinilde Veugelers, “Funding Risky Research,” *National Bureau of Economic Research Working Paper*, June 2021; Mikko Packalen and Jay Bhattacharya, “NIH Funding and the Pursuit of Edge Science,” *Proceedings of the National Academy of Sciences*, vol. 117, no. 22 (June 2, 2020), pp. 12011-12016; and Pierre Azoulay, Erica Fuchs, and Anna Goldstein, “Funding Breakthrough Research: Promises and Challenges of the ‘ARPA Model,’” *National Bureau of Economic Research*, June 2018.

fundamental scientific or technological challenges, involve a high degree of novelty and/or multidisciplinary approaches, but also have a higher risk of failure than other projects.¹²

The FY2022 budget request included \$6.5 billion for ARPA-H “to make pivotal investments in breakthrough technologies and broadly applicable platforms, capabilities, resources, and solutions that have the potential to transform important areas of medicine and health for the benefit of all patients and that cannot readily be accomplished through traditional research or commercial activity.”¹³ According to the proposal, ARPA-H is to “build platforms and capabilities to deliver cures for cancer, Alzheimer’s disease, diabetes, and other diseases.”¹⁴ Additionally, the Administration has provided a list of potential ARPA-H projects, including the development of accurate, wearable, blood pressure technology; the preparation of mRNA vaccines against common forms of cancer; drug or gene therapy delivery systems that can target any organ, tissue, or cell type; and platforms to reduce health disparities in maternal morbidity and mortality, among others.¹⁵

Funding was requested for a period of three years to “allow for both scale-up in FY2022 and redeployment of resources in the next two years if projects fail to meet performance milestones.” The vast majority of funding would support extramural research (i.e., research conducted outside the federal government), with a smaller amount of funding reserved for staffing and administrative functions. Unlike NIH Institutes and Centers (ICs), the proposed ARPA-H would not have its own intramural research program (i.e., research conducted at NIH facilities).¹⁶

The FY2022 budget request described the types of challenges ARPA-H would seek to address through its investments, including:

- Support for complex research and development that requires large-scale, sustained, cross-sector coordination;
- The creation of new capabilities (e.g., technologies, data resources, disease models);
- Support for high-risk exploration that could establish entirely new paradigms; and
- The commercialization of biomedical innovations using financial incentives and other mechanisms.¹⁷

Most ARPA-H awards would support industry, universities, and nonprofit research institutions and may involve some agreements with other federal agencies. While the proposed agency structure would be “operationally distinct” from NIH ICs, ARPA-H would still coordinate research and activities with NIH ICs and other Department of Health and Human Services (HHS) agencies (e.g., the Food and Drug Administration [FDA]).

¹² For a discussion of definitions of “high-risk, high-reward research,” see pages 11-13 of Organization for Economic Cooperation and Development (OECD), *Effective Policies to Foster High-Risk/High-Reward Research*, OECD Science, Technology, and Industry Policy Papers, No. 112, May 2021, <https://read.oecd.org/10.1787/06913b3b-en?format=pdf>.

¹³ White House, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper*.

¹⁴ NIH, *Congressional Justification: FY2022*, pp. 10-11.

¹⁵ NIH, *Congressional Justification: FY2022*, pp. 10-11; and White House, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper*.

¹⁶ NIH, *Congressional Justification: FY2022*, pp. 10-11.

¹⁷ NIH, *Congressional Justification: FY2022*, pp. 10-11.

White House Listening Sessions for ARPA-H

In July and August 2021, OSTP and NIH held 15 listening sessions on the proposed ARPA-H with thousands of biomedical stakeholders. In September 2021, OSTP and NIH summarized participant recommendations, which emphasized the following:¹⁸

- **A focus on technologies, rather than specific diseases:** Stakeholders emphasized that ARPA-H should focus on developing technologies that could have applications across a wide range of diseases, rather than focus on specific diseases. Stakeholders also noted specific types of technologies for the new agency to support, such as data-sharing platforms, diagnostics platforms, artificial intelligence and machine learning algorithms, and wearables and digital technologies.
- **Embracing equity and diversity as a cornerstone of the mission:** Stakeholders suggested that equity and diversity considerations should be incorporated into all aspects of ARPA-H, from staffing to project selection and execution. Some also suggested that ARPA-H should prioritize programs that take a holistic approach that considers health in the context of broader environmental, cultural, economic and social factors.
- **Coordination and collaboration:** Participants emphasized the need to partner and consult with diverse private, academic, and public sector entities. Stakeholders advised that ARPA-H should avoid areas that are well-funded by NIH or the private sector, and should pursue projects that are complementary to currently funded efforts. They also emphasized a need for mechanisms to support commercialization of ARPA-H-supported technologies and programs through collaboration with FDA and the Centers for Medicare & Medicaid Services (CMS).

Executive Action

The Consolidated Appropriations Act, 2022 (P.L. 117-103), gave the HHS Secretary the ability to transfer ARPA-H to any HHS agency or office, including NIH, within 30 days of enactment. It required the Secretary to notify Congress at least 15 days in advance of such a transfer. On March 30, 2022, HHS Secretary Becerra submitted a notice to the appropriations committees that ARPA-H would reside within NIH, with the ARPA-H Director reporting directly to the HHS Secretary.¹⁹

On May 25, 2022, HHS Secretary Becerra announced the formal establishment of ARPA-H within NIH and named Dr. Adam H. Russell as the acting interim director for the agency.²⁰ In addition, an organizational structure for ARPA-H was published in the *Federal Register* on May 27, 2022. As outlined in the federal notice, ARPA-H will be composed of 14 offices, as follows:

- **Acquisition and Contracting Office:** Advises the ARPA-H Director and staff on acquisition and contract and grant financial advisory services.

¹⁸ White House Office of Science and Technology Policy and NIH, *Listening Sessions for ARPA-H: Summary Report*, https://www.whitehouse.gov/wp-content/uploads/2021/09/093021-ARPA-H-Listening-Session-Summary_Final.pdf.

¹⁹ Lev Facher, “Biden’s High-Stakes Biomedical Science Agency ARPA-H Will Be Part of the NIH—But There’s a Twist,” STAT, March 31, 2022.

²⁰ Department of Health and Human Services, “HHS Secretary Becerra Establishes ARPA-H within NIH, Names Adam H. Russell, D.Phil. Acting Deputy Director,” press release, May 25, 2022, <https://www.hhs.gov/about/news/2022/05/25/hhs-secretary-becerra-establishes-arpa-h-within-nih-names-adam-h-russell-phil-acting-deputy-director.html>.

- **Comptroller's Office:** 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.
- **Engagement and Communications Office:** 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.
- **Legislative and Governmental Affairs Office:** 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.
- **Strategic Resources Office:** Advises the ARPA-H Director and staff on all phases of ARPA-H-wide administration and management.
- **Treatment Innovation Office:** Furthers development of novel and innovative therapeutics or other interventions to manage, treat, or cure diseases and conditions.
- **Health Equity, Dissemination, and Implementation Office:** Advances programs that concentrate on promoting health equity, access to care, and ethical aspects of science and technology development.
- **Health Promotion and Disease Detection Office:** Advances approaches, interventions, and technologies that further the overall health and wellness of Americans and prevent diseases.
- **Health Resources and Policies Office:** 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.
- **Systems Technology Office:** Focuses on those systems that impact health—from physiologic systems (e.g., immune) to the health care system and everything in between.
- **Equity and Inclusion Office:** Coordinates, facilitates, and supports programs to ensure equity, diversity, and inclusion in all aspects of ARPA-H's work.
- **Strategic Planning, Evaluation, and Analytics Office:** Oversees ARPA-H-wide planning, evaluation, and analysis/analytic activities.
- **Innovation and Entrepreneurship Office:** Inspires innovation and creativity throughout ARPA-H, including stimulating the culture of innovation, ideation, and dynamic thinking and leveraging design research and design thinking.²¹

²¹ National Institutes of Health, "Establishment of the Advanced Research Projects Agency for Health," 87 *Federal Register* 32174-32176, May 27, 2022.

