• Medicare Modernization Act: Outreach and education strategies.
• Public comment.
• Listening session with CMS leadership.
• 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 Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2–23–05, Baltimore, MD 21244–1850 or by e-mail at *ljohnson3@cms.hhs.gov* no later than 12 noon, e.s.t., March 15, 2005. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson by 12 noon, e.s.t., March 15, 2005. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodation: Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at least 15 days before the meeting.

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).

Dated: March 1, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–4272 Filed 3–3–05; 8:45 am]

BILLING CODE 4120–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request Proposed Projects

Title: Evaluation of the Improving Child Welfare Outcome through Systems of Care Grant Program.

OMB No. New Collection

Description: The 1994 Amendments to the Social Security Act (SSA) authorize the U.S. Department of Health and Human Services to review State child and family service programs to ensure conformance with the requirements in titles IV–B and IV–E of SSA. Under the final Rule, which took effect March 25, 2000, States are assessed for substantial conformity with certain Federal requirements for child-welfare services. The Child and Family Service Reviews (CFSR), administered by the Children's Bureau, are designed to ensure conformity with Federal child-welfare requirements and, ultimately, to help States improve child-welfare services and outcomes, specifically safety, permanency and well-being outcomes for child-welfare-involved children and their families. States determined not to have achieved substantial conformity in any of the areas assessed are required to develop and implement Program Improvement Plans (PIP) addressing the areas of nonconformity.

The Systems of Care grant cluster, from which these data are proposed to be collected, is designed to encourage public child-welfare agencies to address the issues identified in their State's CFSR. Although Systems of Care has shown promise in working with various at-risk and family populations, it has not been applied to a child-welfare target population. The data collected from these demonstration sites will allow the Children's Bureau to test whether this approach can help States reach the goals stated in their PIP and explore how child-welfare can benefit from being part of a system of care. Data will be collected via interviews, forms completed by project staff, surveys, focus groups and case-file reviews. Data also will be collected to determine the extent to which the Technical Assistance (A) provided, brokered or contracted by the TA and Evaluation Center is meeting the needs of the grantees, and how.

Respondents: Systems of Care Project Directors (members of the Systems of Care collaborative may include representatives from mental health, juvenile justice, education, health, among others); child-welfare agency supervisors and caseworkers; partner agency caseworkers, and families who have been involved with the child-welfare system.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response (minutes)	Total burden hours
Stakeholder Survey	240	51 items	.29	59
Child-Welfare Agency Survey	1440	72 items	.29	501
Supervisor Interviews	140	5 questions	5	58
Interviews with family members	140	5 questions	5	58
Stakeholder Interviews	140	5 questions	5	58
Project Director Interviews	30	21 questions	[1]4	42
Child-Welfare agency and Partner agency focus groups	700	6 questions	6	420
Community Description Form	20	14 items	2	9
Organizational Structure Form	20	7 items	4	9
Collaborative Membership Form	20	7 items	2	5
Major Activities Form	20	7 items	6	14
Policy Changes Form	20	7 items	6	14
Other Training and Technical Assistance Form	20	4 items	5	7
Training and Technical Assistance Participant Feedback Forms	1080	37 items	.56	373
Technical Assistance Follow-up Survey	518	15	.29	38
Total estimated total annual burden hours				1,665

[1] One hour for entire interview.

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@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.

Dated: February 28, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–4236 Filed 3–3–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0525]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reports of Corrections and Removals

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 4, 2005.

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 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910–0359)—Extension

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105–115).

Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, within 10 working days of initiating such correction or removal.

Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

In the **Federal Register** of December 14, 2004 (69 FR 74527), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this collection of information are manufacturers and importers of medical devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
806.10	482	1	482	10	4,820
Totals					4,820

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	143	1	143	10	1,430
Totals					1,430

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.