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Registration: There is no fee to attend the public workshop, but attendees must register online at <http://www.aasld.org/additionalmeetings/Pages/aasldfanash.aspx> before September 1, 2013. (FDA has verified this Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Space is limited, and registration will be on a first-come, first-served basis. Those without Internet access should contact Anissa Davis (see *Contact Person*) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Anissa Davis (see *Contact Person*) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: This workshop will provide a forum to discuss the key issues in the design of clinical trials of drugs for the treatment of liver disease secondary to NAFLD. Stakeholders, including industry sponsors, those from academia, patients with NAFLD-associated liver disease, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in clinical trials. Trial design strategies and possible candidates for endpoints will be explored. The state of knowledge of the natural history of NAFLD will also be discussed.

Dated: July 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Requirements and Registration for “Care Counts: Educating Women and Families Challenge”

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

Award Approving Official: Mary K. Wakefield, Ph.D., R.N., Administrator, Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration’s (HRSA) Office of Women’s Health, located within the Department of Health and Human Services (HHS), and in collaboration with the HHS Office on Women’s Health, announces the launch of the Care Counts: Educating Women and Families Challenge.

Women are often at the center of healthy and resilient families; they make approximately 80 percent of all family health care decisions and are more likely to be the primary caregivers for children and elderly parents. To help make women aware of the important benefits available to them and their families through the Affordable Care Act, HHS is initiating this Challenge.

The Affordable Care Act is already making a difference in the lives of millions of Americans. Starting October 1, 2013, millions of uninsured Americans will be able to find affordable health insurance that meets their needs at the new Health Insurance Marketplace (Marketplace). The Marketplace is a one stop shop where people can learn about health insurance, get accurate information on different plans, and make apples-to-apples comparisons of private insurance plans. For the first time, comprehensive information about benefits and quality, side-by-side with facts about price, will help each consumer make the best coverage decision. For more information about how the Marketplace will work, including important deadlines and milestones, visit HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish).

This Challenge will allow teams (the “Contestants”) to create innovative, educational tools (“Tools”) to inform women consumers, particularly women living in medically underserved communities, about enrollment in new

health plans, as well as key provisions of the Affordable Care Act to improve their own health and that of their families.

For purposes of this Challenge, the key provision of the Affordable Care Act is coverage of 22 preventive services for women without copayment. See <https://www.healthcare.gov/what-are-my-preventive-care-benefits#part=2>.

The Tool must refer to two or more of the 22 covered preventive services for women. The Tool must also direct consumers to HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish), and the toll-free Centers for Medicare and Medicaid (CMS) call centers (1-800-318-2596) (English and Spanish) to promote enrollment in the Marketplace. The Tool must also include the TTY/TTD call center number (1-888-871-6594).

The Tool may be designed to be used within systems of health care. For purposes of this Challenge, a system of health care is defined as the organization of people, institutions, and resources to deliver comprehensive culturally competent, quality, services to meet the health needs of the target audience. Examples include HRSA’s Community Health Centers, Healthy Start programs, Ryan White Care service sites, National Health Service Corps sites, and HHS-supported Title X service sites. The Tool may also be designed to be used in community-based settings where women live, work, and purchase goods and services, such as schools, faith-based settings, recreation centers, and shopping centers.

“Tools” are defined as print, web, or other social media (including Facebook, Twitter, Google+, Apps, and/or other innovative resources) used to educate the target audience to improve knowledge and abilities leading to action. The target audience for the Tools is adult women in the United States and its territories, particularly women living in medically underserved communities or who experience difficulty accessing health care. The Tools shall focus on communicating complex information in understandable, culturally competent, and relevant ways. Reading level, common language, and health literacy of the target audiences should be considered in development of the Tools.

Contestants must also submit a Promotion/Outreach Plan for the tools. The Promotion/Outreach Plan shall: (1) Be no more than two pages in length; (2) demonstrate the Contestants’ understanding of the target audience; and (3) demonstrate how they will use the Tools to reach the target audience.