Congressional Action

Appropriations

FY2022

Enacted: On March 15, 2022, the Consolidated Appropriations Act, 2022 (P.L. 117-103) was signed into law. It provided \$1 billion in appropriations to a new account at HHS for ARPA-H, with funding available until September 30, 2024.²² Unlike earlier ARPA-H appropriations proposals, the law did not condition the availability of funds on enactment of legislation specifically establishing ARPA-H. Thus, this legislation does not preclude the Administration from moving forward with establishing ARPA-H and provides for the following implementation activities:

- presidential appointment of the ARPA-H Director;
- hiring and appointment flexibilities;
- the ability to make awards as grants, contracts, cooperative agreement, and other transactions;²³
- exemption from NIH scientific peer review requirements; and
- the ability of the HHS Secretary to transfer ARPA-H to any HHS agency or office, including NIH, within 30 days of enactment. (The HHS Secretary’s response is noted in the text box above).

The explanatory statement accompanying the law does not provide further details on Congress’s policy intentions for ARPA-H.²⁴ The report accompanying the House FY2022 LHHS appropriations bill (H.Rept. 117-96; incorporated by reference) “encourages NIH to collaborate with DARPA to develop the foundational policies, procedures, and staff training for ARPA–H employees.”²⁵

FY2023

Request: Announced on March 28, 2022, President Biden’s FY2023 budget request for NIH proposes \$5 billion for ARPA-H in an NIH account, with funding available until September 30, 2025.²⁶ The FY2023 request reiterates the same vision for ARPA-H as in the FY2022 request, and notes that “opportunities or obstacles identified by the Cancer Moonshot may become candidates for the new approach to transformational change offered by ARPA-H.” The Beau Biden Cancer

²² Title II, Division H of Consolidated Appropriations Act, 2022 (P.L. 117-103).

²³ The law cites the definition of “other transaction” in Public Health Service Act (PHSA) Section 319L(a)(3), which means “transactions, other than procurement contracts, grants, and cooperative agreements.” For further information on OT authorities, see CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters.

²⁴ See U.S. Congress, House Committee on Rules, *Division H- LHHS Appropriations 2022, Explanatory Statement*, committee print, 117th Cong., 1st sess., p. 119.

²⁵ As directed in the Explanatory Statement cited in footnote 23 (page 1), “Unless otherwise noted, the language set forth in H.Rept. 117-96 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.”

²⁶ NIH, *Congressional Justification: FY2023*, March 28, 2022, <https://officeofbudget.od.nih.gov/pdfs/FY23/br/Overview%20of%20FY%202023%20Presidents%20Budget.pdf>, p. 33.

Moonshot is another one of President Biden’s major policy priorities related to biomedical research.²⁷

House: On July 5, 2022, the House Appropriations Committee reported an FY2023 appropriations bill (H.R. 8295) that would provide \$2.75 billion, available until September 30, 2025, to an ARPA-H account under the Office of the Secretary—\$1.75 billion above the FY2022-enacted level. Additionally, the report (H.Rept. 117-403) accompanying the bill states:

The Committee strongly supports the mission of ARPA-H to drive transformational innovation in health research. The Committee believes that given its focus on supporting high-risk, high reward projects and distinct approach to selecting and managing research projects, establishing ARPA-H as a separate entity within HHS will maximize the likelihood of the agency’s success.

Senate: On July 28, 2022, the Senate Appropriations Committee Majority Chair Patrick Leahy released draft Senate appropriations bills.²⁸ The draft LHHS bill would provide \$1 billion, available through September 30, 2025, to an ARPA-H account under NIH.²⁹ This amount would be the same funding level as FY2022-enacted and \$1.75 billion less than in the House-reported bill. Additionally, the draft report accompanying the bill states:³⁰

Following the decision by the Secretary to transfer ARPA-H to NIH in May, funding is provided to ARPA-H as a standalone agency within NIH. However, the Committee believes ARPA-H will require a very different culture and mission than NIH’s other 27 Institutes and Centers. To foster the development of an entrepreneurial culture, the Committee expects ARPA-H to be physically located away from the main NIH campus. The Committee expects NIH to conduct a transparent and competitive process for a location site.

Authorizations

House:

On June 22, 2022, the House passed the Advanced Research Projects Agency-Health Act (H.R. 5585), with amendments to the bill previously reported by the House Committee on Energy and Commerce on June 13, 2022 (H.Rept. 117-365). This standalone bill, introduced by House Energy and Commerce Health Subcommittee Chair Representative Eshoo, would authorize and establish ARPA-H within HHS.

Two other bills to authorize ARPA-H were previously introduced in the House. Representatives Diana DeGette and Fred Upton introduced the Cures 2.0 Act (H.R. 6000) on November 17, 2021. Section 501 of this bill would authorize ARPA-H and establish it within NIH (see “Independence and Autonomy” for more on placement within the federal government). An early version of the Build Back Better Act (H.R. 5376) budget reconciliation measure, reported in the House on September 27, 2021, included authorization language and funding of \$3 billion for ARPA-H. The

²⁷ NIH, *Congressional Justification: FY2023*, pp. 4-13.

²⁸ Senate Committee on Appropriations, “Chairman Leahy Releases Fiscal Year 2023 Senate Appropriations Bills,” press release, July 28, 2022, <https://www.appropriations.senate.gov/news/majority/breaking-chairman-leahy-releases-fiscal-year-2023-senate-appropriations-bills>.

²⁹ U.S. Congress, Senate Committee on Appropriations, *FY2023 LHHS Appropriations*, committee print, 117th Cong., 2nd sess., July 28, 2022, <https://www.appropriations.senate.gov/imo/media/doc/LHHSFY2023.PDF>.

³⁰ U.S. Congress, Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, *Explanatory Statement for FY2023 LHHS Appropriations Bill*, committee print, 117th Cong., 2nd sess., July 2022, <https://www.appropriations.senate.gov/imo/media/doc/LHHSFY23REPT.pdf>.

House-passed version on November 19, 2021, however, did not include ARPA-H related language.

Senate: On March 10, 2022, Senators Patty Murray and Richard Burr, the chair and ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee (the committee of jurisdiction for NIH), introduced S. 3819, the Advanced Research Project Authority for Health Act, which would establish ARPA-H within NIH. This bill was incorporated as Section 331 of S. 3799, the PREVENT Pandemics Act in an amendment in the nature of a substitute, which was ordered to be reported by the Senate HELP Committee on March 15, 2022.

Table A-1 provides a detailed side-by-side comparison of ARPA-H legislative proposals in the House (H.R. 5585) and Senate (S. 3799, as amended).

Selected Policy Issues

The bills that would establish ARPA-H are generally similar; however, some key differences and policy questions remain. The following sections describe select policies under debate and potential issues for congressional consideration.

Independence and Autonomy

Independence at the agency level to shape a distinct mission and culture along with autonomy of program managers to select and fund projects are viewed as key components of the ARPA model.³¹ Stakeholders, the Biden Administration, and Members of Congress have debated where to place ARPA-H within the federal government, particularly whether to house the new entity within NIH or as a separate agency under HHS (NIH's parent department). As noted, HHS Secretary Becerra has decided that ARPA-H is to reside within NIH, while the ARPA-H Director is to report directly to the HHS Secretary. Congress could still decide to change ARPA-H's placement through legislation. Aside from placement, Congress is also debating further options of ensuring ARPA-H's independence and autonomy.

The Biden Administration originally proposed placing ARPA-H within NIH, arguing that "the goals of ARPA-H fall squarely within NIH's mission" and that placing ARPA-H within NIH would promote scientific collaboration and help avoid duplication across programs.³² On the other hand, some stakeholders see NIH's culture as relatively conventional and risk-averse and question whether NIH's leadership and culture could affect ARPA-H's ability to succeed in research for transformational innovation.³³ Such stakeholders support placing ARPA-H outside of NIH to ensure independence and autonomy. For example, in a recent hearing before the House Committee on Energy and Commerce, Keith Yamamoto, Vice Chancellor for Science Policy and Strategy at the University of California San Francisco, stated the following regarding housing ARPA-H outside of NIH:

The main force of that argument is that the mission and goals of ARPA-H are different. NIH is a masterful agency at discovery of new knowledge, but does not actually extend to being able to develop applications for that new knowledge. And the route for being able to

³¹ Azoulay et al., "Funding Breakthrough Research: Promises and Challenges of the 'ARPA Model,'" pp. 9-10.

³² Collins et al., "ARPA-H: Accelerating Biomedical Breakthroughs."

