

Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-7285.

Dated: September 28, 2010.

**Elaine Parry,**

*Director, Office of Management, Technology and Operations.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

#### **Project: Assessment of the Underage Drinking Prevention Education Initiatives State Videos Project—New**

The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention (CSAP) is requesting Office of Management and Budget (OMB) approval of three new data collection instruments—

- State Video Contacts Form.
- Video Viewers Form.
- Dissemination Update Online Form.

This new information collection is for the assessment of the 2010-2013 Underage Drinking Prevention Education Initiatives State Videos project. In 2007, four States participated in a pilot study to produce videos on the topic of underage drinking prevention. Based upon the success of those videos, 10 additional States and 1 Territory were provided funds to produce videos in 2009. Contingent on available funds, CSAP hopes to invite approximately 10 States/Territories per year to produce their own videos.

Over the next 4 years, CSAP will conduct a process and outcome assessment of this project. The process assessment will focus on the experiences associated with planning and producing the State videos. The

outcome assessment will examine the effectiveness of the State Videos project in meeting the core project objectives and will capture the State's dissemination efforts. The process and outcome assessments will encompass State videos that will be produced in 2010-2013 and those that were produced in 2007 and 2009. State contacts will be asked to update their dissemination information online if there have been changes in these figures during the previous 6 months, up through 2013. Additionally, data will be collected from viewers of the State videos using an online survey.

The information will be collected from the primary contact employee designated by the States that have agreed to participate in the production of a video for the State Videos project. The viewers' information will be collected from those who voluntarily decide to complete a short survey after seeing the video.

SAMHSA/CSAP intends to support annual videos on State underage drinking prevention videos. The information collected will be used by CSAP to help plan for these annual video productions and provide technical assistance to the participating States. The collected information will also provide a descriptive picture of the initiative, indicate how the videos have been received, and highlight some factors that may be associated with successful dissemination outcomes.

The information needs to be obtained using a combination of initial telephone interviews to collect process data, followed by online forms to collect outcome and dissemination data. A survey of viewers, collected online, will also be used to assess the effectiveness of the State videos in increasing awareness of the underage drinking prevention activities in these States. This information collection is being implemented under authority of Section 501(d)(4) of the Public Health Service Act (42 U.S.C. 290aa).

State staff members will be contacted once the video has been finalized. These State staff members will be asked to complete a short telephone interview that asks questions about the process of producing the State video. The State Video Contacts Form includes nine items about the State video, including:

- State's objectives for the video on underage drinking prevention.
- Targeted audiences.
- Satisfaction with technical assistance (TA) received.
- Usefulness of preplanning materials.
- Helpfulness of TA during different phases of production.

- Recommendations for improving the process.
- Recommendations for improving the content of the video.
- Advice to other States interested in producing a video.

If the State has disseminated the video at the time of the initial telephone interview, then they will also be asked to complete the second part of the State Video Contacts Form, which collects information on dissemination outcomes. The State Video Contacts Form includes 19 items about the dissemination activities of the State's video, including:

- Time when they disseminated the video.
- Methods of dissemination.
- Number of people who viewed the video.
- Number of DVDs and videotapes requested.
- Effectiveness of the dissemination methods.
- Factors that contributed to the effectiveness of dissemination.
- Effect of TA received.
- Effect of the video in raising awareness about underage drinking prevention successes in the State.
- Effect of the video in raising awareness about underage drinking prevention challenges in the State.
- Effectiveness of the video in presenting State's/Territory's prevention activities.
- Feedback received.
- Unintended positive outcomes.
- Effect of TA in improving the capacity to provide effective prevention services.

After the State points of contact have completed the State Video Contacts Form online, they will be requested to update dissemination activities online if there have been any changes during the past 6 months. This form includes seven items, including:

- If there have been changes in dissemination during the past 6 months.
- Most recent dissemination numbers by method.
- Facilitation factors.
- Additional feedback.
- Additional unintended positive outcomes.

Data will also be collected from viewers of the State videos. Each State video will include instructions to viewers on how to access the Video Viewers Form. The instructions may be a unique URL, or they may consist of instructions on each State's Web site on underage drinking prevention. This information will allow the CSAP to provide feedback to the States on their video and to measure the effectiveness of their video. The Video Viewers Form includes 24 items about the video, including:

- When and where they viewed the video.
- Whom they recommended to view the video.
- What they learned from watching the video.
- What actions they may take because of the video.
- Whether they plan to change behaviors and knowledge about their State's activities.

The process assessment of the State videos will be conducted using telephone interviews with the State points of contact. This interview should take 10 minutes (0.167 hours). The

outcome assessment of the State videos will be collected using an online form that will be completed by no more than 26 respondents and will require only 1 response per respondent. It will take an average of 10 minutes (0.167 hours) to review the instructions, complete the form, and submit it electronically.

Dissemination updates will be requested from each State point of contact every 6 months if there have been changes during that time period. These updates will be submitted electronically, and it should take approximately 5 minutes (0.083 hours) to review the instructions, complete the

short form, and submit it electronically. The burden estimate is based on comments from several potential respondents who completed the online form, submitted it, and provided feedback on how long it would take them to complete it. The respondents will be employees of the State.

A short survey will also be used to collect data from viewers of the State videos. An estimated 1,000 viewers will voluntarily choose to complete this online survey, which will take 10 minutes (0.167 hours) to review, complete, and submit. The viewers are expected to represent the general public.

| Form name                   | Number of respondents | Responses per respondent | Burden per response (hrs.) | Total burden  |
|-----------------------------|-----------------------|--------------------------|----------------------------|---------------|
| Process Interview .....     | 26                    | 1                        | 0.167                      | 4.34          |
| Dissemination Outcome ..... | 26                    | 1                        | 0.167                      | 4.34          |
| Dissemination Updates ..... | 26                    | 1                        | 0.083                      | 2.16          |
| Viewers Survey .....        | 1,000                 | 1                        | 0.167                      | 167           |
| <b>Total .....</b>          | <b>1,078</b>          | <b>.....</b>             | <b>.....</b>               | <b>177.84</b> |

Written comments and recommendations concerning the proposed information collection should be sent by November 3, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-5806.

Dated: September 28, 2010.

**Elaine Parry**

Director, Office of Management Technology and Operations.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2004-N-0451] (formerly Docket No. 2004N-0226)

**Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 025**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 025" (Recognition List Number: 025), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

**ADDRESSES:** Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 025" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by email: *standards@cdrh.fda.gov*. This

document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 025 modifications and other standards related information.

**FOR FURTHER INFORMATION CONTACT:** Carol L. Herman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993-0002, 301-796-6574.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA would implement its standard recognition