DATES: Contestants can begin submission of tools August 1, 2013. The submission period will be open for approximately 4 weeks and end on August 30, 2013. Judging will take place between September 3, 2013, and October 31, 2013. Winners will be notified and prizes awarded no later than December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Sabrina Matoff-Stepp, Ph.D., Director, HRSA Office of Women's Health, 301-443-8664.

SUPPLEMENTARY INFORMATION:

Eligible Entities

Eligible entities include state, local, Tribal, or other non-governmental organizations. To be eligible to win a prize under this Challenge, a team:

(1) Shall have registered to participate in the Challenge under the Official Rules;

(2) Shall be comprised of at least two (2) persons, preferably with a combination of technical expertise that may include design, social media, public health, and health communications expertise. Multi-disciplinary teams are encouraged to apply;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States;

(4) All persons must be at least eighteen (18) years old at the time of entry and a citizen or permanent resident of the United States;

(5) Shall have complied with all the requirements set forth herein; and

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

Competition Submission Period and Other Submission Requirements

(1) Submission Period: ends August 30, 2013.

(2) Review for Eligibility (4 weeks).

(3) Public Voting (2 weeks).

(4) Winners Announced—no later than December 31, 2013.

Contest Guidelines

(1) All Tools must be submitted through the Care Counts: Women, Families, and the Affordable Care Act Challenge Contest page on www.carecounts.challenge.gov.

(2) All Tools must specify Spanish or English audiences. If Spanish, the submission must also include English translation in a separate PDF document.

(3) All Tools must be submitted with a one-paragraph description of the Tool for promotional and public voting purposes. The paragraph should be no

more than 100 words, in a PDF document.

(4) All Tools must be submitted with a Promotion/Outreach plan as a PDF document, double-spaced, 12 point Times New Roman, and no longer than two pages in length. The Plan should demonstrate the Contestants' understanding of the target audience and how to reach that audience with the Tool.

(5) Endorsement of private products, services, or enterprises is prohibited.

(6) References to Congress, legislation, or tools that otherwise suggest or promote lobbying are prohibited.

(7) Tools that contain obscene or offensive information will be disqualified.

(8) All Tools must refer to two or more of the 22 covered preventive services for women. See <https://www.healthcare.gov/what-are-my-preventive-care-benefits#part=2>

(9) All Tools must direct consumers to HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish), to promote enrollment in the Marketplace.

(10) All Tools must mention the toll-free Centers for Medicare and Medicaid Services (CMS) call centers (1-800-318-2596) and 1-888-871-6594 (TTY/TTD).

(11) Mention of Web sites other than HealthCare.gov (English), CuidadoDeSalud.gov (Spanish), or HRSA.gov is not permitted.

(12) Tools should not include any personal identification information (i.e. name, address, Social Security number).

(13) Contestants may submit an entry in each language category, for a limit of two (2) entries per Contestant.

Contestants may also submit their Tools in multiple formats, for example, a print tool that can also be formatted for the web, but this is not a requirement of the Challenge.

(14) Contestants may build upon or tailor existing Tools to integrate the Affordable Care Act key provisions noted under the Contest Guidelines above.

(15) Both color and black/white submissions are acceptable.

(16) Video submissions must be 3 minutes or less in length.

(17) All submissions must be 508 compliant. See <http://www.hhs.gov/web/508/checklists/index.html> for more information.

Categories for Submissions

(1) English print, web-based, or social media.

(2) Spanish print, web-based, or social media.

Formatting Requirements

(1) For photos, please use 300 dpi or higher.

(2) For videos, please use MP4 format.

(3) For videos, please upload to YouTube first; then link to your video in the submission form. Helpful links for YouTube:

How to Upload Your Video Supported YouTube formats

(4) For print materials, please upload a PDF document. Please format print materials for 8½ by 11 or 8½ by 14 size paper.

Winner Selection and Judges

There will be two (2) First Place Winners (one for each category of submission) and two (2) Second Place Winners (one for each category of submission), which will be selected by a panel of judges.

