propose to provide notified workers with a Reader Response postcard for routinely assessing notified study subjects' responses to individual letter notification materials sent to them by NIOSH. We are requesting approval for three years. Participation is voluntary and there is no cost to respondents except for their time. The total estimated annualized burden hours are 1,333.

ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden response (in hours)	Total burden (in hours)
Reader Response Card	8,000	1	10/60	1,333

Dated: November 15, 2007.

Marilyn Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22809 Filed 11–21–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–07AA]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited 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) ways to enhance 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. Written comments should be received within 60 days of this notice.

Proposed Project

Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, Section 301, which authorizes ''research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.'' (2) 42 U.S.C. 247b–4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as ''the Children's Health Act of 2000.'' This portion of the code has also been amended by Public Law 108–154, which is also known as the ''Birth Defects and Developmental Disabilities Prevention Act of 2003''.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because pre-marketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not have a comprehensive early warning system for major adverse pregnancy or infant outcomes related to medication exposures.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the adverse effects of medication exposures during pregnancy and lactation. The objective of this project is to conduct a pilot study to assess whether TIS in the United States can serve as an effective monitoring and early warning system for major adverse effects on (1) pregnancy outcomes (e.g., live birth, stillbirth, premature birth, low birth weight, etc.) and (2) maternal and infant health. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about adverse pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (up to a maximum of 250 enrollees per TIS) who have used any prescription or over-the-counter medication, vitamin, herbal, or other dietary supplement during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will then conduct 4 telephone interviews: At enrollment; during the third trimester of pregnancy; approximately one month after delivery; and when the infant is about 3 months old. For each

breastfeeding woman who agrees to participate, the TIS will then conduct 3 telephone interviews: At enrollment; approximately one month after enrollment; and 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pregnancy Exposure Group	338	5	23/60	648
Lactation Exposure Group	74	4	20/60	99
Pregnancy and Lactation Exposure Group (pregnant women who subsequently breastfeed)	338	5	30/60	845
Total	750			1,592

Dated: November 14, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22811 Filed 11–21–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2272-FN]

Medicare and Medicaid Programs; Approval of the American Osteopathic Association's Deeming Authority for Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the American Osteopathic Association (AOA) for recognition as a national accreditation program for critical access hospitals (CAHs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective December 28, 2007 through December 28, 2013.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a CAH provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Under this authority, the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for CAHs can be found at 42 CFR 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are at part 488, subparts A and B.

A. Verifying Medicare Conditions of Participation

In general, we approve a CAH for participation in the Medicare program if it is participating as a hospital at the time it applies for CAH designation, and it is in compliance with parts 482 (Conditions of Participation for Hospitals) and 485, subpart F (*Conditions of Participation:* Critical Access Hospital (CAHs)).

For a CAH to enter into a provider agreement, a State survey agency must certify that the CAH is in compliance with the conditions or standards set forth in Section 1820 of the Social Security Act and part 485 of our regulations. Thereafter, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys. Certification by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we may ''deem'' those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning re-approval of accrediting organizations are set forth at section § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every six years, or sooner as we determine. The American Osteopathic Association's (AOA) term of approval as a recognized accreditation program for CAHs expires December 27, 2007.

II. Deeming Applications Approval Process

Section 1865 (b) (3) (A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public