

Coordinators, listed under the section titled "Meeting Registration."

C. "5-Minute" Speaker Presentations

Meeting attendees can sign up at the meeting, on a first-come, first-served basis, to make 5-minute presentations on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made at the meeting by the meeting coordinator and the meeting moderator regarding how many 5-minute speakers can be accommodated.

D. Speaker Declaration

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

The primary speakers and the 5-minute speakers must declare in their presentations at the meeting, as well as in their written summaries, whether they have any financial involvement with the manufacturers or competitors of any items or services being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

E. Written Comments From Meeting Attendees

Written comments are welcome from all persons in attendance at a public meeting, regardless of whether they make an oral presentation. Written comments can be submitted either at the meeting or before the meeting via e-mail to <http://www.cms.hhs.gov/medhpcsgeninfo> or via regular mail to the HCPCS Public Meeting Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244. Written comments to this address are also accepted from the general public anytime up to the date of the public meeting at which a request is discussed. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

II. Security, Building, and Parking Guidelines

The meetings are held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to

the building and grounds, participants must bring government-issued photo identification and a copy of your written meeting registration confirmation.

Persons without proper identification may be denied access.

Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes before the convening of the meeting each day.

Security measures will also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation.

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.

III. Special Accommodations

Individuals attending a meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information when registering for the meeting.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 139hh).

Dated: March 10, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of Child Care Subsidy Strategies.

OMB No.: New Collection.

Description: To conduct three experiments to test aspects of the child care subsidy system. One of these

experiments will occur in Cook County, Illinois; one will occur in Washington State; and one will occur in Massachusetts.

Illinois. The State of Illinois has agreed to conduct an experiment in Cook County to test the impact of receiving a child care subsidy on parental employment and income and on the stability of child care arrangements. For the experiment, families with incomes above the current income eligibility ceiling who apply or reapply for subsidies will be approved to receive subsidies. In addition, the experiment will test the effects of a longer certification period by certifying eligibility for some families in the treatment group for six months and other families for one year. Families in the treatment group will retain eligibility for subsidies over the two-year study period, provided their income remains below the experimental limit, they reapply when their certification ends, and they comply with other requirements (*e.g.*, continue to work). Outcomes will be measured through administrative records and periodic interviews with parents.

Washington. In Washington State, the study will test a co-payment schedule that smoothes out the currently abrupt increases in co-payments that occur when a family moves from one income category to the next and reduces the co-payment burden for many families. Families that apply (or reapply) for subsidies and are determined to be eligible under current rules will be randomly assigned to the experimental co-payment schedule or the existing schedule. (Families with co-payments from the experimental schedule will either pay the same amount, or less, than families whose co-payments are calculated using the existing schedule.) Families will retain the same co-payment schedule for two years, provided they continue to be eligible for subsidies. Outcomes will be measured through analysis of administrative data and periodic interviews with parents.

Massachusetts. In Massachusetts, the study is an experimental test of the effectiveness of a developmental curriculum implemented in family child care homes. Family child care providers who serve subsidized and other low-income children and are linked to family child care networks will be randomly assigned to a treatment or control group. Providers in the treatment group will use the developmental curriculum and be trained through regular visits to the home by specially trained mentors. These providers will receive materials to use with children from 0 to 5 years

of age. Providers in the control group will receive the more general technical assistance and support visits that they currently receive. Impacts on provider behavior and the home environment will be measured through direct observations in the homes. Child assessments will be conducted through provider reports for the younger children and through standardized tests for children 30 months and older.

Respondents

Illinois. Parents who apply (or reapply) for subsidies and are eligible

and agree to be in the study will be interviewed by telephone up to three times in the 24 months after they enter the study.

Washington State. Parents who apply (or reapply) for subsidies and are eligible and agree to be in the study will be interviewed by telephone up to three times over the 24 months of the study. Approximately 30 State employees working at the Department of Health and Human Services in the Division of Child Care and Early Learning or the Division of Community Service will be

interviewed as part of the implementation study.

Massachusetts. Children will be assessed 7 months after implementing the curriculum, after 11 months, and after 23 months. Providers will be asked to respond to a brief survey 7 and 23 months after the study begins. Home visitors, who support providers in the treatment and control groups, will be asked to respond to a brief interview at 23 months.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Illinois parent survey	2,000	1.5	.58	1,740
Washington parent survey	2,000	1.5	.58	1,740
Washington process study interview	30	.5	.5	8
Massachusetts child assessments	700	1.5	.5	525
Massachusetts provider interview	350	1	.16	56
Massachusetts home visitor interview	32	.5	.16	3

Estimated Total Annual Burden Hours: 4,072.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail 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, Attn: Desk Officer for ACF, E-mail address: Katherine_T._Astrich@omb.eop.gov.

Dated: March 20, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 24, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management

Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Food and Drug Administration Rapid Response Surveys—(OMB Control Number 0910-0500)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in