

PROGRAM SOLICITATION

HEalth care Rewards to Achieve Improved OutcomES (HEROES)

Resilient Systems Office (RSO)

Advanced Research Project Agency for Health (ARPA-H)

ARPA-H-SOL-24-01

April 17, 2024

PROGRAM SOLICITATION OVERVIEW INFORMATION

FEDERAL AGENCY NAME: Advanced Research Projects Agency for Health (ARPA-H)

PROGRAM SOLICITATION TITLE: HEealth care Rewards to Achieve Improved OutcomES (HEROES)

ANNOUNCEMENT Type: Program Solicitation (PS), Initial Announcement

PROGRAM SOLICITATION NUMBER: ARPA-H-SOL-24-01

DATES (All times listed herein are Eastern Time) (see the Acronym/Definitions Section for identification of Eastern Standard Time versus Eastern Daylight Time):

- Proposer's Day: February 13-14, 2024
- Program Solicitation Posting Date: April 17, 2024
- Solution Summary Due Date: June 28, 2024
- Program Solicitation Questions & Answers (Q&A) submission due date: September 20, 2024
- Proposal Due Date: November 15, 2024
- Estimated Program Performance start date: Second quarter 2025

CONCISE DESCRIPTION OF THE PROGRAM: Under the HEROES program, public health entities and collaborators will have the opportunity to improve the health status of their communities for specific patient populations through the use of a payment model that incentivizes community-based interventions to improve health outcomes across a fixed geographic area. These solutions will investigate a new, regionally focused, outcomes-based financing approach for the healthcare industry, which rewards only positive health outcomes and reduces the healthcare burden on patients, providers, and the economy.

ANTICIPATED INDIVIDUAL AWARD: Multiple awards are anticipated.

BUDGET: Under this program solicitation, \$99M in total funding will be awarded over the three-year program period to the two ARPA-H Performer groups: ARPA-H Funded Health Accelerators and Participating Health Accelerators.

Types of Instruments that MAY BE AWARDED: Other Transaction Agreements awarded under the authority of 42 U.S.C. § 290c(g)(1)(D).

ANY COST SHARING REQUIREMENTS: Cost sharing may be requested.

POINTS OF CONTACT (POC):

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1.0 Program Information

1.1 BACKGROUND

- (a) Despite spending far more per capita on healthcare than any other nation, the United States lags other high-income countries in crucial parameters of health, including overall life expectancy and maternal health. In addition, many health indicators show critical disparities among demographic, ethnic, and income categories. A major contributor to these problems is the misalignment of economic incentives that exist in the U.S. health system. Instead of investing in effective preventive programs, the health system concentrates resources on late-stage and expensive specialized medical interventions. In addition, the lack of timely data to guide interventions and diffused accountability for population-wide preventive measures also contributes to these long-standing issues.
- (b) Funding for population-wide improvements in preventive health behaviors is lacking. This has led to a dependence on grant-based funding, and often non-sustainable funding for community-based interventions focused on health behaviors. Prior efforts to "pay for performance" in both public and commercial health insurance programs have had mixed results due to: focusing only on patients seen in medical settings (not whole populations); targeting process-based metrics and not meaningful outcomes; a lack of timely data to guide interventions; an inability to engage community-based and innovative technologies; and a lack of simplicity and public transparency.

1.2 Program Goals and Health Outcomes

(a) HEROES is a three-year program that aims to demonstrate that novel outcome-based incentives can dramatically improve health outcomes by accomplishing the following three goals: 1) improve healthcare in large, geographically defined populations through implementation of novel technologies and strategies; 2) track changes in quantifiable outcomes metrics in near real-time; and 3) develop economic incentives that reward improvements via a

sustainable, scalable economic model. Leveraging a conceptual framework of outcomes-based financing, the HEROES program will provide payments to organizations, herein referred to as Health Accelerators (Performers under the resulting ARPA-H awards), based on activities that aim to improve health outcomes. These incentives, or outcome payments, will depend on HEROES program Performers achieving transparent and measurable predetermined outcomes that will have major impacts on health.

- (b) The HEROES solicitation highlights four specific health outcomes of interest to the program. These outcome categories were selected because of their significant morbidity and mortality rates despite the availability of effective, evidence-based interventions to prevent such circumstances or reduce their severity. The four outcome categories are as follows:
 - 1. Maternal Health: Reduction in rate of intrapartum and postpartum severe obstetric complications per 10,000 deliveries.
 - 2. Heart Attack and Stroke Risk: Reduction in the aggregate 10-year risk of heart attack and stroke for people aged 40-70 years.
 - 3. *Opioid Overdose*: Reduction in the rate of emergency medical services (EMS) patient encounters for fatal and non-fatal opioid overdoses per 100,000 population.
 - 4. Alcohol-Related Health Harms: Reduction in the rate of EMS patient encounters for alcohol-related emergencies per 100,000 population.
- (c) These outcome categories were chosen following discussions with major federal health authorities and rigorous reviews using a rubric that prioritized public health impact, diversity of ages and populations, presence of highly effective enabling technologies or practices that could be scaled to have impact quickly, well-accepted upstream metrics known to affect long-term outcomes, and availability of data at the population level. Refer to Appendix A, which provides additional background on the aforementioned outcomes.

1.3 NATIONAL IMPACT

1. Maternal Health:

Maternal morbidity is emerging as an important measure in efforts to prevent maternal mortality. Broadening the definition of severe maternal morbidity (SMM) to also encompass serious illnesses during pregnancy and postpartum reveals the broader scope of the problem, as well as the need for further measurement efforts and policy intervention.¹

SMM affected approximately 65,000 women in 2021² (or 1.8 percent), an increase from 1.4 percent in 2016-2017.³ A significant number of women have severe complications that occur after leaving the hospital. Of SMM cases that were identified within the first six weeks (42 days) after delivery discharge, about three-quarters were identified in the first two weeks.⁴ Many health conditions that develop in the postpartum period can be prevented, but timely care has not been readily available or affordable.⁵

In a community of 5M people, roughly 1,000 women will develop an SMM annually. At an estimated economic cost of around \$107,000 per SMM case (including medical, social services, and productivity losses), this equates to nearly \$107M in total economic costs to the community. Reducing the number of SMM cases 20% each year (the target % reduction in the HEROES Program) in this size of community is anticipated to prevent approximately 200 cases of SMM, resulting in an annual economic savings of \$21.4M, or over \$64M over three years.

2. Heart Attack and Stroke Risk:

Nationally, heart disease is the leading cause of death. About 695,000 people in the United States died from heart disease in 2021 (this equates to 1 in every 5 deaths). In 2021, 1 in 6 deaths from cardiovascular disease was due to stroke.

¹ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

² HHS Study Shows In-hospital Delivery-related Maternal Death Rates Decreased More than Half from 2008 to 2021 | HHS.gov

³ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

⁴ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

⁵ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

There are about 1.6M annual total heart attack and stroke-related deaths and 1.2M first-time heart attacks and strokes per year.^{6,7}

In a community with a total population size of 700,000, of which 250,000 are adults ages 40-70, it is estimated that about 1,800 of these adults are at risk for first-time heart and strokes. At an estimated economic cost of \$101,000 per Atherosclerotic Cardiovascular Disease (ASCVD) case (including medical costs and lost productivity), this equates to \$181.8M in total economic costs to the community. Using a 10-year ASCVD risk of 9% as a baseline and reducing it by 1 percentage point (the target % reduction in the HEROES Program) to 8% 10-year ASCVD risk; a 1 percentage point reduction in ASCVD risk from 9% to 8% equates to an 11% relative risk improvement in first time heart attack and stroke events over 10 years. About \$20M of benefit annually, or \$60M over three years, would result.

3. Opioid Overdose:

Opioid Use Disorder (OUD) is the chronic use of opioids that causes clinically significant distress or impairment. It consists of an overpowering desire to use opioids, increased opioid tolerance, and withdrawal syndrome when discontinued. OUD is a life-threatening condition associated with a 20-fold greater risk of early death due to overdose, infectious diseases, trauma, and suicide. Fewer than 10 percent of U.S. patients with diagnosed OUD receive medication-assisted treatment (MAT). Behavioral therapies, when delivered alone, have limited efficacy in addressing the complex symptomatology and physical aspects of OUD.

In a community of 500,000 adults, approximately 3,700 individuals meet the diagnostic criteria for OUD. Each diagnosed OUD case is associated with approximately \$73,000 in annual economic costs (including health care, criminal justice, and productivity losses), which equates to approximately \$270M in average annual economic costs in the community. A 10% reduction in overdoses (the target % reduction in the HEROES Program) could result in approximately 360 fewer OUD cases per year for a community economic savings of about \$26.2M, or \$78.6M over three years.

⁶ Heart Disease Facts | cdc.gov

⁷ Stroke Facts | cdc.gov

4. Alcohol-Related Health Harms:

Drinking excessive amounts of alcohol can cause serious health problems including stroke, cancer, and cirrhosis. People with alcohol use disorders, including binge drinking, are also more likely to get sick and are less able to fight off infections.

Binge drinking is the most common and costly pattern of excessive alcohol use in the United States. It is defined as consuming five or more drinks on an occasion for men or four or more drinks on an occasion for women. Eighteen percent (18%) of Americans have engaged in binge drinking in the past month. In every state, it is illegal to operate a motor vehicle with a blood alcohol content of 0.08% or higher. For every 88 instances of driving, someone is arrested for operating a motor vehicle above the legal limit. Additionally, about 37 people in the United States die in drunk driving crashes every day: one person every 39 minutes.

Binge drinking is a serious but preventable public health problem. A 2019 government survey found less than one in 10 people with an alcohol use disorder received any treatment, and less than 2% of those individuals said they had been offered medication.

In a community of 500,000 adults, 18% (~90,500 individuals) would be expected to engage in binge drinking per year. At an estimated average cost of \$3,900 per binge drinking case (including health care, productivity loss, and property loss), there could be approximately \$352.9 million in average annual economic costs related to binge drinking in the community. A 10% reduction in binge drinking cases (the target % reduction in the HEROES Program) would result in 9,050 fewer cases per year, resulting in a community economic savings of approximately \$35.3M, or \$105.9M over three years.

The HEROES program addresses each of these outcomes with fundamentally novel incentives to develop new technologies and approaches. Rooted in new public-private partnerships, the Program will deliver a critical proof of concept to advance the health of Americans by advancing new capabilities and technologies to improve population health. By focusing on novel approaches to early disease prevention and detection of risk factors, the HEROES Program has the potential to create a new, scalable platform capability (that is, an entirely new tool that can be applied across

numerous additional preventive outcomes) that may harness innovations from multiple disciplines such as social sciences, clinical science, technology advances, and behavioral economics, among other key areas. Importantly, as outlined below, traditional federal, state, and non-federal programs cannot readily accomplish these breakthrough goals (see chart below). Improving the health of entire communities by leveraging innovation is a high-risk, high-reward endeavor and will require overcoming significant long-standing barriers to transforming health. The table below highlights HEROES's contribution to research and development specifically by pushing groundbreaking innovation in payment, accountability for inclusive geographies, measurement of outcomes, and sustainable private partnerships.

Key organizational attributes	Traditional Payers (Medicare, Medicaid, Commercial)	Public Health Departments and Agencies	Venture Capital and Private Equity-Backed Companies	HEROES
Payment for prevention	• Limitations: Churn, provider focus	Strengths: Prevention focus	• Limitations: Focused on high acuity patients	Strengths: Upstream outcomes
Geographic accountability	Limitations: Small fraction of the population	Limitations: Geographic scope, but no accountability	Limitations: Narrow population focus	Strengths: Population-wide accountability
Population-level outcomes measurement	Limitations: Primarily hospital-based	Limitations: Long lags in surveillance data	• Limitations: Primarily hospital-based	Strengths: Near real-time population measurement
Sustainable business model that integrates private capital	Strengths: Established contracting approaches	Limitations: Largely grant- funded, unstable	Limitations: Unproven	Strengths: Meaningful business case

1.4 HEROES PROGRAM SCOPE

- (a) The HEROES program will solicit proposals for innovative, costeffective interventions that can rapidly improve health outcomes for **everyone** living in a specific geographic area and, therefore, will be reviewing proposed solutions for the following:
 - 1. Novel interventions to improve health outcomes that could include new technologies and processes, existing technologies and processes used in new ways, broad dissemination of

standards of care, or any number of approaches not previously scaled.

- 2. A selected geographic area where performance on the outcome is worse than the national average. To advance the agency's mission, ARPA-H will ensure that efforts selected for award are geographically diverse. Approaches that predominantly focus on a single demographic within the target population are not of interest to the HEROES program. See Attachment 2, OT Bundle, Attachment (2) Volume 1: Technical & Management template for proposal preparation instructions.
- If successful, HEROES will significantly reshape the healthcare (b) landscape by addressing the critical need for prevention, ideally through improving the dramatic disparities that currently exist due to an insufficiently proactive healthcare system. Moreover, the HEROES program aims to demonstrate the value and scalability of rewards focused on outcomes and population-wide prevention. This approach will pave a path for the private sector to raise capital for implementing preventive approaches and encourage innovation where it is needed most. The HEROES program will create the foundation for a viable economic model and identify sources for continued support to sustain delivery of these interventions when direct ARPA-H funding is phased away. If scaled nationally, HEROES is estimated to prevent serious health outcomes in over 6 million Americans and save between \$1.4B-\$24B in societal costs annually. These savings include direct healthcare expenditures and indirect costs, such as productivity loss and spending on social services.

