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SUMMARY

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

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 creates a new ARPA-H account at HHS, with funding available until September 30, 2024, and allows 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 cancer, Alzheimer's disease, diabetes, and other diseases.

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 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 introduced in the 117th Congress would codify and further delineate ARPA-H's goals, structure, placement, activities, and authorities. These include H.R. 5585 and H.R. 6000 introduced in the House and S. 3819 introduced in the Senate. Subsequently, 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. 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 provides $1 billion to a new Department of Health and Human Services (HHS) account to establish ARPA-H. In addition, several bills have been introduced that would codify ARPA-H and define its goals, scope, placement, activities, and authorities (e.g., H.R. 5585, H.R. 6000, 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 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 maintaining the economic competitiveness of the United States.[6] In addition, the recent rapid

[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/.

[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/

development of safe and effective Coronavirus Disease 2019 (COVID-19) vaccines based on novel technologies such as 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 authorize 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 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]

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 Reinhilde 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 Reinhilde 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 Science, Technology, and Industry Policy Papers, No. 112, May 2021, https://read.oecd.org/10.1787/06913b3b-en?

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]).

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.[18] The FY2023 request reiterates the same vision for ARPA-H as in the FY2022 request, and also notes

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[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.

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

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 Moonshot is another one of President Biden's major policy priorities related to biomedical research.[19]

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:[20]

- **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:** 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 and Medicaid Services (CMS). Participants also emphasized the need to partner and consult with diverse private, academic, and public sector entities.

[19] NIH, *Congressional Justification: FY2023*, pp. 4-13.

[20] 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.

HHS ARPA-H Placement Decision

As discussed below, 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. In addition, the Secretary was required 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 is to reside within NIH, while the ARPA-H Director is to report directly to the HHS Secretary.

See 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.

Congressional Action

Appropriations

On March 15, 2022, the Consolidated Appropriations Act, 2022 (P.L. 117-103) was signed into law. It provides $1 billion in appropriations to a new account at HHS for ARPA-H, with funding available until September 30, 2024.[21] Unlike earlier ARPA-H appropriations proposals, the law does 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;[22]
- 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.[23]

Earlier appropriations proposals included higher funding levels for ARPA-H, but conditioned funding on authorizing legislation. However, these proposals were not enacted. The Consolidated Appropriations Act, 2022 (H.R. 4502),[24] which passed the House on July 29, 2021, would have provided $3 billion for ARPA-H in a new account at NIH available until September 30, 2024, with the condition that funds would be available only if legislation specifically establishing ARPA-H were enacted into law. Separately, the Senate-introduced Departments of Labor, Health

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

[22] 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.

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

[24] H.R. 4502 contains the text of seven regular appropriations bills reported by the House Appropriations Committee: H.R. 4502 (Labor-HHS-Education) (Div. A), H.R. 4356 (Agriculture) (Div. B), H.R. 4549 (Energy-Water) (Div. C), H.R. 4345 (Financial Services) (Div. D), H.R. 4372 (Interior) (Div. E), H.R. 4355 (Military Construction and Veterans Affairs) (Div. F), and H.R. 4550 (Transportation-HUD) (Div. G).

and Human Services, and Education, and Related Agencies Appropriations Act, 2022 (S. 3062) would have provided $2.4 billion for ARPA-H available through September 30, 2024, also with the condition that funds would be available only if legislation specifically establishing ARPA-H were enacted into law.[25]

Authorizations

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

Two other bills to authorize ARPA-H have been introduced in the House. Representative Anna Eshoo, chair of the House Energy and Commerce (E&C) Health Subcommittee, introduced the Advanced Research Project Agency–Health Act (H.R. 5585) on October 15, 2021. This standalone bill would authorize and establish ARPA-H within HHS. 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).

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 H.R. 6000) 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.[26] 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

[25] The text of the Senate majority draft Labor-HHS-Education bill and accompanying committee report is linked to the press release "Chairman Leahy Releases Remaining Nine Senate Appropriations Bills," October 18, 2021, https://www.appropriations.senate.gov/news/majority/chairman-leahy-releases-remaining-nine-senate-appropriations-bills. See also "Shelby: Democrats' Partisan Bills Threaten FY22 Appropriations Process," October 18, 2021, https://www.appropriations.senate.gov/news/shelby-democrats-partisan-bills-threaten-fy22-appropriations-process.

