

requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0014 (until January 31, 2006), OMB control number 0910–0001 (until May 31, 2008), and OMB control number 0910–0338 (until September 30, 2008).

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930–0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the States, the District of Columbia, the

Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101–645, 42 U.S.C. 290cc–21 et seq., the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 et seq. of the Public Health Service (PHS) Act). Section 522 of the PHS Act requires that the grantee States and Territories must expend their payments under the Act solely for making grants to political subdivisions of the State, and to non-profit private entities (including community-based veterans organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act specifies that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
States	56	1	26	1,456
Local provider agencies	450	1	31	13,950
Totals	506	15,406

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 71–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 11, 2005.

Anna Marsh,

Director, Office of Program Services.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–22721]

Lower Mississippi River Waterway Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC) will meet to discuss various issues relating to navigational safety on the Lower Mississippi River and related waterways. The meeting will be open to the public.

DATES: The next meeting of LMRWSAC will be held on Tuesday, November 15, 2005, from 9 a.m. to 12 p.m. This meeting may adjourn early if all business is finished. Requests to make