1.5 ROLES WITHIN THE HEROES PROGRAM

(a) Improving population health requires a complex set of approaches within the healthcare ecosystem of a community, which involves not only patients and healthcare providers but also employers, payers, community organizations, investors, and many others. The HEROES Regional Team embodies the healthcare ecosystem of a community and will consist of a Health Accelerator, multiple

Outcome Buyers, and at-risk investors. The responsibilities of each are detailed in Figure 1, HEROES Regional Teams. The HEROES Regional Teams will work collaboratively to develop and implement strategies, monitor effectiveness, and participate in regular HEROES program meetings to share lessons learned.

(b) Additional roles and responsibilities of key HEROES stakeholders are discussed in detail within paragraph 1.4.1, Health Accelerators (HAs).

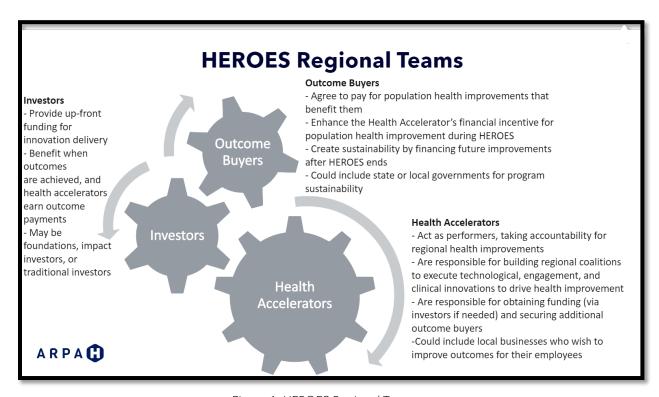


Figure 1: HEROES Regional Teams.

1.5.1 HEALTH ACCELERATORS (HAS)

(a) A Health Accelerator (HA) may comprise a variety of organization types, such as start-up companies; established private companies; healthcare provider organizations; public benefit corporations; non-profit, professional, or advocacy organizations; state universities or other state-funded educational institutions; and other non-governmental entities demonstrating the capacity to impact preventive health at scale. Figure 2, Role of the Health

Accelerator, provides a high-level overview of the role a Health Accelerator plays in the HEROES program. The term Health Accelerator, as stated in Figure 1, is synonymous with an ARPA-H "Performer." There will be two groups of Health Accelerators, ARPA-H funded Health Accelerators (AHAs) and Participating Health Accelerators (PHAs) (see Section 2.1, Acquisition Strategy, for more details). Any reference throughout this solicitation to ARPA-H incentives and payments applies ONLY to AHAs.

- (b) The basic economics of the program would operate as follows: Health Accelerators improve outcomes at a substantial enough level (as determined by lowering the rates of incidence) to provide \$60M of projected societal value by reducing downstream healthcare costs. ARPA-H provides up to \$15M of rewards, and Outcomes Buyers aim to provide up to \$30M of rewards to each Health Accelerator that succeeds in lowering incidence in the selected outcome category by preventing adverse events. Health Accelerators will either self-fund or find at-risk investors to support the implementation of interventions that are designed to meet the health outcome targets at a low enough cost to enable profiting from the reward payments.
- (c) If the Health Accelerators succeed in meeting the health outcome targets and spend, for example, \$32M on successfully implementing interventions in accordance with the goals, objectives, and metrics of the HEROES program solicitation, then the Health Accelerators and at-risk investors would make a \$13M return (\$45M-\$32M) on investment during the program. In addition, the Outcomes Buyers would benefit from over \$60M of reduced healthcare costs in return for \$45M in outcome-based rewards over three years with ARPA-H providing reward payments up to \$15M. Each component is described in Figure 2, Role of the Health Accelerator.

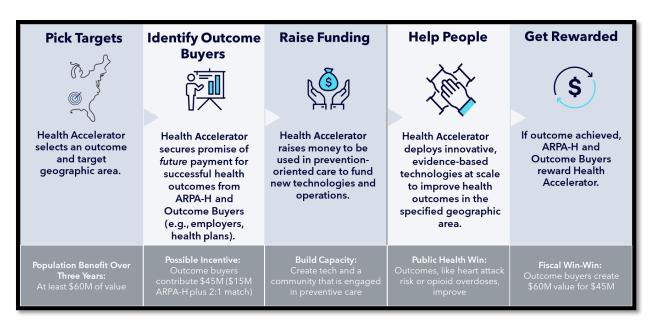


Figure 2: Role of the Health Accelerator.

(d) ACTIVITIES PRIOR TO BECOMING A HEALTH ACCELERATOR (HA):

- (1) Pick Targets. The Proposer will use the HEROES Outcome Toolkit available on the HEROES website⁸ to explore health outcomes data within geographic areas of interest and ultimately select a single outcome in a defined geographic area on which to focus. The Proposer is encouraged to choose a geographic area where the average performance for the selected outcome is below the national average.
- (2) Identify Outcome Buyers. The Proposer will identify other partner organizations in its selected geographic area to provide rewards for meeting health outcome targets. The Proposer will seek Outcome Buyers who can match ARPA-H's commitment (\$15M contribution per HA.) The aspiration is for a Proposer to secure as much funding as possible, with a recommended target of a 2:1 Outcome Buyer to ARPA-H funds match (see Table 6, Financial Sustainability Metrics, within Section 1.6.3, Evaluating Effectiveness of

⁸ https://arpa-h.gov/research-and-funding/programs/heroes.

Interventions, and Progress Toward Financial Sustainability, for more information). These funds will be paid upon meeting or exceeding pre-determined targets for the outcome categories. As described in Figure 1, HEROES Regional Teams, Outcome Buyers may be inclusive of, but not limited to, state and local governments, health plans, employers, and philanthropies.

(3) Raise Funding. The Proposer will raise funds for operations and the supporting costs of its proposed innovative approaches and technologies. See the Solution Summary Template (Attachment 1) and Volume 2: Price Volume Template (included within Attachment 2, OT Bundle) for the level of detail requested in both the Solution Summary and proposal submissions pertaining to funding raised. ARPA-H OT awards will capture the funding levels needed (e.g., self-funding and/or at-risk capital raised) to execute the proposed approach.

(e) ACTIVITIES OF A HEALTH ACCELERATOR (HA)

- (1) Help People. The HAs will deploy, test, and evaluate innovative, evidence-based strategies and technologies at scale within their geographic areas.
- (2) Get Rewarded. Upon success in reaching its target, the HA will be paid from the funds contributed by ARPA-H and the Outcome Buyers through a preestablished methodology (see Section 1.7.1, Reward Payments for Performance). If targets are not met, payments will not be made. Evaluations of the HA's progress, and subsequent reward payments, will

⁹ Health Accelerators will provide at-risk investors with returns as agreed upon in their independent contracts with each other (note that this is not affiliated with the resulting Other Transaction Agreement awards that ARPA-H plans to put in place with Performers).

occur every six months throughout the program period.

- (f) Ideally, the Proposers should have contracts signed with Outcome Buyers that commit to funding by the time proposals are due to ARPA-H; proof of contracts are program deliverable(s), see Section 1.9.2, Program Deliverables. However, ARPA-H will accept and consider the highest level of commitment that the Proposer has at the time of proposal (e.g. Letters of Intent, a promise of commitment, an outline of the level of commitment to-date with a description of the next steps and process to secure the contract, etc.).
- (g) During the HEROES program, both AHAs and PHAs will commit to achieving objectively measurable improvements in the chosen health outcome category. Some Performers who are not engaged as AHAs will be offered the opportunity to enter the program as PHAs. Health Accelerator Commitments are as follows:
 - (1) ARPA-H FUNDED HEALTH ACCELERATORS (AHAs) will enter into Other Transaction agreements with ARPA-H and endeavor to accomplish the following:
 - (i) Improve health outcomes for one health outcome category within a defined community.
 - (ii) Raise capital (if needed) that will (a) support the activities outlined in the Solution Summary and Proposal, and (b) reward the at-risk investors for successful delivery of improved health outcomes based on returns agreed to in their respective contracts with the AHA(s). An AHA that signs an OT Agreement with ARPA-H understands that the agency's funding is capped at \$15M to reward any outcome improvements.

- (iii) Implement their strategies for achieving improvements of the outcome category measures in the populations served. AHAs will receive reward payments if targets are met (see Figure 3, Reward Payment Process Flow, within this Section).
- (2) PARTICIPATING HEALTH ACCELERATORS (PHAs) will enter into Other Transaction agreements with ARPA-H. PHAs are not eligible for reward payments. Instead, the PHA's role is as follows:
 - (i) HEROES program PHA Performers commit to monitor their selected health outcome categories; attend ARPA-H convenings to share lessons learned, available technologies, and intervention details; and provide high-level regular reporting on their outcome category improvement.
 - (ii) PHAs receive fixed payments associated with the successful completion of a measurable event (e.g., completing a baseline execution plan, completing development of a new design process, completing, and submitting a final report, etc.) (see Section 2.1, Acquisition Strategy).

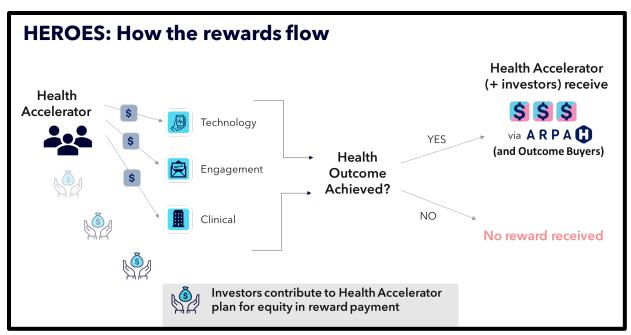


Figure 3: Reward Payment Process Flow.

1.5.2 ROLE OF ARPA-H

ARPA-H will provide the HAs (ARPA-H Performers) with tools, support, and recognition to facilitate success. Specifically, the HEROES program will provide its HAs with the following:

- (a) RECOGNITION AS AN ARPA-H SUPPORTED ORGANIZATION. This 'stamp of support and backing' will serve as the strongest signal to the investor- and buyer market, thus enabling HAs to solicit other buyers and put contracts for their innovation and product(s) in place.
- (b) GUARANTEED FIRST BUYER OF IMPROVED HEALTH OUTCOMES. ARPA-H will serve as the first Outcome Buyer of the Health Accelerators' health outcomes up to a maximum of \$15M per AHA over the life of the HEROES program. ARPA-H contributions will be the first funds to be paid as the AHAs improve health outcomes.
- (c) ARPA-H AWARD INSTRUMENT AND SCOPE. ARPA-H will award Other Transaction agreements that will provide reward payments up to \$15M for AHAs if targets are met (see Monitoring and Evaluation herein, and that will also provide

fixed price milestone-based payments (up to \$600K) over the life of the program for AHAs and PHAs each (see Section 1.8, Fixed Price Schedule of Milestones). The scope of the fixed price, milestone-based portion will be associated with documenting the HA's intervention implementation strategies, including the feasibility of scaling sustainable solutions nationally.

- (d) ACCESS TO THE INVESTOR CATALYST HUB¹⁰. ARPA-H's Investor Hub will help organizations develop strategies for raising capital, 'matchmake' with other at-risk investors, and aid in the formation of investor relationships. (See the Acronyms/Definitions section of this solicitation.)
- (e) ACCESS TO THE HEROES OUTCOME TOOLKIT¹¹. Performers will utilize the HEROES Outcome Toolkit, a government-furnished dataset and data visualization platform. ARPA-H will post tools on the HEROES program website (at https://arpa-h.gov/research-and-funding/programs/heroes
) that enables organizations to understand their innovation's effectiveness. The HEROES Outcome Toolkit will be specifically tailored to each organization's community and public health outcome category of choice, thus removing the organization's need to fund, support, and develop its own monitoring and evaluation program.
- (f) ACCESS TO TECHNICAL AND EDUCATIONAL RESOURCES.

 Organizations have the ability to reach Outcome Buyers and Investors as well as learn about rewards payment structuring

¹⁰ Part of the ARPANET-H Health Innovation Network is called the Investor Catalyst Hub which can be found at https://investorcatalysthub.org.

¹¹ Elements of the Outcome Toolkit include the following: A publicly available front-end interactive website to host data and display it geographically. The website will include the following functionalities:

[•] Visual heat maps of each outcome's prevalence by county or ZIP3, depending on the outcome, along with population data by county (e.g., total residents with breakdown by age, sex, race, and income).

[•] The ability to select multiple counties, as well as view aggregate population data and baseline outcome data across a combined geographic area.

[•] Ability for users to create outputs of their reports with data filters selected.

[•] Over the course of the program, compute, and display (in as near-real time as possible) changes in outcome metrics of the target geographic area and baseline populations thus allowing for Health Accelerators to track performance over time.

through the ARPA-H Teaming page and the Investor Catalyst Hub at the following website:

https://arpa-h.gov/research-and-funding/programs/heroes.

(g) MONITORING AND EVALUATION. ARPA-H will use six-month milestone periods to review progress, identify enhancements in health improvement, and provide opportunities for HAs to share best practices through program meetings and reporting (see Section 1.9, General Requirements, for more information).

1.6 PROGRAM STRUCTURE

1.6.1 OUTCOME CATEGORY SELECTION

(a) The Proposer will select one of the four health outcome categories in geographic areas ranging from 500,000 to 5 million people in the general population (see Table 1, HEROES Program's Prioritized Health Outcomes). The table details specific metrics for each outcome category, along with data type and the minimum general population size needed.

Table 1: HEROES Program's Prioritized Health Outcomes

Health Outcome			Minimum General Population
Category	Specific Metric	Data Type	Size for Target Geographic
Category			Area
Maternal Health	Rate of intrapartum and	Claims-based	5M general population per
	postpartum severe		community
	obstetric complications		OR
	(SOCs) per 10,000		Entire state if general
	deliveries		population is fewer than 5M
Heart Attack and	Aggregate 10-year risk	Electronic health	700K general population per
Stroke Risk	of heart attack and	record (EHR) data	community
	stroke		OR
			Entire state if general
			population is fewer than 700K
Opioid Overdose	Rate of EMS patient	National Emergency	500K general population per
	encounters for fatal and	Medical Services	community*
	non-fatal opioid		

Health Outcome Category	Specific Metric	Data Type	Minimum General Population Size for Target Geographic Area
	overdoses per 100,000	Information System	
	population	(NEMSIS) data feed	
Alcohol-Related	Rate of EMS patient	NEMSIS data feed	500K general population per
Health Harms	encounters for alcohol-		community*
	related emergencies		
	per 100,000 population		

^{*}All states have a general population greater than 500K and can meet this minimum threshold.

(b) Refer to Appendix A, Health Outcome Category Details, for additional details.

1.6.2 FLEXIBILITY OF STRATEGY DEVELOPMENT

- (a) HEROES allows considerable flexibility in the strategies proposed to achieve desired improvements in the specified health outcome categories selected by the interested Proposer. The specific elements of each plan are likely to vary depending on the health outcome category selected and the community served. It is expected that the strategies will involve a broad range of stakeholders. Strategies could include a focus on technical improvements, clinical interventions, and/or community engagement. Proposers will determine the most effective set of activities that will achieve the desired outcomes. (See Attachment 2, OT Bundle, Attachment (2) Volume 1: Technical & Management template, for proposal preparation instructions; and Appendix A, Health Outcome Category Details, for examples of potential strategies and technology enablers that HAs might adopt. Also see Attachment 2, OT Bundle, Attachment (2) Volume 2: Price template, for additional proposal preparation instructions as it pertains to Outcome Buyer support.)
- (b) Proposers have considerable flexibility in their relationships with their Outcome Buyers. A Proposer can set up agreements in which Outcome Buyers fund programmatic, individual-level, and intermediate metrics that demonstrate

alignment and support the work towards the key objective of achieving the targeted rate of reduction in the outcome selected by the Proposer. The funding for programmatic and intermediate metrics that ARPA-H determines align with the outcome category selected will count toward the 2:1 Outcome Buyer/ARPA-H target match. This could enable HAs to potentially receive funding from other Outcome Buyers earlier in the HEROES program period.

1.6.3 DATA STRATEGY

- (a) The Outcomes Toolkit provides data at the ZIP3 (which signifies the first three digits of a five-digit zip code) or county level so Proposers can select their geographic areas of interest and compare performance to the national average for each health outcome category. Once HAs are selected and begin performing, the HEROES program will work with regional sources of data to ensure there is adequate data coverage of the targeted geographic areas. These data would be used to populate the Outcomes Toolkit to track improvements in the metrics and to determine reward payments.
- (b) ARPA-H will ensure the Outcomes Toolkit is populated with the appropriate data. However, ARPA-H may require supplementary data in certain geographic areas to develop accurate population level outcome estimates. Thus, ARPA-H will ask Performers to work with key local data sources (e.g. large hospitals or health systems) to ensure there is sufficient access to data to populate the Outcomes Toolkit.
- (c) During the Solution Summary submission period, Proposers will use the Outcomes Toolkit located on the HEROES website at https://arpa-h.gov/research-and-funding/programs/heroes to identify appropriate geographic areas, and proposers are encouraged to choose an area where the outcome category performance is worse

than the national average. No additional data are required from Proposers during this time.

- 1.6.3.1 DATA STRATEGY BY HEALTH OUTCOME: FULL PROPOSALS

 Depending on the outcome category selected,

 Proposers submitting full proposals should indicate
 how they may work with ARPA-H to ensure access to
 necessary data.
- 1.6.3.2 MATERNAL HEALTH: Existing healthcare vendor contracts provide approximately 70% coverage of all obstetric deliveries; ARPA-H is ideally targeting areas with a healthcare vendor density of 80% or greater in proposal submissions. Performers choosing this Outcome Category will be asked to facilitate access to local Health Information Exchanges or develop relationships with local electronic medical record systems providers to allow for bulk Fast Healthcare Interoperability Resources (FHIR) Application Programming Interface (API) access for ARPA-H or its representatives to access data either directly or through approved middleware. As an alternative, a more simplified approach that involves submission of any data through other mechanisms, such as spreadsheets or downloads in a pre-specified format, may be proposed.
- 1.6.3.3 RISK OF HEART ATTACK AND STROKE: ARPA-H is ideally targeting a density of 80% or greater of the population age 40-70 in the geographic area for computing average risk in proposal submissions. Proposers choosing this Outcome Category would be asked facilitate access to local Health Information Exchanges, or to develop relationships with local electronic medical record systems providers to allow for Bulk FHIR API access for ARPA-H or its representatives, or approved middleware to access data to achieve the recommended threshold. As an

alternative, a more simplified approach that involves submission of additional approved data through other mechanisms, such as spreadsheets or downloads in a pre-specified format, may be proposed.

- 1.6.3.4 OPIOID OVERDOSE: Proposers who choose this Outcome Category must secure permission from their local or state EMS services programs to allow "case rate" data access to ARPA-H or its representatives to enable reporting these data. (Some state-level EMS service providers limit disclosure of their data at the granular level needed to compute programmatic metrics.)
- 1.6.3.5 ALCOHOL-RELATED HEALTH HARMS: Proposers who choose this Outcome Category must secure permission from their local or state EMS services programs to allow "case rate" data access to ARPA-H or its representative(s) to enable reporting these data. (Some state level EMS service providers limit disclosure of their data at the granular level needed to compute programmatic metrics.)

1.6.4 IMPROVING HEALTH OUTCOMES FOR ALL

A critical aspect of the HEROES program is substantial health outcome improvements for all people living in the same region. Accordingly, the Proposers are encouraged to choose areas where the average performance on the selected health outcome category is below the national average. At the program level, ARPA-H will select a portfolio of proposals that cover a breadth of geographic regions throughout the country. See Attachment 2, OT Bundle, Attachment (2) Volume 1: Technical & Management template for proposal preparation instructions regarding health equity.

1.6.5 USE OF THE HEROES OUTCOME TOOLKIT

- (a) One of the primary prior barriers to scaling solutions in outcomes-based financing in public health is the need for expensive, highly customized technologies and data solutions to define populations, identify outcomes, construct estimates of savings and return on investment, and develop detailed contract terms. To assist Proposers, ARPA-H is developing a scalable HEROES Outcome Toolkit to allow entities (both within the HEROES program and throughout the health ecosystem) to improve the health of populations by using defined metrics and novel funding structures. The HEROES Outcome Toolkit provides plug-and-play business-planning-in-a-box that simplifies the development of public health programs, thus allowing for program launch in a matter of weeks or months instead of years.
- (b) While the Toolkit will be used for specific purposes within the HEROES program (specifically to assist Proposers and eventually track HA performance throughout the life of the program), these resources will be publicly available, have general applicability throughout the healthcare sphere, and assist advances pioneered through HEROES to become broadly scalable and sustainable. During the proposal process and program's period, ARPA-H will support technological and process innovation in reaching the outcome metrics selected. Proposers and HAs will have extensive opportunities to learn from ARPA-H and each other about optimal ways to use these tools to drive health improvement.

1.6.6 Sharing Insights and about Successful Intervention Strategies

(a) ARPA-H will facilitate semi-annual Innovation Exchange Sessions with all HAs to discuss best practices for driving health improvement and share lessons learned in the preceding periods. These sessions will enable HAs to learn from each other and ARPA-H to optimize strategies for

improvement in implementing interventions, raising capital, and affecting health outcomes. These sessions will be a portion of the Virtual and Onsite Educational Session requirements, which are described in more detail below in Section 1.9.1.

(b) Through the HEROES Program Annual Symposium, ARPA-H will also bring together the broader public health community, including federal and state government partners to enable ARPA-H and HAs to share best practices, which will allow HAs to further expand their knowledge and connection to governmental partners. HAs may be asked to leverage reporting materials to prepare presentations or research reports on their practices and intervention approaches that will inform broader knowledge within the scientific and clinical community.

1.7 PROGRAM METRICS & MILESTONES

The HEROES program aims to improve specific health outcomes in regions selected by HAs. For each of the health outcomes categories, the targeted value of societal benefit (and thereby ARPA-H's expectation of success) is defined by tracking metrics every six months throughout the three-year performance period as outlined in the following Table 2. Metrics by Health Outcomes. An evaluation of difference-in-difference improvements will compare the national average to the Performer's region, and will be adjusted for age, sex, and race/ethnicity. HAs will be able to track their performance against the national average via the HEROES Outcome Toolkit. The comparison to a national average will serve as a target to assess how well the HA's interventions have improved health outcomes.

Table 2: Metrics by Health Outcomes.

Metric Type	Metric	Overall Target	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36
Maternal Health	Rate of intrapartum and postpartum SOCs per 10,000 deliveries	SOC rate by 20% relative to	Relative 10% reduction	Relative 10% reduction	20%	20%	Relative 30% reduction	Relative 30% reduction
Heart Attack & Stroke Risk	Aggregate 10-year risk of heart attack and stroke	aggregate 10-	reduction in	Relative reduction in risk rate by		Relative reduction in	Relative reduction in risk rate by	Relative reduction in risk rate by

Metric Type	Metric	Overall Target	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36
		attack and stroke by 1% relative to national average	0.5% points	0.5% points	risk rate by 1.0% point	risk rate by 1.0% point	1.5% points	1.5% points
Opioid Overdose	Rate of EMS patient encounters for fatal and non- fatal opioid overdoses per 100,000 population		Relative 5% reduction	Relative 5% reduction	Relative 10% reduction	Relative 10% reduction	Relative 15% reduction	Relative 15% reduction
Alcohol- Related Health Harms	Rate of EMS patient encounters for alcohol-related emergencies per 100,000 population	Reduction in rate of alcohol-related health harms by 10% relative to national average	Relative 5% reduction	Relative 5% reduction	Relative 10% reduction	Relative 10% reduction	Relative 15% reduction	Relative 15% reduction

1.7.1 REWARD PAYMENTS FOR PERFORMANCE (AHAS ONLY)

Outcome Buyer Distribution Process. ARPA-H will be the "first (a) in, first out" Outcome Buyer. This means that any improvements meeting the criteria achieved by the AHA will initially be awarded under the ARPA-H Other Transaction Agreement with the AHA. Once ARPA-H funding is exhausted, further reward payments should be paid proportionally from contributions by other Outcome Buyers. Tracking reward payments from Outcome Buyers other than ARPA-H is the sole responsibility of the AHA. Rewards between the AHA and Outcome Buyers other than ARPA-H shall be monitored and paid out in accordance with the terms and conditions of the agreements put in place between each AHA and Outcome Buyer. Any funds left unallocated to an AHA (out of the \$15M) at the end of the program will not be paid out by ARPA-H.

(b) Release of Funds

(1) ARPA-H will use the HEROES Outcome Toolkit to track improvements in the health outcome metrics selected by the AHAs relative to the adjusted baseline and national averages. If the improvement meets the

criteria for payment, ARPA-H shall release funds to the AHA in the amount specified in Table 3, HEROES Program's Projected Target Outcome Improvement Over Program Period (also, see Table 4, Reward Example). The AHA will be eligible for payments every six months during the HEROES program, based on the level of improvement observed in its health outcome category metrics. It is important to note that the reward payments are directly tied to the reductions in the health outcome metrics, and not to the societal value. Reward payments are not all or nothing; reward payments provided are proportionately based on the level of improvement for the chosen health outcome.

(2) As demonstrated in Table 3, the payouts are weighted over time such that most of the rewards are paid out in the latter half of the HEROES program. This is to ensure that improvements in health outcomes are sustained. It is also critical to note that ARPA-H funds will be depleted first, prior to any Outcome Buyers funds being paid out under HA/Outcome Buyer agreements. Additionally, ARPA-H reserves the right to adjust its payout (illustrated in Table 4) over the life of the program if the 2:1 Outcome Buyer/ARPA-H match is not obtained.

Table 3: HEROES Program's Projected Target Outcome Improvement Over Program Period.

Payout Compris	6	12	18	24	30	36
Payout Scenario	months	months	months	months	months	months
Hypothetical maximum outcome-based payout (assuming \$45M total reward pool)	\$3.75M	\$3.75M	\$7.50M *	\$7.50M	\$11.25M	\$11.25M
Expected reduction of severe obstetric complications (% relative to the national average)	10%	10%	20%	20%	30%	30%

Povent Cooperie	6	12	18	24	30	36
Payout Scenario	months	months	months	months	months	months
Expected reduction of atherosclerotic cardiovascular disease risk (% relative to	0.5%	0.5%	1%	1%	1.5%	1.5%
national average)						
Expected reduction of opioid overdoses (% relative to national average)	5%	5%	10%	10%	15%	15%
Expected reduction of alcohol-related health harms (% relative to national average)	5%	5%	10%	10%	15%	15%

^{*} ARPA-H's \$15M payout is at this point exhausted, so future payments come from additional Outcome Buyers. Payouts in excess of the ARPA-H funds will be paid to HAs outside of agency-resulting awards. Tracking reward payments from Outcome Buyers other than ARPA-H is the sole responsibility of the AHA. The government reserves the right to adjust the reward payout if the 2:1 match is not obtained.