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

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 as discussed below.

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.[27] 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.[28] 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 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.[29]

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."[30]

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.[31] 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.[32] 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.[33] Regardless of where the new agency is placed, it would likely need to consult with NIH programs, HHS

[27] Collins et al., "ARPA-H: Accelerating Biomedical Breakthroughs."

[28] 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.

[29] 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.

[30] 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.

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

[32] HHS, "InnovationX," https://www.hhs.gov/ash/osm/innovationx/index.html.

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

programs such as BARDA, as well as biomedical programs at DOD and FDA to promote collaboration and avoid duplication.

The authorizing bills in the House (H.R. 5585 and H.R. 6000) 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 H.R. 6000 and 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: (1) would prohibit ARPA-H from being located on the NIH campus and in close proximity to the National Capital Region and (2) would 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).

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.[34] 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."[35] All 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 and H.R. 6000 would authorize a five-year appointment term for the ARPA-H Director while S. 3799, as amended, would authorize a four-year term. All bills would allow for one consecutive term. All 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 the development and application of 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.[36] 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

[34] 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.

[35] 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.

[36] 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.'"

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."[37] 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.[38]

The ARPA-H bills (H.R. 5585, H.R. 6000, and S. 3799, as amended) define overall agency goals similarly, with some variations (see **Table A-1**). All the bills emphasize breakthrough biomedical technologies and innovation in ARPA-H's proposed statutory goals. None of the bills establish ARPA-H to focus on specific diseases or areas of research. Differences in ARPA-H goals among the bills include that H.R. 5585 names ensuring U.S. global leadership as an overall goal; that H.R. 6000 mentions reducing the human and economic cost of disease; and that S. 3799, as amended, focuses on advancements that cannot be readily accomplished through traditional commercial or research activity.

Some have expressed concern about the potentially broad scope of ARPA-H.[39] All 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.[40] 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.[41] 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. 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. 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 "Advice" 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 ARRPA-H's efforts with other federal agencies. In addition, all three bills would require ARPA-H to coordinate with the FDA to expedite and facilitate the

[37] Collins et al., "ARPA-H: Accelerating Biomedical Breakthroughs."

[38] 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 Reinhilde 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.

[39] 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/.

[40] 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.

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

transformation and development of ARPA-H activities into medical products and solutions for patients.

There is also concern about duplicating commercial or philanthropic research efforts. 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 duplication during its program development cycle."[42] 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) provides 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.[43] It is also lower than the authorized amounts included in H.R. 5585 and H.R. 6000. H.R. 5585 would authorize $3 billion for ARPA-H, and H.R. 6000 would authorize appropriations at the Administration-requested level of $6.5 billion—both with funding available until expended. 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).[44]

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.[45] 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.[46] In addition, biomedical research—especially medical product R&D—tends to be expensive relative to some other areas of technology R&D.[47] Also, given the long lag time that generally exists between R&D activities and a commercially viable product or service, measuring the contribution of R&D to end the product can be difficult.

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[42] 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.

[43] NIH, *Congressional Justification: FY2022*, pp. 10-11.

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

[45] See, for example, Tollefson, "The Rise of 'ARPA-Everything' and What It Means for Science."

[46] 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.

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

In an effort to separate ARPA-H funding from other NIH programs, all three bills would require a separate ARPA-H budget request from other NIH or HHS budget requests. H.R. 5585 would additionally create a new fund for financing ARPA-H. Both H.R. 5585 and H.R. 6000 would allow for submission of a budget directly to Congress, similar to existing NIH "professional judgment budgets" or "bypass budgets." Existing NIH professional judgment budgets—submitted directly from NIH to Congress for certain research areas—estimate funding needs based solely on scientific priorities and opportunities rather than through the traditional budget development process that weighs other policy objectives and funding priorities.[48]

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. All three 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.

