



UNIVERSITY OF MINNESOTA WASHINGTON UPDATE – MARCH 17, 2023
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As more information on President Biden’s fiscal year (FY) 2024 budget request is released by individual agencies, the newly launched Advanced Research Projects Agency for Health (ARPA-H) made its largest announcement since its creation in 2022 on its one-year anniversary. ARPA-H, which would receive an additional \$1 billion in funding through FY 2026 in the president’s budget request, released its first Open Broad Agency Announcement (Open BAA) funding opportunity and announced more information on its physical locations and key personnel. The agency is expected to continue being a priority of the Biden Administration and more information on its recent major announcements and the full FY 2024 president’s budget request can be found below.

The University of Minnesota Washington Update provides intelligence and analysis on recent federal activities. Faculty visiting Washington, D.C. are encouraged to contact Sarah Neimeyer, Director of Government Relations, at neimeyer@umn.edu. Contact Christina Laridaen, Lewis-Burke Associates LLC, at christina@lewis-burke.com with any questions or comments related to the Update’s content.

Budget, Agency, and Policy Updates

Budget Update: Biden Administration Releases FY 2024 Budget Request

On March 9, 2023, President Biden released his third budget proposal to Congress and the first under divided government. The fiscal year (FY) 2024 President’s budget request proposes close to a 9 percent boost in discretionary spending compared to the FY 2023 enacted level for a total of around \$1.7 trillion. This would include \$886 billion for defense spending—an increase of \$28 billion or 3 percent—and \$809 billion for non-defense spending—an increase of \$49 billion or 6.5 percent—above FY 2023 enacted levels. While similar to previous Biden budget requests, the top FY 2024 budget priorities are expanded to include a new emphasis on cancer, veterans, safer communities, and women’s health while continuing prioritization of economic growth, competition and innovation, manufacturing, climate change and clean energy, equity, and global leadership to confront national security challenges. The budget request also lays out President Biden’s proposed approach to deficit reduction ahead of summer debt ceiling negotiations, including \$2.9 trillion in savings proposed over the next decade.

The release of the budget request kicks off the FY 2024 appropriations process, including congressional budget hearings and mark up of the 12 annual appropriations bills. The process is complicated by divided government and dramatically different budget priorities among the President, the House, and the Senate. House Republicans seek to force major cuts to non-defense discretionary spending through debt ceiling negotiations and have stated their desire to roll back funding to FY 2022 levels, up to a \$130 billion cut in discretionary spending. Meanwhile, the Senate hopes to build on the bipartisan process that enabled passage of FY 2023

appropriations in December 2022. That process saw modest growth to Biden priorities at lower levels than proposed. Amidst these differences, final appropriations are extremely unlikely to feature the major growth sought by the President and may result in a stalemate or year-long continuing resolution. While the budget request is just a recommendation to Congress, it does provide insight into federal agencies' priorities and future directions, many of which can be advanced within existing authorities and without explicit congressional approval. It is ultimately up to Congress to decide which new proposals to embrace, modify, or reject as part of the annual appropriations process, but the budget request is influential in shaping and advancing new initiatives.

A full analysis of the FY 2024 budget request can be found [here](#).

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Agency Update: ARPA-H Makes Major Announcements on Funding Opportunities, Personnel, and Locations

The Advanced Research Projects Agency for Health (ARPA-H) released its first Open Broad Agency Announcement (Open BAA) and [announced](#) a wide range of agency actions, including the hiring of program managers (PMs) and mission office directors, selection of its first of three physical sites or Hubs, solicitation of the remaining two Hubs, and a new "ARPA-H Dash" competition soliciting ideas from the health, scientific, and technology communities. Modeled after the Defense Advanced Research Projects Agency (DARPA), ARPA-H was launched in March 2022 and is tasked with advancing high-risk, high-reward research with transformative potential to drive biomedical and health innovation.

The agency currently has a budget of \$2.5 billion available through fiscal year (FY) 2025. President Biden signaled continued support for ARPA-H in his recently released FY 2024 budget request, which called for an additional \$1 billion in funding for the agency available through FY 2026. Since its launch, the agency has hired a director, [Dr. Renee Wegrzyn](#), as well as agency support staff and program managers (PMs) that have helped shape its initial priority areas and programs. ARPA-H is expected to continue hiring additional PMs going forward, eventually reaching a steady state of 80-120 PMs, each of whom will have significant autonomy in program design and project selection.

