

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* The Medicare/Medicaid Psychiatric Hospital Survey Data Contained in 42 CFR and supporting regulations in 42 CFR 482.60, 482.61, and 482.62.; *Form No.:* CMS-724 (OMB# 0938-0378); *Use:* The collection of this data will assure an accurate data base for program planning and evaluation, and survey team composition for surveys of psychiatric hospitals. All freestanding psychiatric hospitals surveyed will be required to respond.; *Frequency:* Annually; *Affected Public:* Federal Government, Business or other for-profit, Not-for-profit institutions, and State, local and tribal government; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://cms.hhs.gov/regulations/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcf.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 27, 2004.

John P. Burke, III,

*Paperwork Reduction Act Team Leader,
Office of Strategic Operations and Strategic
Affairs, Division of Regulations Development
and Issuances.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2200-N2]

Medicare Program; Establishment of the State Pharmaceutical Assistance Transition Commission

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the establishment of the State Pharmaceutical Assistance Transition Commission (the Commission) that will develop a proposal for addressing the unique transitional issues facing State Pharmaceutical Assistance Programs (SPAP) and SPAP participants due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act.

This notice also announces the signing by the Secretary on March 1, 2004 of the charter establishing the Commission. The charter will terminate 30 days after the date of the submission of the report to Congress, but no later than January 31, 2005.

FOR FURTHER INFORMATION CONTACT: Marge Watchorn, Health Insurance Specialist, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Mail stop S2-01-16, Baltimore, MD 21244-1850, (410) 786-4361.

SUPPLEMENTARY INFORMATION:

I. Background

Section 106 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), enacted on December 8, 2003, mandates that the Secretary of the Department of Health and Human Services (the Secretary) establish a State Pharmaceutical Assistance Transition Commission (the Commission) by March 1, 2004. The Commission will develop a proposal for addressing the unique transitional issues facing State Pharmaceutical Assistance Programs (SPAP) and SPAP participants due to the implementation of the voluntary

prescription drug benefit program under part D of title XVIII of the Social Security Act (the Act), as added by section 101 of the MMA.

The Commission, chartered under section 106 of the MMA, Pub. L. 108-173, is governed by the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2, which sets forth standards for the formation and use of advisory committees.

The composition of the Commission must include the following:

- A representative of each Governor of each State that the Secretary identifies as operating, on a statewide basis, an SPAP that provides for eligibility and benefits that are comparable to, or more generous than, the low-income assistance and eligibility and benefits offered under section 1860D-14 of the Act.
- Representatives from other States that the Secretary identifies have in operation other SPAPs, as appointed by the Secretary.
- Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary.
- Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.
- The Secretary (or the Secretary's designee) and any other members that the Secretary may specify. The Secretary will designate a member to serve as Chair of the Commission and the Commission will meet at the call of the Chair.

II. Provisions of the Notice

This notice announces the signing of the State Pharmaceutical Assistance Transition Commission charter by the Secretary on March 1, 2004. The charter will terminate 30 days after the date of the submission of the report to Congress, but no later than January 31, 2005.

III. Report to Congress

By no later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and other recommendations as the Commission deems appropriate.

IV. Copies of the Charter

You may obtain a copy of the charter for the State Pharmaceutical Assistance Transition Commission by submitting a request to Marge Watchorn, Health Insurance Specialist, Center for

Medicaid and State Operations, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2-01-16, Baltimore, MD 21244-1850. (410) 786-4361, or E-Mail the request to mwatchorn@cms.hhs.gov.

Authority: Section 106 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: February 26, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04-4907 Filed 3-1-04; 4:54 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0086]

Diabetes: Targeting Safe and Effective Prevention and Treatment; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: FDA/National Institutes of Health (NIH) Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment. The purpose of the public meeting is to define the current state of the prevention and management of diabetes and to identify and discuss therapeutic gaps and hurdles to safe and effective prevention and treatment of type 1 and type 2 diabetes mellitus. The public meeting is intended to provide assistance to FDA, clinical and basic scientists, and the interested pharmaceutical industry in their efforts to reduce the burden of diabetes and improve the health of all people with diabetes.