[48] For other NIH professional judgment budgets, see National Cancer Institute, "NCI Professional Judgment Budget, President's Budget and Appropriations," https://www.cancer.gov/about-nci/budget/fact-book/historical-trends/bypass-appropriations; National Institute on Aging, "Bypass Budget Proposal Archive," https://www.nia.nih.gov/about/bypass-budget-proposal-archive; and NIH Office of AIDS Research, "NIH HIV Research Budget," https://www.oar.nih.gov/hiv-policy-and-research/budget. For context, see CRS Report R47019, *The Executive Budget Process: An Overview*, by Dominick A. Fiorentino and Taylor N. Riccard.

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

Table A-1 provides a side-by-side comparison of the three bills that would authorize ARPA-H in the 117th Congress. In the House, H.R. 5585 and H.R. 6000 have been introduced and were discussed in a hearing on March 17, 2022.[49] 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 APRA-H Authorization Legislation

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Authorization	Amends Public Health Service Act (PHSA) Title IV (National Research Institutes) to add new "Part J—Advanced Research Projects Agency-Health" at the end with two sections: (1) Section 499A: Advanced Research Projects Agency-Health and (2) Section 499B: Health Advanced Research and Development Fund. [H.R. 5585 §2]	Standalone provision. Does not amend the PHSA. [H.R. 6000 §501(a)]	Amends the PHSA Title IV to add new "Subpart 3—Advanced Research Projects Authority for Health" to include one section, Section 483: Advanced Research Projects Authority for Health. [S. 3819 §2]
Placement in Federal Government	Would establish ARPA-H within the Department of Health and Human Services (HHS). [Proposed PHSA §499A(a)]	Would direct the Secretary of HHS to establish ARPA-H within the National Institutes of Health (NIH). [H.R. 6000 §501(a)]	Would establish ARPA-H within NIH. [Proposed PHSA §483(b)]

[49] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, 117th Cong., 1st sess., March 17, 2022.

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Goals	The stated goals of ARPA-H would be to: • foster the development of new, breakthrough capabilities, technologies, systems, and platforms to accelerate innovations in health and medicine; • revolutionize diagnosis, mitigation, prevention, and treatment of diseases through the development of transformative health technologies and high-need cures; • promote high-risk, high-reward innovation to develop high-need cures (H.R. 6000 includes similar language in the ARPA-H activities category); and • ensure the United States maintains global leadership in science and innovation, and the highest quality of life and health for its citizens. [Proposed PHSA §499A(b)(1)]	The stated goals of ARPA-H would be to deliver breakthrough capabilities through technologies, systems, and platforms that (key differences from H.R. 5585 *italicized*): • accelerate the discovery and application of transformational innovations in health and medical product development; and • *reduce the human and economic cost of disease.* [H.R. 6000 §501(b)(1)]	The stated purpose of ARPA-H would be to (key differences from H.R. 5585 *italicized*): • 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 *long-term and significant technological and scientific barriers* to advancing such technologies in order to improve the prevention, diagnosis, mitigation, treatment, and cure of health conditions. [Proposed PHSA §483(b)]

Activities ("Means")	Activities of the agency would include: • identifying and promoting revolutionary advances in health sciences; • accelerating transformational technological advances in areas with limited funding or technical certainty; • 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* and the fiscal liability of the federal government with respect to health care; and potential opportunities to advance health equity; • translating scientific discoveries into technological innovations and high-need cures; • providing resources and support to create platform capabilities that draw on multiple disciplines; and • delivering advanced proofs of concept that demonstrate clinically meaningful advances. [Proposed PHSA §499A(b)(2)]	Activities of the agency would include (grouped for comparison; key differences *italicized*): <u>*Similar to H.R. 5585:*</u> • identifying and promoting revolutionary advances in biomedical and health research that enable new paradigms in health; • accelerating transformational health advances in areas that the *relevant industries by themselves* are not likely to undertake because of technical, financial, or other uncertainty; and • prioritizing project investments based on scientific opportunity and uniqueness of fit to ARPA-H strategies and operating practice, together with the prospective impact on disease burden (*regardless of disease prevalence*), *both human and fiscal*, including the health care fiscal liability of the federal government. <u>*Different from H.R. 5585:*</u> • promoting high-risk, high-reward innovation (H.R. 5585 includes similar language as an ARPA-H goal); and • partnering with, and providing funding to, a broad range of institutions, including universities, national laboratories, public sector organizations, private companies, nonprofit organizations, and foreign institutions. (H.R. 5585 lists partnering with a broad range of institutions as an ARPA-H Director authority.) [H.R. 6000 §501(b)(2)]	No similar category of provisions. Comparable language in "Goals" and "Duties of the Director" sections.

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
ARPA-H Director Position	The ARPA-H Director position would be established as follows: **Appointment:** Appointed by the President. Reports to the Secretary of HHS. [Proposed PHSA §499A(c)(1), (3)] **Term:** Five years. May be reappointed for one consecutive term. [Proposed PHSA §499A(c)(5)] **Qualifications:** By 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 across multiple sectors, including generating high-need cures. [Proposed PHSA §499A(c)(2)] **Autonomy Regarding Recommendations and Testimony:** No U.S. officer or agency has authority to require the Director of ARPA-H or 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)]	The ARPA-H Director position would be established as follows (key differences from H.R. 5855 *italicized*): **Appointment:** Appointed by the President. [H.R. 6000 §501(c)(1)] **Term:** Five years. May be reappointed for one consecutive term *at the discretion of the President.* [H.R. 6000 §501(c)(2)] **Qualifications:** By professional background and experience, is qualified to advise the Secretary on, and manage research programs addressing, matters pertaining to long-term and high-risk barriers to the development of health innovation. [H.R. 6000 §501(c)(2)] **Autonomy:** No comparable provision.	The ARPA-H Director position would be established as follows (key differences from H.R. 5855 *italicized*): **Appointment:** Appointed by the President. *Reports to NIH Director.* [Proposed PHSA §483(c)(1)] **Term:** *Four* years. May be reappointed for up to one consecutive term *at the discretion of the President*. [Proposed PHSA §483(c)(3)] **Qualifications:** 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)] **Autonomy:** No comparable provision.

Duties of the Director	**Duties:** • Set research and development priorities with respect to ARPA-H goals and manage the budget of ARPA-H; • Advance ARPA-H goals through consideration of the advice of the ARPA-H Interagency Advisory Committee; • Approve and terminate the projects and programs of ARPA-H; • Develop funding criteria and assess the success of programs through the establishment of technical milestones; • Solicit data, as needed, from NIH and other relevant federal agencies, private entities, academia, nonprofit organizations, and international organizations; • 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); and • 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). [Proposed PHSA §499A(c)(4)]	**Duties** (grouped for comparison)**:** *Similar to H.R. 5585:* • Set national research priorities to advance the mission of the agency as informed by a multi-sectoral board of advisors; • Approve all new programs within ARPA-H; • Have final funding authority to initiate and terminate program funding; and • Establish criteria for funding and assessing the success of programs through the establishment of technical milestones; *Different from H.R. 5585:* • Appoint the personnel necessary to successfully execute the goals of ARPA-H (see "Personnel Authorities" below for other relevant provisions); and • Designate employees to serve as program managers for each of the programs established pursuant to the responsibilities established for ARPA-H (see "Program Managers" below for other relevant provisions). [H.R. 6000 §501(c)(3)]	**Duties:** (grouped for comparison): *Similar to H.R. 5585* • Establish strategic goals, objectives, and priorities for ARPA-H pursuant to ARPA-H's purposes; • Approve all new programs within ARPA-H and terminate any program within ARPA-H that is not achieving its goals; • 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. *Different from H.R. 5585* • 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

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
			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; • Encourage strategic collaboration and partnerships with a broad range of entities, including academia, industry, and non-profit organizations. (H.R. 5585 lists partnering with a broad range of institutions as an ARPA-H Director authority); 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.) [Proposed PHSA §483(c)(4)]

