

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration (HRSA), title III, Section 307, "International Cooperation," of the Public Health Service (PHS) Act, (42 U.S.C. 242J), as amended, as it pertains to the functions assigned to HRSA for international cooperation, to issue reports to Congress. This authority may be redelegated.

Previous delegations and redelegations made to officials within the Department of Health and Human Services for authorities under Section 307 of the PHS Act continue in effect.

This delegation shall be exercised under the Department's existing delegation and policy on regulations. I have ratified any actions taken by the HRSA Administrator or other HRSA officials which involved the exercise of this authority prior to the effective date of this delegation.

This delegation was effective on the date of signature.

Dated: February 19, 2004

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project:

"National Children's Study Pilot: Primary Care Practice-Based Research Networks (PBRNs)." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506 (c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on December 16, 2003 and allowed 60 Days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 Days for public comment.

DATES: Comments on this notice must be received by March 26, 2004.

ADDRESSES: Written comments should be submitted to: Allison Eydt, Human Resources and Housing Branch, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ, Reports Clearance Officer, (301) 427-1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

"National Children's Study pilot project to determine feasibility of NCS data collection in Primary Care Practices."

The project is being conducted in response to a modification of an AHRQ RFP entitled "Resource Center for Primary Care Practice-Based Research Networks (PBRNs)" (issued under Contract 290-02-0008).

In January 2003 AHRQ requested that the PBRN Resource Center assess the potential for PBRNs to participate in the National Children's Study (NCS).

In 2000, Congress passed the Children's Health Act, authorizing an unprecedented study of the impact of the environment on children's health.

The goal of the NCS is to identify sufficient numbers of women of childbearing age to enroll 100,000 pregnant women into the NCS early in gestation, and then to enroll and follow their children through 21 years of age.

A key design issue for the NCS is the manner in which participants will be recruited and enrolled into the study. Previous research states that a well-established relationship between the researcher and the subject, convenient study location and active community ties bolster recruitment success and the likelihood of a parent to enroll their child in longitudinal studies. PBRNs consist mainly of non-academic, community-based primary care practices with well-established relationships with their subject population. PBRNs therefore offer a potentially valuable resource for identifying, enrolling, and following women and children for the NCS.

Recognizing this, AHRQ requested that the Resource Center participate in the design of a pilot study of PBRNs' ability to participate in the NCS. The proposed NC pilot study will test the

ability of PBRNs to collect, process, and manage data similar to that which is expected to be collected and processed in the NCS.

This pilot study will allow the Resource Center to determine the factors that enable or hinder the collection of such data at primary care practices, as well as make an overall determination of the feasibility of PBRN practices' participation in the NCS.

The pilot study will collect data using several instruments and will involve multiple individuals at the clinic: (1) A trained interviewer will administer a questionnaire on medical and nutritional history; (2) the same trained interviewer will conduct a developmental assessment of each child; (3) a nurse or physician's assistant will collect vital signs and a urine specimen; (4) a physician will conduct a brief physical exam; and (5) study participants will complete self-administered questionnaires about the experience of participating in the study. The pilot study will evaluate the feasibility of having PBRNs participate in the NCS using several indicators:

The ability of practices to use self-administered questionnaires to collect and manage the medical and dietary history data of pregnant women and of children ages 1 and 5;

The ability of practices to effectively collect and manage data from a physical examination of study subjects (including health status and urine collection);

The ability of practices to facilitate a developmental assessment of children conducted at age one and age five;

The amount of burden data collection places on practices;

The characteristics of successful and unsuccessful practices in the study;

The ease of data collection across different patient populations and data collection modes and;

To make the necessary determinations, assessments and surveys will be conducted with PBRN practice patients as well as with a small number of patients who ordinarily receive care elsewhere, and PBRN staff will also be surveyed.

Methods of Collection

The data will be collected from 36 practices per respondent category, meaning 36 practices will collect data on pregnant women, 36 practices will collect data on children aged 1 and 5. It is expected that some practices will collect data on more than one respondent group. Each practice will recruit 14 patients per respondent group using convenience sampling procedures. A total of 504 pregnant