found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: December 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–6266 Filed 12–27–07; 3:08 pm]

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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 (SAMHSA) 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: Opioid Treatment Programs (OTPs) Mortality Reporting Form—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), has developed a voluntary reporting form for Opioid Treatment Programs (OTPs) to report mortality data on patients who at the time of death, were enrolled in the Programs that were certified to operate by SAMHSA.

Methadone is a Schedule II controlled substance approved by the Food and Drug Administration for the treatment of opioid dependence and pain. Although it has proven safe and effective, it must be carefully administered and for that reason, treatment of opioid dependence with methadone is provided only through specialized and Federally regulated and accredited clinics, the OTPs. Buprenorphine, a Schedule III controlled ssubstance, is also used in the treatment of opioid addiction by OTPs and office-based physicians.

In recent years, methadone has been associated with an increasing number of deaths around the country. Simultaneously, the use of methadone for pain has increased significantly over the last 5 to 10 years. While the Food and Drug Administration (FDA) maintains oversight of methadone for use in pain, SAMHSA provides oversight of methadone for use in opioid addiction treatment. Currently, there is no national database that tracks mortality among patients receiving methadone in OTPs and as a result, it is not clear whether and to what extent the increase in methadone-associated deaths may be related to treatment in OTPs. MedWatch, a voluntary reporting system maintained by FDA, provides information relevant to its role in its more general oversight of medication and device safety. A similar system is needed within SAMHSA to gather information directly relevant to the agency's mission of overseeing and ensuring safe and effective treatment for patients with opioid dependence.

In order to more accurately understand potential methadone-associated deaths at the OTP level, it is necessary to examine all patient deaths, including those related to buprenorphine. Understanding the actual cause of death of patients enrolled in OTPs can be a challenging task for many reasons, including inconsistencies in methods of reporting causes of deaths across different localities and officials; patients' use of other drugs, including illicit, over-the-counter, and prescription products; and other aspects of the patient's physical and mental condition. The standardized terminology to be used for reporting in the proposed system will contribute to a more precise and relevant analysis of individual cases and higher-level trends. The data will be used by SAMHSA to increase understanding of the factors contributing to these deaths, identify preventable causes of deaths, and ultimately, take appropriate action to minimize risk and help improve the quality of care. Importantly, better data will enable the agency to more proactively manage the oversight of treatment.

The information requested from OTPs should be readily available to any OTP that has met accreditation standards. The OTP should not find any need to otherwise analyze or synthesize new data in order to complete this form.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

Form	Number of facilities (OTPs)	Responses per facility	Burden responses (hours)	Annual burden (hours)
SAMHSA OTP Mortality Report	1,150	2	0.5	1,150

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: December 31, 2007.

Elaine Parry,

Acting Director, Office of Program Services.

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