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Funding Awards	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. Contracts awarded would be subject to Federal Acquisition Regulations (48 C.F.R. Chapter 1), but not to regulations in 48 C.F.R. Chapter 3. [Proposed PHSA §499A(g)]	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. Funded research would not be subject to NIH peer review or advisory council review or approval. [H.R. 6000 §501(i)] Specified information collected from award recipients would be exempted from Freedom of Information Act disclosures (FOIA), including commercialization plans, market studies, and investments provided to the awardee from third parties, among others. [H.R. 6000 §501(j)] The ARPA-H Director would have authority to execute contracts developed by in-house program managers who select external performers, and maintain, enhance, or terminate projects based on performance against explicit milestones. [H.R. 6000 §501(c)(2)(B)]	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)] Funded research would not be subject to NIH peer review or advisory council review or approval. [Proposed PHSA §483(e)(5)] 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)]

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Cooperative Agreements and Other Transactions	ARPA-H Director would be authorized to award other transactions or prototype projects that are directly relevant to enhancing ARPA-H goals. [Proposed PHSA §499A(g)(5)]	When entering into cooperative agreements and other transactions, the ARPA-H Director would be required to ensure that: • Federal funds under the agreement do not exceed the total amount provided by other parties; • Such agreements are used only when the use of standard contracts or grants is not feasible or appropriate; and • To the maximum extent practicable, such agreements do not duplicate research being conducted under existing HHS and other federal programs. In addition, cooperative agreements and other transactions would be authorized to include a clause that requires payments to ARPA-H (or any other federal entity) as a condition for receiving support under such agreement. Authorizes payments to be credited to a Treasury account established for support of advanced research projects provided for in cooperative agreements and other transactions. [H.R. 6000 §501(i)(1)-(4)]	To the maximum extent practicable, competitive procedures would be required when entering into other transactions to carry out projects. Authorizes 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)]

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Facilities	The ARPA-H Director would have the authority to: • Acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary; and • Lease an interest in property for not more than 20 years, notwithstanding Section 1341(a)(1) of title 31, United States Code. [Proposed PHSA §499A(h)]	Same as H.R. 5585. [H.R. 6000 §501(c)(4)]	Same as H.R. 5585. [Proposed PHSA §483(h)(1)] Would require that ARPA-H, including its headquarters, not be located near the National Capital Region 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. [Proposed PHSA §483(h)(2)]

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
Other Authorities of the Director	The ARPA-H Director would have the authority to: • Partner with public and private entities as specified (H.R. 6000 lists partnering with a broad range of institutions in the "activities" category; S. 3799 lists partnering with a broad range of institutions as an "ARPA-H Director duties" category); [Proposed PHSA §499A(e)] • Delegate authorities, except the appointment of the Deputy Director; [Proposed PHSA §499A(c)(7)] • Appoint a Deputy Director to serve as acting ARPA-H Director in the absence of the Director; and [Proposed PHSA §499A(c)(8)] • Waive Paperwork Reduction Act requirements with respect to activities under (c)(3)(F) (NOTE: appears to be drafting error as referenced provision does not exist). [Proposed PHSA §499A(d)]	Does not specify other ARPA-H Director authorities.	Does not specify other ARPA-H Director authorities.

Personnel Authorities	Would grant the ARPA-H Director the authority to waive certain civil service personnel requirements with regard to: • Personnel hired under PHSA Section 207(f); • Additional appointments of scientific, medical, and professional personnel; and • Appointments to positions of administration or management of ARPA-H. Such authorities are in addition to existing hiring authorities granted to the Secretary of HHS. 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. The ARPA-H Director would also be authorized to contract with private entities in appointing qualified personnel. Would provide the ARPA-H Director with the authority 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. [Proposed PHSA §499A(i)]	<u>*Similar to H.R. 5585*</u> (key differences *italicized*): Would grant the ARPA-H Director the authority to waive certain civil service personnel requirements with regard to: • Personnel hired under PHSA Section 207(f); • Additional appointments of scientific, medical, and professional personnel (*would place a limitation each year on additional payments an employee could receive under such appointment to the lesser of $25,000 or the amount equal to 25% of the employee's annual rate of basic pay*); and • Appointments to positions of administration or management of ARPA-H. Would allow the ARPA-H Director to use all authorities in existence on the date of enactment that are provided to the Secretary of HHS *to hire administrative, financial, information technology staff, and any other staff the ARPA-H Director determines are necessary*. Would also authorize the ARPA-H Director to recruit and retain a diverse workforce, including individuals underrepresented in science and medicine and racial and ethnic minorities. [H.R. 6000 §501(d)]	<u>*Similar to H.R. 5585*</u>: 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)] 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)] 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)] <u>*Different from H.R. 5585*</u> 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 academia, industry, government, nonprofit organizations, or other sectors. [Proposed PHSA §483(d)(3)(A)] Would require the ARPA-H Director to ensure that personnel appointed to staff or support ARPA-H

