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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Challenge Competition: Improving Remote Monitoring of Pregnancy

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB) announces a prize competition to support the development and testing of low-cost, scalable technology-based innovations to improve the ability of prenatal care providers to monitor the health and wellbeing of pregnant women remotely, especially women who live in rural and medically-underserved areas who have limited access to on-site prenatal care.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010.

This challenge, structured in three phases, will reach a diverse population of innovators and

problem solvers including families, coders, public health experts, community leaders, individuals affiliated with academic institutions, research and development communities in the private sector, and others.

All submissions will be evaluated; separate prizes will be awarded for each of the three phases below.

Phase 1: Design

Phase 2: Development and Small Scale Testing

Phase 3: Scaling

Estimated dates for each phase are as follows:

Phase 1: Effective on January 2, 2018

Phase 1 Submission Period Ends: January 31, 2018, 11:59 p.m. ET

Phase 1 Judging Period: February 1-February 28, 2018

Phase 1 Winners Announced: March 12, 2018

Phase 2 Begins: March 13, 2018

Phase 2 Submission Period Ends: July 11, 2018

Phase 2 Judging Period: July 12-August 12, 2018

Phase 2 Winners Announced: August 20, 2018

Phase 3 Begins: August 21, 2018

Phase 3 Submission Period Ends: February 21, 2019

Phase 3 Winner Announced: March 1, 2019

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

On January 4, 2011, the America COMPETES Reauthorization Act of 2010 was signed into law allowing the use of challenges and prize competitions increasing agencies' ability to promote and harness innovation. Competitions run by the federal government result in a number of benefits to the public, including the following:

- a) Increasing the number and diversity of the individuals, teams, and organizations that are addressing a particular problem or challenge of national significance;
- b) Improving the skills of the participants in the competition; and
- c) Directing attention to new market opportunities and stimulating private sector investment.

Subject of Challenge Competition

In recent years, technological advances have improved the ability of healthcare providers to monitor their patients from afar. For example, wearable biosensors provide for the remote monitoring of patients, athletes, premature infants, children, psychiatric patients, people who need long-term care, the elderly, and people in rural and medically underserved areas.

Telemedicine is improving access for patients, while smartphone apps are improving patients' ability for self-care.

At the same time, recent scientific advances around developmental origins of health and disease point to the important role that environmental exposures, nutrition, and stress play in maternal health and fetal programming. Remote, real-time, and more continuous monitoring of harmful environmental exposures, nutritional intake and energy expenditure, and stress and sleep, along with blood pressure, proteinuria, blood glucose, and fetal heart rate, has the potential to improve prenatal care quality and pregnancy outcomes while reducing healthcare costs.

Recent trends in hospital closures in rural America also increase the need for technological innovations that support remote monitoring of pregnant women. Between 2004 and 2014, 179 rural counties (9 percent of all rural counties) lost access to in-county hospital obstetric services, and the percent of all rural counties in the U.S. that lacked hospital obstetric services increased from 45 to 54 percent, due to hospital and obstetric-unit closures.¹ Many low-income women, in both rural and urban communities, do not access prenatal care. Fully conflicting priorities such as work, childcare, and transportation make it difficult to make the approximately 15 visits to their provider's office, which include critical medical assessments and instructions about self-care. This challenge is designed to make technology work for pregnant women, increase access, improve communications (between patients and providers and across providers), and empower pregnant women to take better care of themselves.

¹ http://rhrc.umn.edu/wp-content/files_mf/1491501904UMRHRCOBclosuresPolicyBrief.pdf

This challenge will support the development and testing of low-cost, scalable technology-based innovations to improve the ability of prenatal care providers to monitor the health and wellbeing of pregnant women from afar (e.g., in their homes); utilizing technology to empower patients and providers with more complete and up-to-date information.

Key design features of the innovations should include:

- The innovation is low-cost to families and scalable;
- The innovation is safe, accurate, and effective;
- The innovation supports remote, real-time, and more continuous monitoring and early detection;
- The innovation improves communication between patients and providers;
- The innovation improves patient-centeredness of prenatal care;
- What gets monitored is grounded in science (e.g., developmental origins of health and disease); and
- The innovation empowers patients to use their own health data to improve behaviors.

Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by HRSA and the U.S. Department of Health and Human Services (HHS).

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) May not be a federal entity or federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) May not be employees of HRSA or any other company, organization, or individual involved with the design, production, execution, judging, or distribution of the Challenge and their immediate family (*i.e.*, spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (*i.e.*, people who share the same residence at least 3 months out of the year).

(7) In the case of a federal grantee, may not use federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) In the case of a federal contractor, may not use federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

(9) Shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made equitably available to all individuals and entities participating in the competition.

(10) Must agree to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from the

participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

(11) Must also agree to indemnify the federal government against third party claims for damages arising from or related to competition activities.

(12) Shall not be currently on the Excluded Parties List (<https://www.epls.gov/>).

Submission Requirements

The Challenge has three phases.

