

OMB No. 0930-0106). However, a separate OMB approval will be requested for the OTP survey.

The OTP survey will use the same point prevalence date as the N-SSATS and will offer the same response options (paper questionnaire, online via the Internet, or by telephone with an interviewer). The information collected will include detailed information on

OTP client characteristics and OTP facility operations, information that is not currently obtained by the N-SSATS or other federally-sponsored surveys.

The findings will supplement information collected by the annual N-SSATS and will be published by SAMHSA in a separate report on Opioid Treatment Programs. Survey data will also be used to update SAMHSA's

"Medication-Assisted Treatment for Opioid Addiction State Profiles." These publications will be used by the Federal government, State and local governments, the U.S. Congress, researchers, and other health care professionals. The following Table summarizes the estimated response burden for the survey.

#### ESTIMATED TOTAL RESPONSE BURDEN FOR THE 2011 OTP SURVEY

	Number of respondents	Responses per respondent	Average hours per response	Total hour burden
Certified OTP Facilities—2011 Survey .....	1,200	1	.83	996

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 AND e-mail a copy to [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received within 60 days of this notice.

Dated: September 23, 2010.

**Elaine Parry,**

Director, Office of Management, Technology, and Operations.

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**BILLING CODE 4162-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-367]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506I(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 function; (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.

1. *Type of Information Collection Request:* Revision of a currently approval collection; *Title of Information Collection:* Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; *Use:* In order for payment to be made under Medicaid, the drug labeler must complete and sign a drug rebate agreement and fill in the information on the related documents. The Patient Protection and Affordable Care Act of 2010 added two new data elements to potentially be reported by manufacturers. In addition, the Food and Drug Administration has informed us that "DESI" is now obsolete; therefore, we are replacing it with a more appropriate "rebate eligibility code" that will more accurately describe how a product is eligible for coverage under the drug rebate program. *Form Number:* CMS-367 (OMB#: 0938-0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 580; *Total Annual Responses:* 9,280; *Total Annual Hours:* 137,344 (For policy questions regarding this collection contact Gail Sexton at 410-786-4583. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m.

on November 1, 2010. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: September 24, 2010.

**Michelle Shortt,**

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0488]

#### Enforcement Action Plan for Promotion and Advertising Restrictions; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Enforcement Action Plan for Promotion and Advertising Restrictions" (Enforcement Action Plan), which describes FDA's plan to enforce the restrictions on promotion and advertising of menthol and other cigarettes to youth and other requirements relating to tobacco product promotion and advertising established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). As described in the Enforcement Action Plan, FDA intends to use a multipronged approach that includes surveillance, inspections, enforcement actions, and education to enforce and facilitate compliance with these restrictions and requirements. The Enforcement Action Plan includes