

on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### IV. 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 PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 10, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04–21317 Filed 9–22–04; 8:45 am]

**BILLING CODE 4160–01–S**

## 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 (301) 443–7978.

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: Medicaid Mental Health Services Program and Analytic Reports—New

The Substance Abuse and Mental Health Services Administration (SAMHSA) will conduct a survey of state Medicaid directors to learn about the relationships between state mental health authorities and state Medicaid agencies in each state and the District of Columbia. In addition, SAMHSA will ask about the administration of Medicaid mental health services, the development of Medicaid mental health policy, mental health services statistics generated by Medicaid programs, and the characteristics of mental health-related data maintained by Medicaid agencies and used by mental health and other state agencies.

The survey will contact state Medicaid directors in all fifty states (and the District of Columbia) and will gather information on the following five survey domains: Organizational structure; Medicaid mental health services policy infrastructure; Medicaid mental health

services, rates, and funding; Medicaid mental health providers; and, Data.

The survey will identify and describe, at the state level, how Medicaid mental health policy is developed; whether Medicaid mental health services and providers are treated differently from other Medicaid services and providers, and if so, how; and the availability of data and reports on Medicaid mental health service use and/or expenditures.

This information collection supports the New Freedom Initiative, one of SAMHSA's current priorities. As part of this effort, the President launched the New Freedom Commission on Mental Health to address the problems in the current mental health system. The Commission noted that fragmentation of responsibility for mental health services is a serious problem at the state level. Two of the Commission's 19 recommendations for the improvement of the mental health system were aimed at this problem. One was directed to states (create a comprehensive state mental health plan) and the other to the federal government (align relevant federal programs to improve access and accountability for mental health services). This survey is aimed at providing information that can help in carrying out these recommendations by further illuminating the relationships between state Medicaid and mental health agencies in the development and implementation of mental health policy.

Telephone interviews will be conducted with state Medicaid directors. Each interview will last one hour. Because of the open-ended nature of many of the survey questions and the general reluctance of state Medicaid directors to complete detailed paper or electronic surveys, we propose to conduct all the interviews by telephone, unless interviewees prefer to respond to a paper or electronic version.

#### ESTIMATES OF ANNUALIZED HOUR BURDEN

	Number of respondents	Responses per respondent	Hours per response	Total hour burden
51 .....		1	1	51

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, 1 Choke Cherry Road, Rockville, MD 20850. Written comments should be received by November 22, 2004.

Dated: September 16, 2004.

**Anna Marsh,**

*Executive Officer, SAMHSA.*

[FR Doc. 04-21372 Filed 9-22-04; 8:45 am]

**BILLING CODE 4162-20-P**

---

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2004-0005]

### Revised Privacy Impact Assessment and Privacy Policy; US-VISIT Program

**AGENCY:** Department of Homeland Security.

**ACTION:** Notice; Privacy Impact Assessment and Privacy Policy.

**SUMMARY:** The Department of Homeland Security (Department) intends to modify

the United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT) to expand coverage to include Visa Waiver Program entrants into this entry and exit system and to include the 50 busiest land ports of entry, and to modify the business process by which the Department shares information with other Federal law enforcement agencies. Accordingly, the original privacy impact assessment (PIA) for US-VISIT, which was published in the **Federal Register** on January 16, 2004, has been amended to reflect these changes in accordance with the E-Government Act of 2002, and is being made available to the public by this notice and in conjunction with the Interim Final Rule of August 31, 2004, United States Visitor and Immigrant Status Indicator Technology Program ("US-VISIT") Authority to Collect Biometric Data From Additional Travelers and Expansion to the 50 Most Highly Trafficked Land Border Ports of Entry, published at 69 FR 53318.

**ADDRESSES:** Written comments about this revised PIA for the US-VISIT

Program, Increment 2, may be submitted to the DHS Privacy Office, Attn: US-VISIT PIA, Increment 2, U.S. Department of Homeland Security, Washington, DC 20528, fax (202) 298-5201, or e-mail at [privacy@dhs.gov](mailto:privacy@dhs.gov). If submitting comments by e-mail, please include the words "US-VISIT PIA" in the subject line.

Additional comments may be made through the e-docketing system by referencing docket number [DHS-2004-0005] at <http://docket.epa.gov/edkfed/index.jsp>.

**FOR FURTHER INFORMATION CONTACT:** Steve Yonkers, Privacy Officer, US-VISIT, Border and Transportation Security, U.S. Department of Homeland Security, Washington, DC 20528, telephone (202) 298-5200, fax (202) 298-5201, e-mail [usvisitprivacy@dhs.gov](mailto:usvisitprivacy@dhs.gov).

Dated: September 14, 2004.

**Nuala O'Connor Kelly,**  
*Chief Privacy Officer.*

**BILLING CODE 4910-15-P**