Open BAA

ARPA-H released its first agency-wide Open BAA, which is expected to be the agency's primary funding opportunity announcement. BAAs are used across the federal government as umbrella mechanisms to solicit proposals across a range of topics, and they are less targeted and less time bound than Requests for Proposals/Applications. ARPA-H's Open BAA solicits proposals that support the agency's mission to drive innovative approaches to biomedical and health issues through revolutionary advances in science, technology, or systems that can facilitate better health outcomes across diseases, health conditions, patient populations, and communities. The solicitation also specifically highlights that proposals can support the reignited Cancer Moonshot Initiative, a priority of the Biden Administration.

The solicitation is organized around the four previously announced focus areas of ARPA-H:

1. "[Health Science Futures](#): A disease agnostic approach to accelerating advances across research areas and removing limitations that stymie progress towards solutions.

2. **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.
3. **Proactive Health:** 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.
4. **Resilient Systems:** Developing capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability."

Additional details on the focus areas, including individual interest areas, can be found in the full Open BAA. ARPA-H intends to continue to use the Open BAA as a mechanism for soliciting and funding research projects in the future.

Interested applicants are invited to submit an abstract of not more than three pages in length, containing a plain-language concept summary, description of the challenge to be addressed and the disruptive potential of the solution, milestones and final deliverables for the project, roles and capabilities of the team, and a "Rough Order of Magnitude" estimate of the timeline and budget. ARPA-H will respond to each abstract and may request a full proposal following review of that abstract. ARPA-H also "reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without negotiations with proposers." The agency encourages proposers to consider requesting an Other Transaction Agreement (OTA) and this funding vehicle is expected to be preferred by ARPA-H, although not required. **The BAA is open through March 14, 2024. The full Open BAA can be found [here](#) or at www.sam.gov under the Notice ID "75N99223S0001."**

ARPA-H Personnel

ARPA-H program managers will play a crucial role in the design of research programs and project selection among proposals submitted under the Open BAA. As of March 15, two PMs have been announced: Dr. Paul Sheehan and Dr. Ross Uhrich. [Dr. Sheehan](#) most recently served as a program manager at DARPA with a focus on "bi-directional conversion between electronic and biochemical signals, the study of how nanostructures interact with cells and biomolecules, and new approaches for the rapid development and manufacture of bioassays." [Dr. Uhrich](#) most recently served as an Assistant Professor of Surgery at Walter Reed National Military Medical Center. ARPA-H is expected to continue hiring additional program managers in the coming months.

In addition, ARPA-H has named the directors of two of its mission offices. As described above, ARPA-H has four initial mission areas: Health Science Futures, Scalable Solutions, Proactive Health, and Resilient Systems. Dr. Jennifer Roberts will serve as Director of Resilient Systems and Dr. Amy Jenkins will serve as Director of Health Science Futures. [Dr. Roberts](#) joined ARPA-H from the White House Office of Science and Technology Policy (OSTP), previously worked at DARPA, and has a background in engineering and computer science. [Dr. Jenkins](#) joined ARPA-H from DARPA's Biological Technologies Office (BTO), where she managed programs addressing infectious disease and manufacturing techniques for responding to microbial threats.

Hub Selection and Additional Hub Solicitation

ARPA-H [announced](#) that the first of its three physical sites, or Hubs, will be located within the National Capital Region and will focus on stakeholder engagement and operations adjacent to the agency's regulatory and

legislative stakeholders. The agency also [released](#) a draft Request for Consortium Agreement (RCA) in search of two other Hubs, which will operate as a network with each other, with designated Spoke sites, and with the broader ARPA-H research community. Each Hub will have different priorities that support the agency's broader mission:

- Hub 2: "Customer Experience Hub: Drives user testing, adoption, access, and trust of ARPA-H projects, taking a human-centered approach to design products and services that people need and want to use. It will also take a proactive approach to enhance clinical trials, reach representative patient populations, and capture outcomes data for future research."
- Hub 3: "Investor Catalyst: Provides resources to help performers bring their ideas to market."

All three hubs will have a minimal physical footprint, "housing a small number of ARPA-H team members alongside key personnel at each hub to support agency objectives." ARPA-H expects to announce Hub awards by early fall 2023, and the period of performance for each Hub is five years. The primary awardees of Hubs 2 and 3 will be Consortium Management Firms, but a broad array of health-focused organizations may participate as Spokes in collaboration with the primary awardees to form a nation-wide health innovation network. Full details can be found in the draft RCA.

The agency is holding an informational Hubs proposers' day on **Friday March 24** to review the draft solicitation, gather feedback, and answer questions from potential proposers. Additional information on the proposers' day can be found [here](#).

Dash to Accelerate Health Outcomes (Dash) Competition

ARPA-H [announced](#) the ARPA-H Dash to Accelerate Health Outcomes competition (Dash) to "help identify revolutionary evidence-based ideas to transform health." The competition is open to the public and calls for evidence-based ideas to transform health from "bold thinkers across health, scientific, and technology communities." Sixty-four submissions will be chosen and placed in a tournament-style bracket, with each region of the bracket corresponding to one of ARPA-H's four strategic focus areas. Online discussion, debate, and voting to narrow submissions to quarterfinalists, semifinalists, finalists, and a champion idea will occur during March and April 2023.

Submissions to Dash will be accepted **from March 29 through April 7, 2023**. Each submission should include a piece of evidence with citation published after January 1, 2018; a short descriptive title for display in the brackets; identification of which ARPA-H focus area is targeted for transformation; and answers to three questions about the proposed transformation.

\$15,000 will be awarded to the winning idea with additional prizes for the runner-up, semi-finalists, and quarter-finalists. More information on Dash, including submission information, can be found [here](#).

Sources and Additional Information:

- The full ARPA-H Open BAA can be found [here](#) or at www.sam.gov under the Notice ID "75N99223S0001."
- A press release with additional details on the announcements described above can be found [here](#).

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Policy Update: CMS Releases Initial Medicare Prescription Drug Price Negotiation Guidance and Part B Rebatable Drugs

Medicare Drug Price Negotiation Program Initial Guidance

The Centers for Medicare and Medicaid Services (CMS) released initial [guidance](#) on the requirements and parameters of the Medicare Drug Price Negotiation Program (Program) that was included in the [Inflation Reduction Act](#). The Program, which goes into effect in 2026, allows Medicare to negotiate the maximum fair price of certain single source drugs and biological products in Part D.

By September 1, 2023, CMS will publish the first ten Medicare Part D drugs selected for negotiation in 2026 under the Program. The negotiated maximum fair prices for these drugs will be published by September 1, 2024, and will go into effect starting January 1, 2026. Beyond 2026, CMS will select for negotiation up to fifteen more Part D drugs for 2027, up to fifteen more Part B or Part D drugs for 2028, and up to twenty more Part B or Part D drugs for each year after that.

For a drug to be selected among the first ten subject to negotiation, it must have been on the market for at least seven years (eleven years for a biological product). The drug also may not be listed as a reference drug for a generic or biosimilar product. CMS will first review the top fifty drugs based on total expenditures during the twelve-month period beginning June 1, 2022, and ending May 31, 2023. Orphan drugs, drugs with less than \$200 million in combined expenditures under Medicare Parts B and D, and plasma-derived products are excluded from being a qualifying single source drug. Once the ten drugs subject to negotiation are published on September 1, 2023, manufacturers will have until October 2, 2023 to submit manufacturer-specific data for CMS to consider when determining the maximum fair price.

Under the guidance, CMS will provide a written offer to the manufacturer by February 1, 2024 that aims to achieve the lowest maximum fair price for each drug. Companies will then have thirty days from receiving the initial offer to either accept or provide a counteroffer. The guidance also allows manufacturers the possibility of “1-3 meetings between CMS and the Primary Manufacturer.” On August 1, 2024, the negotiation ends, on September 1, 2024, CMS will publish the negotiated maximum fair prices, and on January 1, 2026 the maximum fair prices will go into effect. CMS is seeking comments on the initial guidance, specifically on topics that can be found in the full notice. Comments must be sent to IRAREbateandNegotiation@cms.hhs.gov with the subject: “Medicare Drug Price Negotiation Program Guidance” by **April 14, 2023**.

Medicare Prescription Drug Inflation Rebate Program Rebatable Drugs

The *Inflation Reduction Act* also requires drug manufacturers to pay a rebate to Medicare if the price of a drug in Medicare Parts B and D increases faster than the rate of inflation. CMS [announced](#) twenty-seven “rebatable drugs” under Medicare Part B that will be subject to a rebate under this policy. A rebatable drug under the law is a single source injectable, infused drug, or biological product, administered by a physician in a doctor’s office or hospital outpatient setting. Certain drugs, such as preventive vaccines are excluded. In addition, beginning April 1, 2023, a beneficiary’s coinsurance will be 20 percent of the inflation-adjusted payment amount. In 2025, CMS will issue invoices to manufacturers for 2023 and 2024 rebates.

Sources:

- Guidance: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>
- Medicare Drug Price Negotiation Program Factsheet: <https://www.cms.gov/files/document/factsheet-medicare-drug-price-negotiation-program-initial-guidance.pdf>

- Drug Inflation Rebate Program and Part B Rebatable Drug Coinsurance Reduction Factsheet: <https://www.cms.gov/files/document/fact-sheet-part-b-rebatable-drug-coinsurance-reduction.pdf>
- Part B Rebatable Drugs: <https://www.cms.gov/files/document/reduced-coinsurance-part-b-rebatable-drugs-apr-1-june-30.pdf>

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