Phase 1—Design

The first stage of the prize competition aims to attract a large set of ideas and innovators. The target product of the first stage will be the conceptualization of the most promising innovations to improve the ability of prenatal care providers to monitor the health and wellbeing of pregnant women remotely, especially women who live in rural and medically underserved areas who have limited access to on-site prenatal care.

The submissions should aim to demonstrate that the proposed intervention will be accessible across diverse backgrounds and easily implemented by users.

The Phase 1 Submission shall include:

1. A comprehensive description of the proposed intervention in five pages or less, including:
 - a. A one-paragraph executive summary that clearly states the question to be solved;
 - b. Background information linking the evidence to support the intervention;

- c. A descriptive analysis of how the applicant arrived at their idea;
- d. Descriptions of the methods and technologies involved in implementation of the intervention; and
- e. An assessment describing the applicant's ability to execute the proposed solution in Phase 2 and 3.

Phase 2—Development and Small Scale Testing

The winners of Phase 1 of the prize competition will then advance to a second stage focused on prototyping the intervention, and testing the effectiveness of the intervention. Using support from the Phase 1 prize funding, intervention developers will test the efficacy of their models to show that the proposed intervention demonstrates an impact on the outcomes of interest for providers and pregnant women. The applicants should demonstrate both the evidence base for the intervention and its usability. Mentors will be available to help participants design appropriate testing methodologies and learn more about the evidence base.

Phase 3—Scaling

The winners of Phase 2 will move to the final phase of the incentive prize, which will involve testing the most promising models at greater scale through rollout at the program or community level. This will test the scalability of the device at low-cost, the feasibility of implementation, and the impact on the intended outcomes.

Registration Process for Participants

Participants will be able to register and submit an entry at the Improving Remote Monitoring of Pregnancy Challenge website. Participants can find out more information at <https://www.challenge.gov/list/>.

Prizes

- **Total: \$375,000 in Prizes**
- Phase 1: 7-10 winners; up to a total of \$100,000 in prizes
- Phase 2: 3-5 winners; up to a total of \$125,000 in prizes
- Phase 3: 1 winner; up to a total of \$150,000 prize

Payment of the Prizes

Prize payments will be paid by a contractor. Phase 1 winners may be expected to use a portion of the prize money for travel and lodging to attend a 2-day meeting in Washington, D.C., to demonstrate their innovation to the judges.

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis for Winner Selection

A review panel composed of HHS employees and experts will judge challenge entries in compliance with the requirements of the America COMPETES Act and HHS judging guidelines:

<http://www.hhs.gov/idealab/wp-content/uploads/2014/04/HHS-COMPETITION-JUDGING-GUIDELINES.pdf>.

The review panel will make selections based upon the following criteria:

Phase 1

Accessibility

- Is the proposed intervention easily utilized by families of diverse economic, social, and cultural backgrounds? Is it functional across disciplines/users?

Measurability

- How easily will the proposed intervention be evaluated in order to determine its efficacy (in both lab testing and in the real world)? Is the proposed intervention measurable among various audiences?

Sustainability

- Does the proposed intervention compel users to utilize the technology often and/or for long periods of time? Does it fit into daily life? Is it fun to use?

Impact

- Does the applicant present a theory or explanation of how the proposed intervention would result in concrete change?

Phase 2

Impact

- How did the intervention impact outcomes for providers and patients? What did data show?

Evidence base

- Is the intervention grounded in existing science related to improving health care and related services for pregnant women?

Sustainability

- Was the intervention compelling to users and did it encourage users to use the technology often? Did users want to continuously engage with the technology?

Implementation

- How feasible is the intervention? How much support for implementation will the intervention require (estimated financial and time commitment)?

Phase 3

Impact

- How effective was the intervention when implemented at scale? Did the impacts on users from Phase 2 remain consistent?

Implementation

- How feasible was the intervention on a larger scale? How much support for implementation did the model require (financial and time commitment)? How challenging was the actual program implementation?

Scalability

- How costly was the intervention in a real-world setting? How likely are cost efficiencies for program delivery at greater scale? Can the technology be used in existing platforms?

Additional Information

General Conditions:

- HRSA reserves the right to cancel, suspend, and/or modify the contest, or any part of it, for any reason, at HRSA's sole discretion.
- The interventions submitted across all phases should not use the HHS or HRSA logos or official seals in the submission, and must not claim endorsement.

Intellectual Property

- Each entrant retains full ownership and title in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement.
- By participating in the challenge, each entrant hereby irrevocably grants to HRSA a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission for internal HHS business and to the extent necessary to administer the challenge, and to publically perform and publically display the

submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

- Record Retention and FOIA: All materials submitted to HRSA as part of a submission become HRSA records and cannot be returned. Any confidential commercial information contained in a submission should be designated at the time of submission. Participants will be notified of any Freedom of Information Act requests for their submissions in accordance with 45 CFR 5.65.

Dated: September 19, 2017.

George Sigounas,

Administrator.

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