³³ Sarah Omermhle, "Skeptics Question If Biden's New Science Agency Is a Breakthrough or More Bureaucracy," *Politico*, July 5, 2021; Jacqueline Alemany, "Biden Has Proposed a New Agency to Turbocharge Medical Treatments. But There's a Fight over Where It Should Live," *Washington Post*, June 23, 2021.

do that has already been cast and demonstrated extremely well in DARPA and ARPA-E. And so, I think that's the reason that it should be outside. Setting up that new culture and operating model within the culture and operating model of NIH, as successful as it is, right, would be challenging at best.³⁴

In the same hearing before the House Committee on Energy and Commerce, Esther Krofah, Executive Director of FasterCures and Center for Public Health at the Milken Institute, stated, "we do not see a reason ARPA-H could not be situated within NIH and still accomplish its mission, including advantages to having easy access to other NIH infrastructure, personnel, programs, and expertise."³⁵

There is precedent for innovative biomedical science efforts both at NIH and at other HHS units. NIH has supported projects such as the Human Genome Project; the Common Fund for cross-cutting and milestone-driven innovative projects; NCATS, which focuses on innovation in medical product development; and, more recently, the Rapid Acceleration of Diagnostics program to boost innovation for COVID-19 diagnostics.³⁶ The HHS Office of Science and Medicine under the Assistant Secretary for Health has managed InnovationX, which includes several public-private partnerships aimed at accelerating innovation, including for kidney disease and Lyme disease.³⁷ Additionally, the Biomedical Advanced Research and Development Authority (BARDA) at HHS under the Assistant Secretary for Preparedness and Response engages in efforts to develop medical countermeasures to address public health emergencies.³⁸ Regardless of where the new agency is placed, it would likely need to consult with NIH programs, HHS programs such as BARDA, as well as biomedical programs at DOD to promote collaboration and avoid duplication.

The authorizing bills under consideration in the House (H.R. 5585) and Senate (S. 3799, as amended) differ in ARPA-H's placement. H.R. 5585 would establish ARPA-H as an independent entity within HHS while S. 3799 (as amended) would establish ARPA-H as an agency under NIH.

Additionally, the authorizing bills include provisions that seek to ensure the independence and autonomy of ARPA-H. Specifically, H.R. 5585 would prohibit another federal agency or department from requiring that an ARPA-H official submit legislative recommendations, testimony, or comments on legislation to any officer or agency for approval prior to submission to Congress if such recommendations, testimony, or comments are those of the Director or such officer, and do not necessarily reflect the views of the President or another agency. The provisions related to independence in S. 3799 (as amended) would (1) prohibit ARPA-H from being located on the NIH campus and in close proximity to the National Capital Region and (2) prohibit the ARPA-H Director from appointing personnel to the agency who were employed by NIH three years prior to such appointment. Additionally, all of the authorizing bills would require that any budget request for the agency be separate and distinct from either HHS or NIH (see "Appropriations" below for additional discussion).

³⁴ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *ARPA-H: The Next Frontier of Biomedical Research*, 117th Cong., 2nd sess., February 8, 2022.

³⁵ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *ARPA-H: The Next Frontier of Biomedical Research*, 117th Cong., 2nd sess., February 8, 2022.

³⁶ White House, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper*, p. 4.

³⁷ HHS, "InnovationX," <https://www.hhs.gov/ash/osm/innovationx/index.html>.

³⁸ HHS Office of the Assistant Secretary for Preparedness and Response, "Biomedical Advanced Research and Development Authority," <https://phe.gov/about/barda/Pages/default.aspx>.

Some have argued that ARPA-H’s founding director would play a crucial role in developing a unique culture that guides the agency to success.³⁹ For example, the report accompanying the House FY2022 LHHS appropriations bill (H.Rept. 117-96) “strongly encourages NIH to recruit an ARPA-H Director with extraordinary technical and leadership skills, who has a proven track-record in innovation and partnership-building.”⁴⁰ Both of the proposals would require the ARPA-H Director to be appointed by the President (consistent with enacted appropriations), though they differ in whether the Director would report to the NIH Director or the HHS Secretary. The proposals also specify different appointment terms. H.R. 5585 would authorize a five-year appointment term for the ARPA-H Director while S. 3799 (as amended) would authorize a four-year term. Both bills would allow for one consecutive term. Both of the proposals similarly specify that the Director have qualifications to manage advanced biomedical research programs, with some slight differences.

Defining Goals and Preventing Duplication

Existing ARPAs address their mandate to advance high-risk, high-reward research and technologies by seeking to fill what is called the *white space*, a perceived gap or opportunity in the technology landscape.⁴¹ The Biden Administration has argued that the current ecosystem of biomedical R&D—with curiosity-driven research funded by NIH and the public sector and commercialization-driven R&D funded largely by industry—is adequate for most biomedical innovation but leaves certain critical gaps that ARPA-H could fill. Specifically, project ideas that the Administration asserts are left unfunded by the current system include those that (1) are high risk and/or require significant funding, (2) involve complex coordination among multiple parties, (3) have a focus that is too applied for academia, and (4) have a scope that “is so broad that no company can realize the full economic benefit.”⁴² Some empirical research supports these claims: recent economic analyses provide some evidence that both the pharmaceutical industry and NIH underinvest in high-risk R&D.⁴³

The ARPA-H bills (H.R. 5585 and S. 3799, as amended) define overall agency goals similarly, with some variations (see **Table A-1**). Both of the bills emphasize breakthrough biomedical technologies and innovation in ARPA-H’s proposed statutory goals. Neither of the bills establish ARPA-H to focus on specific diseases or areas of research. A main difference in ARPA-H goals between the bills is that H.R. 5585 explicitly names ensuring U.S. global leadership in science and innovation, especially with respect to global health threats, as an overall goal.

³⁹ Jocelyn Kaiser, “The U.S. Just Created a Big New Biomedical Research Agency. But Questions Remain,” *Science*, March 15, 2022, <https://www.science.org/content/article/u-s-just-created-big-new-biomedical-research-agency-questions-remain>.

⁴⁰ Omermohle, “Skeptics Question If Biden’s New Science Agency Is a Breakthrough or More Bureaucracy;” Sampat and Cook-Deegan, “An ARPA for Health Research?;” and U.S. Congress, House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Report to Accompany H.R. 4502*, 117th Cong., 1st sess., July 19, 2021, pp. 165-166.

⁴¹ National Academies of Sciences, Engineering, and Medicine, *An Assessment of ARPA-E* (Washington, DC: The National Academies Press, 2017), p. 95; and Azoulay et al., “Funding Breakthrough Research: Promises and Challenges of the ‘ARPA Model.’”

⁴² Collins et al., “ARPA-H: Accelerating Biomedical Breakthroughs.”

⁴³ Joshua L. Krieger, Danielle Li, and Dimitris Papanikolaou, “Missing Novelty in Drug Development,” *National Bureau of Economic Research*, vol. 35, no. 2 (2022), pp. 636-679; Chiara Franzoni, Paula Stephan, and Reinilde Veugelers, “Funding Risky Research,” *National Bureau of Economic Research Working Paper*, June 2021; and Mikko Packalen and Jay Bhattacharya, “NIH Funding and the Pursuit of Edge Science,” *Proceedings of the National Academy of Sciences*, vol. 117, no. 22 (June 2, 2020), pp. 12011-12016.

Some have expressed concern about the potentially broad scope of ARPA-H.⁴⁴ Both of the authorizing bills would require ARPA-H to develop and submit to Congress a strategic plan for the new agency and submit annual reports to Congress that detail current, proposed, and planned ARPA-H projects.

Some have expressed concern that ARPA-H could duplicate existing medical and health research efforts across the federal government.⁴⁵ Myriad federal agencies support medical and health research, not only NIH—the largest supporter of such research—but also DOD, the Department of Veterans Affairs (VA), and other agencies within HHS.⁴⁶ The authorizing bills address considerations related to aligning ARPA-H efforts with those of other federal agencies, as shown in the sections on “Coordination and Cooperation” and “Advisory Committees” in the **Appendix**. For example, S. 3799 (as amended) and H.R. 5585 would both require the establishment of an interagency advisory committee tasked with avoiding duplication and improving the coordination of ARPA-H’s efforts with other federal agencies. H.R. 5585 would also require the Government Accountability Office to conduct an independent review of HHS’s research portfolio every three years to assess the degree of unnecessary duplication and make recommendations regarding any potential reorganization, consolidation, or termination of duplicative program and projects.