- (3) At the end of each six-month period, the performance of AHAs will be evaluated and reward payments will be issued proportionally based on health outcomes that have been achieved. At the conclusion of the first (and only the first) six-month period, each AHA will receive an initial zero-equity investment payment of \$2M to facilitate operational implementation and the success of each AHA's program. This means that for the first six-month payout period, the payout minimum has a floor of \$2M and a ceiling of \$3.75M. In other words, even if the AHA does not meet the expected rate reduction in the outcome category at the end of the first six-month period, it will still receive a reward payment of \$2M.
- (4) Reward payments will be scaled proportionally to the outcomes delivered with a maximum payment threshold determined by the total Outcome Buyer pool. For every six-month period, the maximum reward payment will occur at a pre-specified improvement amount. See Table 4 for more information on pre-specified amounts. In no instance will the AHAs be entitled to payment of more than the

total value of the outcome-based reward pool. HA Outcome Buyer contracts should demonstrate an alignment with this incentive structure (see Section 1.9.2, Program Deliverables).

- (5) At month 36, ARPA-H will conduct a "true-up" analysis to compare the AHA's performance over the full program term against the total target outcome reductions and issue any ARPA-H payments due. In other words, if an AHA underperformed in early periods and overperformed in later periods, but still achieved the targeted three-year average improvement thresholds, the AHA will receive full payment. No over-payments made during the program will be returned to ARPA-H as part of the true-up analysis.
- (6) The following Table 4, Reward Example, depicts two scenarios for an AHA working on reducing Severe Obstetric Complications (a targeted 20% reduction). The table shows six-month checkpoints, AHA performance, and the resulting reward payments.

Table 4: Reward Example.

Payout opportunity milestones	6 months	12 months	18 months	24 months	30 months	36 months	Total payout (\$) and average outcome reduction (%) over entire 3- year program
Hypothetical maximum outcome-based payout (assuming \$45M total reward pool)	\$3.75M	\$3.75M	\$7.5M ARPA-H funding exhausted	\$7.5M Outcome Buyer funds (if secured) used going forward**	\$11.25 M	\$11.25 M	\$45M*
Expected reduction of severe obstetric complications (% relative to comparator)	10%	10%	20%	20%	30%	30%	20%

Payout opportunity milestones	6 months	12 months	18 months	24 months	30 months	36 months	Total payout (\$) and average outcome reduction (%) over entire 3- year program		
<u>Scenario 1:</u> Slow start with moderate sustained progress but does not achieve the expected three- year average outcome reduction.									
Relative reduction achieved by the Health Accelerator	0%	0%	17%	15%	24%	30%	14.3%		
Reward earned by Health Accelerator	\$2M	\$0M	~\$6.4M	~\$5.6M	\$9M	\$11.25 M	~\$34.2M (~\$32.2M via outcome improvemen ts + \$2M zero-equity investment)		
Scenario 2: Strong perfor program, the three-year a eligible to receive the ba	average ou	ıtcome rec	luction exc	eeds the	expected a	amount. Th			
Health Accelerator's relative reduction	6.7%	10%	15%	20%	30%	38.3%	20%		
Health Accelerator Reward Payment	~\$2.5M	\$3.75M	~\$5.6M	\$7.5M	\$11.25 M	\$11.25 M	~\$42M earned and trued-up to \$45M		

^{*}The actual value of the outcome-based reward pool is dependent on additional advanced commitments from Outcomes Buyers secured by the AHA. The government reserves the right to adjust the rewards table if the 2:1 match is not obtained.

Scenario 1: In the first six-month payout period, despite showing no improvement, the AHA earns the zero-equity investment of \$2M. In each subsequent payout period, the AHA earns a reward value proportional to the improvement, except for the last payout period where it performs at the target improvement rate. At the end of program, the AHA's overall outcome reduction is 14.3% compared to the target of 20%. While the proportional value of this improvement equates to around \$32.2M, it receives a total of \$34.2M. As stated previously, the over-payment of \$2M made during the program will not be returned to ARPA-H.

^{**} Outcome Buyer funds paid out under and in accordance with HA/Outcome Buyer negotiated agreements.

Scenario 2: The AHA receives the full reward amount of \$45M. In each six-month period, the AHA earns a payout proportional to its improvement performance (e.g., in the first six-month payout period, a 6.7% reduction relative to a 10% target rate reduction earns two-thirds of the maximum payout of \$3.75M, or around \$2.5M). Toward the end of the program period, the AHA starts to perform better than the targets. However, the reward pools are capped regardless of the AHA over-performing. As a result, at the end of the implementation period, ARPA-H reviews the overall improvement and determines that the AHA meets its overall improvement target of 20%. Therefore, the AHA is trued-up to earn the full \$45M reward.

1.7.2 Transparency

ARPA-H will ensure AHAs have appropriate transparency on the metrics and data sources that will be used to assess performance in the program prior to signing their Other Transaction Agreements with ARPA-H. Through the ongoing program reporting (see Section 1.9.2, Program Deliverables), the AHA may submit a request to review the methodology for any outcomes-based financing.

1.7.3 EVALUATING EFFECTIVENESS OF INTERVENTIONS, AND PROGRESS TOWARD FINANCIAL SUSTAINABILITY

- (a) ARPA-H will use six-month milestone periods to review progress, measure enhancement in health improvement, and share best practices. ARPA-H will provide direct, ongoing support and conduct site visits as well as convene technical experts and other participating organizations at a regular cadence to share best practices and lessons learned over the life of the program.
- (b) In addition to the outcome measures, the HAs will also collect data to assess which interventions and engagement strategies are most effective. This additional analysis will enable HAs to collect- and share lessons learned. Further, this will provide ARPA-H, government partners, and private

stakeholders with information that can assist in generalizing the approach to new geographic areas, and ultimately to a national scale.

(c) Intervention Effectiveness Metrics (AHAs and PHAs).

The intervention effectiveness metrics enhance scientific understanding of population health interventions. Metric results will not impact the reward payments earned. The metrics will serve as a basis for program management and shared learning discussions with other HAs at the semi-annual Innovation Exchange Sessions.

Table 5: Intervention Effectiveness Metrics.

Metric Type	Metric	Overall Target	Project Start (intervention baseline)	6 months	12 months	18 months	24 months	30 months	36 months
Technology Deployment Rates	Number of technology adoption measures achieved (Proposers will define up to 5 technology approaches with adoption measures)	New technologies implemented and scaled	Ready to execute contracts with intervention partners	Intervention partner contracts finalized	20% Technology adoption measures achieved	40% Technology adoption measures achieved	60% Technology adoption measures achieved	80% Technology adoption measures achieved	100% Technology adoption measures achieved
Engagement Rate	Percentage of patients exposed to intervention	Population- wide penetration across multiple targeted strategies and interventions		25%	50%	75%	80%	90%	100%
Intervention Effectiveness	Percentage of intermediate endpoints achieved (Proposers will define up to 5 clinical strategies/interventions with intermediate endpoints*)	Improvement in clinical process measures on the causal pathway to the primary outcomes		10% Intermediate clinical endpoints achieved*	20% Intermediate clinical endpoints achieved*	40% Intermediate clinical endpoints achieved*	60% Intermediate clinical endpoints achieved*	80% Intermediate clinical endpoints achieved*	100% Intermediate clinical endpoints achieved*

^{*}A process measure that is on the causal pathway and is strongly correlated with the health outcome (e.g., rate of statin prescriptions as an intermediate endpoint for cardiovascular risk).

Assumption: Organizations will use engagement rates and intermediate endpoints to evaluate whether proposed interventions are producing the desired results and will use this information to pivot as necessary (e.g., leveraging different intervention partners or engagement strategies to increase penetration and impact).

(d) Financial Sustainability Metrics (AHAs only).

HAs will be required to submit reports at six-month intervals on progress toward long-term outcomes sustainability. The metrics in Table 6, Financial Sustainability Metrics, will be used to evaluate financial sustainability goals. The metrics will serve as a basis for program management and shared learning discussions with other HAs at the semi-annual Innovation Exchange Sessions.

Table 6: Financial Sustainability Metrics

Metric Type	Metric	Overall Target	Project Start (intervention baseline)	6 months	12 months	18 months	24 months	30 months	36 months
Private Sector Participation	Amount of funding secured from outcome buyers	2:1 ratio of private funding to ARPA-H funding per Performer;	Confirmed funding available for intervention plan	1.5:1	2:1	2:1	2:1	2:1	2:1
Outcome Value Generated	Total outcome payments earned/societal value generated	At least 80% of AHAs receive outcomes payments of at least \$20M over the lifetime of the project			\$10M	\$20M	\$30M	\$45M	\$55M
Outcome Buyer ROI*	Ratio of estimated economic benefit to total reward paid by outcome buyers (Economic benefit / Total rewards paid)	Positive ROI* (Ratio >1)	Ready-to- execute contracts with Outcome Buyers			1.0	1.0	1.1	1.25
At-Risk Investor ROI*	Ratio of invested capital to total return	Positive ROI* (Ratio >1)				1.0	1.0	1.1	1.25
Sustainability	Percentage of participants with a new pay-for-outcomes contract at conclusion of program (either in same, or a new, geographic area).	At least 50% of AHAs secure new pay-for- outcomes contracts without ARPA- H matching funds			-	-	25% of AHAs have at least one new pay- for- outcome contract in develop ment	50% of AHAs have at least one new pay- for- outcome contract in develop ment	50% of AHAs have executed at least one new pay-for- outcome contract

1.8 FIXED PRICE SCHEDULE OF MILESTONES

- (a) If selected for award negotiation, the fixed payable milestones discussed in paragraph (c) of this Section will be directly incorporated into Attachment 3, Agreement Term, Deliverables, and Payment Schedule, of the awarded OT Agreement (see Attachment 2, OT Bundle, Attachment (4) Volume 2, Model OT), with milestone amounts calculated based on a steady burn rate over the course of the program (e.g., \$100K per milestone for a total amount of \$600K).
- (b) For planning and budgetary purposes, Proposers should assume a program start date of <u>April 1, 2025</u>.
- (c) Fixed Milestones for this project must include:

Milestone #	Milestone Description	Exit Criteria/Deliverable	Due Date (after agreement award)	Notional Milestone amount
1	Report on intervention	Exit Criteria:	6 months	\$100,000
	implementation strategies to include	Participate in program kickeff meeting		
	the feasibility of scaling	kickoff meeting, virtual check-ins, and		
	sustainable solutions	semi-annual		
	nationally and	innovation exchange		
	outcome	sessions.		
	improvements.	 Up to date on 		
	Attend semi-annual	technical status		
	innovation exchange	reporting requirements		
	sessions with all Health	requirements		
	Accelerators across the	Deliverable:		
	HEROES program.	 Kickoff presentation 		
		materials (to include		
		slides, mater		
		schedule, spend		
		plan). • Presentation materials		
		to facilitate		
		discussions during		
		virtual check ins.		

Milestone #	Milestone Description	Exit Criteria/Deliverable	Due Date (after agreement award)	Notional Milestone amount
		 Presentation materials to facilitate discussions during innovation exchange sessions. Quarterly technical status reports 		
2	Report on intervention implementation strategies, to include updates to the feasibility of scaling sustainable solutions nationally and outcome improvements during the six-month period. Attend annual program symposium.	Participate in program virtual check-ins, and HEROES program symposium; share best practices, lessons learned, etc. Up to date on technical status reporting requirements Deliverable: Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during annual program symposium. Quarterly technical status reports	12 months	\$100,000
3	Report on intervention implementation strategies, to include updates to the feasibility of scaling sustainable solutions nationally and outcome improvements during the six-month period.	Participate in program virtual check-ins, and semi-annual innovation exchange sessions. Up to date on technical status reporting requirements	18 months	\$100,000

Milestone #	Milestone Description	Exit Criteria/Deliverable	Due Date (after agreement award)	Notional Milestone amount
	Attend semi-annual innovation exchange sessions with all Health Accelerators across the HEROES program.	Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during innovation exchange sessions. Quarterly technical status reports		
4	Report on intervention implementation strategies, to include updates to the feasibility of scaling sustainable solutions nationally and outcome improvements during the six-month period.	Participate in program virtual check-ins, and HEROES program symposium; share best practices, lessons learned, etc. Up to date on technical status reporting requirements	24 months	\$100,000
	symposium	Deliverable: • Presentation materials to facilitate discussions during virtual check ins. • Presentation materials to facilitate discussions during annual program symposium. • Quarterly technical status reports		
5	Report on intervention implementation	Exit Criteria:	30 months	\$100,000

Milestone #	Milestone Description	Exit Criteria/Deliverable	Due Date (after agreement award)	Notional Milestone amount
	strategies, to include updates to the feasibility of scaling sustainable solutions nationally and outcome improvements during the six-month period. Attend semi-annual innovation exchange sessions with all Health Accelerators across the HEROES program.	 Participate in program virtual check-ins, and semi-annual innovation exchange sessions. Up to date on technical status reporting requirements Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during innovation exchange sessions. Quarterly technical status reports 		
6	Report on intervention implementation strategies, to include updates to the feasibility of scaling sustainable solutions nationally and outcome improvements during the six-month period. Attend annual program symposium. End of program final report on research accomplishments to include but not limited to, lessons learned,	Presentation materials to facilitate discussions during annual program symposium. Up to date on technical status reporting requirements Deliverable: Presentation materials to facilitate discussions during virtual check ins. Presentation materials to facilitate discussions during virtual check ins.	36 months	\$100,000

Milestone #	Milestone Description	Exit Criteria/Deliverable	Due Date (after agreement award)	Notional Milestone amount
	scalability potential, and outcome improvement	annual program symposium. • Quarterly technical status reports • Final Program Report		

1.9 GENERAL REQUIREMENTS

- (a) Proposals are expected to show involvement with teams with the expertise needed to achieve the goals of the HEROES program. Specific content, communications, networking, and team formation are the sole responsibility of the Proposer. Establishment of relationships and resulting agreements with Outcome Buyers and at-risk investors are also the sole responsibility of the Proposer. Proposers must submit a single integrated proposal that indicates the program will be led by a Principal Investigator (PI), will be under a single prime awardee, and that addresses all program components. Interested organizations may only submit one proposal under the prime Proposer.
- (b) Note that an HA can receive an award from ARPA-H for one outcome category and be an Outcome Buyer/investor for another HA working on a different health outcome category. Additionally, an HA can receive an award from ARPA-H for one outcome category and be an Outcome Buyer/investor for another HA implementing the same health outcome. However, a Health Accelerator cannot be both the HA and the Outcome Buyer for the same effort. Proposers interested in proposing to more than one outcome category MUST submit a separate Solution Summary and proposal for each outcome category/ geographic area pairing.