DATES: The public meeting will be held on May 13, 2004, from 8:30 a.m. to 4:30 p.m. and on May 14, 2004, from 8 a.m. to 12 noon. Registration is required to attend the public meeting and must be received by April 30, 2004, at 3 p.m.

ADDRESSES: The public meeting will be held at the Natcher Conference Center, Bldg. 45, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet

at <http://www.nih.gov/about/visitor/index.htm>.

Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at <http://www.nih.gov/about/visitorsecurity.htm>. Due to the limited available parking, visitors are encouraged to use public transportation.

FOR FURTHER INFORMATION CONTACT:

For General Information: James Cross, Center for Drug Evaluation and Research, Food and Drug Administration (HFD-020), 5515 Security Lane, Rockville, MD 20852, 301-443-5355, FAX: 301-480-8329, e-mail:

james.cross@fda.hhs.gov, or Sanford Garfield, National Institute for Diabetes and Digestive and Kidney Diseases, National Institutes of Health, 6707 Democracy Blvd., rm. 685, Bethesda, MD 20892-5460, e-mail: garfields@ep.niddk.nih.gov.

For Registration Information: Iain MacKenzie, The Hill Group, 6903 Rockledge Dr., suite 540, Bethesda, MD 20817, 301-897-2789, FAX 301-897-9587, e-mail: imackenzie@thehillgroup.com

SUPPLEMENTARY INFORMATION:

I. Background

Diabetes mellitus constitutes a significant and growing threat to the U.S. public health, largely through its comorbid clinical features and long-term complications, including blindness, kidney disease, amputations, and cardiovascular disease. On January 31, 2003, FDA launched an initiative to improve the development and availability of innovative medical products by creating clearer guidance on priority therapeutic areas, including diabetes. Information about the initiative is available on the Internet at <http://www.fda.gov/bbs/topics/news/2003/beyond2002/report.html>.

As outlined in the initiative, FDA intends to develop regulatory guidance on diabetes in collaboration with scientists and relevant parties through public meetings such as the FDA/NIH Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment. This public meeting also relates to a recent initiative of the

National Institute for Diabetes and Digestive and Kidney Diseases (NIDDKD) entitled "Bench to Bedside, Research on Type 1 Diabetes and Its Complications," which aims to translate molecular understanding of type 1 diabetes into novel therapies.

The public meeting will provide a forum for discussion of diabetes-related topics, including the following topics:

- Important disease outcomes that are or should be targeted in the development of drugs, devices, and cell-based therapies for type 1 and/or type 2 diabetes;

- Issues surrounding the use of surrogate or intermediate measures of clinical effect in assessments of novel therapeutic approaches to prevention and treatment; and

- Clinical, scientific, and regulatory issues surrounding development of new medical technologies for the treatment of metabolic syndrome and for the prevention of type 2 diabetes.

Participants include FDA and NIH staff, academic experts from the United States and abroad, members of trade associations representing commercial industry, and representatives of the major diabetes patient advocacy groups.

FDA and NIH are currently developing a web page where interested persons can register to attend the public meeting, submit comments, and to obtain related information. Information about the public meeting will be posted at <http://www.niddk.nih.gov/fund/other/conferences.htm>.

II. Registration

If you would like to attend the public meeting, you must register with Iain MacKenzie (see **FOR FURTHER INFORMATION CONTACT**) by April 30, 2004, at 3 p.m. by providing your name, title, organizational affiliation, address, telephone, fax number (optional), and e-mail address (optional). Registration will be conducted on a first-come, first-served basis, and seating will be limited. To expedite processing, this registration information may also be faxed or e-mailed to Iain MacKenzie. If you need special accommodations due to a disability, please contact Iain MacKenzie at least 7 days in advance.

The public meeting will include morning and afternoon sessions during which a discussion of diabetes and related issues associated with diabetes prevention and treatment will be presented. FDA and NIH are asking experts to provide presentations on specific issues, with discussion time following each presentation.