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Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues

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Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues

The Advanced Research Projects Agency for Health (ARPA-H) “advances high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity.” The Biden Administration originally proposed ARPA-H as part of the President’s FY2022 budget request for the National Institutes of Health (NIH). Congress first funded ARPA-H through FY2022 appropriations (P.L. 117-103) with \$1 billion in initial funding and then codified ARPA-H as a part of the PREVENT Pandemics Act (P.L. 117-328; Division FF; Title II), included in the Consolidated Appropriations Act, 2023. FY2023 appropriations also included an additional \$1.5 billion for ARPA-H.

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 ARPA-H have argued 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.

In 2022, the Department of Health and Human Services (HHS) established ARPA-H’s structure and leadership. The Consolidated Appropriations Act, 2022 (P.L. 117-103) 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 was to be housed within the National Institutes of Health (NIH), while the ARPA-H Director was to report directly to the HHS Secretary. In September 2022, President Biden appointed Dr. Renee Wegrzyn as the inaugural ARPA-H Director. ARPA-H has announced cross-cutting focus areas that center on creating tools and platforms that apply to a broad range of diseases and health issues. In late 2022 and early 2023, ARPA-H began hiring and announced its first funding opportunities.

Throughout 2022, the House and Senate considered separate bills to formally authorize ARPA-H. Legislative debates surrounding ARPA-H focused, in large part, on the agency’s placement within HHS and how to ensure its independence. Congress ultimately enacted formal authorization for ARPA-H through the PREVENT Pandemics Act (P.L. 117-328; Division FF, Title II). The law granted the agency many of the authorities common in other ARPA agencies, including flexible hiring and funding authorities (e.g., other transaction authorities). The law formally established ARPA-H as a part of NIH, with the Director reporting directly to the HHS Secretary. The law also specified that ARPA-H is required to have offices or facilities in at least three geographic areas and that ARPA-H cannot be located on NIH’s existing campus. In March 2023, ARPA-H announced that one of its three locations will be in the Washington, DC, National Capital Region. ARPA-H expects to announce the other two locations in fall FY2023.

As ARPA-H continues to take shape, ongoing issues for Congress include ensuring the independence and autonomy of the new agency; defining ARPA-H’s role in the biomedical research and health care ecosystem; facilitating the transition of ARPA-H supported inventions to broader implementation; and determining the appropriate level of funding to support the goals and mission of 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 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 played a key role in 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]). In 2022, both chambers considered legislation to codify ARPA-H and define its goals, scope, placement, activities, and authorities (H.R. 5585 and S. 3819/S. 3799, 117th Congress). Congress ultimately authorized ARPA-H in the Consolidated Appropriations Act, 2023, as part of the PREVENT Pandemics Act (P.L. 117-328; Division FF; Title II).

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 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 uses the following questions 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, “Media Availability: Lander, Collins Set Forth A Vision for ARPA-H,” <https://www.whitehouse.gov/ostp/news-updates/2021/06/22/media-availability-lander-collins-set-forth-a-vision-for-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 ribonucleic acid (mRNA), built partly upon investments by the Defense Advanced Research Projects Agency (DARPA), has spurred increased interest in the 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 Administration and congressional action as of the date of the report, and discusses selected policy and oversight issues.

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. In addition, Administration officials 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 was to be modeled after the Defense Advanced Research Projects Agency (DARPA), which is part of the Department of Defense (DOD), and was to 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 evidence suggest 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 fundamental scientific or technological challenges, involve a high degree of novelty and/or multidisciplinary approaches, and have a higher risk of failure than other projects.¹²

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.

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 (continued...)

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 was to “build platforms and capabilities to deliver cures for cancer, Alzheimer’s disease, diabetes, and other diseases.”¹⁴ In addition, the Administration 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

Congressional Action

Congress funded ARPA-H through FY2022 appropriations before formally establishing the agency in law as a part of the Consolidated Appropriations Act, FY2023. The Consolidated Appropriations Act, 2022 (P.L. 117-103), provided \$1 billion in appropriations to a new account at HHS for ARPA-H, with funding available until September 30, 2024.¹⁶ The law also provided 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 agreements, and other transactions;¹⁷
- 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.

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.¹⁸ The explanatory statement accompanying the law did not provide further details on Congress’s policy intentions for ARPA-H.¹⁹ The report accompanying the House FY2022 LHHS appropriations bill (H.Rept. 117-96, incorporated by reference) “encourage[d] NIH to collaborate

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

¹⁷ 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.

¹⁸ 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.

¹⁹ See U.S. Congress, House Committee on Rules, *Division H- LHHS Appropriations 2022, Explanatory Statement*, committee print, 117th Cong., 1st sess., p. 119.

with DARPA to develop the foundational policies, procedures, and staff training for ARPA-H employees.”²⁰

Throughout 2022, the House and Senate each considered legislation to authorize ARPA-H. In the Senate, the PREVENT Pandemics Act (S. 3799, as amended), which incorporated 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. In the House, H.R. 5585 was passed on June 22, 2022.

The two bills differed primarily in ARPA-H’s placement within HHS and the means of ensuring its independence. 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.²¹ Stakeholders, the Biden Administration, and Members of Congress 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). H.R. 5585 would have established ARPA-H as a separate agency within HHS, independent of NIH. S. 3799 (as amended) would have established ARPA-H within NIH, but would have facilitated independence by requiring ARPA-H’s headquarters to be located away from the National Capital Region and NIH’s campus, as well as by prohibiting the Director from appointing staff who had worked at NIH in the prior three years.

Through the Consolidated Appropriations Act, 2023, Congress enacted formal authorization for ARPA-H in Section 2331 of the PREVENT Pandemics Act (P.L. 117-328; Division FF; Title II).²² The law established the new agency as one focused on driving breakthroughs in biomedical science and medicine. It also granted the agency many of the authorities common for ARPA agencies, including flexible hiring and funding authorities (e.g., other transaction authorities). The authorization included the following key provisions:

- ARPA-H is established as part of NIH; the ARPA-H Director reports to the HHS Secretary.
- ARPA-H is required to have offices or facilities in at least three geographic areas. ARPA-H cannot be located on NIH’s existing campus.
- The Director is to ensure that staff have not worked at NIH in the prior three years but may grant an exemption for individuals who are uniquely qualified to advance ARPA-H’s goals.
- ARPA-H is to prioritize awards to domestic recipients and cannot award funding to nondomestic recipients organized under the laws of Russia, Iran, North Korea, China or other countries determined to be a covered foreign country under Section 119C of the National Security Act of 1947.²³
- ARPA-H’s funded research will not be subject to NIH peer or advisory council review requirements.²⁴ The HHS Secretary may exempt ARPA-H from NIH

²⁰ As directed in the explanatory statement cited in footnote 23, “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.”

²¹ Azoulay et al., “Funding Breakthrough Research: Promises and Challenges of the ‘ARPA Model,’” pp. 9-10.

²² Codified at Public Health Service Act (PHSA) §499A (42 U.S.C. §290c).

²³ 50 U.S.C. §3059.

²⁴ PHSA, §499A(g)(3).

policies that apply to preexisting NIH Institutes and Centers (IC), except as otherwise required in statute.²⁵

Through FY2023 LHHS appropriations (P.L. 117-328; Division H), ARPA-H received \$1.5 billion, available through FY2025, in an account under the Office of the Secretary.

Table I. ARPA-H Appropriations to Date

Fiscal Year; Law	Amount	Availability
FY2022; P.L. 117-103	\$1 billion	End of FY2024
FY2023; P.L. 117-328	\$1.5 billion	End of FY2025

Source: CRS analysis of appropriations.

Executive Action

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 deputy director for the agency.²⁶ Notice of the ARPA-H organizational structure, which included 14 offices, was published in the *Federal Register* on May 27, 2022.²⁷ ARPA-H’s subsequent statutory authorization limits the number of offices within the agency to no more than eight program offices and such special project offices as the Director may establish.²⁸ It is unclear if the agency’s organizational structure will change in response to that provision.²⁹

In September 2022, President Biden announced his intention to appoint Dr. Renee Wegrzyn as the inaugural ARPA-H Director.³⁰ ARPA-H has since announced four “focus areas” for its work.³¹

- **Health Sciences Futures:** “Accelerating advances across research areas and removing limitations that stymie progress towards solutions. The tools and platforms developed apply to a broad range of diseases.”
- **Scalable Solutions:** “Addressing challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.”

²⁵ PHSa, §499A(a)(3).

²⁶ 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>.

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

²⁸ PHSa, §499A(a)(2)(A); 42 U.S.C. §290c(a)(2)(A).

²⁹ The ARPA-H FY2024 budget request states that it is working to address this direction; see footnote 1 on page 5 of ARPA-H, *FY2024 Congressional Justification*, https://arpa-h.gov/assets/files/ARPA-H_FY_2024.pdf.

³⁰ White House, “President Biden Announces Intent to Appoint Dr. Renee Wegrzyn as Inaugural Director of Advanced Research Projects Agency for Health (ARPA-H),” press release, September 12, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/12/president-biden-announces-intent-to-appoint-dr-renee-wegrzyn-as-inaugural-director-of-advanced-research-projects-agency-for-health-arpa-h/>.

³¹ ARPA-H, “Our Research,” <https://arpa-h.gov/research/>.

- **Proactive Health:** “Reducing the likelihood that people become patients. Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans’ health, whether those are viral, bacterial, chemical, physical, or psychological.”
- **Resilient Systems:** “Developing capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Resilient systems need to sustain themselves between crises—from the molecular to the societal—to better achieve outcomes that advance American health and wellbeing.”

In early 2023, ARPA-H began recruiting program managers and other staff and announced its first funding opportunities. In March 2023, ARPA-H announced that one of the three offices would be located in the Washington, DC, National Capital Region. According to the agency, this office will focus on “stakeholder engagement and operations.” The agency also identified the primary focuses of the other two offices: (1) “a customer experience hub” centered on user testing and adoption, and (2) “an investor catalyst” that will help performers bring their ideas to market. ARPA-H expects to announce the location of the other two offices in fall 2023.³²

“The ARPA-H Model”

ARPA-H has adopted a version of the ARPA model to address health-related challenges. Like DARPA program managers, each ARPA-H program manager will be responsible for leading a program focused on a specific, well-defined challenge. ARPA-H’s funded programs will therefore be shaped by its program managers and their ideas. ARPA-H program managers generally will not focus on specific diseases or health issues, but rather on a specific health-related challenge that (1) is not easily solvable through existing research activities (e.g., government or commercial research) and (2) has measurable outcomes.³³ As specified in statute, each ARPA-H program manager is to serve a three-year term and may be reappointed and serve up to two terms.³⁴ These term-limited appointments are intended to give a sense of urgency to the programs and allow ARPA-H to continually pursue new ideas and approaches.³⁵

ARPA-H has adopted a version of the “Heilmeier Catechism,” a set of questions that DARPA uses, to assess program proposals for ARPA-H investment. The questions include some that DARPA currently uses, such as, “How is it done today? What are the limitations of present approaches?” and “What is new about your approach? Why do you think you can be successful at this time?”³⁶ New questions specific to ARPA-H include, “To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?” and “How might this program be misperceived or misused (and how can we prevent that from happening)?”³⁷

Once hired, a program manager is to solicit program-related proposals and select projects for funding. These projects are carried out by “performers”—teams from academia, industry,

³² ARPA-H, “Agency Releases Funding Opportunities, Site Selection Process, and Idea Competition,” March 15, 2023, <https://arpa-h.gov/news/one-year/>.

³³ ARPA-H, “The ARPA-H Model,” <https://arpa-h.gov/research/model>, and Max Kozlov, “‘Open for Business’: Risk-Taking US Health Agency Ready to Spend \$2.5-Billion Budget,” *Nature*, March 21, 2023.

³⁴ Public Health Service Act (PHSA), §499A(j)(2).

³⁵ See CRS Report R45088, *Defense Advanced Research Projects Agency: Overview and Issues for Congress*.

³⁶ For more information, see Defense Advanced Research Projects Agency, “The Heilmeier Catechism,” <https://www.darpa.mil/work-with-us/heilmeier-catechism>.

³⁷ ARPA-H, “Program Manager Application,” <https://arpa-h.gov/careers/program-managers/>.

