

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

number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by July 3, 2000:

Health Care Financing Administration,
Office of Information Services,
Security and Standards Group,
Division of HCFA Enterprise
Standards, Attention: Dawn
Willingham (HCFA-10008), Room N2-
14-26, 7500 Security Boulevard,
Baltimore, Maryland 21244-1850
and

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Fax Number: (202) 395-6974
or (202) 395-5167, Attn: Allison
Herron Eydt, HCFA Desk Officer.

Dated: June 15, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-15800 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10006]

Notice; Correction

SUMMARY: In the **Federal Register** issue of Tuesday, June 6, 2000, make the following correction:

Correction

In the **Federal Register** issue of Tuesday, June 6, 2000, Volume 65: FR Doc. 00-14263, on page 35947, the fourth sentence of the first paragraph in column 1 (beginning "Prior to that time") should be deleted and replaced with the following sentence: "Prior to that time, we must send a State Medicaid Directors letter soliciting applications and have sufficient time to review all applications adequately."

Dated: June 8, 2000.

Victoria Quigley,

Acting Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-15799 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: July 25, 2000.

Time: 8:30 AM to 12:00 PM.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonina Blvd., Gaithersburg, MD 20878.

Contact Person: John D. Harding, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, (301) 435-0810.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: June 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-15756 Filed 6-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute, Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Clinical Research Curriculum Awards (K30s)

Date: July 11-12, 2000.

Time: 7:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Contact Person: Diane M. Reid, MD, Scientific Review Administrator, NIH, NHLBI, DEA, Two Rockledge Center, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892-7924 (301) 435-0277.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, In Vitro Inactivation of Viruses in Blood Components.

Date: July 20, 2000.

Time: 8:00 AM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn-Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Eric H. Brown, PhD, Scientific Review Administrator, NIH/NHLBI/DEA Review Branch, Rockledge Building II, Suite 7204, 6701 Rockledge Drive, Bethesda, MD 20892-7924, 301/435-0299, browneg@gwgate.nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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