The First Place Winners will be awarded prize dollars in the amount of \$7,500 each and receive a signed certificate from the HRSA Administrator. The First Place Winners' Tools will be posted to the HRSA Web site and will be broadly disseminated through the U.S. Department of Health and Human Services distribution channels.

The Second Place Winners will be awarded prize dollars in the amount of \$5,000 each, receive a signed certificate from the HRSA Administrator, and their Tools will be posted to the HRSA Web site.

HHS will review the submissions for eligibility and merit according to the challenge criteria, and the public may be asked to vote for their favorite entries in each category. An expert panel comprised of federal employees will recommend the First and Second Place winners in each category. Judges will be fair and impartial; may not have a personal or financial interest in, or be an employee, officer, director, or agent of any entity that is a registered participant in the competition, and may not have a familial or financial relationship with an individual who is a registered Contestant. The panel will provide expert advice on the merits of each submission to HRSA officials responsible for final selections for award. Winners will receive cash prizes and recognition from the HRSA Administrator, as well as have their promotion material featured on the Health Resources and Services Administration's Web site and distributed across HHS.

Judging Criteria

- (1) Design and ease of use (35%)
- (2) Clarity of ACA-related information (35%)
- (3) Promotion/Outreach plan (30%)

Special Considerations

Contestants must direct consumers to HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish), and the toll-free Centers for Medicare and Medicaid Services (CMS) call centers (1-800-318-2596) (English and Spanish) in their Tools. Contestants will create relevant, timely, culturally competent educational Tools for reaching adult women as consumers and family health care decision makers.

Winners and Recognition

Winners will be identified and notified prior to the date of public announcement and promotion of winners. All winning tools will be featured on HRSA.Gov and disseminated via social media channels, including but not limited to HHS and HRSA Facebook, Twitter, and YouTube pages.

Intellectual Property Rights

Each contestant grants the Challenge (HRSA) and others acting on behalf of the Challenge an irrevocable, royalty-free, non-exclusive worldwide license to use, copy for use, distribute, display publicly, perform publicly, create derivative works, and license others to do so for the purpose of the Challenge and/or for the purpose of raising awareness of ACA provisions for adult women consumers.

Publicity

Except where prohibited, participation in the Challenge constitutes the winning Contestants' consent to use of its name, likeness, photograph, voice, opinions, and/or hometown and state by HRSA and/or HHS for promotional purposes in any media, worldwide, without further payment or consideration.

Copyright

Contestants warrant that they are the sole author and owner of the Challenge submission and that the contest submission completely originates with the Contestants, that it does not infringe upon any copyright or any other rights of any third party of which the Contestants is aware, and is free of malware.

Liability

By entering, each Contestant team agrees to: (a) Comply with and be bound by these Official Rules and the decisions of the Challenge and judges which are binding and final in all matters relating to this Challenge; (b) 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 (including any damage that may result from a virus, malware, etc. to HRSA systems), revenue, or profits, whether direct, indirect, or consequential, arising from the Contestant's participation in the Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. The Contestant/Submitter shall be liable for, and shall indemnify and hold harmless the government against, all actions or claims for any claim, demand, judgment, or other allegation arising from alleged violation of an individual's trademark, copyright, or other legally protected interest in tools submitted to HRSA—provided, however, that Contestants are not required to waive claims arising out of the unauthorized use or disclosure by the Sponsor and/or Administrator of the intellectual property, trade secrets, or confidential business information of the Contestant; (c) Be responsible for obtaining their own liability insurance to cover claims by any third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in the Challenge, and claims by the federal government for damage or loss to government property resulting from such an activity; and (d) Indemnify the federal government against third party claims for damages arising from or related to Challenge activities.

Privacy Policy

Challenge Sponsor collects personal information from contestants when they enter the Challenge. The information collected is subject to the privacy policy located at www.challengepost.com/privacy.

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. Participation in this Contest constitutes a contestant's full and unconditional agreement to abide by the Contest's Official Rules found at www.carecounts.challenge.gov.

Authority: 15 U.S.C. 3719.

Dated: July 25, 2013.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857; (301) 443-6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated her responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table