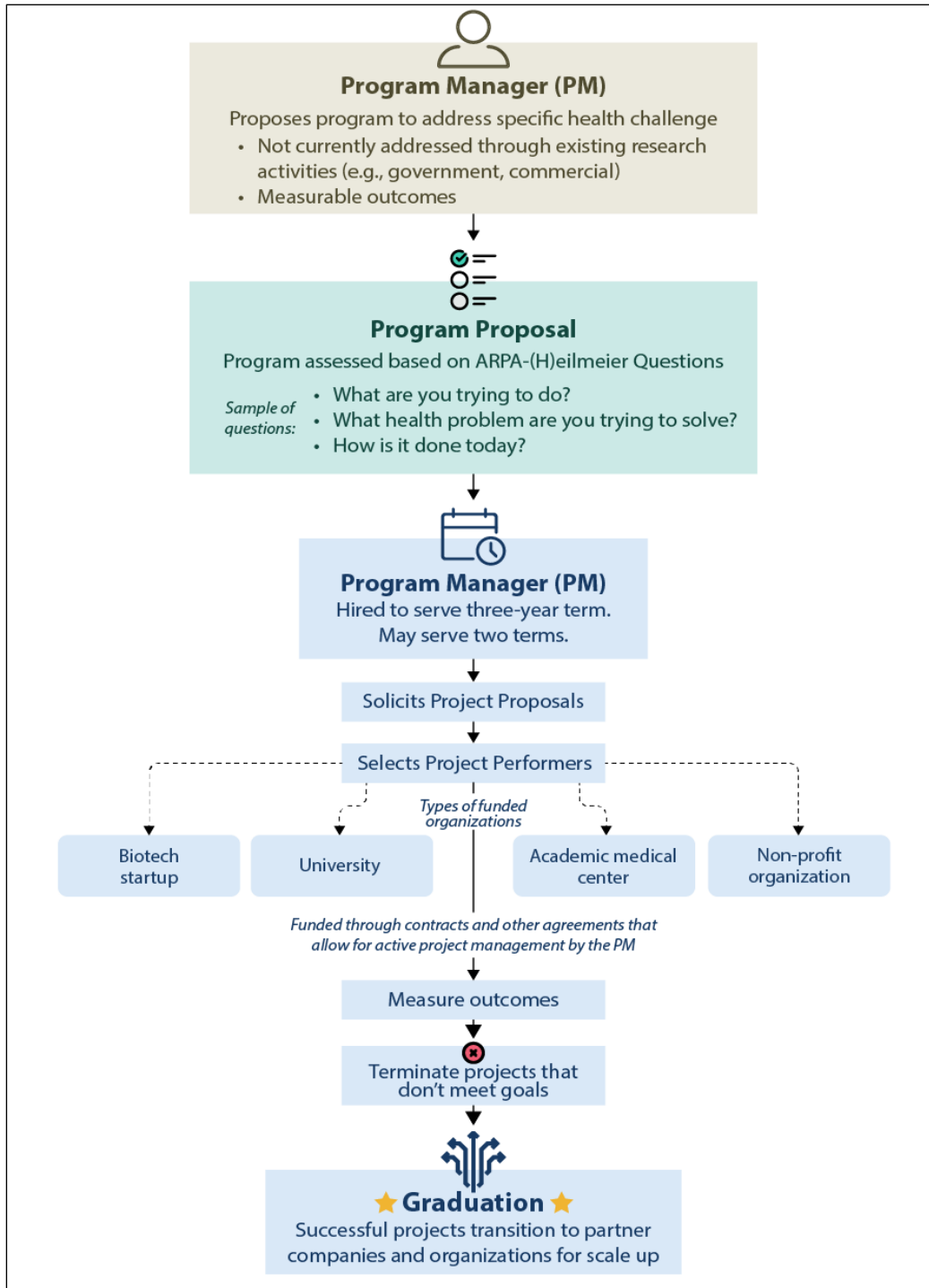
government, and elsewhere—outside of the agency.³⁸ Projects will likely be funded mostly through contracts, cooperative agreements, and other transaction agreements rather than through traditional research grants.³⁹ These types of funding agreements allow program managers to play a more active role in the projects, including by assessing performance regularly and terminating projects that fail to meet their goals.⁴⁰

³⁸ ARPA-H, “The ARPA-H Model,” <https://arpa-h.gov/research/model/>, and PHSA, §499A(j)(2).

³⁹ Max Kozlov, “‘Open for Business’: Risk-Taking US Health Agency Ready to Spend \$2.5-Billion Budget,” *Nature*, March 21, 2023.

⁴⁰ ARPA-H, “The ARPA-H Model,” <https://arpa-h.gov/research/model/>, and PHSA, §499A(j)(2).

Figure I. “The ARPA-H Model”



Source: Developed by CRS, based on information at arpa-h.gov and from Section 499A of the Public Health Service Act.

Selected Policy and Oversight Issues

The formal establishment of ARPA-H in the Consolidated Appropriations Act, 2023 (P.L. 117-328), in addition to recent actions taken by the Biden Administration, raises a number of potential implementation and execution issues for congressional consideration.