1.9.1 VIRTUAL AND ONSITE EDUCATIONAL SESSION REQUIREMENTS

ARPA-H will conduct site visits and convene technical experts and other participating organizations on a regular cadence to share

best practices and lessons learned over the life of the program. The following approaches will be undertaken:

- (a) VIRTUAL CHECK-INS. HAs will meet with ARPA-H on a regular cadence, and at the Program Manager's discretion, to provide updates on the implementation of the intervention strategy (AHAs monthly; PHAs quarterly). This enables the HAs to share any roadblocks they're encountering and allows ARPA-H to make determinations regarding the mobilization of resources.
- (b) PROGRAMMATIC EVALUATION MEETINGS (AHAS ONLY). ARPA-H will schedule Programmatic Evaluation meetings with the AHAs every six months to review progress, answer questions, and discuss anticipated award payments.
- (c) SITE VISITS (AHAS ONLY). At least once a year, and more often if needed, ARPA-H will conduct a site visit with each selected AHA. This will provide an opportunity to hear first-hand accounts from the AHA, as well as the experiences of community partners and Outcome Buyers. ARPA-H will monitor progress and assess the success-level of efforts towards achieving the health outcome metric selected. These in-person site visits will complement regular, frequent interaction between ARPA-H and the HAs.
- (d) LEARNING WITHIN THE PROGRAM. ARPA-H will facilitate semiannual Innovation Exchange Sessions with all HAs to discuss best practices for driving health improvement and share lessons learned in the preceding periods. These sessions will enable HAs to learn from each other and from ARPA-H to optimize strategies for improvement in implementing interventions, raising capital, and affecting health outcomes.
- (e) DISSEMINATING BEST PRACTICES TO THE PUBLIC HEALTH COMMUNITY. Through the HEROES Program Annual Symposium, ARPA-H will bring together the broader public health community, including federal and state government

partners to enable ARPA-H and HAs to share best practices. HAs may be asked to leverage reporting materials for preparing presentations on their practices and intervention approaches.

(f) DISSEMINATING BEST PRACTICES WITHIN THE GOVERNMENT: HAS may be asked to participate in at least two meetings per year with other government agencies (e.g. Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), etc.) to brief the HA's program progress. HAs may be asked to leverage reporting materials for preparing presentations if participation is requested.

1.9.2 PROGRAM DELIVERABLES

(a) The following Table provides descriptions of the Program Deliverables required.

Deliverable	Deliverable Description	HA Awarded	Frequency
Final Program Plan	A final program plan that clearly outlines key components of the interventions, and notes final partners with signed agreements (e.g., signed commitment letters for any secured internal financing and/or at-risk investors and Outcome Buyers).	AHAs	Within three months of project award
Proof of Contracts	A core tenet of this program is the recruitment of additional Outcome Buyer contracts and atrisk investors. AHAs are required to submit proof of contracts signed with Outcome Buyers and at-risk investors (e.g., excerpts from awarded agreements which illustrate the following: signatures, period of performance, dollar amounts, and a snapshot of the rewards structure negotiated). Additionally, demonstrate that the rewards structure of those contracts aligns with and supports the proposed intervention plans and goals and/or describes alternative approaches taken and how said approaches will lead to outcome sustainability once the ARPA-H funding is exhausted.	AHAs	Ongoing as contracts are signed

Deliverable	Deliverable Description	HA Awarded	Frequency
Technical	AHAs and PHAs shall submit a report to ARPA-	AHAs	Quarterly
Status Reports	H that describes current activities and planned	and	
	implementations; reports on changes to	PHAs	
	staffing mixes/levels, provides status updates		
	on Outcome Buyers and at-risk investors (as		
	appropriate); and reports progress on the		
	metrics during the current reporting period		
	(e.g., the prior six months). These metrics		
	include the target outcome metric as well as		
	metrics for intervention effectiveness and		
	financial sustainability as detailed below.		
Presentation	Materials to facilitate discussions during virtual	AHAs	Every 6 months
materials	check-ins, annual program symposia, and/or	and	
	programmatic evaluation meetings. The format	PHAs	
	of requested materials (high level written		
	report, slides, etc.) will be discussed with		
	Performers prior to the events.		
End of	HAs will be required to produce a culmination	AHAs	Once at the end of
Program	report of the program that will detail	and	program
Report	interventions completed, community	PHAs	
	stakeholders engaged, impact on reporting		
	metrics and data, lessons learned, and		
	sustainability planning.		

(b) ARPA-H held a Proposer's Day (see Section 8, Proposer's Day) to facilitate formation of Proposer teams and enable sharing of information among interested parties.

2.0 PROGRAM SELECTION AWARD INFORMATION_

(a) This Program Solicitation (PS) may result in multiple awards of Other Transaction (OT) Agreements. However, ARPA-H reserves the right to select all, some, one, or none of the proposals received in response to this solicitation for negotiation. ARPA-H also reserves the right to NOT make awards in all four health outcomes categories. The number of awards selected, and in which health outcome categories, will depend on the quality of the proposals received and the availability of funds. If awards are made in multiple health outcomes, the Government is interested in funding at least 2 awards within a health outcome to support robust learning activities throughout the program. Lastly, the presence of

Outcome Buyer matching funds and their level of commitment will be factored into the Government's evaluation as denoted in evaluation factor 1 (see Section 5.0).

- (b) If warranted, portions of resulting awards may be segregated into prepriced options. In the event that ARPA-H desires to award only portions of a proposal, negotiations will commence upon proposal selection notification. ARPA-H reserves the right to fund proposals in phases with options for continued work, as applicable.
- (c) ARPA-H reserves the right to request any additional documentation to support the negotiation and award process. ARPA-H reserves the right to remove a proposal from award consideration should the parties fail to reach agreement on award terms, conditions, cost, and/or the Proposer fails to provide requested additional information in a timely manner.
- (d) A model Agreement with basic terms and conditions will be provided within two months of solicitation posting to SAM.gov. <u>It will be provided as an Amendment to ARPA-H-SOL-24-01</u> (see additional details in Section 4.3.2, Model Other Transaction Agreement).
- (e) Any resulting OT Agreement will not require cost-sharing; however, ARPA-H reserves the right to negotiate cost-sharing as appropriate to the situation.
- (f) While scientific publications are highly encouraged, ARPA-H will apply publication (or other) restrictions, as necessary, if it is determined that the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information, including Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, and any information marked Sensitive but Unclassified (SBU), Controlled Unclassified Information (CUI), etc. Any award resulting from such a determination will include a requirement for ARPA-H permission before publishing any information or results on the effort.

2.1 ACQUISITION STRATEGY

- (a) ARPA-H aims to lower the administrative burden typically associated with working with the federal government, reduce program risk, foster competition, and have Performers/HAs begin work faster. To facilitate this objective, ARPA-H will use the following acquisition process for HEROES:
 - (1) **DRAFT SOLICITATION**: ARPA-H utilized the comment period associated with the draft solicitation, in conjunction with the Letters of Interest (LOI) and Proposer's Day, to gauge interest in the four health outcome categories.
 - (2) LETTERS OF INTEREST: To gauge the level of interest in the HEROES program, ARPA-H strongly encouraged the submission of an LOI by all entities interested in participating in the HEROES program (as an HA, Outcome Buyer, or at-risk investor). Submission of an LOI is NOT required to submit an Solution Summary or a proposal. (The LOI submission period closed in advance of the issuance of the final HEROES Solicitation.)
 - (3) SOLUTION SUMMARY: Solution Summaries must be submitted in advance of a full proposal submission. The ARPA-H team will review all Solution Summaries for compliance; only conforming Solution Summaries will receive feedback. ARPA-H will provide feedback to encourage or discourage submission of a full proposal; however, proposals can be submitted regardless of the Solution Summary feedback received. See Section 4.3, Proposal Instructions, for further details.
 - (4) PROPOSALS: All Proposers who submit a Solution Summary will have the opportunity to submit a full proposal. Any proposals received from Proposers who did not submit a Solution Summary will be deemed non-conforming and will not be reviewed. All conforming proposals will be reviewed and evaluated. Multiple awards are anticipated.

- (b) ARPA-H will not pay the costs associated with the preparation or submission of a Solution Summary and/or Proposal.
- (c) ARPA-H will review and evaluate proposals based on the evaluation criteria described in Section 5.0, Evaluation of Proposals.
- (d) Two types of HAs will be designated, AHAs and PHAs. Their Agreements will be structured as follows:
 - (1) (A) AHAs will enter into an Other Transaction Agreement with ARPA-H for health outcome improvements. The AHAs will implement their proposed strategies, technologies, and interventions. The outcomes will be measured based on metrics identified in Section 1.7, Program Metrics and Milestones, and reported in near real-time in six-month increments over the program's 36-month period. Based on the magnitude of improvements achieved, AHAs will receive pre-defined success payments from ARPA-H funding up to a maximum of \$15 million over the life of the program and, where applicable, will receive matching funding from Outcome Buyers.
 - (B) AHAs will also have a fixed-price, milestone-based component to their resulting OT Agreement with ARPA-H; up to \$600K over the life of the program, based on the successful completion of a milestone. The fixed price component is associated with documenting the HA's intervention implementation strategies, to include the feasibility of scaling sustainable solutions nationally, participating in ARPA-H convenings to share lessons learned from the solution implementation, and high-level regular reporting on outcome improvement (see Sections 1.8, Fixed-Price Schedule of Milestones, and 1.9.2, Program Deliverables).
 - (2) PHAs will enter into a fixed price, milestone-based Other Transaction Agreement with ARPA-H for up to \$600K over the life of the program, also based on the successful

completion of a milestone. PHAs will have access to the HEROES toolkit to monitor their selected health outcomes; will attend ARPA-H convenings to share lessons learned, available technologies, and intervention details; and will provide high-level regular reporting on their outcome improvement (see Sections 1.8, Fixed-Price Schedule of Milestones, and 1.9.2, Program Deliverables).

(e) As stated herein, the HEROES program is particularly interested in improving health outcomes for all individuals in the geographic target areas, with an emphasis on populations with the greatest health burdens and unmet needs. Additionally, a key aspect of this program is to demonstrate the value and feasibility of realigning rewards focused on population-wide prevention, paving a path for the private sector to raise capital to implement preventive approaches, and encourage innovation where it is needed most. By laying the foundation for a viable economic model, the program will be primed for sustainability when direct ARPA-H funding is phased away. Proposals will be evaluated in accordance with the evaluation criteria stated in Section 5.0, Evaluation of Proposals. If deemed "selectable," the designation between an AHA and a PHA will be associated with the strength of Outcome Buyer and financial resources secured, along with geographic diversity for the selected health outcome category.

2.2 OTHER TRANSACTION (OT) AWARDS

- (a) The flexibility of the OT award instrument is beneficial to the HEROES program as the government will be better able to implement this program's novel payment structure, which rewards Performers based on activities that aim to improve health outcomes. Moreover, use of an OT will also allow for streamlined practices to be employed, such as milestone-driven performance, intended to reduce time and effort on award administration tasks and permit Performers to focus on the research effort.
- (b) Regarding the fixed price component of the HEROES program, Proposers must only propose fixed price payable milestones

included within Section 1.8, Fixed-Price Schedule of Milestones. Payable milestones are fixed payments based on successful completion of the milestone accomplishments agreed to in the Milestone Plan.

3.0 ELIGIBILITY INFORMATION

3.1 ELIGIBLE APPLICANTS

All responsible sources capable of satisfying the government's needs may submit a proposal in response to this PS. Specifically, universities, non-profit organizations, and for-profit businesses are eligible and encouraged to propose.

