

SUPPLEMENTARY INFORMATION: On March 23, 2010, the President signed into law the Affordable Care Act (ACA), Public Law 111–148. ACA is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation and ACA has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to “provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs.” ACA and the Prevention and Public Health Fund make improving public health a priority with investments to improve public health.

The PPHF states that the Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Service Act, for prevention, wellness and public health activities including prevention research and health screenings, such as the Community Transformation Grant Program, the Education and Outreach Campaign for Preventative Benefits, and Immunization Programs.

Therefore, increasing funding available to applicants under this FOA using the PPHF will allow them to sustain their existing to provide for a national investment in prevention and public health programs. Further, The Secretary allocated funds to CDC, pursuant to the PPHF, for the types of activities this FOA is designed to carry out.

Dated: August 16, 2011.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

[FR Doc. 2011–24750 Filed 9–26–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Intent To Award Affordable Care Act (ACA) Funding, RFA–TP–08–001

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

Overview Information

Notice of Intent to award Affordable Care Act (ACA) funding to Preparedness and Emergency Response Research Centers (PERRCs). This award is proposed for the grantees' Fiscal Year (FY) 2011 non-competing continuation application under Funding Opportunity Announcement RFA–TP–08–001, “Preparedness and Emergency Response Research Centers: A Public Health Systems Approach.”

SUMMARY: This notice provides public announcement of CDC's intent to award Affordable Care Act (ACA) appropriations to the following 4 Preparedness and Emergency Response Research Center (PERRCs) grantees: the University of North Carolina in Chapel Hill, NC; the University of Minnesota in Minneapolis, MN; the University of California in Berkeley; and the University of California in Los Angeles, CA.

The purpose of the PERRC program is to conduct public health systems research to strengthen preparedness and response capabilities at the national, state, local, and tribal levels for preventing morbidity and mortality from threats to the public's health such as infectious disease outbreaks, and man-made and natural disasters.

These activities are proposed by the above mentioned grantees in their FY 2011 application for continuation submitted under Funding Opportunity Announcement RFA–TP–08–001, “Preparedness and Emergency Response Research Centers: A Public Health Systems Approach,” Catalogue of Federal Domestic Assistance Number (CFDA): 93.061 Approximately \$5,000,000 in ACA funding will be awarded to these grantees for sustaining approved program activities. Funding is appropriated under the Affordable Care Act (Pub. L. 111–148), Section 4002 (42 U.S.C. 300u–11) (Prevention and Public Health Fund).

Accordingly, CDC adds the following information to the previously published Funding Opportunity Announcement of RFA–TP–08–001:

Authority: Sections 311 and 317 (k)(2) of the Public Health Service Act, [42 U. S. C. Section 243 and 247b(k)(2)] as amended, Patient Protection and Affordable Care Act (ACA), Section 4002 (42 U.S.C. 300u–11).

CFDA #: 93.607 (Affordable Care Act—Preparedness and Emergency Response Research Centers: A Public Health Systems Approach)

Award Information

Type of Award: Non-Competing Continuation Cooperative Agreement.

Approximate Total Current Fiscal Year ACA Funding: \$5,000,000.

Anticipated Number of Awards: 4.

Fiscal Year Funds: 2011 .

Anticipated Award Date: September 30, 2011.

Application Selection Process

Funding will be awarded to the applicants based on the following criteria from the funding opportunity announcement:

- Accomplishments reflected in the progress report of the continuation application that indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual work plan and satisfactory progress is being demonstrated. The report should contain progress in core activities, including a report on advisory committee meeting(s), activities, *etc.*, and progress in individual research projects.

- Objectives for the new budget period are realistic, specific, and measurable. Methods described will clearly lead to achievement of these objectives. An evaluation plan that will allow management to monitor whether the methods are effective.

- Any impediments to progress are described, *e.g.*, milestones that are deficient or deferred are fully explained, and the corrective action taken to address the impediment is described including specific information on revised dates of completion of the milestones impacted.

A budget request that is clearly explained, adequately justified, reasonable and consistent with the intended use of program project grant funds.

Funding Authority

CDC will add the ACA Authority to that which is reflected in the published Funding Opportunity Announcement RFA–TP–08–001. The revised funding authority language will read:

—This program is authorized under the Sections 311 and 317 (k)(2) of the Public Health Service Act, [42 U.S.C. Section 243 and 247b(k)(2)] as amended, Patient Protection and Affordable Care Act (ACA), Section 4002 (42 U.S.C. 300u–11).

DATES: The effective date for this action is the date of publication of this Notice and remains in effect until the expiration of the project period of the ACA funded applications.

FOR FURTHER INFORMATION CONTACT:

Mildred Williams-Johnson, PhD., Director, Extramural Research Program Office, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention,

telephone 770-488-8806, *MWilliams-Johnson@cdc.gov*

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Dated: September 16, 2011.

Tanja Popovic,

*Deputy Associate Director for Science,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0672]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 reprocessed single-use device labeling.

DATES: Submit either electronic or written comments on the collection of information by November 28, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.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 requests 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’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.

Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (OMB Control Number 0910-0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Thus, the name for this information collection activity has been changed to more accurately describe the information collection content.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (Pub. L. 109-43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original