

Obtain Additional Information” section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page

Internet address—<http://www.cdc.gov>. Click on “Funding” then “Grants and Cooperative Agreements.” To receive additional written information and to request an application kit, call 1-888-GRANTS (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146. Telephone Number: 770-488-2753; Email Address: gcg4@cdc.gov.

For program technical assistance, contact: Rana A. Hajjeh, M.D., National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone Number: 404-639-4753; E-mail Address: rfh5@cdc.gov.

Dated: June 16, 2000.

Henry S. Cassell, III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-15769 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State Human Services System.

OMB No.: New Collection.

Description: Collect Data from States to Provide Updated Information on what systems software each State has created in the area of State Systems which effect TANF, CW, OCSE and Child Care Projects.

Respondents: 54 States and Territories.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey	54	4	1	216

Estimated Total Annual Burden Hours: 216.

In compliance with the requirements of Section 350(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 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.

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: June, 15, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00-15844 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Temporary Deferment of Activities Relating to Certain Biologics Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation

and Research (CBER) will be converting its current biologics license application (BLA) data base system into a new data base system. During the period required for this conversion, the agency will temporarily defer certain submissions subject to CBER review and approval, and the review period, if any, on pending submissions will be suspended. FDA plans to temporarily defer action on submissions related to BLA’s, product license applications (PLA’s), establishment license applications (ELA’s), and any related correspondence. FDA is also requesting that sponsors voluntarily refrain from filing the affected submissions during this period. FDA estimates that the deferment period will be about 1 month.

FOR FURTHER INFORMATION CONTACT:

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000.

SUPPLEMENTARY INFORMATION:

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*) and section 351 of the Public Health Service Act (42 U.S.C. 262), CBER is responsible for

receiving, reviewing, evaluating, and taking appropriate action on a variety of submissions concerning various regulated products, including: (1) Investigational new drug applications (IND's) and investigational device exemption applications (IDE's) for certain products for which CBER has been assigned responsibility; (2) BLA's, PLA's, and ELA's submitted for biological products; and (3) new drug applications (NDA's), premarket approval applications (PMA's), and premarket notifications (510k's) for which CBER has been assigned responsibility.

In an effort to upgrade CBER's data base and tracking system for license applications, CBER is converting to a new data base system starting in June 2000. Because of this conversion, CBER will be unable to start work or continue work on certain pending submissions and reports until conversion to the new system is ready; therefore, FDA plans to temporarily defer action on certain submissions subject to CBER review and approval, including BLA's, PLA's, ELA's, and related correspondence. Other submissions subject to CBER review and approval, including IND's, NDA's, 510k's, PMA's, or IDE's will not be affected by the conversion and temporary deferment. FDA is requesting that applicants voluntarily refrain from filing the affected submissions during the conversion period, which will begin on June 26, 2000, and is expected to continue until July 20, 2000. CBER will try to complete the conversion and begin processing submissions sooner than the specified timeframe. Confirmation of the resumption of normal review procedures and any change in this timeframe will be announced on the Internet on CBER's home page at <http://www.fda.gov/cber/genadmin.htm>.

FDA anticipates that this period will be about 1 month or less. Although FDA will continue to accept mail during this period, affected submissions and related correspondence will neither be officially logged in nor will review of affected submissions or related correspondence begin. Any review period will not begin until the conversion is completed and CBER review functions resume. CBER will attempt to keep the mail in the order of the day received. When work resumes, the mail will be handled in the order in which it was received. Also, the review periods on pending submissions will be suspended during the conversion period. The action due date for all pending submissions will be extended by the length of the actual deferment. CBER will attempt to

minimize the period during which regular procedures are suspended.

Persons who may be affected by this temporary deferment should call the contact person listed above or CBER's Office of Communication, Training, and Manufacturer's Assistance at 301-827-2000 with any questions regarding the conversion.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-15554 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10008]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This collection of information will

be used to determine items eligible for payment as new technology within the ambulatory payment classification (APC) system as well as items eligible for the transitional pass-through payment provision as required by section 201 of the BBRA. Without this information, HCFA would be unable to determine eligible items for transitional pass-through or new technology payments; therefore being unable to make additional payments to hospitals for a period of 2 to 3 years as required by the BBRA of 1999. The Agency cannot reasonably comply with the normal clearance procedures because of a statutory deadline imposed by the Balanced Budget Refinement Act of 1999 (Section 201(b)). Without this information, HCFA would not be able to properly implement the requirements set forth in the statute.

HCFA is requesting OMB review and approval of this collection by July 6, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 3, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection

Request: New Collection;

Title of Information Collection:

Recognition of New Technology/Pass-Through Items Under the Prospective Payment System for Hospital Outpatient Services;

Form No.: HCFA-10008 (OMB# 0938-NEW);

Use: This information is necessary to determine items eligible for payment as new technology within the ambulatory payment classification (APC) system as well as items eligible for the transitional pass-through payment provision as required by section 201 of the BBRA. This collection will enable HCFA to implement those special payment provisions;

Frequency: On Occasion;

Affected Public: Business or other for-profit;

Number of Respondents: 500;

Total Annual Responses: 500;

Total Annual Hours: 1,500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone