

and Worksheet D have been modified to implement provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003. On Worksheet B, the allocation of Administrative and General cost to Separately Billable Drugs was eliminated. On Worksheet C, two columns were sub-divided to identify services before, on or after 4/1/2005. A line was added to Worksheet D to report bad debts for dual eligible beneficiaries. None of these changes request new information; rather, the changes require reporting of data in greater detail than was previously reported. *Frequency: Reporting—Annually; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 4,885; Total Annual Responses: 4,885; Total Annual Hours: 957,460.*

**2. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Medicare Participating Physician or Supplier Agreement; **Form No.:** CMS-460 (OMB# 0938-0373); **Use:** The CMS-460 is the agreement a physician, supplier or their authorized official signs to participate in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term a supplier means any person or entity that may bill Medicare for Part B services (e.g. DME supplier, nurse practitioner, supplier of diagnostic tests) except a Medicare provider of services (e.g. hospital), which must participate to be paid by Medicare for covered care.

There are additional benefits associated with payment for services paid under the Medicare fee schedule. Payments made under the Medicare fee schedule for physician services to participating physicians and suppliers are based on 100 percent of the Medicare fee schedule amount, while the Medicare fee schedule payment for physician services by nonparticipating physicians and suppliers is based on 95 percent of the fee schedule amount. Physicians and suppliers who do not participate in Medicare are subject to limits on their actual charges for unassigned claims for physician services. These limits, known as limiting charges, cannot exceed 115 percent of the non-participant fee schedule, which is set at 95 percent of

the full fee schedule amount. In addition, if a physician or supplier does not accept assignment on a claim for Medicare payment, the physician or supplier must collect payment from the beneficiary. If the physician or supplier accepts assignment on the claim, Medicare pays its share of the payment directly to the physician or supplier, resulting in faster and more certain payment. *Frequency: Reporting, Other—when starting a new business; Affected Public: Business or other for-profit; Number of Respondents: 6000; Total Annual Responses: 6000; Total Annual Hours: 1500.*

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on May 8, 2007. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 2, 2007.

**Michelle Shortt,**

*Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory Affairs.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Submission for OMB Review; Comment Request**

**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:* Mentoring Children of Prisoners (MCP) grantees and non-MCP mentoring organizations.

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.

*Additional Information:* Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, FAX: 202-395-6974, Attn: Desk Officer for ACF.

Dated: March 5, 2007.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0301]

#### Guidance for Industry: Animal Drug User Fees; Fees Exceed Costs Waiver/Reduction; Availability

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

#### **ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#183) entitled "Guidance for Industry: Animal Drug User Fees; Fees Exceed Costs Waiver/Reduction." This guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of the Animal Drug User Fee Act of 2003 (ADUFA).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Dave Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: [david.newkirk@fda.hhs.gov](mailto:david.newkirk@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### **I. Background**

In the **Federal Register** of August 17, 2006 (71 FR 47502), FDA published the notice of availability of the draft guidance entitled "Guidance for Industry: Animal Drug User Fees; Fees Exceed Costs Waiver and Reductions" giving interested persons until October 31, 2006, to submit comments. FDA received no comments.

ADUFA (Public Law 108-130) amended the Federal Food, Drug, and Cosmetic Act (the act) and requires the FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from or a reduction of those fees in certain circumstances.

This guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of ADUFA. These procedures may be modified in the future as FDA gains more experience with waiver requests.

To qualify for waiver consideration, a written request to the agency for a waiver/reduction, including under the fees exceed costs waiver provision, must be submitted no later than 180 days after the fee is due (section 740(i) of the act (21 U.S.C. 379j-12(i))).

#### **II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the topic. The document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches may be used as long as they satisfy the requirements of the applicable statutes and regulations.