to the Affordable Care Act, food security, children's mental health, disability and functioning, smokeless tobacco and e-cigarettes, hepatitis screening, immunizations, and computer use. In addition, a Web/CATI multimode follow-back survey will be conducted from sample adult respondents from the 2013 NHIS. The follow-back survey will focus on topics related to the Affordable Care Act including health care access and use, and health insurance coverage and will include Web, telephone, and mail interviews. Questions related to federal and state health insurance marketplaces will be included.

To improve the analytic utility of NHIS data, minority populations are oversampled annually. In 2014, in addition to ongoing sample augmentation procedures, NCHS will introduce a Native Hawaiian and Pacific Islander oversample of 4,000 addresses identified from the 2012 American Community Survey. These individuals and households will be administered the 2014 NHIS questionnaire. Results will be released as a separate file from the regular NHIS.

In accordance with the 1995 initiative to increase the integration of surveys within the DHHS, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, diabetes, and access to health care. It is a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2020.''

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per respondent in hours	Total burden in hours
Adult	Screener Questionnaire	10,000	1	5/60	833
Adult Family Member	Family Core	45,000	1	23/60	17,250
Sample Adult	Adult Core	36,000	1	15/60	9,000
Adult Family Member	Child Core (adult family member)	14,000	1	10/60	2,333
Medical Provider	Child/Teen Record Check	8,000	1	5/60	667
Adult Family Member	Supplements	45,000	1	12/60	9,000
Adult Family Member	Multi-mode study	5,000	1	30/60	2,500
Adult Family Member	Native Hawaiian/ Pacific Islander Survey.	4,000	1	60/60	4,000
Adult	Reinterview Survey	5,000	1	5/60	417
Total Burden Hours					46,000

LeRoy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Center for Disease Control and Prevention.

[FR Doc. 2013–23302 Filed 9–24–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Tribal Child Support Enforcement Direct Funding Request: 45 CFR 309-Plan.

OMB No.: 0970–0218.

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity, establishing, modifying, and enforcing support orders, and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV–D program. Tribes and Tribal organizations must respond if they wish to operate a fully funded program. This paperwork collection activity is set to expire in September, 2013.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 309—Plan	60	2	480	57,600.

Estimated Total Annual Burden Hours: 57,600.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of

Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–23265 Filed 9–24–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0530]

Mobile Medical Applications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Mobile Medical Applications.'' The FDA is issuing this guidance to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or ''mobile apps''). At this time, the FDA intends to apply regulatory requirements to only a small subset of mobile apps referred to in this guidance as mobile medical applications (mobile medical apps).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Mobile Medical Applications'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. 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 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: *For devices regulated by CDRH:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–5528.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

I. Background

Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority. Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

Consistent with the FDA's existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. Should FDA determine at a later date that the policy in this guidance should be changed in light of new information, the agency would follow a public process, including the opportunity for public input, consistent with FDA's good guidance practices (GGP) regulation in 21 CFR 10.115.

In the **Federal Register** of July 21, 2011 (76 FR 43689), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 19, 2011. FDA reviewed the comments and revised the guidance, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on mobile medical applications. 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 guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Mobile Medical Applications'' from CDRH, you may either send an email request to *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 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved information collections found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction