

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 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; and

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

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.

Registered participants shall be required to 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 their participation in a competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants shall be required to obtain liability insurance or demonstrate financial responsibility, in amounts determined by the head of the Office of the National Coordinator for Health Information Technology, for claims by—

(1) A third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a competition, with the Federal Government named as an additional insured under the registered participant's insurance policy and registered participants agreeing to indemnify the Federal Government against third party claims for damages arising from or related to competition activities; and

(2) the Federal Government for damage or loss to Government property resulting from such an activity.

Participants must be teams of at least two people.

All participants are required to provide written consent to the rules upon or before submitting an entry.

Dates:

• Submission Period Begins: 12:01 a.m., E.D.T., September 12, 2011.

• Submission Period Ends: 11:59 p.m., E.D.T., November 16, 2011.

Registration Process for Participants:
To register for this challenge participants should:

• Access the <http://www.challenge.gov> Web site and search for the “Ensuring Safe Transitions from Hospital to Home”.

• Access the ONC Investing in Innovation (i2) Challenge Web site at:
○ <http://www.health2challenge.org/category/onc/>

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

Amount of the Prize:

- First Prize: \$25,000.
- Second Prize: \$10,000.
- Third Prize: \$5,000.

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

Basis Upon Which Winner Will Be Selected:

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

1. Innovation.
2. Usability/Design.
3. Potential for impact.
4. Data integration.
5. Use of NwHIN standards and services.

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.

Dated: September 8, 2011.

Farzad Mostashari,

National Coordinator for Health Information Technology.

[FR Doc. 2011-23704 Filed 9-14-11; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for “Reporting Device Adverse Events Challenge”

Authority: 15 U.S.C. 3719.

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

ACTION: Notice.

SUMMARY: Medical devices will play an increasingly large role in the monitoring and collection of patient data with the spread of electronic health records. The United States has a limited system for the post-market surveillance of medical devices, specifically as it relates to monitoring product safety and effectiveness. The “Reporting Device Adverse Events Challenge” asks multi-disciplinary teams to develop an application that facilitates the reporting of adverse events related to medical devices, whether implanted or used in the hospital, clinic, or home.

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

DATES: Effective on September 12, 2011.

FOR FURTHER INFORMATION CONTACT:

Adam Wong, 202-720-2866.

Wil Yu, 202-690-5920.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition:

The “Reporting Device Adverse Events Challenge” asks multi-disciplinary teams to develop an application that facilitates the reporting of adverse events related to medical devices, whether implanted or used in the hospital, clinic, or home. The application would make it easy for patients to report adverse events to their provider, support the download of information from EMR or PHR systems to populate the adverse event report and provide high quality data, capture useful information including patient demographics and device data that is easily accessible to all stakeholders (patients, providers, manufacturers, and researchers) using current technologies including PC-based browsers, mobile phones, and tablets, and leverage NwHIN standards and services including transport, content, and vocabularies.

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 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; and

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

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.

Registered participants shall be required to 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 their participation in a competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants shall be required to obtain liability insurance or demonstrate financial responsibility, in amounts determined by the head of the Office of the National Coordinator for Health Information Technology, for claims by—

(1) A third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a competition, with the Federal Government named as an additional insured under the registered participant's insurance policy and registered participants agreeing to indemnify the Federal Government against third party claims for damages arising from or related to competition activities; and

(2) the Federal Government for damage or loss to Government property resulting from such an activity.

Participants must be teams of at least two people.

All participants are required to provide written consent to the rules upon or before submitting an entry.

Dates:

• Submission Period Begins: 12:01 a.m., E.D.T., September 12, 2011.

• Submission Period Ends: 11:59 p.m., E.D.T., December 2, 2011.

Registration Process for Participants:

To register for this challenge participants should:

• Access the <http://www.challenge.gov> Web site and search for the "Reporting Device Adverse Events Challenge".

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

○ <http://www.health2challenge.org/category/onc/>.

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

Amount of the Prize:

- First Prize: \$25,000.
- Second Prize: \$10,000.
- Third Prize: \$5,000.

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

Basis Upon Which Winner Will Be Selected:

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

1. Effectiveness in facilitating adverse event reporting.
2. Usability and design.
3. Ability to integrate with electronic health records and other data sources.
4. Creativity and Innovation.
5. Use of NWHIN standards and services.

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.

Dated: September 8, 2011.

Farzad Mostashari,

National Coordinator for Health Information Technology.

[FR Doc. 2011-23702 Filed 9-14-11; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Health Literacy Item Set Supplemental to CAHPS Health Plan Survey—Pretest of Proposed Questions and Methodology." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on July 7th, 2011 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 17, 2011.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Health Literacy Item Set Supplemental to CAHPS Health Plan Survey—Pretest of Proposed Questions and Methodology

The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program is a multi-year initiative. AHRQ first launched the program in October 1995 in response to concerns about the lack of good information about the quality of health plans from the enrollees' perspective. Numerous public and private organizations collected information on