Additionally, other federal agencies would play a critical role in commercialization of implementation of ARPA-H technologies or innovations—for example, FDA would regulate many ARPA-H-supported medical products. Both bills would require ARPA-H to coordinate with the FDA to expedite and facilitate the transformation and development of ARPA-H activities into medical products and solutions for patients. Federal health care programs, such as the Centers for Medicare & Medicaid Services (CMS) and the VA, could end up implementing or paying for ARPA-H supported innovations. H.R. 5585 would require ARPA-H to share timely information with CMS for coverage decisions. Both bills also provide for follow-on production or procurement and demonstration programs, as shown in the section on “Other Transactions, Follow-on Production, Technology Transfer, and Procurement and Demonstration” in **Table A-1**.

There is also concern about duplicating commercial or philanthropic research efforts. Both bills direct ARPA-H to prioritize investments in areas that are underfunded by the public and private sector, and to facilitate public-private partnerships. S. 3799 (as amended) includes provisions that are aimed at preventing ARPA-H funding from crowding out private sector investment. For example, S. 3799 (as amended) would require the ARPA-H Director to ensure that ARPA-H does not provide funding for a research program or project unless the applicant demonstrates that it has made sufficient unsuccessful attempts to secure private financing, and that there is a lack of significant private support for the program or project.

Another *ARPA* agency, the Advanced Research Projects Agency-Energy (ARPA-E) faced similar concerns regarding potential duplication; however, a recent study by the U.S. Government Accountability Office found that “ARPA-E has practices in place to help manage overlap and

⁴⁴ See, for example, Jeff Tollefson, “The Rise of ‘ARPA-Everything’ and What It Means for Science,” *Nature*, July 8, 2021, <https://www.nature.com/articles/d41586-021-01878-z>; and Bhaven N. Sampat and Robert Cook-Deegan, “An ARPA for Health Research?,” *Milbank Quarterly*, <https://www.milbank.org/quarterly/opinions/an-arpa-for-health-research/>.

⁴⁵ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *ARPA-H: The Next Frontier of Biomedical Research*, 117th Cong., 2nd sess., February 8, 2022.

⁴⁶ Research!America, *U.S. Investments in Medical and Health Research and Development*, 2019, https://www.researchamerica.org/sites/default/files/Publications/InvestmentReport2019_Fnl.pdf.

duplication during its program development cycle.”⁴⁷ Congress may consider whether to identify any best practices from ARPA-E that could be applied to ARPA-H program development.

Funding

The Consolidated Appropriations Act, 2022 (P.L. 117-103) provided ARPA-H with \$1 billion in funding available until September 30, 2024. This is in contrast with the \$6.5 billion in initial funding proposed by the Biden Administration for the same period.⁴⁸ It is also lower than the authorized amounts in H.R. 5585. H.R. 5585 would authorize \$500 million for each of FY2023 through FY2027. S. 3799 (as amended) does not specify an authorization level and instead would authorize “such sums as may be necessary” for FY2023 through FY2027. In comparison, DARPA is funded at \$3.9 billion for FY2022, ARPA-E has FY2022 funding of \$450 million, and fewer than half of NIH ICs have an annual budget that exceeds \$1 billion (11 out of 25 accounts).⁴⁹ Taking a wider view, total U.S. investments in health and medical research (both public and private) were estimated at \$194.175 billion in 2018.⁵⁰

Stakeholders have debated the appropriate initial funding level for ARPA-H. Given that ARPA-H is an untested new agency, some argue that it should start small and grow over time depending on its success.⁵¹ However, in the context of the ARPA model, there is a risk of providing too little funding. Insufficient funding is seen by some as one of the reasons another agency modeled after DARPA, the Homeland Security Advanced Research Projects Agency (HSARPA), has not been viewed as a success.⁵² In addition, biomedical research—especially medical product R&D—tends to be expensive relative to some other areas of technology R&D.⁵³ Also, given the long lag time that generally exists between R&D activities and a commercially viable product or service, as well as the focus on high-risk projects, it can be difficult to determine the appropriate ARPA-H funding level in the short term.

In an effort to separate ARPA-H funding from other NIH programs, S. 3799 (as amended) would provide that ARPA-H’s budget be separate from other NIH budget requests. (As an independent agency, the ARPA-H established by H.R. 5585 would likely have a separate budget request).

Members of Congress also have considered whether and how to leverage private funding—such as from industry or philanthropy—to help support ARPA-H’s efforts. Currently, NIH structures many of its medical product development and biomedical innovation programs as public-private partnerships. Both bills would direct ARPA-H to partner with a range of public and private entities. In addition, S. 3799 (as amended) would direct the ARPA-H Director, as a part of the Director’s duties, to prioritize investments in areas that require public-private partnerships.

⁴⁷ U.S. Government Accountability Office, *Advanced Research Projects Agency-Energy: Agency Has Practices for Avoiding Duplication and Involving Stakeholders in the Development of Research Programs*, GAO-22-104775, February 3, 2022, p. 1, <https://www.gao.gov/assets/gao-22-104775.pdf>.

⁴⁸ NIH, *Congressional Justification: FY2022*, pp. 10-11.

⁴⁹ See CRS Report R46869, *Federal Research and Development (R&D) Funding: FY2022*, coordinated by John F. Sargent Jr.

⁵⁰ Research!America, “U.S. Investments in Medical and Health Research and Development: 2013-2018,” Fall 2019, https://www.researchamerica.org/sites/default/files/Publications/InvestmentReport2019_Fnl.pdf.

⁵¹ See, for example, Tollefson, “The Rise of ‘ARPA-Everything’ and What It Means for Science.”

⁵² For example, see Nate Bruggeman and Ben Rohrbaugh, “Closing Critical Gaps that Hinder Homeland Security Technology Innovation,” Belfer Center, Harvard Kennedy School, April 2020, p. 3, <https://www.belfercenter.org/sites/default/files/files/publication/HSP%20paper%20series%205-2.pdf>.

⁵³ GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 2017, pp. 28-37.

Appendix. Comparison of Key Provisions in ARPA-H Authorization Legislation

Table A-1 provides a side-by-side comparison of the two bills under consideration that would authorize ARPA-H in the 117th Congress. In the House, H.R. 5585 was passed on June 22, 2022. In the Senate, the PREVENT Pandemics Act (S. 3799, as amended), which incorporates the previously introduced Advanced Research Project Authority for Health Act (S. 3819) as Section 331, was ordered to be reported by the Senate HELP Committee on March 15, 2022.

H.R. 5585 is used as a comparator bill, as it was first introduced. The provisions are not presented in the order they appear in the comparator bill, but rather are grouped categorically to facilitate topical comparison of the proposals. Provision references are included in brackets. In some instances, similar language is used in different categorical sections of the bills; such instances are noted throughout the table.

Table A-1. Comparison of Key Provisions in ARPA-H Authorization Legislation

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
Authorization	Would amend Public Health Service Act (PHSA), Title IV (National Research Institutes) to add at the end “Part J—Advanced Research Projects Agency-Health,” which includes one section, Section 499A: Advanced Research Projects Agency-Health. [H.R. 5585 §2]	Would amend the PHSA, Title IV to add at the end “Subpart 3—Advanced Research Projects Authority for Health,” which includes one section, Section 483: Advanced Research Projects Authority for Health. [S.3799 §331]
Placement in Federal Government and Organizational Structure	Placement: Would establish ARPA-H within the Department of Health and Human Services (HHS) and, not later than 180 days after enactment, require the transfer of all existing functions, personnel, missions, activities, authorities, and funds of APRA-H within NIH to the ARPA-H established by the bill. [Proposed PHSA §499A(a)(1)] Organizational Structure: Would require ARPA-H to be organized to include an Office of the Director; no more than six program offices; and such special project office as the Director may establish. [Proposed PHSA §499A(a)(2)(A)]. Would also require that no fewer than two-thirds of the program offices be exclusively dedicated to research and development. [Proposed PHSA §499A(a)(2)(B)].	Placement: Would establish ARPA-H within NIH. [Proposed PHSA §483(b)] Organizational Structure: No similar provisions.
Goals/Purpose	The stated goals of ARPA-H would be to: <ul style="list-style-type: none"> • foster the development of new, breakthrough capabilities, technologies, 	The stated purpose of ARPA-H would be to (key differences from H.R. 5585 <i>italicized</i>):