3.1.1 FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS AND GOVERNMENT ENTITIES

Federally Funded Research and Development Centers (FFRDCs) and Government Entities may not propose to this PS as a prime performer. Subject to any restrictions (i.e., direct competition limitations as determined by the entity or potential limiting organizational conflicts of interest, etc.), FFRDCs and Government Entities may be included as part the prime performer's proposal, as a sub-awardee. As with all prime/sub-awardee teaming arrangements, the Government will only have privity of contract with the prime performer, and all payments will be made through the prime awardee. The Government will not facilitate the relationship between the prime and sub-awardees, nor will the Government pay or enter into a relationship with any sub-awardee directly.

3.1.2 Non-US Entities

Non-U.S. entities may participate to the extent that such participants comply with necessary non-disclosure agreements, security regulations, export control laws, and other governing statutes applicable under their circumstances. Non-US entities are encouraged to collaborate with domestic U.S. entities, as ARPA-H may prioritize awards in accordance with 42 U.S.C. § 290(c)(n)(1). In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the

National Security Act of 1947 (50 U.S.C. § 3059)) or entities suspended or debarred from business with the government

3.2 ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

- (a) Proposers, through submission of a proposal, are required to identify and disclose all facts relevant to a potential OCI involving the Proposer, the Proposer's organization and/or any proposed team member (proposed sub-awardee). Along with the disclosure, the Proposer shall submit a mitigation plan, which is a description of the action the Performer has taken to avoid, neutralize, or mitigate the stated OCI. ARPA-H may require Proposers to provide additional information to assist it in evaluating the OCI mitigation plan.
- (b) If ARPA-H determines a Proposer failed to fully disclose an OCI; or failed to provide the affirmation of ARPA-H support; or failed to reasonably provide additional information requested by ARPA-H to assist in evaluating the OCI mitigation plan, ARPA-H may reject the proposal and withdraw it from consideration for award. The disclosure and mitigation plan(s) do not count toward the page limit.

3.3 AGENCY SUPPLEMENTAL OCI POLICY

- (a) ARPA-H restricts Performers from concurrently providing professional support services (including Advisory and Assistance Services or similar support services) and being a technical Performer. Therefore, as part of the disclosure requirement within Section 3.2, Organizational Conflicts of Interest (OCI), a Proposer must affirm whether it or any proposed team member (proposed sub-awardee, etc.) is providing professional support services to any ARPA-H office(s) under: (1) a current award or subaward; or (2) a past award or sub-award that ended within one calendar year prior to the proposal's submission date.
- (b) If any professional support services are being, or were, provided to any ARPA-H office(s), the proposal must include:

- The name of the ARPA-H office receiving the support;
- The prime contract number; and
- Identification of proposed team member (proposed subawardee) providing the support.

3.4 RESEARCH SECURITY DISCLOSURE

In accordance with National Security Presidential Memorandum (NSPM)-33, Presidential Memorandum on United States Government-Supported Research and Development National Security Policy, research organizations should identify and mitigate conflicts of commitment and conflicts of interest (CoC/CoI) to receive federal funding. Research organizations submitting a proposal in response to this PS must provide additional documentation for Senior/Key Personnel when requested for ARPA-H to determine whether there is any CoC/CoI risk. The format for this submission can be found in Attachment 2, OT Bundle, Attachment (5) Volume 2, Admin & National Policy Requirements.

4.0 Instructions for Solution Summary & Proposal Submission

4.1 GENERAL GUIDELINES

- (a) All submissions must be written in English, with type Times New Roman font not smaller than 12-point. Font sizes of 8 or 10 point may be used for figures, tables, and charts.
- (b) Use of a diagram(s) or figure(s) to depict the essence of the proposed solution is permitted.
- (c) Do not include elaborate brochures or marketing materials; only include information relevant to the submission requirements or evaluation criteria.
- (d) All Solution Summaries and Proposals shall be unclassified. Files containing Controlled Unclassified Information (CUI) must be encrypted when sending over the Internet. NOTE: "Confidential" is a classification marking used to control the dissemination of U.S. government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

- (e) Proposers are responsible for clearly identifying proprietary information.
- (f) Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary."
- (g) ARPA-H will post a consolidated Questions & Answers document on a regular basis. See Section 7.0, Communications.
- (h) Submissions sent through other mediums, channels other than what is prescribed herein, or after the prescribed PS deadline will not be considered, reviewed, nor evaluated.

4.2 SOLUTION SUMMARY INSTRUCTIONS

Proposers MUST submit a Solution Summary in advance of a full proposal. Solution Summaries submitted in response to the HEROES PS must follow the content and page count guidelines detailed in the Solution Summary template, Attachment 1 to this PS. Proposers are highly encouraged, but not required, to use the Solution Summary template when submitting Solution Summary responses.

4.2.1 SOLUTION SUMMARY DUE DATE AND TIME

Solution Summaries in response to this solicitation should be submitted to https://solutions.arpa-h.gov/ no later than 3:00 PM Eastern Daylight Time (EDT) on June 28, 2024. Solution Summaries received late may not be reviewed.

4.2.2 SOLUTION SUMMARY REVIEW PROCESS

ARPA-H will respond to Solution Summaries with a statement as to whether ARPA-H encourages submission of a full proposal. If ARPA-H does not encourage the Proposer to submit a full proposal, ARPA-H will provide feedback regarding the rationale for its decision. Regardless of ARPA-H's response to the Solution Summary, Proposers may submit a full proposal.

4.3 Proposal Instructions

4.3.1 Proposal Volume Templates

Proposers must provide the following information when submitting a proposal. Templates and instructions for Volumes 1, 2, and 3 are

provided as attachments to the PS (see Attachment 2, OT Bundle). Failure to utilize the templates and/or provide the information requested may result in a proposal being deemed non-conforming and/or delay the evaluation process discussed in Section 5.2, Review and Selection Process. Please see the templates within Attachment 2 for more information.

- (a) VOLUME 1, Technical and Management, must consist of the following documents (page count stipulated within Volume 1 templates):
 - TASK DESCRIPTION DOCUMENT (TDD)
 - TECHNICAL & MANAGEMENT
- (b) VOLUME 2, Price, must consist of the following documents (no page count):
 - PRICE PROPOSAL
 - MODEL AGREEMENT
- (c) VOLUME 3, Administrative & National Policy Requirements, must consist of the following documents (no page count):
 - ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

4.3.2 MODEL OTHER TRANSACTION AGREEMENT

- (a) Prior to submitting a proposal, Proposers must review the model OT Agreement (Model Agreement) (see Section 2.0 (d)).
- (b) ARPA-H will provide the Model Agreement to expedite the negotiation and award process. The Model Agreement is representative of the terms and conditions that ARPA-H intends to include in the resulting award. Proposers should suggest edits to the Model Agreement for consideration by ARPA-H and provide a copy of it with changes identified (using revision markings) as part of the proposal package in order to expedite subsequent negotiations if selected. It is required that Proposers include comments providing the

rationale for any suggested edits of a non-administrative nature. Regarding the Model Agreement:

- For selected AHAs: ARPA-H will review any red-line edits to the basic terms and conditions of the Model Agreement included within a proposal submission. In all cases, the government Agreements Officer (AO) shall have sole discretion to negotiate the Agreement terms and conditions with selected Proposers.
- For PHAs: ARPA-H will not entertain proposed edits to the Model Agreement.

4.4 PROPOSAL DUE DATE AND TIME

- (a) Proposals should be submitted to h.gov/Submit-Proposal/ no later than 3:00 PM Eastern Standard Time (EST) on November 15, 2024. Full proposal packages must be submitted per the instructions outlined in the HEROES PS and in accordance with the templates within Attachment 2, OT Bundle, and received by ARPA-H by the specified time and date. Late proposals may not be reviewed.
- (b) Proposers are warned that the proposal deadline outlined herein is Eastern Time (ET) and will be strictly enforced. When planning a response to this notice, Proposers should consider that some parts of the submission process may take from one business day to one month to complete.

5.0 EVALUATION OF PROPOSALS

5.1 EVALUATION CRITERIA FOR AWARD

Proposals will be evaluated using the following evaluation criteria, listed in descending order of importance.

(a) OVERALL TECHNICAL MERIT & SUSTAINABILITY

The proposed technical approach demonstrates Outcome Buyer support and investor capital commitment. The evaluation will take into consideration the following pertaining to any level of matching funds and secured at risk capital and/or internal financing (listed in order of strength of commitment):

- signed agreements,
- signed commitment letters, or
- timeline showing the pathway to signed agreements.

The proposed solution is innovative (in technology and/or process) feasible, achievable, complete, and represents a robust coalition to support the proposed intervention needed to deliver improvement on the chosen health outcome category. The intervention methods are personalized to multiple segments of the target population. Analysis of state- and local policy that might impact the reasonableness of implementation will also be considered.

(b) POTENTIAL CONTRIBUTION AND RELEVANCE TO THE ARPA-H MISSION

The proposed technical approach is diverse (geographically, among health outcomes chosen, and with populations served) and the proposed project aims to achieve equitable population-based transformation in healthcare delivery and health outcomes in a community where performance on health outcomes in the geographic area defined is worse than the national average. Additionally, the proposed approach includes robust data strategies for augmenting data capture. The proposed approach, where applicable, leverages technology and data analytics (e.g. Al) and digital platforms that enhance patient engagement and health management. In addition, the evaluation may take into consideration the extent to which the proposed intellectual property (IP) rights structure will potentially impact the scalability of the proposed solution.

(c) FINANCIAL FEASIBILITY ANALYSIS

The Government will assess the reasonableness of the overall proposed price associated with the implementation of the proposed technical solution. The Government will take into consideration the secured-at risk capital obtained and/or internal financing in hand when assessing the financial feasibility of the technical approach.

5.2 REVIEW AND SELECTION PROCESS

- (a) It is the policy of ARPA-H to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed and to select the source (or sources) whose offer meets the government's technical, policy, and programmatic goals.
- (b) ARPA-H will conduct a scientific and technical review of each conforming proposal. All proposal evaluations will be based solely on the evaluation criteria in Section 5.1, Evaluation Criteria for Award, regardless of the response to the organization's Solution Summary.
- (c) Relative to the evaluation criteria, ARPA-H will evaluate each conforming proposal in its entirety, documenting its strengths and weaknesses. Based on the identified strengths and weaknesses, ARPA-H will determine whether a proposal will be selected for negotiation and/or award. Proposals will not be evaluated against each other during the scientific review process, but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in the HEROES PS.
- (d) An award will be made to the Proposer(s) whose proposal is determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified herein and based on availability of funding.
- (e) See Section 2.0, Program Selection Award Information, and 2.1, Acquisition Strategy, for additional details regarding the desire to fund at least 2 awards within a health outcome if awards are made in multiple health outcomes and for the designation process between an AHA and a PHA.
- (f) For the purposes of this proposal evaluation process, a selectable proposal is defined as:

SELECTABLE: A selectable proposal is a proposal that has been evaluated by the government against the evaluation

criteria listed in the PS, and the positive aspects of the overall proposal outweigh its negative aspects. Additionally, there are no accumulated weaknesses that would require extensive negotiations.

(g) For the purposes of this proposal evaluation process, a non-selectable proposal is defined as:

NON-SELECTABLE: A proposal is considered non-selectable when the proposal has been evaluated by the government against the evaluation criteria listed in the PS, and the positive aspects of the overall proposal do not outweigh its negative aspects. Additionally, there are accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

- (h) CONFORMING PROPOSALS: Conforming proposals contain all requirements detailed in the HEROES PS to which the proposal is submitted. Proposals that fail to include required information may be deemed non-conforming and may be removed from consideration. Non-conforming submissions may be rejected without further review. A proposal will be deemed non-conforming if the proposal <u>fails</u> to meet one or more of the following requirements:
 - (1) The proposed concept is applicable to the goals and objectives described in the HEROES PS.
 - (2) The Proposer meets the eligibility requirements of the HEROES PS.
 - (3) The proposal meets the submission requirements of the HEROES PS.
 - (4) The proposal meets the content and formatting requirements of this HEROES PS.
 - (5) The proposal provides sufficient information to assess the validity/feasibility of its claims.
 - (6) The Proposer has not already received funding or a positive funding decision for the proposed concept

(whether from ARPA-H or another government agency).

Non-conforming proposals may be removed from consideration. Proposers will be notified of non-conforming determinations via email correspondence.

5.3 HANDLING OF COMPETITIVE SENSITIVE INFORMATION

- (a) It is the policy of ARPA-H to protect all proposals as "competitive sensitive information" and to disclose their contents only for the purpose of evaluation and only to screened personnel for authorized reasons to the extent permitted under applicable laws. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by ARPA-H support contractors for administrative purposes and/or to assist with technical evaluation.
- (b) All ARPA-H support contractors are expressly prohibited from performing ARPA-H-sponsored technical research and are bound by appropriate non-disclosure agreements. Input on technical aspects of the proposals may be solicited by ARPA-H from non-government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

6.0 AWARDS

6.1 GENERAL GUIDELINES

- (a) The Agreement Officer reserves the right to negotiate directly with the Proposer on the terms and conditions prior to award of the resulting OT Agreement, including payment terms, and will execute the agreement on behalf of the government. Proposers are advised that only a government Agreements Officer has the authority to enter into, or modify, a binding agreement on behalf of the United States government.
- (b) To receive an award:

- (1) Proposers must register in the System for Award Management (SAM). See Section 6.3.1, System for Award Management Registration and Unique Entity Identifier Requirements.
- (2) Proposers must be determined to be responsible by the Agreements Officer and must not be suspended or debarred from award by the federal government, nor be prohibited by Presidential Executive Order and/or U.S. law from receiving an award.

6.2 NOTICES

- (a) The following notices will be provided as applicable:
 - Request for clarifying details (if applicable) (May occur at any time during the evaluation process after proposal submission. Will not include requests for proposal changes and changes will not be permitted.);
 - Notice of non-selection; or
 - Notice of selection.
- (b) As soon as the evaluation of proposals is complete, the Proposers will be notified that:
 - (1) The proposal has been selected for funding and may be subject to OT Agreement negotiations. This notification may indicate that only a part of the effort has been selected for negotiation and may request a revised proposal for only those selected portions, if not apparent through the delineation of proposed tasks; or
 - (2) The proposal has not been selected for funding.
- (c) The above-listed notifications will be sent via electronic mail to the Technical and Administrative points of contact identified on the proposal coversheet.

6.3 Administrative and National Policy Requirements

6.3.1 SYSTEM FOR AWARD MANAGEMENT (SAM) REGISTRATION AND UNIQUE ENTITY IDENTIFIER (UEI) REQUIREMENTS

- (a) All Proposers must be registered in SAM and have a valid Unique Entity Identifier (UEI) number at time of proposal submission. You must maintain an active registration in SAM.gov with current information at all times during which you have an active federal award or idea under consideration by ARPA-H. Information on SAM.gov registration is available at https://sam.gov/content/home.
- (b) **NOTE**: New registrations can take an average of 7-10 business days to process in SAM.gov. Registration requires the following information:
 - TIN (Taxpayer Identification Number)
 - Commercial and Government Entity (CAGE) code. If a Proposer does not already have a CAGE code, one will be assigned during SAM registration.
 - Electronic Funds Transfer (EFT) information (e.g., Proposer's bank account number, routing number, and bank telephone or telefacsimile (fax) number).
- 6.3.2 CONTROLLED UNCLASSIFIED INFORMATION (CUI) OR CONTROLLED TECHNICAL INFORMATION (CTI) ON NON-DOD INFORMATION SYSTEMS Information on Controlled Unclassified Information identification, marking, protecting, and control is incorporated herein and can be found at 32 CFR § 2002 (https://www.ecfr.gov/current/title-32/subtitle-B/chapter-XX/part-2002).

6.3.3 INTELLECTUAL PROPERTY

(a) The HEROES program aims to create the foundation for a viable economic model by identifying sources for continued support to sustain delivery of the proposed interventions

(e.g. the portion of the research financed and/or self-funded) when ARPA-H funding is phased away. The below represents the Government's expectations regarding the program deliverables. Any proposed Intellectual Property assertions should align with how the Government intends to utilize the deliverables provided to the Government.¹²

Deliverable:	Intended use of deliverable (e.g. who ARPA-H	
	may share information with once delivered):	
Kickoff presentation materials	Within ARPA-H and with other government	
	entities (e.g. federal and/or state governments)	
Presentation materials for	 Within ARPA-H and with other 	
innovation exchange sessions	government entities	
	 HEROES Performer teams (AHAs and 	
	PHAs)	
Presentation materials for annual	Within ARPA-H and with other	
program symposium	government entities	
	 HEROES Performer teams 	
	 Public Health Community 	
Program Plan	ARPA-H HEROES program team	
Proof of Contracts	ARPA-H HEROES program team	
Quarterly Technical Status	Within ARPA-H and with other	
Reports	government entities	
	Highlights on progress to date, taken from	
	these reports, to be shared with the	
	broader health community	
Final Program Report	Within ARPA-H and with other government	
	entities	

(b) Proposers must provide a good faith representation that the Proposer either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized for the proposed effort. Proposers should appropriately identify any desired restrictions on the Government's use of any Intellectual Property contemplated under the award

 $^{^{12}}$ Sample Intellectual property rights definitions will be provided within the Model OT Agreement which **will** be provided - see Section 2.0 (d).

instrument in question. This includes both noncommercial items and commercial items. Respondents should utilize the prescribed format within the Administrative & National Policy Requirements Document Template (Volume 3 of Attachment 2 to this PS) when asserting restrictions. If no restrictions are intended, then the proposal should state "NONE."

Note: Intellectual Property assertions will be reviewed under evaluation criteria 2 stated in Section 5.1.

6.3.4 HUMAN SUBJECTS RESEARCH

(a) All entities submitting a proposal for funding that will involve engagement in Human Subjects Research (as defined in 45 CFR § 46)(https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) must provide documentation of one or more current Assurance of Compliance with federal regulations for human subject protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection (OHRP), Federal Wide (https://www.hhs.gov/ohrp/index.html). Assurance research involving Human Subjects must be reviewed and approved by an Institutional Review Board (IRB), under 45 **CFR** ξ applicable 46 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) and/or 21 δ 56

A/subchapter-A/part-46) and/or 21 CFR § 56 (https://www.ecfr.gov/current/title-21/chapter-

<u>I/subchapter-A/part-56</u>). The entity's Human Subjects Research protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for the ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of Human Subjects research, such as the U.S. federal regulations protecting human subjects in research

- (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.
- (b) The informed consent document utilized in human subject research funded by ARPA-H must comply with all applicable laws, regulations, and policies, including but not limited to U.S. federal regulations protecting human subjects in research (45 CFR § 46 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) and, as applicable, 21 CFR § 50 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50). The protocol package submitted to the IRB must contain evidence of completion of appropriate Human Subject Research training by all investigators and key personnel who will be involved in the design or conduct of the ARPA-H funded human subject research. Funding cannot be used toward human subject research until ALL approvals are granted.

6.3.5 ANIMAL SUBJECTS RESEARCH

- (a) Award recipients performing research, experimentation, or testing involving the use of animals shall comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in: (i) 9 CFR parts 1-4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); (ii) the Public Health Service Policy on Humane Care and Use of Laboratory Animals, which incorporates the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," and "Guide for the Care and Use of Laboratory Animals" (8th Edition)."
- (b) Proposers must complete and submit the Vertebrate Animal Section worksheet (see https://olaw.nih.gov/sites/default/files/VASchecklist.pdf) for all proposed research anticipating Animal Subject Research. All Animal Use Research must undergo review and approval

by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research.

6.4 ELECTRONIC INVOICING AND PAYMENTS

Performers will be required register in, and to submit invoices for payment to the Payment Management System (PMS). PMS is a centralized payment-and cash management system that is operated by the HHS Program Support Center (PSC). ARPA-H Other Transaction payments are made by PMS, in accordance with Department of the Treasury and Office of Management and Budget (OMB) requirements. PMS guidance can be found here: https://pms.psc.gov/training/grant-recipient-training.html.

7.0 COMMUNICATIONS

(a) All questions regarding this notice must be submitted to the following:

HEROES Program Solicitation (PS)
ARPA-H Solutions

https://solutions.arpa-h.gov/Ask-A-Question/

ATTN: ARPA-H-SOL-24-01

E-mails sent directly to the Program Manager, or any other address will be discarded.

- (b) ARPA-H will post a Q&A document to SAM.gov (https://sam.gov) and the HEROES Team webpage (https://arpa-h.gov/research-and-funding/programs/heroes) regarding all administrative questions submitted to this PS on an as needed basis. All questions must be in English. ARPA-H encourages all Proposers to review the Q&As provided before submitting additional questions to the link noted above. The Government may not answer repetitive questions already answered in the posted Q&As.
- (c) ARPA-H will attempt to answer questions in a timely manner. In order to receive a response sufficiently in advance of the proposal due date, send your question/s on or before the Q&A deadline stated herein.

8.0 Proposers' Day

The HEROES Proposers' Day was held on February 13 and 14, 2024. Attendance at the HEROES Proposer's Day is NOT required to propose to this PS. Recordings from Proposers' Day are posted to the HEROES TEAM webpage (https://arpa-h.gov/research-and-funding/programs/heroes).

DEFINITIONS/ACRONYMS

AHA: ARPA-FUNDED HEALTH ACCELERATOR: HEROES program Performer. AHAs enter into an Other Transaction Agreement with ARPA-H for health outcome improvements. The AHAs will implement their proposed strategies, technologies, and interventions. Based on the magnitude of improvements achieved, AHAs will receive pre-defined success payments from ARPA-H funding to a maximum of \$15 million over the three-year performance period and, where applicable, matching funding from Outcome Buyers. AHAs will also have a fixed price, milestone-based component to their resulting agreement with ARPA-H; up to \$600K for a three-year program period, based on the successful completion of a milestone.

Al: Artificial intelligence.

AO: Agreements Officer.

API: Application Programming Interface

ASCVD: Atherosclerotic Cardiovascular Disease

AT-RISK INVESTOR: An entity that provides up-front funding for the HA's proposed innovation approach/strategy.

ARPA-H: Advanced Research Project Agency for Health.

B: Billion.

CAGE: Commercial and Government Entity.

CFR: Code of Federal Regulations.

COI: Conflict of Interest.

CUI: Controlled, Unclassified Information.

ECOM: Electronic Clinical Quality Measure

EASTERN DAYLIGHT TIME (EDT): When observing daylight saving time (spring/summer), is four hours behind Coordinated Universal Time (UTC-04:00).

EASTERN STANDARD TIME (EST): when observing standard time (autumn/winter), it is five hours behind Coordinated Universal Time (UTC-05:00).

EHR: Electronic Health Record

EFT: Electronic Funds Transfer.

EMS: Emergency Management Services.

FFRDC: Federally Funded Research and Development Center.

FHIR: Fast Healthcare Interoperability Resources.

FTE: Full-Time Equivalent

GOVERNMENT: As represented by ARPA-H.

HA: HEALTH ACCELERATOR. HEROES program Performer, taking accountability for regional health improvement and are responsible for building regional coalitions to execute technological, engagement, and clinical innovations to drive health improvement. A Health Accelerator may comprise a variety of organization types such as start-up companies; established private companies; healthcare provider organizations; public benefit corporations; non-profit, professional, or advocacy organizations; state universities or other state-funded educational institutions; and other non-governmental entities demonstrating capacity to impact preventive health at scale.

HEROES: Health Care Rewards to Achieve Improved Outcomes.

HEROES OUTCOME TOOLKIT: A Government-furnished dataset and data visualization platform. Provides plug-and-play business-planning-in-a-box that simplifies the development of public health programs thus allowing for program launch in a matter of weeks or months. The HEROES Outcome Toolkit enables organizations to understand their innovation's effectiveness. The HEROES Outcome Toolkit will be

used by ARPA-H to track improvement in the health outcome metrics selected by the AHAs relative to a national average.

IACUC: Institutional Animal Care Use Committee.

INVESTOR CATALYST HUB: Part of the ARPANET-H Innovation Network. ARPA-H's Investor Hub will help organizations develop strategies for raising capital, 'matchmake' with other at-risk investors, and aid in the formation of investor relationships.

K: Thousand.

M: Millon.

NEMSIS: National Emergency Medical Services Information System.

NSPM: National Security Presidential Memorandum.

OCI: Organizational Conflict of Interest.

ODC: Other Direct Cost.

OMB: Office of Management and Budget.

OUD: Opioid Use Disorder.

OTHER TRANSACTION: An Agreement awarded under the authority of 42 U.S.C. § 290c(g)(1)(D) and the award instrument for the HEROES program. The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements.

OUTCOME BUYERS: Enhance the Health Accelerator's financial incentive for population health improvement during HEROES program and create sustainability by financing future improvements after the HEROES program ends. ARPA-H will serve as the first buyer of the AHA's health outcomes up to a maximum of \$15M over the program period.

PHA: PARTICIPATING HEALTH ACCELERATORS: HEROES program Performer. PHAs enter into a fixed price, milestone-based Other Transaction Agreement with ARPA-H for up to \$600K based on the successful completion of a series of milestones. PHAs are not

eligible for reward payments. PHAs, instead, are Performers committed to 1) monitoring their selected health outcomes; 2) attending ARPA-H convenings to share lessons learned, available technologies, and intervention details; and 3) providing high-level regular reporting on their outcome improvement of focus.

PI: Principial Investigator

PMS: Payment Management System.

PS: PROGRAM SOLICITATION. The document issued requesting proposals in response to the Research and Development outcomes desired as stated within the document. The Program Solicitation only allows for the award of Other Transaction Agreements.

Q&As: Questions and Answers.

RPM: Remote Patient Monitoring.

SAM: System for Award Management.

SMM: Severe Maternal Morbidity.

SOC: Severe Obstetric Complications.

TIN: Taxpayer Identification Number.

UEI: Unique Entity Identifier.

U.S.: United States.

U.S.C: United States Code.

APPENDIX A: HEALTH OUTCOME CATEGORY DETAILS

1. MATERNAL HEALTH

A. SCOPE OF THE PROBLEM

- (1) Maternal morbidity is emerging as an important measure in efforts to prevent maternal mortality. Broadening the definition of severe maternal morbidity (SMM) to also encompass serious illnesses during pregnancy and postpartum reveals the broader scope of the problem, as well as the need for further measurement efforts and policy intervention.¹³
- (2) SMM affected approximately 65,000 women in 2021¹⁴ (or 1.8 percent), an increase from 1.4 percent in 2016-2017.¹⁵ A significant number of women have severe complications that start after they leave the hospital. Of SMM cases that were identified within the first six weeks (42 days) after delivery discharge, about three-quarters were identified in the first two weeks.¹⁶ Many health conditions that develop in the postpartum period can be prevented, but timely care has not been readily available or affordable.¹⁷

B. Performance Monitoring

Currently, there are no measures to capture total severe obstetric complications during delivery and including the postpartum period. A modified version of the electronic clinical quality measure (eCQM) called Severe Obstetric Complications that has been developed by The Joint Commission, the Centers for Medicare and Medicaid Services (CMS), and the Yale New Haven Health Service Corporation/ Center for Outcomes Research and Evaluation (CORE) could be leveraged The measure is claims-based and capture severe obstetric complications that occur during the delivery hospitalization, and ARPA-H would extend that period to include 60-days post-delivery. Additional ARPA-H modifications may

¹³ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

 $^{^{14}}$ HHS Study Shows In-hospital Delivery-related Maternal Death Rates Decreased More than Half from 2008 to 2021 | HHS.gov

¹⁵ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

¹⁶ Severe Maternal Morbidity after Delivery Discharge among U.S. Women, 2010-2014 | CDC

¹⁷ Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

¹⁸ https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS1028v1.html

include hospitalizations associated with intentional self-harm, interpersonal violence, or life-threatening overdose.

C. POTENTIAL ENABLING TECHNOLOGIES AND INNOVATIVE APPROACHES REPORTED OR PROPOSED TO HAVE BENEFICIAL IMPACT

Below are some examples of recent enabling technologies, clinical interventions, and engagement strategies. The HEROES Program expects Proposers to develop their own innovative ideas that may or may not include aspects of the approaches below. The approaches below are merely examples and no indication of the HEROES program's preferred innovations.

- (1) New technologies possibly can help assess, screen, diagnose, treat, monitor, and follow-up for conditions and diseases that are common in pregnant and postpartum women that contribute to maternal morbidity and mortality. 19 Some examples may include:
 - Remote patient monitoring (RPM) uses technology to gather and assess patient health data while patients are outside a healthcare facility. Devices, such as wearables like smart watches or blood pressure monitoring devices, could alert the wearer if some collected data reach a particular threshold, at which point the wearer could contact their physician or seek care.²⁰
 - Telehealth/Virtual physician consultations may reduce need for travel and other obstacles that may result in 20-40% of women not seeing their maternity provider between three and eight weeks after delivery.²¹
 - Point-of-care testing for certain infections (e.g., perinatally acquired infections) may assist with identifying and treating preventable infections that can impact pregnancies or newborns.
 - Technologies, including mobile apps or those that improve health record integration, may join electronic health records to facilitate continuity of care and to integrate obstetrics care

¹⁹ Technology to Improve Maternal Health: Workshop summary | National Institute of Biomedical Imaging and Bioengineering (nih.gov)

²⁰ How new technologies boost postpartum care in "fourth trimester" | American Medical Association (ama-assn.org)

²¹ How new technologies boost postpartum care in "fourth trimester" | American Medical Association (ama-assn.org)

- with mental health services, perinatal psychiatric care, and other specialty care services.²²
- Artificial intelligence, or algorithms, coupled with updated information from electronic health records potentially could predict high risk situations and allow for alerts to prevent maternal morbidity and mortality.²³
- Screening tools. For example, medical checklists or integrated clinical pathways could predict complications in pregnancy.
- (2)Improvements in clinical care and coordination have been shown to improve maternal health outcomes. As an example, implementation of patient safety bundles provides a structured way of improving the processes of care and patient outcomes. The bundles are clinical condition-specific (e.g., obstetric hemorrhage, severe hypertension) and follow an evidence-based that, when performed collectively and reliably, have been proven to improve patient outcomes.²⁴ In addition, establishing mechanisms to provide high-reliability post-natal follow-up to support women during the postpartum period can help to identify women at risk for developing complications and to address any issues that may be arising. Well-organized perinatal quality collaboratives may also act as force multipliers for improving evidence-based care for large populations. For example, one such program was associated with a mortality decline by 65 percent between 2006 to 2016, while the national maternal mortality rate continued to rise.²⁵
- (3) Multi-stakeholder collaborations that include local health departments, payers, schools, and employers can promote the use of best practices, research, quality improvement toolkits, and performance monitoring in communities can improve health outcomes.

²² <u>Technology to Improve Maternal Health: Workshop summary | National Institute of Biomedical Imaging and Bioengineering (nih.gov)</u>

²³ How AI Could Help Doctors Reduce Maternal Mortality (hbr.org)

²⁴ Patient Safety Bundles For Safer Birth | AIM

²⁵ Who We Are | California Maternal Quality Care Collaborative (cmqcc.org)

2. HEART ATTACK AND STROKE RISK

A. SCOPE OF THE PROBLEM

Nationally, heart disease is the leading cause of death. About 695,000 people in the United States died from heart disease in 2021 (this equates to one in every five deaths). In 2021, one in six deaths from cardiovascular disease was due to stroke. There are about 1.6M annual total heart attack and stroke related deaths and 1.2M first-time heart attack and strokes per year.^{26,27}

B. PERFORMANCE MONITORING

- (1) To track progress, the American College of Cardiology (ACC) Atherosclerotic Cardiovascular Disease (ASCVD) calculator to compute long-term risk could be used. These predictive models can be fed clinical variables (e.g., age, sex, race, blood pressure, cholesterol, smoking history, diabetes history, hypertension treatment, statin medication, and aspirin therapy) that, in aggregate, are used to estimate a patient's 10-year ASCVD risk at initial visit and in subsequent follow-up visits. Tracking changes in ASCVD risk overtime may allow the Health Accelerator to identify impacts of different interventions on patient risk and make changes to their deployed interventions and technologies.
- (2) To reduce the aggregate ten-year risk of atherosclerotic cardiovascular disease (ASCVD) for intermediate-high risk people (>7.5% risk) aged 40-70 in a community of approximately 700,000 people, Proposers could partner with an EHR entity to obtain hospital and primary care data in the identified geographies to calculate risk.

C. POTENTIAL ENABLING TECHNOLOGIES AND INNOVATIVE APPROACHES REPORTED OR PROPOSED TO HAVE BENEFICIAL IMPACT

Below are some examples of recent enabling technologies, clinical interventions, and engagement strategies. The HEROES Program expects

²⁶ Heart Disease Facts | cdc.gov

²⁷ Stroke Facts | cdc.gov

Proposers to develop their own innovative ideas that may or may not include aspects of the approaches below. The approaches below are merely examples and no indication of the HEROES program's preferred innovations.

- (1) Home-based technologies can be used to monitor health parameters and promote medication adherence. Some examples include:
 - Integration of 10-year ASCVD risk calculation into consumeroriented digital or other health products, such as smartwatches or lifestyle modification programs.
 - Collaboration with home-based technology-enabled services to address medication compliance, home-based blood pressure management, and other technology-enabled platforms for chronic condition management.
 - Establishment of simplified prescription refills to prevent disruption or discontinuation of medication therapy by individuals.
- Wider adoption of existing ASCVD risk scoring at routine clinical visits may prevent heart attacks and stroke. Adoption could be achieved through broader clinician education and integration of clinical tools in routine workflows at primary care or other visits. Wider engagement of community partners through integration of ASCVD risk management into value-based care contracting by managed care organizations, clinical health systems, or other large population-serving entities (such as professional societies) can promote the use of risk scores in primary care in broad geographies.

3. OPIOID OVERDOSE

A. SCOPE OF THE PROBLEM

Opioid Use Disorder (OUD) is the chronic use of opioids that causes clinically significant distress or impairment. It consists of an overpowering desire to use opioids, increased opioid tolerance, and withdrawal syndrome when discontinued. OUD is a life-threatening condition

associated with a 20-fold greater risk of early death due to overdose, infectious diseases, trauma, and suicide. Fewer than 10 percent of U.S. patients with diagnosed OUD receive medication-assisted treatment (MAT). Behavioral therapies, when delivered alone, have limited efficacy in addressing the complex symptomatology and physical aspects of OUD.

B. Performance Monitoring

The National Emergency Medical System Information System (NEMSIS) is a national system used to collect, store, and share EMS data in the U.S. It is a data collaboration funded in part by the Office of National Drug Control Policy, the National Highway Traffic Safety Administration, and the Department of Health and Human Services. The metric to monitor performance will be the combined rate of fatal and non-fatal opioid overdoses/100,000 population/rolling 28-day period, which is an indicator of the severity of the opioid crisis in each community.

C. ENABLING TECHNOLOGIES AND INNOVATIVE APPROACHES CAN BE SCALED TO CREATE IMPACT

Below are some examples of recent enabling technologies, clinical interventions, and engagement strategies. The HEROES Program expects Proposers to develop their own innovative ideas that may or may not include aspects of the approaches below. The approaches below are merely examples and no indication of the HEROES program's preferred innovations.

- (1) New technologies can help identify, assess, and monitor individuals at risk for opioid overdose. Some examples include:
 - Remote monitoring and patient feedback for avoidance of high-risk situations via connected devices.
 - Dispensing technologies to track appropriate compliance with MAT.
 - Development of claims-based algorithms to identify high risk individuals for outreach.
 - Natural language and Al-enabled support services for individuals with OUD.

(2) In addition, the promotion and use of clinical interventions, such as MAT, can improve outcomes dramatically. Some innovative models of care include digital and telemedicine access to MAT services and emergency department-based initiation of MAT following overdose. Screening for and addressing social risks and needs in high-risk populations may also be beneficial. The use of data to track MAT compliance by clinicians and informing them of their patient's overdose has been proposed to improve opioid prescribing behaviors. Through engagement of community organizations and leaders, revision of public policies may eliminate barriers to effective intervention and enhance peoples' willingness to seek evidence-based preventive care.

4. ALCOHOL-RELATED HEALTH HARMS

A. SCOPE OF THE PROBLEM

- (1) Drinking excessive amounts of alcohol can cause serious health problems including stroke, cancer, and cirrhosis. People with alcohol use disorders, including binge drinking, are also more likely to get sick and are less able to fight off infections.
- (2) Binge drinking is the most common and costly pattern of excessive alcohol use in the United States. It is defined as consuming five or more drinks on an occasion for women or four or more drinks on an occasion for women. Eighteen percent (18%) of Americans have engaged in binge drinking in the past month. In every state, it is illegal to operate a motor vehicle with a blood alcohol content of 0.08% or higher. For every 88 instances of driving, someone is arrested for operating a motor vehicle above the legal limit. Additionally, about 37 people in the United States die in drunk-driving crashes every day: one person every 39 minutes. In 2021, 13,384 people died in alcohol-impaired driving traffic deaths, a 14% increase from 2020.
- (3) Binge drinking is a serious but preventable public health problem. A 2019 government survey found fewer than one in 10 people with

an alcohol use disorder received any treatment, and less than 2% of those individuals said they had been offered medication.

B. Performance Monitoring

The National Emergency Medical System Information System (NEMSIS) is the national system used to collect, store, and share EMS data in the U.S. The metric used to monitor performance will be the number of alcoholrelated emergencies reported by EMS services/100,000 population.

C. ENABLING TECHNOLOGIES AND INNOVATIVE APPROACHES CAN BE SCALED TO CREATE IMPACT

Below are some examples of recent enabling technologies, clinical interventions, and engagement strategies. The HEROES Program expects Proposers to develop their own innovative ideas that may or may not include aspects of the approaches below. The approaches below are merely examples and no indication of the HEROES program's preferred innovations.

- (1) New technologies can help to reduce alcohol-related emergencies. Some examples include:
 - Ignition interlock devices
 - Driver Alcohol Detection System for Safety (DADSS) breathbased, and touch-based
 - Ridesharing applications
 - Education/support applications
- (2) Wider use of effective medication-assisted treatment (MAT) for alcohol abuse disorder (e.g., naltrexone) could reduce EMS activations. The use of brief intervention strategies (e.g., Screening, Brief Intervention and Referral to Treatment (SBIRT)) within settings (e.g., clinic, school, community centers) screens for substance use with brief interventions designed to guide individuals in a conversation to identify goals for improving health and identifies individuals at higher risk for referral to specialty services and support.²⁸

²⁸ Screening, Brief Intervention, and Referral to Treatment (SBIRT) | SAMHSA

- (3) Example engagement strategies might include collaborating with community stakeholders to:
 - Develop and promote public education campaigns can increase awareness and improve outcomes.
 - Create safety sobriety checkpoints within a community can identify individuals at risk.
 - Working with purveyors of alcohol on voluntary reductions in days and hours of liquor sales (by holding sellers accountable for injuries caused by drunken patrons and ensuring consistent enforcement to reduce underage drinking and alcohol sales to minors to help reduce alcoholrelated EMS calls).

ATTACHMENT 1: SOLUTION SUMMARY TEMPLATE (SEE ATTACHED DOCUMENTS)

ATTACHMENT 2: OT BUNDLE (SEE ATTACHED DOCUMENTS)

- (1) Attachment 2, Volume 1 Task Description Document (TDD)
- (2) Attachment 2, Volume 1 Technical and Management
- (3) Attachment 2, Volume 2 Price (inclusive of spreadsheet templates)
- (4) Attachment 2, Volume 2 Model OT (to be provided via an Amendment to ARPA-H-SOL-24-01; see Section 2.0 (d)).
- (5) Attachment 2, Volume 3 Admin & National Policy Requirements