

healthcare professional and provider engagement, interdisciplinary discussion, and general public awareness. Utilizing Project Hope's best practices, this new investment will offer HHS and the healthcare community the opportunity to explore, identify, and propose key policy ideas and initiatives for developing, strengthening and preparing a regionalized, accountable, coordinated, and integrated system of emergency care that is able to meet daily demands and respond to and recover from a public health emergency or disaster.

In summary, Project Hope's experience, status as a trusted policy source, and widespread subscribership and global audience will be critical to the viability of this cooperative agreement. This collaboration will support HHS efforts to develop a resilient U.S. healthcare system that is capable of providing integrated, cost-effective and high-quality emergency care both daily and in response to a public health emergency or disaster.

#### Additional Information

The agency program contact is Kristen Finne, who can be contacted by phone at (202) 691-2013 or via email at [kristen.finne@hhs.gov](mailto:kristen.finne@hhs.gov).

Dated: July 25, 2012.

**Edward J. Gabriel,**

*Principal Deputy Assistant Secretary for Preparedness and Response.*

[FR Doc. 2012-18683 Filed 7-30-12; 8:45 am]

**BILLING CODE 4150-37-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of Requirements and Registration for "The Million Hearts Risk Check Challenge"

**AGENCY:** Office of the National Coordinator for Health Information Technology, HHS.

**AWARD APPROVING OFFICIAL:** Farzad Mostashari, National Coordinator for Health Information Technology.

**ACTION:** Notice.

**SUMMARY:** In communities across America, there are thousands of convenient and inexpensive ways to know your risk for heart-related conditions—often, all it takes is making an appointment for a screening with your doctor or pharmacies. But, according to recent studies, up to 1 in 3 people at risk for cardiovascular disease (CVD) have not been screened and are therefore less likely to take preventative action. Through an initiative sponsored by Million Hearts

and the Office of the National Coordinator for Health IT, we are reaching out to the millions of Americans who have significant risks for CVD and do not know it, and those that suspect it but have not yet overcome the inertia to act on their concern. By connecting these individuals to pharmacies for lipid and blood pressure screenings, we are intending to make it easy for them to turn their back-of-mind worries into personal knowledge and then help them hook into the delivery system if necessary.

This new campaign and technology product will follow three steps:

1. Reach out to individuals across the country, taking special aim at those who may be at risk for CVD and don't know it.

2. Conduct a "light" health risk assessment that roughly estimates risk in an engaging interface and then "hooks" the user by showing that with the addition of LDL and BP readings, the accuracy of the risk assessment could be much more robust. This is done to drive folks to scale the next hurdle: The BP and blood test.

3. Direct individuals to nearby, convenient options for biometric screenings. National pharmacies and others will offer locations and special offers for this step.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Public L. 111-358).

**DATES:** Effective on July 27, 2012. Challenge submission period ends October 31, 2012, 11:59 p.m. et.

**FOR FURTHER INFORMATION CONTACT:** Adam Wong, 202-720-2866.

#### SUPPLEMENTARY INFORMATION:

##### Subject of Challenge Competition

The purpose of the challenge is threefold:

1. Encourage further testing (specifically lipids and BP), especially for those with some risk,
2. Encourage lifestyle changes for those at some risk, and
3. Encourage seeing a health professional if they are at high risk.

In order to engage individuals about their heart risk, and then connect them with nearby options for a biometric screening, we require a new consumer app. Developers will have access to, and will need to hew closely to, two sources of content when responding to the challenge and designing the app:

1. A new Application Programming Interface (API) for conducting the "light" health risk assessment over a

consumer-facing interface, hosted by Archimedes and built using their Indigo product.

2. Locations (and specific descriptors) of places where individuals can go for a lipid and blood pressure screening, made available through flat files from Million Hearts and a new API hosted by Surescripts.

Each of these source APIs are described in more detail at the challenge registration sites. Unlike some other challenges, HHS would like to formally "sponsor" the winning app. For this reason, it will be important (and it is part of the reviewing criteria) for applicants to follow the inputs and outputs of the two APIs specifically.

The app should begin with a "light" health risk assessment, designed to engage individuals by asking them personal questions about their health. To conduct the "light" health risk assessment, the app should ask questions to follow the required inputs of the Archimedes API (see registration sites and <https://demo-indigo4health.archimedesmodel.com> and <https://demo-indigo4health.archimedesmodel.com/IndiGO4Health/IndiGO4Health>). The app should also ask whether the individual has recent data on their blood pressure and cholesterol measurements (biomarker data). Once an individual has entered complete data including blood pressure and cholesterol measurements, the app should generate and communicate the individual's risk.

In the case that the user does not enter blood pressure and cholesterol values, after prompting individuals about the importance of a blood pressure and lipid screening, the app should then prompt them to enter their address (or use a device-enabled technology for getting their latitude and longitude such as the iPhone's "current location" feature). The app should send individuals the closest locations where they can go for a risk screening in a map-like output. Screening locations will be provided from two sources.

1. Through an API from the Surescripts Corporation. This API will be located on the Surescripts network, where it can be accessed by developers working on responding to this challenge, and available for free to the winning app throughout the campaign period. See registration sites for specific detail on the API. This information will also be available via the Million Hearts Challenge Web site.

2. Flat file, which the developers will receive from participating cities and/or HHS, and will be expected to make available to users via the app.

Developers should create an app that uses locations from both sources, and which feeds the closest locations back to the individual.

After connecting individuals with the screening locations, the app should do everything it can to get them to complete the screening. Periodically after connecting individuals to the screening locations, the app should follow-up on whether they have completed their lipid and blood pressure screening. Once the individuals indicate that they have completed their screening, the app should prompt them to enter the values from the blood pressure and lipid screening. Based on these values, and based on the Archimedes API, the app should then update the risk score and the communication of this risk to the individual.

After communicating the risk, the app should provide information about possible approaches to reducing that risk relevant to that individual. The Archimedes API will provide a series of possible interventions associated and associated risk reduction values.

Along with their app submission, entrants must submit a plan for how they will operationalize and sustain their product, and how many users they are capable of supporting, throughout the length of a 12-month promotional campaign associated with this product. The winning app may have the opportunity to be heavily promoted in a campaign supported by the Department of Health and Human Services, the Million Hearts Initiative, and their partners. As a focal point of this campaign, Million Hearts will maintain a Web site that will route consumers to apps that it sponsors. The Web site will be promoted prominently throughout the campaign. The winning app may have the opportunity to receive routings from this Web site.

Although apps are not likely to collect personally identifiable health information, submissions should consider relevant privacy and security issues, laws, and policies, and ensure apps include appropriate privacy and security protections where necessary.

#### **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 the Office of the National Coordinator for Health Information Technology.

(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) Shall not be an employee of Office of the National Coordinator for Health IT.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors 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.

An individual or entity 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 available to all individuals and entities participating in the competition on an equitable basis.

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

Entrants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

A contingency for entering the contest and submitting an app is that the winning app must be available for free, to all users, until December 31, 2013. This includes hosting and maintaining the Web service in a scalable format, providing technical support with bug fixes, and so on.

#### **Registration Process for Participants**

To register for this challenge participants should either:

- Access the [www.challenge.gov](http://www.challenge.gov) Web site and search for “The Million Hearts Risk Check Challenge”.

- Access the ONC Investing in Innovation (i2) Challenge Web site at:

- <http://www.health2con.com/devchallenge/challenges/onc-i2-challenges/>.

- A registration link for the challenge can be found on the landing page under the challenge description.

#### **Amount of the Prize**

- \$5,000 each for up to five finalists
- \$100,000 to the winner

Awards may be subject to Federal income taxes and HHS will comply with IRS withholding and reporting requirements, where applicable.

#### **Payment of the Prize**

Prize will be paid by contractor.

#### **Basis Upon Which Winner Will Be Selected**

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

1. How well the apps follow the specific input and output requirements of the two APIs
2. Effectiveness in getting individuals to answer all the questions for the initial risk assessment
3. Effectiveness in communicating initial risk to individuals, based on guidelines provided by Archimedes API
4. Effectiveness in encouraging further testing (specifically lipids and BP), especially for those with some risk
5. Effectiveness in communicating final risk to individuals, based on guidelines provided by Archimedes API
6. Effectiveness in encouraging lifestyle changes for those at some risk
7. Effectiveness in encouraging seeing a health professional if they are at high risk
8. How user-friendly, engaging, and accessible the app is, for the largest and most demographically-diverse group of people possible. Which app is the most likely to get the largest number of people to know their full cardiovascular risk?
9. Submissions will be judged for their operating plans for the year, and their likelihood of the submitter in successfully maintaining the app to support the campaign. Has the entrant provided a viable plan for initial and ongoing technical capacity to meet projected usage as well as for support, maintenance and enhancement of the application?
10. Demonstration of submitter's current or prior ability to engage consumers.

#### **Additional Information**

Ownership of intellectual property is determined by the following:

- Each entrant retains title and full ownership 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 Sponsor and Administrator a limited, non-exclusive, royalty free, worldwide, license and right to reproduce, publically perform, publically display, and use the Submission 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.

- The winning app must be available for free, to all users, until December 31, 2013. This includes hosting and maintaining the Web service in a scalable format, providing technical support with bug fixes, and so on.

**Authority:** 15 U.S.C. 3719.

Dated: July 17, 2012.

**Farzad Mostashari,**

*National Coordinator for Health Information Technology.*

[FR Doc. 2012-18593 Filed 7-30-12; 8:45 am]

**BILLING CODE 4150-45-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Delegation of Authority; International Cooperation

Notice is hereby given that I have delegated to the Director, Center for Global Health, Centers for Disease Control and Prevention (CDC) without authority to redelegate, the authority vested in the Director, CDC, under section 307 of the Public Health Service (PHS) Act (42 U.S.C. 242(1)).

This delegation became effective upon date of signature. I hereby affirm and ratify any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: July 3, 2012.

**Thomas R. Frieden,**

*Director, CDC.*

[FR Doc. 2012-18466 Filed 7-30-12; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Senior Medicare Patrol (SMP) Program Outcome Measurement

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Senior Medicare Patrol Program outcome measurement.

**DATES:** Submit written or electronic comments on the collection of information by October 1, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to:

*doris.summey@aoa.hhs.gov.*

Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201. Attention: Doris Summey.

**FOR FURTHER INFORMATION CONTACT:** Doris Summey, by telephone 202-357-3533 or by email: *doris.summey@aoa.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Grantees are required by Congress to provide information for use in program monitoring and for Government Performance and Results Act (GPRA) purposes. This information collection reports the number of active volunteers, issues and inquiries received, other SMP program outreach activities, and the number of Medicare dollars recovered among other SMP performance outcomes.

ACL estimates the burden of this collection of information as follows: 44 SMP grantees at 23 hours per month (276 hours per year, per grantee). Total Estimated Burden Hours: 7,452 hours per year. The proposed data collection tool may be found on the AoA Web site for review at [http://www.aoa.gov/AoARoot/AoA\\_Programs/Tools\\_Resources/Cert\\_Forms.aspx](http://www.aoa.gov/AoARoot/AoA_Programs/Tools_Resources/Cert_Forms.aspx).

Dated: July 25, 2012.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

[FR Doc. 2012-18645 Filed 7-30-12; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0524]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Acceptance and Filing Review for Premarket Approval Applications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.