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
	<p>systems, and platforms to accelerate innovations in health and medicine that are not being met by federal programs or private entities;</p> <ul style="list-style-type: none"> • revolutionize detection, diagnosis, mitigation, prevention, treatment and curing of serious diseases and medical conditions through the development of transformative health technologies; • promote high-risk, high-reward innovation for the development and translation of transformative health technologies; and • contribute to ensuring the United States maintains global leadership in science and innovation; the highest quality of life and health for its citizens; and an aggressive agenda for innovation to address global health threats that place U.S. citizens at risk. <p>[Proposed PHSA §499A(b)(1)]</p>	<ul style="list-style-type: none"> • support high-impact, cutting-edge research in biomedicine and broadly applicable breakthrough technologies that have the potential to significantly transform and advance areas of biomedical science and medicine in a manner that cannot readily be accomplished through traditional biomedical research or commercial activity; and • overcome <i>long-term and significant technological and scientific barriers</i> to advancing such technologies in order to improve the prevention, diagnosis, mitigation, treatment, and cure of health conditions. <p>[Proposed PHSA §483(b)]</p>
Methods	<p>Methods of the agency would include:</p> <ul style="list-style-type: none"> • discovering, identifying, and promoting revolutionary advances in health sciences; • translating scientific discoveries into transformative health technologies; • providing resources and support to create platform capabilities that draw on multiple disciplines; • using researchers in a wide range of disciplines, including the life sciences, the physical sciences, engineering, and the computational sciences; • delivering advanced proofs of concept that demonstrate clinically meaningful advances; • developing new capabilities, advanced computational tools, predictive models, or analytical techniques to identify potential targets and technological strategies for early disease detection and intervention; • accelerating transformational technological advances in areas with limited technical certainty; and • prioritizing investments based on such considerations as scientific opportunity and uniqueness of fit to the strategies and operating practices of ARPA-H; the effect on disease burden, including unmet patient need, quality and 	<p>No similar category of provisions. Comparable language in “Goals” and “Duties of the Director” sections.</p>

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
	<p>disparity gaps, and the potential to preempt progression of serious disease; and the effect of the fiscal liability of the federal government with respect to health care and the ability to reduce the cost of care through innovation.</p> <p>[Proposed PHSA §499A(b)(2)]</p>	
<p>ARPA-H Director Position</p>	<p>The ARPA-H Director position would be established as follows:</p> <p>Appointment: Appointed by the President. Reports to the Secretary of HHS. [Proposed PHSA §499A(c)(1), (3)]</p> <p>Term: Five years. May be reappointed for one consecutive term. [Proposed PHSA §499A(c)(5)]</p> <p>Qualifications: An individual who, by reason of professional background and experience, is qualified to manage: (1) research and advanced development programs; and (2) large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, including generating transformative health technologies and improving health outcomes for patients. [Proposed PHSA §499A(c)(2)]</p> <p>Autonomy Regarding Recommendations and Testimony: No U.S. officer or agency has authority to require the Director of ARPA-H or any other ARPA-H officer to submit legislative recommendations, testimony, or comments on legislation to any officer or agency for approval prior to submission to Congress if such materials include a statement indicating that the views expressed are those of such officer and do not reflect the views of the President or another agency. [Proposed PHSA §499A(c)(6)]</p>	<p>The ARPA-H Director position would be established as follows (key differences from H.R. 5585 <i>italicized</i>):</p> <p>Appointment: Appointed by the President. <i>Reports to NIH Director.</i> [Proposed PHSA §483(c)(1)]</p> <p>Term: <i>Four</i> years. May be reappointed for up to one consecutive term <i>at the discretion of the President.</i> [Proposed PHSA §483(c)(3)]</p> <p>Qualifications: Individual who, by professional background and experience, is qualified to advise the Secretary on, and manage research programs that advance the purposes of ARPA-H in, promoting biomedical and novel technology innovation, and who has demonstrated ability to identify and develop partnerships to address strategic needs in meeting such purposes. [Proposed PHSA §483(c)(2)]</p> <p>Autonomy: No comparable provision.</p>
<p>Duties and Authorities of the Director</p>	<p>Duties:</p> <ul style="list-style-type: none"> Approve and terminate the projects and programs of ARPA-H; Set research and development priorities with respect to ARPA-H goals and manage the budget of ARPA-H; 	<p>Duties: (grouped for comparison): <i>Similar to H.R. 5585</i></p> <ul style="list-style-type: none"> Approve all new programs within ARPA-H and terminate any program within ARPA-H that is not achieving its goals;

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
	<ul style="list-style-type: none"> • Develop funding criteria and assess the success of programs through the establishment of technical milestones; • Advance ARPA-H goals through consideration of the advice of the ARPA-H Interagency Advisory Committee; • Solicit data, as needed, from NIH and other relevant entities; • Coordinate with the Director of NIH to ensure that the programs of ARPA-H build on and are informed by scientific research supported by NIH (see “Cooperation and Coordination” below for other relevant provisions); • Coordinate with the heads of federal agencies and, to the extent practicable, ensure that the activities of ARPA-H supplement (and do not supplant) the efforts of other federal agencies (see “Cooperation and Coordination” below for other relevant provisions); and • Ensure that ARPA-H does not provide funding for a project unless the program manager determines that the project meets ARPA-H goals. <p>[Proposed PHSA §499A(c)(4)]</p> <p>Authorities:</p> <ul style="list-style-type: none"> • Delegate authorities, except the appointment of the Deputy Director; [Proposed PHSA §499A(c)(7)] • Appoint a Deputy Director to serve as the first assistant to the office; and [Proposed PHSA §499A(c)(8)] • Waive Paperwork Reduction Act requirements with respect to ARPA-H methods (subsection (b)(2)). [Proposed PHSA §499A(d)] 	<ul style="list-style-type: none"> • Establish strategic goals, objectives, and priorities for ARPA-H pursuant to ARPA-H’s purposes; • Establish criteria for funding and assessing the success of programs through the establishment of technical milestones; and • Facilitate coordination between HHS and its agencies, and other relevant federal departments and agencies. <p><i>Different from H.R. 5585</i></p> <ul style="list-style-type: none"> • Ensure that applications for funding disclose current and previous research and development efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing funding; • Support transformative, translational, applied, and advanced research in areas of biomedical science to address specific technical or scientific questions by (1) prioritizing investments based on scientific potential and impact on the field of biomedicine, especially in areas that require public-private partnerships; (2) translating scientific discoveries and cutting-edge innovation into technological advancements; (3) encouraging opportunities to develop broadly applicable technologies using a multi-disciplinary approach; and (4) making investments in high-risk, high-reward research that may have application for medicine and health (H.R. 5585 includes similar language in “Methods” category); • Encourage strategic collaboration and partnerships with a broad range of entities, including academia, industry, and non-profit organizations (H.R. 5585 lists partnering with other entities in “Program Managers” category); and • Ensure that the United States maintains global leadership in researching and developing health technologies (H.R. 5585 includes similar language in the “Goals” category). <p>[Proposed PHSA §483(c)(4)]</p>

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
		Authorities: No additional authorities specified.
Funding Awards	<p>The ARPA-H Director would be authorized to make awards in the form of grants, contracts (including multi-year contracts), cooperative agreements, prizes, and other transactions.</p> <p>Grants and cooperative agreements awarded would be subject to the uniform administrative requirements, cost principles, and audit requirements for federal awards under part 200 of Title 2, Code of Federal Regulations. Total line-item and itemized facilities and administrative costs would be required to be made publicly available and published in a machine-readable format.</p> <p>Contracts awarded would be subject to Federal Acquisition Regulation.</p> <p>Funded research would not be subject to NIH peer review or advisory council review or approval. [Proposed PHSA §499A(h)]</p> <p>In accordance with existing federal requirements as specified, the ARPA-H Director would be required to only award new awards to recipients who do not have more than three ongoing ARPA-H awards. [Proposed PHSA §499A(o)(4)]</p> <p>Domestic Prioritization: In making awards, the ARPA-H Director would be required to prioritize domestic recipients conducting research on transformative health technology in the United States. As appropriate and practicable, the Director would be required to ensure that nondomestic recipients are conducting research in collaboration with a domestic recipient.</p> <p>The ARPA-H Director would not be allowed to make awards to nondomestic recipients organized under the laws of Russia, Iran, North Korea, China or other countries as determined to be a covered foreign country</p>	<p>The ARPA-H Director would be authorized to make awards in the form of grants, contracts (including multi-year contracts), cooperative agreements, prizes, and other transactions. Defines “other transactions” to mean “transactions, other than procurement contracts, grants, and cooperative agreements.” (by reference to PHSA §319L(a)(3) in the Proposed PHSA §483(a)(3)). [Proposed PHSA §483(e)(1)]</p> <p>Would allow the ARPA-H Director to use authorities and processes under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. §3719) for prize competitions (H.R. 5585 references the Stevenson-Wydler definition for “prize” in the Definitions section). [Proposed PHSA §483(e)(3)]</p> <p>Funded research would not be subject to NIH peer review or advisory council review or approval. [Proposed PHSA §483(e)(5)]</p> <p>Would require the ARPA-H Director to ensure that ARPA-H does not provide funding for a research program or project unless the applicant demonstrates that it has made sufficient unsuccessful attempts to secure private financing, and that there is a lack of significant private support for the program or project. In addition, the ARPA-H Director would be required to ensure that the program or project is in the best interests of the United States and has the potential to significantly transform and advance biomedicine. [Proposed PHSA §483(f)(2)]</p> <p>Domestic Prioritization: No similar provisions. (Note: May follow NIH policy for foreign award eligibility, see NIH, “Who is Eligible?” https://grants.nih.gov/grants/who-is-eligible.htm).</p>

