

Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

#### RETENTION AND DISPOSAL:

Records are maintained for a period of 6 years and 3 months. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

#### SYSTEM MANAGER AND ADDRESSES:

Director, Division of Business Analysis & Analysis, Enterprise Databases Group, Office of Information Services, CMS, Room N1-14-08, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

#### NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

#### RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification

Procedures above. Requestors should also specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

#### CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

#### RECORDS SOURCE CATEGORIES:

The data collected and maintained in this system are retrieved from the following databases: Medicare Drug Data Processing System, System No. 09-70-0553 (70 Federal Register (FR) 58436 (October 6, 2005)); Medicare Beneficiary Database, System No. 09-70-0536 (71 FR 11425 (March 7, 2006)); Medicare Advantage Prescription Drug System, System No. 09-70-4001 (70 FR 60530 (October 18, 2005)); Medicaid Statistical Information System, System No. 09-70-0541 (71 FR 65527 (November 8, 2006)); Retiree Drug Subsidy Program, System No. 09-70-0550 (70 FR 41035 (July 15, 2005)); Common Working File, System No. 09-70-0526 (71 FR 64955 (November 6, 2006)); National Claims History, System No. 09-70-0005 (67 FR 57015 (September 6, 2002)); Enrollment Database, System No. 09-70-0502 (67 FR 3203 (January 23, 2002)); Multi-Carrier Claims System (formerly known as the Carrier Medicare Claims Record), System No. 09-70-0501 (71 FR 64968 (November 6, 2006)); Fiscal Intermediary Shared System (formerly known as the Intermediary Medicare Claims Record), System No. 09-70-0503 (71 FR 64961 (November 6, 2006)); Unique Physician/Provider Identification Number, System No. 09-70-0525, (69 FR 75316 (December 16, 2004)); Medicare Supplier Identification File, System No. 09-70-0530 (71 FR 65527 (November 8, 2006). Information will also be provided from the application submitted by the individual through state Medicaid agencies, the Social Security Administration and through other entities assisting beneficiaries.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity: Comment Request

##### Proposed Projects

*Title:* Evaluation of the Mentoring Children of Prisoners (MCP) Program. *OMB No.* New Collection.

*Description:* The Promoting Safe and Stable Families Amendments, as reauthorized (2006), amended Title IV-B of the Social Security Act (42 U.S.C. 629-629e) providing funding for nonprofit agencies that recruit, screen, train, and support mentors for children with an incarcerated parent or parents. The Family and Youth Services Bureau (FYSB) of the Administration for Children and Families, United States Department of Health and Human Services, administers the Mentoring Children of Prisoners (MCP) program. The MCP program provides children of prisoners with caring adult mentors, supporting one-to-one mentoring relationships. Research in other populations has shown that such relationships can lead to reductions in risk behaviors and improvements in academic, behavioral and psychological outcomes in children and youth. Although the MCP program was developed based on research documenting the efficacy of mentoring as a general intervention strategy, it is not yet known whether or not this particular intervention yields positive outcomes for the children of prisoners population. Little is known about how mentoring relationships work for these youth, and how effective mentoring relationships for children of prisoners differ from effective mentoring relationships for other youth. In addition, little is known about children of prisoners in general and thus a survey of MCP program youth has the potential to provide important data about this relatively unstudied population.

The evaluation and data collection proposed in this notice are to fulfill the statutory requirement under Section 8, subsection h(1) of the Child and Family Services Improvement Act of 2006, as amended, that the Secretary of the Department of Health and Human Services evaluate outcomes of the MCP program and report to Congress on the findings. The proposed data collections will support a study of the MCP program that measures the program's child outcomes and compares these outcomes in similar programs. The data collection also will provide general

information about youth in the program. Finally, the study will include an administrative survey of grantees participating in the study. The proposed study will include baseline and follow-up surveys (to be administered approximately 12 months apart) of youth ages 9–16 in the MCP program and will compare changes in key behaviors for program youth against changes in behaviors of similar youth not enrolled in mentoring programs. By comparing changes for youth in the MCP program against changes for youth not in the program, we will be able to determine if MCP youths' behaviors are closer to the norm for their age group at follow-up than at program intake. If MCP youths' behaviors and outcomes

are shown to improve relative to other groups, the MCP program has demonstrated the potential for positive impacts. The survey also will include some general informational questions about youth in the study so that HHS, policy makers, and practitioners can have a greater understanding of the life circumstances of these youth and of some of the challenges they may face.

The youth surveys will focus on measuring both attitudinal and behavioral changes in areas targeted by the MCP program including attitudes towards and performance in school; relationships with parents, peers and teachers; self-esteem; and engagement in a variety of risk behaviors, including alcohol and drug use and physical

violence. They also will include questions about the living situations of youth in the study, their relationships with both incarcerated and non-incarcerated caregivers, and their relationships with other supportive adults in their communities.

The administrative survey of grantees will include questions about the programmatic structure of each grantee. It will provide information about variations in program administration, mentor activities, and youth served.

*Respondents:* The proposed study sample consists of a cohort of 625 youth ages 9–16 in MCP programs operated at 10 or more different program sites. Survey data will also be collected from approximately 72 grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Student Baseline Survey .....	625	1	.5	312.5
Student follow-up Survey .....	500	1	.5	250
Grantee Survey .....	72	1	1	72

*Estimated Total Annual Burden Hours:* 634.5

In compliance with the requirements of Section 3506(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](mailto: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: November 8, 2006.

**Robert Sargis,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006N-0104]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by January 12, 2007.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format—(OMB Control Number 0910-0530)—Extension**

FDA is requesting that OMB extend approval under the PRA for the information collection contained in the final rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (68 FR 69009, December 11, 2003) (the 2003 final rule). The 2003 final rule amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs), certain biological license applications (BLAs),