DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–SP1]

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

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicaid Post-Eligibility Preprint and Supporting Regulations in 42 CFR 435.310; *Form No.:* HCFA–SP–0001 (OMB# 0938–0673); *Use:* The post-eligibility preprint is part of the comprehensive statement that a State submits to show that it is meeting the requirements for Federal funding of its Medicaid program. It comprises part of each State's Plan which outlines the mandatory and optional aspects of a State's Medicaid program. Accurate submission of this information is necessary in order for States to receive federal funding; *Frequency:* On occasion; *Affected Public:* State, local or tribal government; *Number of Respondents:* 13; *Total Annual Responses:* 5; *Total Annual Hours:* 15.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA 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: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 29, 2001.

John P. Burke, III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Proposed Collection; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer.

Type of Information Collection Request: NEW. *Need and Use of Information Collection:* We are proposing to study genetic and environmental risk factors for the development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, there were approximately 180,000 new cases in 1997, accounting for 30% of all new cancer cases among women. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect about 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. The sister design will also facilitate study of sib-pairs to evaluate similarities in tumor characteristics, prognosis, and risk factors. We propose to enroll a cohort of 50,000 women who have not had breast cancer. In addition, we will enroll 500 of the index sisters whose breast cancer diagnosis was within the past four months. Initial recruitment of the first 2,000 women will take place from October 2001–January 2002 before beginning recruitment in earnest in April 2002. The data collected in the initial phase will allow us to evaluate subject recruitment and data collection procedures, and collect other data that will help us better target our recruitment efforts. We estimate that a cohort of 50,000 sisters aged 30–74 years would provide about 1,500 breast cancer cases over five years.

Frequency of Response: On occasion (one initial 15-minute screening [either on the telephone OR on the internet], followed by an hour and a half-long telephone interview, one mailed self-administered questionnaire, and some biological specimens collection). Women will be advised that subsequent shorter interviews or questionnaires will be sought every 1–2 years for follow-up.

Affected Public: Individuals or households.

Type of Respondents: Unaffected sisters of women diagnosed with breast cancer, aged 30–74, from all socioeconomic backgrounds and ethnicities and women with recently diagnosed breast cancer. The annual reporting burden is as follows:

Estimated Number of Respondents: 63,000 (20,833 unaffected sisters per year, on average, plus a total of 500 index sisters with incident breast cancer).

Estimated Number of Responses per Respondent: See table below.

Average Burden Hours Per Response: 4.6; and

Estimated Total Burden Hours Requested: 293,500 (over 3 years). The average annual burden hours requested is 97,833. The annualized cost to respondents is estimated at $115 (assuming $20 hourly wage × 5 hours + $15 babysitting/travel allowance). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.