Independence and Autonomy

Key components of the ARPA model include independence at the agency level to shape a distinct mission and culture, along with autonomy of program managers to select and fund projects.⁴¹ Stakeholders, the Biden Administration, and Members of Congress initially debated where to place ARPA-H within the federal government, particularly whether to house the new entity within NIH or to create a separate agency under HHS (NIH's parent department). 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.⁴² On the other hand, some Members of Congress and stakeholders saw NIH's culture as relatively conventional and risk-averse and questioned whether NIH's leadership and culture could affect ARPA-H's ability to succeed in research for transformational innovation.⁴³

As noted above, Congress decided to place ARPA-H within NIH, but with the ARPA-H Director reporting directly to the HHS Secretary.⁴⁴ This arrangement is consistent with how the HHS Secretary chose to establish ARPA-H in 2022. Congress also enacted a number of provisions to ensure ARPA-H's independence and autonomy. Specifically, the ARPA-H authorizing statute (1) prohibits ARPA-H from being located on the NIH campus;⁴⁵ (2) requires ARPA-H to have offices or facilities in not less than three geographic areas;⁴⁶ and (3) prohibits the ARPA-H Director from appointing personnel to the agency who were employed by NIH three years prior to such appointment (with some exceptions).⁴⁷ In addition, the law requires that the agency's budget request propose a separate appropriation from the other NIH accounts.⁴⁸ The law also prohibits 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, comments, or review prior to submission to Congress (as long as the Director indicates that the views are his or her own and do not reflect the views of the President or other agency or department).⁴⁹

⁴¹ Azoulay et al., "Funding Breakthrough Research: Promises and Challenges of the 'ARPA Model,'" pp. 9-10.

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

⁴³ Sarah Omermohle, "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; and 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.

⁴⁴ PHSA, §499A(a)(1) and PHSA, §499A(c)(3).

⁴⁵ PHSA, §499A(h)(C)(ii).

⁴⁶ PHSA, §499A(h)(C)(ii).

⁴⁷ PHSA, §499A(i).

⁴⁸ PHSA, §499A(t).

⁴⁹ PHSA, §499A(c)(6).

Some have argued that ARPA-H's founding director will play a crucial role in developing a unique culture that guides the agency to success.⁵⁰ 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."⁵¹ Similarly, the ARPA-H authorizing statute specifies that the Director have qualifications to manage advanced biomedical research programs, including large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, and have a demonstrated ability to identify and develop partnerships to address strategic needs in meeting ARPA-H goals.⁵² The authorizing statute also requires the ARPA-H Director to be appointed by the President for a four-year term, allowing for reappointment for one consecutive term.⁵³

As noted above, in September 2022, President Biden appointed Dr. Renee Wegrzyn as the first ARPA-H Director. In addition to her private sector experience, Dr. Wegrzyn was previously a program manager in the DARPA Biological Technologies Office.⁵⁴ Dr. Renee Wegrzyn has stated publicly that the initial placement within NIH has been helpful in providing ARPA-H with the administrative support that has allowed her to focus on the task of hiring program managers and standing up the new agency's programs.⁵⁵

I wouldn't be able to have my whole team focus on that without having NIH doing our IT, doing our security background reviews, and all of the things that are required to set up a government agency ... it's a start-up that's really been able to lean on the NIH.

It remains to be seen if the provisions in the enacted law will facilitate sufficient agency independence. In the near term, implementation activities and organizational, structural, and strategic planning may be areas of potential interest for congressional oversight.

Questions and Considerations for Congress

- How will the requirement for offices in three distinct geographic locations separate from NIH's main campus affect ARPA-H's ability to maintain its independence from NIH? Will the distributed offices and facilities enable or hinder the agency's ability to recruit highly qualified program managers and create a distinctive organizational culture among them?
- If ARPA-H is part of NIH, to what extent is it subject to NIH agency policies and general provisions, which may be largely under the purview of the NIH Director? While the ARPA-H Director may report directly to the Secretary of HHS, to what extent does the NIH Director exert control over any ARPA-H operations and to what extent is ARPA-H independent of NIH?

⁵⁰ 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>.

⁵¹ 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.

⁵² PHSA, §499A(c)(2).

⁵³ PHSA, §499A(c)(5).

⁵⁴ ARPA-H, "Renee Wegrzyn, Ph.D.," <https://arpa-h.gov/people/renee-wegrzyn/>.

⁵⁵ Milken Institute Future of Health Summit, "A Commitment to Accelerating Cures: The Future of Biomedical Innovation," December 6, 2022, <https://milkeninstitute.org/video/biomedical-cures-accelerating-innovation>.

- For FY2024, ARPA-H’s first budget request to Congress was included as a part of NIH’s overall budget request.⁵⁶ Is this in line with Congress’s intention in ARPA-H’s authorizing statute for ARPA-H to propose a separate appropriation from the other NIH accounts?⁵⁷ How does grouping ARPA-H’s budget request with the rest of NIH affect the relationship, or perceived relationship, between ARPA-H and NIH? How does it affect ARPA-H’s representation at budget and appropriations hearings?

Defining ARPA-H’s Role in the Biomedical R&D and Health Care Ecosystem

Existing ARPAs address their mandates 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.⁵⁸ 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 has asserted 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.”⁵⁹ 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.⁶⁰

Congress defined ARPA-H’s goals as follows:⁶¹

- to foster the development of novel, breakthrough, and broadly applicable capabilities and technologies to accelerate transformative innovation in biomedical science and medicine in a manner that cannot be readily accomplished through traditional federal biomedical R&D programs or commercial activity;
- to revolutionize the detection, diagnosis, mitigation, prevention, treatment, and cure of diseases and health conditions by overcoming long-term and significant technological and scientific barriers to developing transformative health technologies;
- to promote high-risk, high-reward innovation to enable the advancement of transformative health technologies; and

⁵⁶ See NIH Office of the Budget, “Institute/Center Submissions,” https://officeofbudget.od.nih.gov/insti_center_subs.html.

⁵⁷ PHSa, §499A(t).

⁵⁸ 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.’”

⁵⁹ Collins et al., “ARPA-H: Accelerating Biomedical Breakthroughs.”

⁶⁰ 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.

⁶¹ PHSa, §499A(b).

- to contribute to ensuring the United States pursues initiatives that aim to maintain global leadership in science and innovation and improve the health and wellbeing of Americans by supporting the advancement of biomedical science and innovation.⁶²

ARPA-H's statutorily defined goals may differ somewhat from the agency's chosen focus areas announced in late 2022, prior to enactment of the ARPA-H statute (see "Executive Action"). The goals in statute appear to emphasize biomedical science and technology, whereas the announced focus areas appear to reflect a broader focus on health and the health care system. As mentioned above, ARPA-H's programs and projects will ultimately be shaped by its program managers. ARPA-H's authorization requires that the agency regularly develop a strategic plan and submit an annual report on programs and projects funded.⁶³ The strategic plan will likely be important in ensuring that ARPA-H has effectively delineated and defined its role in the broader biomedical R&D and health care ecosystem. In addition, the required annual reports to Congress—detailing current, proposed, and planned ARPA-H projects—may provide insight into areas of potential overlap and duplication.⁶⁴

Some have raised concerns that the agency could duplicate existing medical and health research efforts across the federal government and in the commercial and philanthropic sectors.⁶⁵ 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.⁶⁶ The law addresses concerns related to aligning ARPA-H efforts with those of other federal agencies by requiring the establishment of an interagency advisory committee tasked with avoiding duplication and improving the coordination of ARPA-H's efforts with other federal agencies.⁶⁷ The law also requires the Government Accountability Office (GAO) to conduct an independent review of HHS's research portfolio every four years to assess the degree of unnecessary duplication and make recommendations regarding any potential reorganization, consolidation, or termination of duplicative programs and projects.⁶⁸ In addition, the law addresses concerns about the duplication of private sector efforts by directing ARPA-H to prioritize investments in areas that are underfunded by the public and private sector, and to facilitate public-private partnerships.⁶⁹

Questions and Considerations for Congress

- ARPA-H's funded projects will ultimately be shaped by the agency's program managers. Is ARPA-H able to recruit the appropriate talent and expertise? Are there any known challenges or barriers to recruitment? The law requires GAO to

⁶² PHSA, §499A(b)(1).

⁶³ PHSA, §499A(l).

⁶⁴ PHSA, §499A(k)(1).

⁶⁵ 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>; 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/>; and 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.

⁶⁶ Research!America, "U.S. Investments in Medical and Health Research and Development: 2016-2020," January 2022, https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf.

⁶⁷ PHSA, §499A(p).

⁶⁸ PHSA, §499A(m).

⁶⁹ PHSA, §499A(c)(4).

- submit a report to Congress within two years of enactment on personnel at ARPA-H, to include challenges, limitations, and gaps associated with the use of personnel authorities.⁷⁰
- Congress might seek to better understand the processes that ARPA-H has in place to avoid duplication with other federal programs and the private sector. Another ARPA agency, the Advanced Research Projects Agency-Energy (ARPA-E), faced similar concerns regarding potential duplication; however, a recent study by GAO found that “ARPA-E has practices in place to help manage overlap and duplication during its program development cycle.” How does Congress use the insights from past experience with other ARPA agencies to assess ARPA-H’s practices for addressing duplication and overlap?

Facilitating Implementation of ARPA-H Innovations

In its ARPA-H concept paper, the Biden Administration identified the unique challenge of transitioning ARPA-H funded innovations to the health care ecosystem as a key difference between ARPA-H and DARPA.⁷¹

Although DARPA is an excellent inspiration for ARPA-H, it is not a perfect model for biomedical and health research. It serves the needs of a single customer, the DOD, and its mission is focused on national security. Its projects typically involve engineered systems. By contrast, health breakthroughs (i) interact with biological systems that are much more complex and more poorly understood than engineered systems, requiring close coupling to a vast body of biomedical knowledge and experience; (ii) interact with a complex world of many customers and users—including patients, hospitals, physicians, biopharma companies, and payers; (iii) interact in complex ways with human behavior and social factors; and (iv) require navigating a complex regulatory landscape. ARPA-H can learn from DARPA but will need to pioneer new approaches.

ARPA-H has already taken steps to tailor the ARPA model to health problems. For example, ARPA-H has added two new questions to the “Heilmeier Catechism” that DARPA uses to assess research program proposals: “To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?” and “How might this program be misperceived or misused (and how can we prevent that from happening)?”⁷² In addition, ARPA-H has stated that partners who can transition successful projects to broader implementation will be involved from the start of a new program.⁷³ ARPA-H also intends one of its geographic locations to facilitate implementation and serve as a “customer experience hub” centered on user testing and adoption.⁷⁴

The Biden Administration has noted that the health care sector consists of a complex set of payers, regulators, and other stakeholders that could affect adoption of ARPA-H innovations. Other federal agencies will likely play a critical role in the commercialization and implementation of ARPA-H technologies and innovations. For example, the U.S. Food and Drug Administration (FDA) would regulate many ARPA-H-supported medical products. The ARPA-H authorizing

⁷⁰ PHS Act, §499A(k)(3)(C).

⁷¹ 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>.

⁷² ARPA-H, “Program Manager Application,” <https://arpa-h.gov/careers/program-managers/>.

⁷³ ARPA-H, “The ARPA-H Model,” <https://arpa-h.gov/research/model/>.

⁷⁴ ARPA-H, “Agency Releases Funding Opportunities, Site Selection Process, and Idea Competition,” March 15, 2023, <https://arpa-h.gov/news/one-year/>.

statute authorizes FDA to meet with ARPA-H and any other federal partners at appropriate intervals to discuss the development status of ARPA-H projects, including high-priority projects and actions that may facilitate the development of medical products.⁷⁵ In addition, federal health care programs, such as the Centers for Medicare & Medicaid Services (CMS) and VA, could end up implementing or paying for innovations supported by ARPA-H. Other types of ARPA-H-supported innovations (e.g., data-sharing platforms and research tools) could transition to other health agencies such as NIH or the Centers for Disease Control and Prevention (CDC).

Questions and Considerations for Congress

- What processes and policies is ARPA-H putting into place to facilitate eventual broader implementation of ARPA-H-supported inventions? Are they sufficient?
- Effective coordination with other federal agencies, including, as appropriate, the leveraging of funding and expertise, will likely be critical to ensuring that ARPA-H technologies and innovations are adopted in the health sector. In the near term, how is ARPA-H collaborating with other federal agencies? Are the statutory coordination and collaboration requirements sufficient? Do they add administrative burden?
- ARPA-H-supported innovations may take a long time to become commercially available products or services. In the meantime, how does Congress assess the progress of ARPA-H-supported inventions in transitioning to market? Are patents, commercial investments, user testing results, or other measures best suited to determine success?
- What role should Congress play in facilitating the implementation of ARPA-H-supported innovations? Some newer health technologies (e.g., artificial intelligence platforms, cellular therapies) may warrant regulatory or financing reforms to enable broader implementation. In addition, some ARPA-H-supported projects might transition to government agencies for long-term implementation. How can Congress determine when statutory changes or appropriations could help transition ARPA-H innovations to broader use or implementation?

Funding

The Consolidated Appropriations Act, 2022 (P.L. 117-103), provided ARPA-H with \$1 billion in funding available until September 30, 2024. This amount is in contrast with the \$6.5 billion in initial funding proposed by the Biden Administration for the same period.⁷⁶ The Consolidated Appropriations Act, 2023 (P.L. 117-328), provided the agency with \$1.5 billion in funding available until September 30, 2025—an amount comparable to the authorized amount of \$500 million for each of FY2024 through FY2028 included in the ARPA-H statutory authorization. For FY2024, the Biden Administration is requesting \$2.5 billion for ARPA-H, \$1 billion more than the FY2023-enacted amount.

What is the appropriate funding level for ARPA-H? Congress might look to other agencies for comparison: DARPA is funded at \$4.1 billion for FY2023, ARPA-E has FY2023 funding of \$470 million, and fewer than half of preexisting NIH Institutes and Centers (ICs) have an annual budget that exceeds \$1 billion (12 out of 25 accounts).⁷⁷ Taking a wider view, total U.S.

⁷⁵ PHS, §499A(f).

⁷⁶ NIH, *Congressional Justification: FY2022*, pp. 10-11.

⁷⁷ See HHS, *Budget in Brief: FY2024*, p. 53, <https://www.hhs.gov/sites/default/files/fy-2023-budget-in-brief.pdf>.

investments in health and medical research (both public and private) were estimated at \$245.1 billion in 2020.⁷⁸

Stakeholders have debated the appropriate funding level for ARPA-H. Dr. Wegrzyn has stated that most programs will cost about \$50 to \$100 million each.⁷⁹ Given that ARPA-H is an untested new agency, some argue that it should start small and grow over time depending on its success.⁸⁰ 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.⁸¹ In addition, biomedical research—especially medical product R&D—tends to be expensive relative to some other areas of technology R&D.⁸² 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, determining the appropriate ARPA-H funding level in the short term can be difficult.

Some have expressed concern that ARPA-H funding may compete with funding for NIH ICs during the annual budget and appropriations process.⁸³ Given current consideration of discretionary spending limits to reduce federal debt levels, Congress may face tradeoffs in deciding how much funding to allocate to ARPA-H compared with preexisting NIH ICs or other discretionary spending levels.

Members of Congress have considered whether and how to leverage private funding—such as from industry or philanthropy—to support ARPA-H’s efforts. Currently, NIH structures many of its medical product development and biomedical innovation programs as public-private partnerships. The authorizing statute directs ARPA-H to partner with a range of public and private entities and requires that the ARPA-H Director consider the need for public-private partnerships to effectively advance R&D activities when prioritizing agency investments.⁸⁴

Questions and Considerations for Congress

- Congress may wish to conduct oversight on the initial funding opportunities and awards made by the agency. Is the agency pursuing activities that align with congressional intent?

⁷⁸ Research!America, “U.S. Investments in Medical and Health Research and Development: 2016-2020,” January 2022, https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_January-2022-1.pdf.

⁷⁹ Milken Institute Future of Health Summit, “A Commitment to Accelerating Cures: The Future of Biomedical Innovation,” December 6, 2022, <https://milkeninstitute.org/video/biomedical-cures-accelerating-innovation>.

⁸⁰ See, for example, Tollefson, “The Rise of ‘ARPA-Everything’ and What It Means for Science.”

⁸¹ 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>.

⁸² GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 2017, pp. 28-37.

⁸³ Ariel Cohen, “Health Research Focus Could Give NIH Competition for Funding,” *Congressional Quarterly*, March 29, 2023.

⁸⁴ PHS, §499A(c)(4).

- In FY2024, ARPA-H submitted its first budget request alongside other NIH budget requests and as a part of the total request for NIH.⁸⁵ How does this budget structure affect Congress’s consideration of ARPA-H’s budget compared with

⁸⁵ NIH Office of the Budget, “Institute and Center Submissions,” https://officeofbudget.od.nih.gov/insti_center_subs.html.

- NIH's preexisting ICs? Is this structure consistent with congressional direction that ARPA-H propose a separate appropriation from other NIH accounts?
- Congress may wish to examine the effectiveness of ARPA-H's collaborations and cooperation with the private sector. What are ARPA-H's policies for addressing conflicts of interest and managing the potential for undue industry influence in order to maintain ARPA-H's public trust?
- Given ARPA-H's focus on high-risk innovation, how does Congress evaluate its investment in ARPA-H in the near term? ARPA-H's authorizing statute directs an evaluation of ARPA-H by the National Academies of Sciences, Engineering, and Medicine⁸⁶ no later than five years after enactment to determine if ARPA-H is meeting its goals and functions.⁸⁷ This evaluation may help Congress determine initial outcomes for the agency. Some failures are to be expected for ARPA-H's funded programs given the focus on risky projects. Yet, how does Congress determine if the agency as a whole is achieving an appropriate return on federal investment?

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⁸⁶ The National Academies of Sciences, Engineering, and Medicine is a nongovernmental organization that provides independent, objective advice to inform federal policy. NASEM's charter was established by a law passed by Congress in 1863. See NASEM, "A Selection of Highlights from the History of the National Academy of Sciences, 1863-2005," <http://www.nasonline.org/about-nas/history/highlights/>.

⁸⁷ PHS, §499A(k)(2).