

records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. Parents are asked to collect cheek cells from themselves and their infants for DNA testing. Information gathered from

both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

The program is requesting approval for an additional three years. There is no cost to the respondent other than their time. The total estimated annualized burden hours are 600.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument	Number of respondents	Frequency of response	Average burden/response (in hours)
NBDPS case/control interview	400	1	1
Biologic specimen collection	1,200	1	10/60

Dated: February 27, 2006.

Joan F. Karr,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-06-0006]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

National Exposure Registry—Extension—(OMB No. 0923-0006)—Agency for Toxic Substances and Disease Registry (ATSDR)—Centers for Disease Control and Prevention (CDC).

Background and Brief Description

ATSDR is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Re-authorization Act (SARA), to establish and maintain a national registry of persons who have been exposed to hazardous substances in the environment and a national registry of persons with illnesses or health problems resulting from such exposure. In 1988, ATSDR created the National Exposure Registry (NER) as a result of this legislation in an effort to provide scientific information about potential adverse health effects people develop as a result of low-level, long-term exposure to hazardous substances.

The NER is a program which collects, maintains, and analyzes information obtained from participants (called registrants) whose exposure to selected toxic substances at specific geographic

areas in the United States has been documented. Relevant health data and demographic information are also included in the NER databases. The NER databases furnish the information needed to generate appropriate and valid hypotheses for future activities such as epidemiologic studies. The NER also serves as a mechanism for longitudinal health investigations that follow registrants over time to ascertain adverse health effects and latency periods.

Participants in each subregistry are interviewed initially with a baseline questionnaire. An identical follow-up telephone questionnaire is administered to participants every three years until the criteria for terminating a specific subregistry have been met. The annual number of participants varies greatly from year to year. Two factors influencing the number of respondents per year are the number of subregistry updates that are scheduled and whether a new subregistry will be established. There is no cost to the respondents other than their time. The total estimated annualized burden hours are 834.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of responses	Responses per respondent	Average burden per response (in hours)
NER Registrant	1,667	1	30/60

Dated: February 27, 2006.

Joan F. Karr,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a Modified or Altered System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a Modified or Altered System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to modify or alter an existing SOR, "Medicare Beneficiary Database (MBD)," System No. 09-70-0536. This system was last published at 66 FR 63392 (December 6, 2001). The initial stage of development of the MBD contained data of interest to the Medicare Managed Care program. Since publication of the notice in 2001, all proposed phases of development for this system have been completed. We propose to broaden the scope of this system to collect and maintain data elements necessary for the new voluntary prescription drug benefit program required by Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). This new prescription drug benefit program was enacted into law on December 8, 2003, and amended Title XVIII of the Social Security Act (the Act). The regulations establishing the new Medicare "Part D" Prescription Drug Benefit program are codified at Title 42 of the Code of Federal Regulations (CFR), Parts 403, 411, 417 and 423.

Although the database has always contained the entire Medicare beneficiary population, the broadened scope of this modification will document the completion of the following phases: Phase II completed the development of data elements of interest to the Medicare Fee-For-Service Program; Phase III incorporated data elements necessary to implement the Medicare prescription drug discount card program; and Phase IV will complete the development of the MBD to include all provisions mandated by the MMA.

To more accurately reflect the information maintained in this system

we will change any reference to the program under Part C of Title XVIII currently referred to as the "Medicare+Choice Program" to read the "Medicare Advantage (MA) Program." The MA Program shall consist of the program under Part C of Title XVIII of the Act, to include MA and MA-PD. Information maintained in this system related to the MA and MA-PD shall be derived from the Medicare Advantage Prescription Drug System (MARx) (formerly known as the "Medicare Managed Care System (MMCS)) System No. 09-70-4001.

Generally, coverage for the prescription drug benefit under Part D will be provided under PDPs, which will offer only prescription drug coverage. Under Part C, Medicare Managed Care Organizations will offer prescription drug coverage that is integrated with the health care coverage they provide to beneficiaries and will be referred to as Part C of the Medicare Program.

The broadened scope of the Part D benefit will include the following activities; (1) determination of the status of Medicare beneficiaries who are eligible for the Low Income Subsidy Program (LIS) and are deemed to receive certain drug benefits; and (2) auto-assignment/auto-enrollment of beneficiaries as required by the MMA, to include all LIS and deemed individuals who are not voluntarily enrolled in a drug plan, will automatically be assigned to a Prescription Drug Plan (PDP) or Medicare Advantage (MA) Prescription Drug Plan (MA-PD). Information will be received from state organizations and from the Social Security Administration (SSA) and the MBD will make the final determination as to the status of the beneficiary.

We propose to modify existing routine use number 1 that permits disclosure to agency contractors and consultants to include grantees who perform a task for the agency. The modified routine use will remain as routine use number 1. We will also modify existing routine use number 5 to change the name from Peer Review Organizations to read Quality Improvement Organizations (QIO) and to reflect requirements established for QIOs related to the Medicare Part D Program. The modified routine use will remain as routine use number 5. We further propose to modify published routine use number 6 that permits disclosure to other insurers. We will expand the stated requirements related to coordination of benefits for the Medicare program, to implement the Medicare Secondary Payer (MSP) provisions, and to clarify CMS' policy

on disclosure of privacy protected data elements maintained in this system. The modified routine use will remain as routine use number 6.

We will modify the language in the remaining routine uses to provide clarity to CMS's intention to disclose individual-specific information contained in this system. The routine uses will then be prioritized and reordered according to their proposed usage. We will also take the opportunity to update any sections of the system that were affected by recent reorganizations and to update language in the administrative sections to correspond with language used in other CMS SORs.

The primary purpose of this modified system is to provide CMS with a singular, authoritative, database of comprehensive data on individuals in the Medicare program to support ongoing and expanded program administration, service delivery modalities, and payment coverage options. This collection will contain a complete "beneficiary insurance profile" that reflects the individual Medicare and Medicaid health insurance coverage and Medicare health plan and demonstration enrollment. This system will also include data necessary to process certain activities associated with the new Medicare prescription drug benefit program. Information retrieved from this system of records will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant or grantee; (2) assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent; (3) support providers and suppliers of services for administration of Title XVIII; (4) assist third parties where the contact is expected to have information relating to the individual's capacity to manage his or her own affairs; (5) support Quality Improvement Organizations (QIO); (6) assist other insurers for processing individual insurance claims; (7) facilitate research on the quality and effectiveness of care provided, as well as payment related projects; (8) support constituent requests made to a congressional representative; (9) support litigation involving the agency; and (10) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the routine uses, CMS invites comments on all portions of this