Provision(s)	Advanced Research Project Agency—Health Act (H.R. 5585)	Section 501 of Cures Act 2.0 (H.R. 6000)	Advanced Research Project Authority for Health Act (Sec. 331 of S. 3799, as amended)
			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)] 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)]

Program Managers	**Term:** Three years. May serve two terms. **Duties:** • Establish research and development goals for programs in accordance with guidance from the Director; • 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 novelty and scientific and technical merit of the proposed projects; the demonstrated capabilities of the applicants to successfully carry out the proposed project; the unmet needs within patient populations; the consideration by the applicant of future commercial applications of the project, including the feasibility of partnering with one or more commercial entities; and such other criteria as are established by the Director of ARPA-H; • Identify milestones and monitor progress of such milestones with respect to each project; • Provide recommendations to the Director of ARPA-H with respect to advancing the goals of the agency; • Provide recommendations to expand, restructure, or terminate research partnerships or projects; • Collaborate with experts from NIH and other federal agencies and experts in relevant scientific fields to identify research and development opportunities; • Convene workshops, as needed, with relevant federal agencies, institutions of higher education, nonprofit	**Term:** Three years. May serve two terms. **Duties** (grouped for comparison): *Similar to H.R. 5585:* • Define the research and development goals and milestones of the program involved, in line with guidance from the ARPA-H Director; • Select, on the basis of merit and need, each of the projects to be supported under the program involved after considering the novelty and scientific and technical merit of the proposed projects; the demonstrated capabilities of the applicants to successfully carry out the proposed project; the consideration by the applicant of future commercial applications of the project; or the unmet need within patient populations; • Track progress and course-correct projects when needed; and • Recommend, as necessary, the restructuring or termination of projects supported by ARPA-H. [H.R. 6000 §501(e)]	**Term:** Three years. May serve two terms. [Proposed PHSA §483(d)(C)] **Duties** (grouped for comparison): *Similar to H.R. 5585* • 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; • 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; • Recommend program restructuring, expansion, or termination of research projects or whole projects, as necessary; and • Communicate with leaders in the health care and biomedical research and development fields, from both the public

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	research institutions, companies, venture capital firms, and nonprofit organizations for the development of high-need cures; • Issue funding opportunity announcements; and • Identify opportunities for the commercial application of successful projects, including through the establishment of partnerships between or among awardees. [Proposed PHSA §499A(j)]		and private sectors, to identify areas of need and scientific opportunity with the potential to transform biomedicine. *Different from H.R. 5585* • Provide project oversight and management of strategic initiatives to advance the purpose of the program. [Proposed PHSA §483(d)(2)(B)]

