

Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Andrew N. Finkel (“respondent”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter involves the advertising of a mobile software application (“app”) called Acne Pwner which respondent developed and sold in Google’s Android Marketplace. Respondent claimed that Acne Pwner effectively treats acne. The instructions for this app directed consumers to hold the light-emitting display screen next to the area of skin to be treated for a few minutes each day.

The Commission’s complaint alleges that respondent violated Sections 5 and 12 of the FTC Act by claiming, without substantiation, that the app provided an effective treatment for acne.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar practices in the future. Part I of the order prohibits respondent from making any representation that Acne Pwner, or any other device as defined by Section 15 of the FTC Act, provides effective treatment for acne, unless respondent has competent and reliable scientific evidence to substantiate that claim.

Part II of the order requires respondent to have competent and reliable scientific evidence before making any safety, performance, benefits, or efficacy claim about any device.

Part III of the order requires respondent, within 15 days of the date the order becomes final, to pay the Commission \$1,700.

The remaining parts of the proposed order are standard provisions regarding recordkeeping, dissemination of the order to officers and employees, prior notification to the Commission of corporate changes, notification of new employment, filing of compliance reports, and sunset of the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of

the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011-23595 Filed 9-14-11; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the General Electric Co. in Evendale, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On August 31, 2011, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at General Electric Co. in Evendale, Ohio, from January 1, 1961 through June 30, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on September 30, 2011, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 877-222-7570. Information requests can also be submitted by e-mail to DCAS@CDC.gov.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2011-23568 Filed 9-14-11; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for “Ensuring Safe Transitions From Hospital to Home”

Authority: 15 U.S.C. 3719.

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

ACTION: Notice.

SUMMARY: The “Ensuring Safe Transitions from Hospital to Home” challenge tasks developers with creating technology solutions that empower discharged patients to take charge of their health care during transitions of places of care. Innovative applications will help patients and their caregivers insure that they have all the information and materials, such as drug prescriptions, medical equipment, follow-up appointments, and emergency contacts, that they need to move safely to their next care setting.

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: ONC, in collaboration with the Partnership for Patients, seeks to stimulate innovative approaches to care transitions and improving patient safety. Nearly one in five patients discharged from a hospital will be readmitted within 30 days. A large proportion of readmissions can be prevented by improving communications and coordinating care before and after discharge. The Centers for Medicare and Medicaid Services (CMS) provides a discharge checklist to help patients and their caregivers prepare to leave a hospital, nursing home, or other care setting. Research has shown that empowering patients and caregivers with information and tools to manage the next steps in their care more confidently is a very effective way to reduce errors, decrease complications, and prevent a return visit to the hospital. ONC is challenging software developers to improve care transitions and build upon these tools by generating an intuitive and easy-to-use application to empower patients and caregivers that leverages NwHIN standards and services.

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]

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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