- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–7 Executive Order 12372.
- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities.
- AR–14 Accounting System Requirements.
- AR–22 Research Integrity.
- AR–23 States and Faith-Based Organizations.
- AR–24 Health Insurance Portability and Accountability Act Requirements (HIPAA).

Additional information on AR–1 through AR–24 can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

- AR–25 Release and Sharing of Data.

Starting with the December 1, 2004, receipt date, all ''Requests for Applications (RFA)/Program Announcements (PA)'' soliciting proposals for individual research projects of $500,000 or more in total (direct and indirect) costs per year require the applicant to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing and release, including information on the timeliness of the data and the name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing and release may also be appropriate in other sections of the application (*e.g.* background and significance, or human subjects requirements). The content of the data sharing and release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing and release plan will not count towards the application page limit and will not factor into the determining scientific merit or the priority scoring. Investigators should seek guidance from their institutions on issues related to institutional policies, and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or by visiting the NCIPC Internet Web site at: *http://www.cdc.gov/ncipc/osp/sharing_policy.htm.*

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of Effectiveness.

f. Dissemination activities.

g. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: 770/488–2700.

For scientific/research issues, contact: L.J. David Wallace, MS, Injury Prevention Specialist, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02, Atlanta, GA 30341; Telephone: 770/488–4712, E-mail: *Dwallace2@cdc.gov.*

For questions about peer review, contact: Gwendolyn Cattledge, PhD., Scientific Review Administrator, Associate Director for Extramural Research, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02; Atlanta, GA 30341; Telephone: 770/488–1430, E-mail: *gxc8@cdc.gov.*

For financial, grants management, or budget assistance, contact: James Masone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: 770/488–2736, E-mail: *ZFT2@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: November 10, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–25672 Filed 11–18–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10052 and CMS–370, 377, 378, R–54]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (new) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419; *Use:* Information is necessary to determine eligibility of medical devices for establishment of additional device categories for payment under

transitional pass-through payment provisions as required by section 1833(t)(6) of the Social Security Act. *Form Number:* CMS–10052 (OMB#: 0938–0857); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 12; Total *Annual Responses:* 12; Total *Annual Hours:* 192.

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center (ASC) Health Insurance Benefit Agreement, ASC Request for Certification, ASC Survey Report and Supporting Regulations in 42 CFR 416.41, 416.43, 416.47, and 416.48; *Use:* The ASC Health Insurance Benefits Agreement form is utilized for the purpose of establishing eligibility for payment under Title XVIII of the Social Security Act. The ASC Request for Certification form is utilized as an application for facilities wishing to participate in the Medicare program as an ASC. This form initiates the process of obtaining a decision as to whether the conditions of coverage are met. It also promotes data retrieval from the Online Data Input Edit (ODIE system, a subsystem of the Online Survey Certification and Report (OSCAR) system by the Centers for Medicare and Medicaid Services (CMS) Regional Offices (RO)). The ASC Report Form is an instrument used by the State survey agency to record data collection in order to determine supplier compliance with individual conditions of coverage and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ODIE/OSCAR system at the CMS ROs. This form includes basic information on compliance (*i.e.*, met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself; *Form Number:* CMS–370, 377, 378, R–54 (OMB#: 0938–0266); *Frequency:* Annually and Other: once; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 4,312; Total *Annual Responses:* 4,312; Total *Annual Hours:* 2,241.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 10, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–25720 Filed 11–18–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10102]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* National Implementation of the Hospital CAHPS Survey; *Form No.:* CMS–10102 (OMB# 0938–NEW); *Use:* Hospital CAHPS, part of the Hospital Quality Alliance, is an effort to provide comparative performance information on hospitals to the public. HCAHPS includes a standardized survey instrument and data collection protocol allowing for flexibility in the mode of administration. The goals of the HCAHPS are to offer consumers choice and create incentives for hospitals to improve performance in areas that are important to patients. The current version of the questionnaire and implementation strategy has been tested and modified to reflect public input. CMS will begin training and implementation for HCAHPS following National Quality Forum endorsement and the Office of Management and Budget approval.; *Frequency:* Monthly; *Affected Public:* Individuals or households; *Number of Respondents:* 2,855,250; *Total Annual Responses:* 2,855,250; *Total Annual Hours:* 285,525.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 10, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–25721 Filed 11–18–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992; Extension of Application Deadline

AGENCY: Food and Drug Administration, HHS.