CMS will also evaluate work and improvement with a small number of poorly performing nursing homes. CMS will evaluate the nursing homes' perception of the effectiveness of QIO technical assistance and on improvement in the quality measures.

Prevention (See Sections C.5 and C.6.3. of the 9th SOW)

CMS will evaluate achievement of minimum performance thresholds on specific clinical measures at the 18th and 28th month evaluation periods. CMS will evaluate the work with a selected group of participating practices (PPs) in its state/jurisdiction with already implemented electronic health records (EHRs) to assess improvements in breast cancer and CRC screening rates and to improvements in immunization rates for influenza and pneumococcal pneumonia among Medicare beneficiaries.

Sub-National Theme Requirements Prevention: Disparities (Directed Sub-National Task, See Sections C.5 and C.7.1. of the 9th SOW

CMS will evaluate achievement of minimum performance thresholds on specific measures on a quarterly basis and at the 18th and 28th month evaluation periods. CMS will evaluate recruitment of targeted providers and enrollment of targeted patients. CMS will also evaluate improvements in the rates for hemoglobin A1c testing, eye exams, lipid testing and blood pressure control for diabetic patients.

Care Transitions, (Optional Sub-National Theme, See Sections C.5 and C.7.2. of the 9th SOW)

CMS will evaluate achievement of minimum performance thresholds on specific clinical measures at the 18th and 28th month evaluation periods. CMS will evaluate patient care transitions that are: attributable to participating providers; related to implementation of interventions that address hospital/community system-wide processes; the potential subject of an implemented intervention that addresses acute myocardial infarction, congestive heart failure, and pneumonia; the potential subject of an implemented intervention that addresses specific reasons for readmission. CMS will also evaluate the percentage of implemented interventions that are measured and the percentage of patient care transitions to which implemented and measured interventions apply and show improvement. CMS will also evaluate patient satisfaction and patient readmission rates.

Prevention: Chronic Kidney Disease (Optional Sub-National Task, See Sections C.5 and C.7.3 of the 9th SOW)

CMS will evaluate achievement of minimum performance thresholds on all clinical outcome measures at the 18th and 28th month evaluation periods. CMS will evaluate timely testing to reduce the rate of kidney failure due to diabetes, improvement in the use of ACE inhibitor and/or ARB agent, and improvement in the rate of AV fistula placement.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: April 25, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–16757 Filed 7–18–08; 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

Proposed Projects

Title: Child Care Quarterly Case Record Report—ACF–801.

OMB No.: 0970–0167.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101–508, 42 U.S.C. 9858) requires that States and Territories submit monthly case-level data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Case-level reports, submitted quarterly or monthly (at grantee option), include monthly sample or full population case-level data. The data elements to be included in these reports are represented in the ACF–801. ACF uses disaggregate data to determine program and participant characteristics as well as costs and levels of child care services provided. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF–801. With this extension, ACF is proposing several changes and clarifications to the reporting requirements and instructions.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	20	4,480

Estimated Total Annual Burden Hours: 4,480.

In compliance with the requirements of Section 506(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: *infocollection@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: July 16, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–16616 Filed 7–18–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Food and Drug Administration Critical Path Workshop on Clinical Trials for Local Treatment of Breast Cancer by Thermal Ablation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss the issues associated with the development and implementation of feasibility trials for local treatment of breast cancer by thermal ablation (i.e., cryoablation, focused ultrasound, interstitial laser, microwave, radiofrequency ablation). We are inviting individuals, companies, organizations, and other stakeholders to attend this public workshop to discuss how standardized protocols for evaluation of tissue biopsy pathology, selection of tumors amenable to ablation, image guidance for ablation, post-ablation imaging and assessment, and tissue pathology of ablated specimens can be developed and used in breast cancer thermal ablation clinical trials. The public workshop will also serve as a forum for discussing where within the multispecialty care path involving operative therapy, chemotherapy, and radiation therapy, thermal ablation may play a role.

Date and Time: The public workshop will be held on September 15, 2008, from 9 a.m. to 6 p.m. Online registration is available at *http://www.blsmeetings.net/2008ThermalAblationWorkshop* until 5 p.m. on August 30, 2008 (see section III of this document for details).

Location: The public workshop will be held at the FDA White Oak Campus, conference rooms 2047 F and G (*http://grouper.ieee.org/groups/scc34/sc2/meeting_info/Meeting_WhiteOak_15-18OCT2007/White_Oak_Campus_Info_2007.pdf*) located at 10903 New Hampshire Ave., Silver Spring, MD 20993.

Contact: Binita Ashar, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3600, e-mail: *Binita.Ashar@FDA.HHS.gov.*

If you need special accommodations due to a disability, please contact Paula Gumbs at 301–594–4453 at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

On July 24, 2003, the FDA's General and Plastic Surgery Devices Advisory Panel discussed issues pertaining to the use of thermal ablation devices to percutaneously or non-invasively treat breast cancer by causing coagulation necrosis of the tumor. The panel discussed clinical trial issues pertaining to the local treatment of breast cancer using thermal ablation versus operative resection.

The panel addressed the following issues: (1) The level of evidence that would be required, in initial studies of treatment of primary breast cancer by minimally invasive ablation followed by immediate lumpectomy for pathologic examination of margins (i.e., feasibility ablate and resect studies), to permit initiation of studies that use minimally invasive ablation to definitively treat the cancer without followup resection (i.e., ablate and follow studies); (2) the type of pivotal study that could demonstrate the efficacy of a thermal ablation device to provide local breast cancer treatment in lieu of lumpectomy; (3) how to mitigate concerns regarding the effect of thermal ablation on surrounding breast tissue and radio/chemosensitivity; and (4) the limitations of breast imaging and its effect on patient selection and treatment followup. This panel's discussion of these issues has significantly contributed to FDA's evaluation of these technologies.

Investigators studying the feasibility of thermal ablation devices for the treatment of breast cancers have refined their techniques. In fact, there have been small studies demonstrating nearly 100 percent ablation accuracy. Unfortunately, the lack of uniformity among different feasibility study protocols has resulted in various study results that cannot be easily compared. Uniformity with respect to standardized evaluation of tissue biopsy pathology, selection of tumors amenable to ablation, image guidance for ablation, timing of ablation (with respect to lymph node biopsy, radiation therapy and chemotherapy), post-ablation imaging and assessment, and tissue pathology of ablated specimens would facilitate the assembly of results across both studies and ablation modalities and better allow the formulation of science-based hypotheses regarding best practices for breast cancer ablation therapy. The purpose of this critical path effort is to motivate the breast cancer ablation industry to standardize its feasibility study protocols so that data emerging are comparable in all respects except for the specific ablation modality. Such data could be used to create a validated imaging tool that correlates pathological results with imaging findings of an ablated breast cancer and hypothesize best practices that could potentially serve as the basis for longitudinal prospective clinical trials.

We believe that there may be a variety of opinions and experiences regarding the information required to obtain uniformity with respect to standardized evaluation of tissue biopsy pathology, selection of tumors amenable to ablation, image guidance for ablation, timing of ablation (with respect to lymph node biopsy, radiation therapy and chemotherapy), post-ablation imaging and assessment, and tissue pathology of ablated specimens to facilitate the assembly of results across both studies and ablation modalities and better allow the formulation of science-based hypotheses regarding best practices for breast cancer ablation therapy. We therefore published a notice in the **Federal Register** of May 28, 2008 (73 FR 30619) (*http://www.access.gpo.gov*) requesting comments by November 24, 2008, to help the agency understand how a potential registry of breast cancer treatment using thermal ablation devices may motivate this effort.