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
	<p>under section 119C of the National Security Act of 1947. [Proposed PHSA §499A(o)]</p>	
<p>Other Transactions, Follow-on Production, Technology Transfer, and Procurement and Demonstration</p>	<p>ARPA-H Director would be authorized to award other transactions. [Proposed PHSA §499A(h)(1)(E)]</p> <p>Follow-On Production Award Authority: An “other transaction” entered into may provide for the award of a follow-on production contract or transaction, either to the participants in the transaction by ARPA-H or another federal agency. For the purposes of this authority, “other transaction” would include all individual subprojects awarded under the transaction to a consortium of United States industry and academic institutions.</p> <p>A follow-on production contract may be awarded without the use of competitive procedures (as defined in federal requirements) if (1) competitive procedures were used for the selection of parties for participation in the other transaction; and (2) the participants in the other transaction successfully completed the project provided for in the transaction.</p> <p>As a precondition, the ARPA-H Director would be allowed to award a follow-on production contract or transaction when the Director determines that the individual project or subproject as a part of a consortium is successfully completed by the participants. However, the award may not be made contingent on successful completion of <i>all</i> activities within a consortium. Contracts and other transactions under this authority may be awarded pursuant to existing federal procurement law or under such procedures, terms, and conditions as the Director may establish by regulation. [Proposed PHSA §499(s)]</p> <p>Technology Transfer Office: The ARPA-H Director would be allowed to establish an Office of Technology Transfer to facilitate the transfer of federally-owned or federally-originated technology to recipients of an ARPA-H award (other than federal government entities). [Proposed PHSA §499(r)]</p>	<p>The ARPA-H Director would be authorized to enter into other transactions. [Proposed PHSA §483(e)(1)]</p> <p>To the maximum extent practicable, competitive procedures would be required when entering into other transactions to carry out projects.</p> <p>Would authorize other transaction authorities to be exercised for a project if the project manager submits a proposal to the ARPA-H Director for each use of such authority before conducting or supporting a project, including why other transaction authority is essential to project success. The project manager must receive approval from the ARPA-H Director before using other transaction authority, and then must report to the Director on project activities for each fiscal year in which the project manager used the authority. [Proposed PHSA §483(e)(2)]</p> <p>Procurement and Demonstration: The ARPA-H Director would have authority to seek opportunities to partner with procurement programs of other federal agencies to demonstrate technologies resulting from ARPA-H activities. [Proposed PHSA §483(e)(4)]</p> <p>Technology Transfer Office: No comparable provisions.</p>

Provision(s)	Advanced Research Projects Agency-Health Act (H.R. 5585)	Advanced Research Projects Authority for Health Act (Section 331 of S. 3799, as amended)
<p>Confidentiality and Protection of Information</p>	<p>The following types of information collected by ARPA-H from award recipients would be considered commercial and financial information from a person, which is not subject to disclosure under the Freedom of Information Act (FOIA; 5 U.S.C. §552(b)(4)):</p> <ul style="list-style-type: none"> Plans for commercialization of technologies developed under the award, including business plans, technology-to-market plans, market studies, and cost and performance models; Investments provided to an awardee from third parties, including amounts and the percentage of ownership of the awardee provided in return for the investments; Additional financial support that the awardee (1) plans to invest or has invested in the technology developed under the award, or (2) is seeking from third parties; and Revenue from the licensing or sale of new products or services resulting from research conducted under the award. <p>[Proposed PHSA §499(e)]</p>	<p>Would provide that nothing in the new ARPA-H PHSA section is to be construed as authorizing disclosure of trade secrets or other privileged or confidential information under FOIA or other laws.</p> <p>[Proposed PHSA §483(j)(1)]</p>
<p>Facilities</p>	<p>The ARPA-H Director would have the authority to:</p> <ul style="list-style-type: none"> Acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary; and Lease any nonexcess real property and related personal property under the jurisdiction of ARPA-H. <p>The Director would be required to deposit amounts received for a lease into the ARPA-H account as discretionary offsetting collections, and such amounts would be available to the extent, and in the amounts provided in advance appropriations acts, to cover ARPA-H costs for the lease and for maintenance and other property improvements as specified.</p> <p>[Proposed PHSA §499A(i)]</p> <p>Would require that ARPA-H, including its headquarters, not be located on any part of the existing NIH campus. Would require the ARPA-H Director to consider characteristics of the intended location and the extent to</p>	<p>The ARPA-H Director would have the authority to (key differences from H.R. 5855 <i>italicized</i>):</p> <ul style="list-style-type: none"> Acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary; and <i>Lease an interest in property for not more than 20 years, notwithstanding Section 1341(a)(1) of title 31, United States Code.</i> <p>[Proposed PHSA §483(h)(1)]</p> <p>Would require that ARPA-H, including its headquarters, not be located <i>near the National Capital Region</i> and not on any part of the NIH campus. Would require the ARPA-H Director to consider characteristics of the intended location and the extent to which such location would facilitate advancement of ARPA-H's purposes.</p> <p>[Proposed PHSA §483(h)(2)]</p>

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	<p>which such location would facilitate advancement of ARPA-H’s purposes. [Proposed PHSA §499A (i)(4)]</p>	
<p>Personnel Authorities</p>	<p>Would grant the ARPA-H Director the authority to waive certain civil service personnel requirements in making and rescinding scientific, medical, and professional personnel appointments.</p> <p>Would grant the ARPA-H Director the ability to use existing hiring authorities granted to the Secretary of HHS to hire administrative, financial, contracts, legislative affairs, information technology, ethics, and communications staff as necessary.</p> <p>The ARPA-H Director would also be directed to make efforts to recruit and retain a diverse workforce, including individuals underrepresented in science and medicine and racial and ethnic minorities (as long as such efforts comply with applicable federal civil rights law).</p> <p>The ARPA-H Director would also be authorized to contract with private entities in hiring qualified personnel.</p> <p>Would allow the ARPA-H Director to use the Intergovernmental Personnel Act to staff ARPA-H with employees from other federal agencies, state and local governments, Indian tribes and tribal organizations, institutions of higher education, and other organizations.</p> <p>Would allow the ARPA-H Director to accept detailees from other federal agencies for a period of up to three years. [Proposed PHSA §499A(j)]</p>	<p><i>Similar to H.R. 5585:</i></p> <p>Would grant the ARPA-H Director the authority to waive certain civil service personnel requirements in making and rescinding scientific, medical, and professional personnel appointments. [Proposed PHSA §483(d)(4)(A)]</p> <p>In making personnel or staff appointments, the ARPA-H Director would be authorized to consider as appropriate factors such factors as populations that are traditionally underrepresented in the biomedical research enterprise. [Proposed PHSA §483(d)(3)(B)]</p> <p>The ARPA-H Director would be authorized to contract with private recruiting firms for hiring of qualified technical staff. [Proposed PHSA §483(d)(4)(D)]</p> <p><i>Different from H.R. 5585</i></p> <p>Would require the ARPA-H Director to ensure that personnel appointed to staff or support ARPA-H are individuals who, at the time of appointment and for three years prior to such appointment, were not employed by NIH. [Proposed PHSA §483 (d)(4)(E)(i)]</p> <p>The ARPA-H Director would be authorized to appoint no more than 120 personnel under the agency’s hiring authority. The ARPA-H Director would be required to notify Congress if he/she determines that additional personnel are required. [Proposed PHSA §483 (d)(4)(E)(ii)]</p>
<p>Program Managers</p>	<p>Recruitment: Would require the ARPA-H Director to recruit program managers with expertise in a wide range of disciplines, including life sciences, physical sciences, engineering, and computational sciences. [Proposed PHSA §499A(j)(3)(C)]</p> <p>Term: Three years. May serve two terms.</p>	<p>Recruitment: In designating program managers, the ARPA-H Director would be required to consider individuals with demonstrated scientific expertise and management skills required to advance ARPA-H and who represent a diverse set of professional experiences or backgrounds, including experience in</p>

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	<p>Duties:</p> <ul style="list-style-type: none"> • Establish research and development goals for programs, including timelines and milestones, in consultation with the Director, and make such goals publicly available; • Collaborate with experts from NIH and other federal agencies and experts in relevant scientific fields to identify research and development gaps and opportunities; • Convene workshops and meetings, as needed, with entities such as patients, patient advocacy groups, practitioners, professional societies, and other stakeholders to solicit input on programs and goals; • Manage applications and proposals for making grants, cooperative agreements, contracts, prizes and other transaction awards for advanced research that may show particular promise, especially in areas in which the federal government and the private sector may not have undertaken sufficient research; • Issue funding opportunity announcements using uniform administrative processes; • Select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA-H, taking into consideration the scientific and technical merit of the proposed projects; the capabilities of the applicants to successfully carry out the proposed project; the unmet needs or ability to improve outcomes within patient populations; future commercial applications of the project or feasibility of partnering with one or more commercial entities; the potential for interdisciplinarity of the approach of the project; and such other criteria as are established by the ARPA-H Director; and • Conduct project reviews within 18 months of funding awards to identify milestones and monitor progress of such milestones with respect to each project and prior to the disbursement of new funds; 	<p>academia, industry, government, nonprofit organizations, or other sectors. [Proposed PHSA §483(d)(3)(A)]</p> <p>Term: Three years. May serve two terms. [Proposed PHSA §483(d)(C)]</p> <p>Duties (grouped for comparison): <i>Similar to H.R. 5585</i></p> <ul style="list-style-type: none"> • Establish research and development goals for the programs in consultation with the Director, including timelines and milestones, and make such goals available to the public; • Communicate with leaders in the health care and biomedical research and development fields, from both the public and private sectors, representatives of patient organizations, institutions of higher education, and nonprofit organizations to identify areas of need and scientific opportunity with the potential to transform biomedicine. • Select the projects to be supported under the program after considering: (1) the novelty and scientific and technical merit of the proposed project; (2) the demonstrated capabilities of the applicants; (3) potential future commercial applications as proposed; (4) the degree to which the project addresses a scientific or technical question and has the potential to transform biomedicine; and (5) other criteria as established by the ARPA-H Director; • Encourage research collaborations, including by identifying and supporting applicable public-private partnerships; and • Recommend program restructuring, expansion, or termination of research projects or whole projects, as necessary. <p><i>Different from H.R. 5585</i></p> <ul style="list-style-type: none"> • Provide project oversight and management of strategic initiatives to advance the purpose of the program.

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	<ul style="list-style-type: none"> • Provide recommendations to the ARPA-H Director with respect to advancing the goals of the agency; • Cultivate opportunities for the commercial application or community use of successful projects, including through the establishment of partnerships between or among awardees; • Identify innovative cost-sharing arrangements for ARPA-H projects; • Provide recommendations to expand, restructure, or terminate research partnerships or projects; and • Ensure that animal studies meet requirements in the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and applications apply statistical modeling approaches and appropriately justify animal sample sizes to meet project goals. <p>[Proposed PHSA §499A(k)]</p>	<p>[Proposed PHSA §483(d)(2)(B)]</p>
<p>Coordination and Cooperation</p>	<p>Would require the ARPA-H Director to share timely and relevant information with the Administrator of the Centers for Medicare & Medicaid Services (CMS) that may help to expedite determinations of coverage of transformative health technologies developed by ARPA-H.</p> <p>[Proposed PHSA §499A(f)]</p> <p>Would authorize the HHS Secretary, through the Commissioner of Food and Drugs and in consultation with the ARPA-H Director, to take actions to facilitate the translation of transformative health technologies into solutions for patients and to expedite the development of drugs, devices, and biological products, including through:</p> <ul style="list-style-type: none"> • Helping to ensure that drug, device, or biological product development programs gather the nonclinical and clinical data necessary to advancing the development of such products and to obtaining their approval, licensure, or clearance by the U.S. Food and Drug Administration (FDA); • Expediting review of investigational new drug applications, review of investigational device exemptions, and review of applications for approval 	<p>Would require the ARPA-H Director to ensure, to the maximum extent practicable, that ARPA-H activities are coordinated with and do not duplicate efforts of: (1) other HHS programs, including NIH and the Biomedical Advanced Research and Development Authority (BARDA) programs, and (2) other relevant efforts or research operated or overseen by other federal departments and agencies.</p> <p>[Proposed PHSA §483(f)(1)]</p> <p>Would authorize the FDA to meet with ARPA-H and appropriate federal partners such as BARDA at appropriate intervals to discuss the development status and actions that may be taken to facilitate the development of medical products and projects that are of highest priority for ARPA-H. Would require the ARPA-H Director to reimburse FDA for FDA activities conducted under the authority of the section.</p> <p>[Proposed PHSA §483(f)(4)]</p>

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	<p>licensure, and clearance of drugs, devices, or biological products; and</p> <ul style="list-style-type: none"> Meeting at appropriate intervals with the ARPA-H Director and any member of the ARPA-H Interagency Research Council to discuss the development status of drugs, devices, or biological products that the highest priorities to the ARPA-H Director, unless determined the meetings are not necessary. <p>The authority is not to be construed as limiting FDA's authority with respect to drugs, devices, or biological products. The ARPA-H Director may reimburse FDA for related expenditures. [Proposed PHSA §499A(g)]</p>	
<p>Advisory Committee</p>	<p>Advisory Committee: Would require the ARPA-H Director to establish an interagency advisory committee—the ARPA-H Interagency Research Council—tasked with advising the Director, including by making recommendations on research priorities that would provide the greatest return on investment with respect to improving human health, avoiding duplication of efforts in the federal government, and improving coordination with other federal agencies; and identifying and developing strategies to address regulatory, reimbursement, and market barriers to commercialization or adoption of transformative health technologies, including technologies intended to preempt serious disease. Members could include (1) the heads of several HHS operating divisions or their designees, including NIH, FDA, CMS, BARDA, the Centers for Disease Control and Prevention (CDC), the National Center for Advancing Translational Sciences [part of NIH], the Agency for Healthcare Research and Quality, the Office of Minority Health, the Assistant Secretary for Preparedness and Response (ASPR), the Health Resources and Services Administration; (2) the Director of Office of Science and Technology Policy; (3) Director of DARPA; (4) the Director of the National Science Foundation (NSF); (5) the Director of the Office of Science of the Department of Energy (DOE); (6) Director of the Advanced Research Projects Agency-Energy (ARPA-E); and (7) representatives of any federal agency with subject matter expertise</p>	<p>Advisory Committee: Would establish an ARPA-H Interagency Advisory Committee to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA-H. Members would include the heads of the following agencies or their designees: NIH, CDC, FDA, ASPR, HHS Office of the Assistant Secretary of Health, DARPA, the DOE Office of Science, NSF, and any other agency with subject matter expertise that the ARPA-H Director determines appropriate. <i>The Federal Advisory Committee Act (5 U.S.C. App.) would not apply to this committee.</i> The Committee would be advisory in nature only. [Proposed PHSA §483(g)]</p> <p>Other Advice: Would also authorize the ARPA-H Director to seek input from PCAST; representatives of professional or scientific organizations with expertise in technology under consideration or development by ARPA-H; and representatives of patient organizations, public health, innovators, and other public and private entities. [Proposed PHSA §483(f)(3)]</p>

