

physical inactivity, poor diet, and obesity, has critical importance for public health.

The Prevention and Public Health Fund (PPHF) of the Patient Protection and Affordable Care Act of 2010 (ACA) provides an important opportunity for states, counties, territories and tribes to advance public health across the lifespan and to reduce health disparities. The PPHF authorizes Community Transformation Grants (CTG) for the implementation, evaluation, and dissemination of evidence-based community preventive health activities. The CTG program will create healthier communities by building capacity to implement broad evidence and practice-based policy, environmental, programmatic and infrastructure changes, and supporting implementation of such interventions. The CTG program emphasizes five strategic areas: Tobacco-free living, active living and healthy eating, high impact evidence-based clinical and other preventive services, social and emotional wellness, and a healthy and safe physical environment. The CTG program is administered by the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

CDC awarded 68 CTG cooperative agreements to state and local governmental agencies, tribes and territories, state or local non-profit organizations, and national networks of community-based organizations. Fifty-four awardees were from state, local and tribal government, and 14 awardees were from the private, non-profit sector. Each awardee is charged with implementing a community-or awardee-specific work plan that will lead to specific, measurable health outcomes in its jurisdiction (or service area) among an entire population or a specific population subgroup. Each CTG awardee is required to provide semi-annual reports to CDC describing its work plan, objectives, activities, partnerships, resources, and progress.

CDC plans to collect the required progress report information using an electronic management information system (MIS), which has a number of advantages when compared to the collection of narrative reports. First, the MIS will help awardees formulate objectives that are specific, measurable, achievable, relevant and time-framed (SMART), as required by CDC's evaluation strategy. Second, awardees will have the capacity to enter updates on an ongoing basis. This capacity is expected to improve respondent satisfaction and result in more complete

enumeration of CTG-funded efforts. In addition, this feature will facilitate communications with CDC and prompt, data-driven technical assistance. Third, information stored in the MIS can be used to satisfy routine, semi-annual reporting requirements while minimizing data re-entry for information that has not changed. Finally, the electronic MIS will allow CDC to formulate ad hoc analyses and reports that would be impracticable using paper-based information sources. Information collected through the MIS will be used to monitor awardee progress, identify and support CDC technical assistance to awardees, and respond to inquiries from the Department of Health and Human Services (HHS), the White House, Congress and other sources. NCCDPHP has successfully implemented similar MIS-based information collections with other chronic disease prevention and control programs.

OMB approval is requested for three years. Awardees will report information to CDC twice per year. The average burden per response is estimated to be three hours. CDC's collection of this information is authorized by section and sections 311 and 317(k)(2) of the Public Health Service Act, 42 U.S. Code 243 and 247b(k)2. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Community Transformation Grant Awardees (state, local and tribal government sector) .....	54	2	3	324
CTG Awardees (private sector) .....	14	2	3	84
<b>Total</b> .....				<b>408</b>

Dated: November 29, 2011.

**Daniel Holcomb,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2011-D-0464]**

**Draft Guidance for Industry and Food and Drug Administration Staff; the Content of Investigational Device Exemption and Premarket Approval Applications for Artificial Pancreas Device Systems; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance

document entitled "Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems." This draft guidance document provides industry and the Agency staff with guidelines for developing premarket submissions for artificial pancreas device systems, in particular, the Control-to-Range (CTR) and Control-to-Target (CTT) device systems. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the

final version of the guidance, submit either electronic or written comments on the draft guidance by March 5, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Phil Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993-0002, (301) 796-5678.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Diabetes mellitus has reached epidemic proportions in the United States and more recently, worldwide. The morbidity and mortality associated with diabetes is anticipated to account for a substantial proportion of health care expenditures. Although there are many devices available that help patients manage the disease, FDA recognizes the need for new and improved devices for treatment of diabetes. One of the more advanced diabetes management systems is an artificial pancreas device system. An artificial pancreas system is a type of autonomous system that adjusts insulin infusion based upon the continuous glucose monitor (CGM) via control algorithm. There are a variety of types of artificial pancreas systems depending upon the nature of the control algorithm, including CTR, CTT, and Low Glucose Suspend systems. On June 22, 2011 (76 FR 36542), FDA announced the availability of the draft guidance document entitled "Draft Guidance for

Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device Systems." In this notice, FDA is announcing a draft guidance document with recommendations developing premarket applications for other types of artificial pancreas systems.

CTR and CTT systems link a continuous glucose monitor to an insulin pump and automatically reduce or increase insulin infusion based upon specified thresholds of measured interstitial glucose levels. These types of systems are designed to aid in the management of diabetes. There are significant challenges in creating an autonomous system, which were discussed in a joint FDA and NIH (National Institutes of Health) artificial pancreas workshop on November 10, 2010 (information available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm>). Currently, there is no FDA-approved artificial pancreas device. This workshop sought feedback on ways to overcome the obstacles toward developing an artificial pancreas. The feedback received from this workshop and the continued communication with investigators in this field has provided valuable input for FDA's guidances for artificial pancreas device systems. This guidance will outline considerations for development of clinical studies, and recommends elements that should be included in IDE and PMA applications, focusing on critical elements of safety and effectiveness for approval of this device type.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing investigations of and premarket applications for Artificial Pancreas Device systems, particularly the CTT and CTR device systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at [\[DeviceRegulationandGuidance/GuidanceDocuments/default.htm\]\(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm\).](http://www.fda.gov/MedicalDevices/</a></p>
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Guidance documents are also available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please use the document number 1786 to identify the guidance you are requesting.

##### **IV. Paperwork Reduction Act of 1995**

This draft guidance refers to currently approved collections of information found in FDA regulations and guidance documents. These collection of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 56.11 are approved under OMB control number 0910-0130; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910-0485, the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078, and the collections of information in 21 CFR part 814 are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073.

##### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 28, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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