Barbara Ferrer, Executive Director, Boston Public Health Commission; Shelby Gonzales, Senior Health Outreach Associate, Center on Budget & Policy Priorities; Jan Henning, Benefits Counseling & Special Projects Coordinator, North Central Texas Council of Governments' Area Agency on Aging; Warren Jones, Executive Director, Mississippi Institute for Improvement of Geographic Minority Health; Cathy Kaufmann, Administrator, Oregon Health Authority; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; Miriam Mobley-Smith, Dean, Chicago State University, College of Pharmacy; Ana Natale-Pereira, Associate Professor of Medicine, University of Medicine & Dentistry of New Jersey; Megan Padden, Vice President, Sentara Health Plans; David W. Roberts, Vice-President, Healthcare Information and Management System Society; Julie Bodën Schmidt, Associate Vice President, National Association of Community Health Centers; Alan Spielman, President & Chief Executive Officer, URAC; Winston Wong, Medical Director, Community Benefit Director, Kaiser Permanente and Darlene Yee-Melichar, Professor & Coordinator, San Francisco State University.

The agenda for the March 27, 2013 meeting will include the following:

- Welcome and Listening Session with CMS Leadership
- Recap of the Previous (December 18, 2012) Meeting
- Affordable Care Act Initiatives
- An Opportunity for Public Comment
- Meeting Summary, Review of Recommendations, and Next Steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 13, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–03928 Filed 2–21–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Project LAUNCH Cross-Site Evaluation.

OMB No.: 0970–0373.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is collecting data as part of a cross-site evaluation of a Substance Abuse and Mental Health Services Administration(SAMHSA) initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health). Project LAUNCH promotes the healthy development and wellness of children ages birth to eight years. A total of 35 Project LAUNCH grantees are funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees implement a range of public health strategies to support young child wellness in a designated locality.

Grants were awarded in four cohorts. Three of these cohorts will end on a rolling basis over the next three years and one cohort of grantees was recently awarded and will end in five years. Annual estimates of burden take into account rolling graduation of cohorts and represent an average of burden over three years.

Data for the cross-site evaluation of Project LAUNCH will be collected through: (1) Interviews conducted either via telephone or during site-visits to Project LAUNCH grantees, (2) semi-annual reports that will be submitted electronically on a web-based data reporting system, and (3) outcome data tables included in grantee specific end-of-year evaluation reports.

During either telephone interviews or the site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in states/tribes and local communities of focus. Interviewers will ask program administrators questions about all Project LAUNCH activities, including: Infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports on state/tribal and local systems development and on services that children and families receive. The electronic data reports also will collect data about other Project LAUNCH-funded service enhancements, such as trainings, Project LAUNCH systems change activities, and changes in provider settings and practice. Information provided in these reports will be aggregated on a quarterly basis, and reported semi-annually.

As a final part of the proposed data collection, the cross-site evaluation will utilize outcome data provided by grantee evaluators as part of their end-of-year evaluation reports to the SAMHSA. Information provided in these reports is aggregated.

Respondents: State/Tribal Child Wellness Coordinator, Local Child Wellness Coordinator, Chair of the State/Tribal Child Wellness Council (during site visit only), Chair of the Community Child Wellness Council, and Local Service Providers/ Stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Child Wellness Coordinator Interview Guide	19	1	1.5	87	29
Chair of Local Child Wellness Council Interview Guide	19	1	1	57	19
Local Stakeholder Interview Guide	114	1	.75	258	86
State Child Wellness Coordinator Interview Guide	19	1	1.25	72	24
Chair of State Child Wellness Council Interview Guide	11	1	1.25	14	14
Electronic Data Reporting: Systems Measures	19	2	4	456	152

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Electronic Data Reporting: Services Measures	19	2	8	912	304
Outcomes Data Tables in End of Year Reports	27	1	8	648	216

Estimated Total Annual Burden Hours: 844.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2013–03787 Filed 2–21–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0114]

Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements; Draft 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 draft guidance entitled ''Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements.'' This draft guidance intends to clarify for industry when a potential change to a device is a medical device recall, distinguish those instances from product enhancements, and identify the reporting requirements for both recalls and product enhancements. 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 May 23, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements'' 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: Ron Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2654, Silver Spring, MD 20993–0002, 301–796–6163.

I. Background

Defects or performance failures of marketed medical devices can pose serious risks to public health. Recalls serve both to correct the defect in current and future devices and to notify users of potential risks and steps to minimize the impact of device failure or function. The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct violative devices or remove them from the marketplace when correction or removal is necessary to protect the public health.

When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines a recall is appropriate, and triggers the initiation of the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. These issues can result in delays in notifying the public about unsafe medical devices.

FDA also recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When new iterations of a device involve improvements to device design, it does not necessarily mean that the existing device needs to be recalled. Such changes may be appropriately characterized instead as product enhancements.

In addition to determining whether a proposed change to a marketed device meets the definition of a device recall or