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	<p>as determined by the ARPA-H Director. The Council would be advisory in nature only.</p> <p>The council would be required to meet one year after enactment, then, during subsequent fiscal years, the Director would convene the committee as needed. The Council may function through established or ad-hoc committees, task forces, or interagency groups to share information on health innovations funded by ARPA-H and receive input on areas of particular promise for ARPA-H projects.</p> <p>[Proposed PHSA §499A(q)]</p> <p>Other Advice: Would also authorize the ARPA-H Director to consult with the President’s Committee of Advisors on Science and Technology (PCAST); peers in the scientific community, including academia and industry; an existing advisory committee providing advice to the HHS Secretary or head of other HHS operating division; the new interagency research council (above); and any other entity the Director may deem appropriate.</p> <p>[Proposed PHSA §499A(p)]</p>	
<p>Annual Report and Strategic Plan</p>	<p>Annual Report: Beginning not later than one year after the date of the enactment, and each fiscal year thereafter, the ARPA-H Director would be required to submit a report to Congress on the actions undertaken, and results generated, by ARPA-H, including:</p> <ol style="list-style-type: none"> (1) A description of projects supported by ARPA-H in the previous fiscal year and whether such projects are meeting the goals developed by the Director; (2) A description of projects terminated in the previous fiscal year, and the reason for such termination; (3) A description of projects starting in the next fiscal year, as available; (4) Activities conducted in coordination with other federal agencies; (5) An analysis of the extent of coordination with NIH and CMS, including successes and barriers with respect to achieving the goals of the agency. (6) A description of the demographic diversity (including racial and gender) if available of direct recipients and performers in funded projects and of the ARPA-H workforce; and 	<p>Annual Report: As part of the annual budget request submitted for each fiscal year, the ARPA-H Director would be required to provide Congress a report describing:</p> <ol style="list-style-type: none"> (1) Projects supported by ARPA-H during the previous fiscal year including the stage of development and details as to whether the project is meeting its milestones; (2) Projects supported by ARPA-H during the previous fiscal year that were terminated and the reasons for termination; (3) Projects supported by ARPA-H during the previous fiscal year that examine topics and technologies related to other activities funded by HHS, including an analysis of whether in supporting such projects, the ARPA-H Director is in compliance with relevant requirements; and (4) Current, proposed, and planned projects to be carried out. <p>[Proposed PHSA §483(k)(1)]</p> <p>Strategic Plan: <i>Not later than 180 days after the appointment of the first ARPA-H Director, and every four years thereafter, the ARPA-H Director would be required to</i></p>

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	<p>(7) Disclosure by the reward recipient of whether the principal investigators named on the award participate in foreign talent programs, including the provision of copies of all grants, contracts, or other agreements or supporting documentation related to such programs as a condition of receipt of federal biomedical research funds.</p> <p>[Proposed PHSA §499A(l)(1)]</p> <p>Strategic Plan: Not later than one year after the date of the enactment, and every three years thereafter, the ARPA-H Director would be required to provide Congress a strategic plan describing how ARPA-H will carry out investments each fiscal year in the next three-year period.</p> <p>[Proposed PHSA §499A(m)]</p>	<p>submit to Congress a plan describing the strategic plan that ARPA-H will use to guide future investments over the following four fiscal years. Every two years after initial submission, the ARPA-H Director would be required to submit a supplemental strategic plan that details any changes. Requirements for NIH Institute and Center strategic plans would not apply to ARPA-H.</p> <p>[Proposed PHSA §483(k)(2)]</p>
<p>Evaluation and Performance Measurement</p>	<p>Evaluation by the National Academies of Sciences, Engineering, and Medicine (NASEM): Not later than five years after the date of enactment, the Secretary of HHS would be required to enter into an agreement with NASEM to study and evaluate whether ARPA-H has met its goals. NASEM would be required to submit the results of the evaluation to Congress and the Secretary of HHS.</p> <p>[Proposed PHSA §499A(l)(2)]</p>	<p>NASEM Evaluation: <i>Not later than three years after enactment</i>, the ARPA-H Director would be required to enter into a contract with NASEM for an evaluation of ARPA-H, including the goals and purposes of ARPA-H and the degree to which ARPA-H activities support and align with such goals and purposes. The evaluation may include (1) recommendations to improve ARPA-H, which may include lessons learned from other advanced research and development agencies or authorities in HHS or elsewhere in the federal government; (2) lessons learned from ARPA-H's establishment and their applicability to other HHS programs, and (3) an analysis of whether ARPA-H projects were duplicative of other research programs supported by HHS or other federal agencies. NASEM would be required to submit the evaluation to Congress and make it publicly available.</p> <p>[Proposed PHSA §483(l)]</p> <p>Performance Measures Framework: Would require the ARPA-H Director, in consultation with the advisory committee, to develop a performance measures framework for ARPA-H programs and projects in order to facilitate evaluation required under subsection (m), including data needed to perform such evaluation as consistent with the NASEM evaluation.</p> <p>[Note: There appears to be drafting error as subsection (m) is an authorization of appropriations.]</p> <p>[Proposed PHSA §483(g)(5)]</p>

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Other Reports	<p>Independent Review: Not later than one year after enactment and every three years thereafter, the Government Accountability Office (GAO) would conduct an independent review of the research portfolio of HHS, including ARPA-H, NIH, FDA, and BARDA, to assess the degree of unnecessary duplication of existing federal programs and projects; and to make recommendations regarding any potential reorganization, consolidation, or termination of such program and projects.</p> <p>[Proposed PHSA §499A(n)]</p>	<p>Report on Personnel: The ARPA-H Director would be required to maintain records regarding the use of ARPA-H personnel authorities, including the number of positions filled with such authorities, types of appointments, demographic information, and other specified information. Not later than one year after enactment and annually thereafter, the Director would be required to submit a report to specified congressional committees on the total number of appointments filled and how the positions relate to ARPA-H's purposes.</p> <p>[Proposed PHSA §483(d)(4)(B)-(C)]</p> <p>GAO Report on Personnel: Not later than two years after enactment, GAO would be required to report to Congress on the use of ARPA-H personnel authorities, including on the number of positions, the types of appointments, how the positions relate to ARPA-H's mission, how the appointments were made, sources used for identifying candidates, and aggregate demographic information. Would also require GAO to report on any challenges, limitations, or gaps related to the use of personnel authorities, and any related recommendations.</p> <p>[Proposed PHSA §483(d)(4)(F)]</p> <p>Confidentiality Clarification and Reporting: Beginning not later than one year after the date of enactment, and each fiscal year thereafter, the ARPA-H Director would be required to submit a report to Congress on the number of times the Secretary has used the authority to withhold information from disclosure and the nature of any request for information that was denied.</p> <p>[Proposed PHSA §483(j)]</p>
Funding	<p>Would authorize to be appropriated \$500 million for each of FY2023 through FY2027 to remain available until expended.</p> <p>[Proposed PHSA §499A(v)(1)]</p> <p>Would authorize the use of not more than 15 percent of the amounts made available to ARPA-H for any fiscal year for administrative expenses to operate ARPA-H.</p>	<p>Would authorize the appropriation of such sums as may be necessary for each of FY2023 through FY2027.</p> <p>[Proposed PHSA §483(m)]</p> <p>Would provide that any budget request for ARPA-H be separate from other NIH budget requests.</p>

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	[Proposed PHSA §499A(v)(2)]	[Proposed PHSA §483(n)]
Definitions	<p>Advanced Proofs of Concept: data, a prototype, or other experimental evidence that may precede the development of transformative health technologies and demonstrates the feasibility of a new concept.</p> <p>Transformative Health Technology: a drug, biological product, intervention, platform, tool, or device that should be prioritized to detect, diagnose, mitigate, prevent, cure, or treat a serious disease or medical condition for which there are unmet needs; and for which significant scientific uncertainty and regulatory risk exist, or incentives in the commercial market are unlikely to result in the adequate or timely development of such drug, biological product, intervention, platform, tool, or device.</p> <p>Also references existing terms in statute for “biologic product,” “drug,” “device,” “federal acquisition regulation,” “federal agency,” and “prize.”</p> <p>[Proposed PHSA §499A(u)]</p>	<p>No definitions for these terms, although definitions provided for other specified terms as noted elsewhere.</p> <p>[Proposed PHSA 483(a)]</p>

Source: CRS analysis of H.R. 5585, as passed by the House on June 22, 2022, at Congress.gov and text of the amendment in the nature of a substitute to S. 3799 at <https://www.help.senate.gov/imo/media/doc/PREVENT%20Pandemics%20Managers.pdf>.

Notes: H.R. 5585 serves as the baseline for comparison.

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