Dated: November 6, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 15, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–28274 Filed 11–16–12; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Parents and Children Together (PACT) Evaluation.

OMB No.: 0970–0403.

Description: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing data collection activity as part of the Parents and Children Together (PACT) Evaluation.

The PACT project is a formative evaluation whose overall objective is to document and provide initial assessment of selected Responsible Fatherhood and Healthy Marriage grant programs that were authorized under the 2010 Claims Resolution Act. This information will be critical to informing decisions related to future investments in this kind of programming as well as the design and operation of such services.

To meet the objective of the study, PACT is utilizing three major, interrelated evaluation strategies:

(a) Impact evaluation;

(b) Implementation evaluation; and

(c) Qualitative evaluation.

Each of these strategies will be employed separately with (1) Responsible Fatherhood and (2) Healthy Marriage grantees. Specifically, we anticipate the following studies:

(a) Impact evaluation:

(1) Responsible Fatherhood grantee evaluation; and (2) Healthy Marriage grantee evaluation.

(b) Implementation evaluation:

(1) Responsible Fatherhood grantee evaluation;

(1—additional substudy) Responsible Fatherhood grantee evaluation with a focus on Hispanic populations; and

(2) Healthy Marriage grantee evaluation.

(c) Qualitative evaluation:

(1) Responsible Fatherhood grantee evaluation.

The following instruments have been approved for this study: Site selection: a discussion guide to assist in selecting sites was approved by OMB on April 20, 2012.

(a) Impact evaluation:

(1) Responsible Fatherhood grantee evaluation:

- Introductory script, approved October 31, 2012.
- Baseline survey, approved October 31, 2012.

(b) Implementation evaluation:

(1) Responsible Fatherhood grantee evaluation:

- Responsible Fatherhood Study MIS, approved October 31, 2012.

This 60-Day **Federal Register** Notice requests clearance of new instruments:

(a) Impact evaluation:

(1) Healthy Marriage grantee evaluation:

- Introductory script, which program staff will use to introduce the study to participants.
- Baseline survey, to capture participant characteristics and experiences prior to randomization.

(b) Implementation evaluation:

(1) and (2) Responsible Fatherhood and Healthy Marriage grantee evaluation:

- Semi-structured interview topic guide, to gather information on program implementation from program staff.
- On-line survey, to capture program staff experiences.
- Telephone interviews (with staff at referral organizations), to document linkages between the program and referral agencies.
- Working Alliance Inventory, to assess the strength of the participant-program staff working relationship.
- Focus group guide, to elicit participant experiences.
- Telephone interviews (with program dropouts), to determine reasons why those eligible for the program choose not to participate.

(1—additional substudy) Responsible Fatherhood grantee evaluation with a focus on Hispanic populations:

- Semi-structured interview topic guide, to examine how agencies adapt programs to address the needs of Hispanic populations.
- Focus group guide, to elicit participant experiences.
- Participant questionnaire, to capture participant characteristics and experiences.

(2) Healthy Marriage grantee evaluation:

- Study MIS (for use in HM programs), to track participation in the program.

(c) Qualitative evaluation:

(1) Responsible Fatherhood grantee evaluation:

- Guide for in-person, in-depth interviews, to understand the experiences, both in and out of the program, of a subset of men.
- Check-in call guide, to follow-up from the in-person, in-depth interviews, to ascertain new experiences by these men since last discussion.

This 60-Day **Federal Register** Notice also serves as a request for OMB to waive subsequent 60-day **Federal Register** notices pertaining to the PACT Evaluation.

Respondents:

Respondents include program applicants, program participants, program staff, and staff at referral agencies. Specific respondents per instrument are noted in the burden tables below.

Annual Burden Estimates

Some burden has already been approved for this study, and the following instruments are still in use. Approved burden is provided below:

Instrument respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Site Selection				
Selecting Study Grantees:				
Discussions/grantee and partner organization staff	50	1	60	50

Instrument respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Impact Responsible Fatherhood Grantee Evaluation				
Introductory Script:				
Grantee staff	30	70.2	10	351
Program applicants	2,105	1	10	351
Baseline Survey:				
Study participants	2,000	1	30	1,000
Implementation Responsible Fatherhood Grantee Evaluation				
RF Study MIS:				
Grantee staff	30	2,533	2	2,533
Total				4,285

This current 60-Day **Federal Register** Notice covers many new instruments:

Instrument respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Impact Healthy Marriage Grantee Evaluation				
Introductory script:				
Program staff	20	246	10	820
Program applicants	4,211	1	10	702
Baseline survey:				
Study participants	4,000	1	30	2,000
Implementation Responsible Fatherhood and Healthy Marriage Grantee Evaluation				
Semi-structured interview topic guide:				
Program staff	250	2	62	517
On-line survey:				
Program staff	250	2	30	250
Telephone interviews (with staff at referral organizations):				
Program staff at referral organizations	50	1	30	25
Working Alliance Inventory:				
(1) Program staff	50	20	10	167
(2) Participants	1,000	1	10	167
Focus group guide:				
Study participants	600	1	90	900
Telephone interviews (with program dropouts):				
Study participants (program dropouts)	150	1	15	38
Additional Substudy: Responsible Fatherhood Grantee Evaluation With a Focus on Hispanic Populations				
Semi-structured interview topic guide:				
Program staff	42	1	65	45
Focus group guide:				
Study participants	25	1	90	38
Participant questionnaire:				
Study Participants	25	1	30	13
Healthy Marriage Grantee Evaluation				
HM Study MIS (for use in HM programs):				
Program staff	30	3,400	2	3,400
Qualitative Responsible Fatherhood Grantee Evaluation				
Guide for in-person, in-depth interviews:				

Instrument respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Study participants	95	3	120	570
Check-in call guide:				
Study participants	63	4	10	42
Total				9,694

Estimated Total Annual Burden Hours (for instruments previously approved and currently in use, as well as those associated with this 60-Day Notice): 13,969.

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.

Robert Sargis,

Administration for Children and Families, Reports Clearance Officer.

[FR Doc. 2012–28321 Filed 11–20–12; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1040]

Antiseptic Patient Preoperative Skin Preparation Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing to obtain input on how to address microbial contamination of patient preoperative skin preparation drug products. Currently, patient preoperative skin preparations are not required to be sterile. Bacteria can contaminate these products at the time of manufacture or during product use. Contaminated patient preoperative skin preparations have been associated with clinical infections and adverse outcomes. At this public hearing, FDA is interested in obtaining public comment about certain scientific and product use issues related to patient preoperative skin preparations.

*Date and Time:*The public hearing will be held on December 12 and 13, 2012, from 9 a.m. to 4 p.m. The meeting may be extended or may end early, depending on the level of public participation.

Location: The public hearing will be held at the DoubleTree by Hilton Hotel Washington, DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3441, FAX: 301- 847–8753, email: *AntisepticPreOpPublic Meeting@fda.hhs.gov*.

Registration: The public hearing is free, and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register. If you need special accommodations due to disability, please contact Lee Lemley (see *Contact Person*) at least 7 days in advance.

Requests for Oral Presentations: If you wish to make an oral presentation during the hearing, you must register by submitting a written or electronic request by close of business on November 27, 2012, to Lee Lemley (see *Contact Person*). Provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., pharmaceutical company or consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to Lee Lemley (see *Contact Person*) no later than December 7, 2012. We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see *Comments*). We will mail, email, or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

Comments: Interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov*. Comments will be accepted after the hearing until February 12, 2013. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and