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Coordination and Cooperation	Would require the ARPA-H Director to coordinate with the Commissioner of Food and Drugs and the Administrator of the Centers for Medicare & Medicaid Services (CMS) to expedite the development, application, coverage, and implementation of high-need cures. [Proposed PHSA §499A(f)]	Would require the ARPA-H Director to ensure effective, early, and frequent coordination between ARPA-H and: (1) the heads of the research, public health, and regulatory agencies of HHS, including NIH, the Food and Drug Administration (FDA), CMS, the Centers for Disease Control and Prevention (CDC), and the Assistant Secretary for Preparedness and Response; (2) the Director of the National Science Foundation; and (3) the Director of the Office of Science of the Department of Energy. [H.R. 6000 §501(g)(1)] The ARPA-H Director would also be required to coordinate among the full set of advanced research projects agencies, including the Defense Advanced Research Projects Agency, the Advanced Research Projects Agency-Energy, and others that may be established. [H.R. 6000 §501(g)(2)] Would authorize the Secretary of HHS, acting through the FDA and in consultation with ARPA-H, to take actions to facilitate the transformation of biomedical breakthroughs into tangible solutions for patients and expedite the development and review of medical products. The ARPA-H Director must reimburse the FDA for related expenditures. This authorization is not to be construed as limiting FDA's authorities for medical product review and approval. [H.R. 6000 §501(k)]	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 BARDA programs, and (2) other relevant efforts or research operated or overseen by other federal departments and agencies. [Proposed PHSA §483(f)(1)] 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)] 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. [Proposed PHSA §483(f)(4)]

Advice	**Advisory Committee:** Would require the ARPA-H Director to establish an interagency advisory committee 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 market barriers to commercialization or adoption of high-need cures. Members could include (1) the heads of several HHS operating divisions or their designees, including NIH, FDA, CMS, CDC, and BARDA; (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), and (6) representatives of any federal agency with subject matter expertise as determined by the ARPA-H Director. The Federal Advisory Committee Act (5 U.S.C. App.) would not apply to this committee. [Proposed PHSA §499A(n)] **Other Advice:** Would also authorize the ARPA-H Director to seek advice from the President's Committee of Advisors on Science and Technology; peers in the scientific community, including academia and industry; experts in other federal agencies; any professional or scientific organization with expertise in technologies under development by ARPA-H or a relevant scientific discipline; and representatives of patient communities. [Proposed PHSA §499A(m)]	**Advisory Committee Consultation:** Would authorize the ARPA-H Director to seek advice on any aspect of the agency from any advisory committee that, as of the date of enactment, provides advice to the Secretary of HHS (or any head of a research, public health, or regulatory agency of HHS), as well as an advisory committee established on or after enactment to support the programs of ARPA-H. [H.R. 6000 §501(h)(1)] **Other Advice:** Would also authorize the ARPA-H Director to seek advice and review from the President's Committee of Advisors on Science and Technology; any professional or scientific organization with expertise in specific processes or technologies under development by ARPA-H; and representatives of patient communities. [H.R. 6000 §501(h)(2)]	**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 are to include the heads of the following agencies or their designees: NIH, CDC, FDA, HHS Office of the Assistant Secretary for Preparedness and Response, 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. The Federal Advisory Committee Act (5 U.S.C. App.) would not apply to this committee. [Proposed PHSA §483(g)] **Other Advice:** Would also authorize the ARPA-H Director to seek input from the President's Council of Advisors on Science and Technology; 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)]

Annual Report and Strategic Plan	**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 (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; activities conducted in coordination with other federal agencies; and (4) An analysis of the extent of coordination with NIH, FDA, and CMS, including successes and barriers with respect to achieving the goals of the agency. [Proposed PHSA §499A(k)(1)] **Strategic Plan:** Not later than one year after the date of the enactment, and every four 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 four-year period. [Proposed PHSA §499A(l)]	**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: (1) Projects supported by ARPA-H during the previous fiscal year, including the transition of project outcomes to clinical practice; the impact on clinical outcome; and the creation of biomedical capabilities; (2) Successes and barriers to scientific interchanges; (3) Rapid knowledge transfer; (4) Resource optimization; and (5) Heightened investment impact among collaborators. [H.R. 6000 §501(f)(2)] **Strategic Vision:** Not later than 180 days after enactment, the ARPA-H Director would be required to provide Congress with a report describing the strategic vision that ARPA-H will use to guide the choices for future health investments over the following three fiscal years beginning on or after the date of enactment. [H.R. 6000 §501(f)(1)]	**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: (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. (4) Current, proposed, and planned projects to be carried out. [Proposed PHSA §483(k)(1)] **Strategic Plan:** 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 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.

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			[Proposed PHSA §483(k)(2)]
Evaluation and Performance Measurement	**Evaluation by the National Academies of Sciences, Engineering, and Medicine (NASEM):** Not later than eight 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. [Proposed PHSA §499A(k)(2)]	No similar provisions.	**NASEM Evaluation:** Not later than three years after enactment, 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. [Proposed PHSA §483(l)] **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

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			consistent with the NASEM evaluation. [NOTE: Appears to be drafting error as subsection (m) is an authorization of appropriations.] [Proposed PHSA §483(g)(5)]
Other Reports	No additional reports.	**Report on Cooperative Agreements and Other Transactions:** Not later than 90 days after the end of each fiscal year, the ARPA-H Director would be required to submit a report to Congress on all cooperative agreements and other transactions entered into during such fiscal year. The report would be required to detail specific information, including a general description of the cooperative agreement or other transaction and the reasons for not using a contract or grant to provide support for such advanced research, and the amount of payments received by the federal government, among other things. [H.R. 6000 §501(f)(3)]	**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. [Proposed PHSA §483(d)(4)(B)-(C)] **GAO Report on Personnel:** Not later than two years after enactment, Government Accountability Office (GAO) would be required to report to Congress on 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

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			to the use of personnel authorities, and any related recommendations. [Proposed PHSA §483(d)(4)(F)] **Confidentiality Clarification and Reporting:** 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 confidentiality laws. Beginning not later than oneyear 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. [Proposed PHSA §483(j)]

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Funding	Would require the establishment of the Health Advanced Research and Development Fund in the Treasury to be administered by the ARPA-H Director. Would authorize the appropriation of $3 billion to the fund in FY2022 to remain available until expended. [Proposed PHSA §499B(a), (c)(1)] Would require that the annual budget request for ARPA-H be separate from the rest of the budget for HHS and that the ARPA-H Director prepare and submit directly to the President, for review and transmittal to Congress, an annual budget for ARPA-H after reasonable opportunity for comment (but without change) by the Secretary of HHS. [Proposed PHSA §499B(b)] Would require that appropriations to the Fund be separate and distinct from other appropriations for HHS. Would require for each fiscal year beginning with FY2022 that discretionary new budget authority provided in an appropriations act for ARPA-H be made available for that fiscal year and include advance discretionary new budget authority that first becomes available for the first fiscal year following the budget year. [Proposed PHSA §499B(c)]	Would authorize the appropriation of $6.5 billion to ARPA-H in FY2022 to remain available until expended. [H.R. 6000 §501(l)(1)] Would require that the budget of ARPA-H be a separate line item in the annual budget request submitted by the President to Congress and that ARPA-H have the authority to submit its annual budget request directly to Congress concurrently with its submission to the Office of Management and Budget. [H.R. 6000 §501(l)(2)] Also specifically establishes an account for other transactions and cooperative agreements; see "Cooperative Agreements and Other Transactions." [H.R. 6000 §501(i)(7)]	Would authorize the appropriation of such sums as may be necessary for each of FY2023 through FY2027. [Proposed PHSA §483(m)] Would provide that any budget request for ARPA-H be separate from other NIH budget requests. [Proposed PHSA §483(n)]

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Definitions	**Advanced Proofs of Concept:** data, a prototype, or other experimental evidence that may precede the development of a high-need cure or health technology and demonstrates the feasibility of a new concept. **High-Need Cure:** means a drug, biological product, or device that should be prioritized to detect, diagnose, mitigate, prevent, or treat any disease or medical condition; and for which incentives in commercial markets are unlikely to result in the adequate or timely development of such drug, biological product, or device. Also references existing terms in statute for "biologic product," "drug," "device," "federal acquisition regulation," and "prize competitions." [Proposed PHSA §499A(p)]	**Medical Product:** means a "drug," "device," or "biological product," as defined in relevant sections of the Federal Food, Drug, and Cosmetic Act and the PHSA. [H.R. 6000 §501(k)(4)]	No definitions for these terms, although definitions provided for other specified terms as noted elsewhere. [Proposed PHSA 483(a)]

Source: CRS analysis of H.R. 5585, H.R. 6000, and S. 3799.

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

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