

Send comments to Summer King, SAMHSA Reports Clearance Officer, OAS, Room 7-1044, 1 Choke Cherry Road, Rockville, MD 20857. Written comments should be received by October 1, 2010.

Dated: July 27, 2010.

Elaine Parry,

Director, Office of Program Services.

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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 Town Hall Meetings on Underage Drinking Prevention—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP), is proposing a revision to the information collection regarding the Assessment of the Town Hall Meetings (THMs) on Underage Drinking (UAD) Prevention. The current data collection has approval under OMB #0930-0288, which expires on January 31, 2011. Revisions were made to the Town Hall Meeting Feedback Form, now being referred to as the Organizers Survey; the data collection method; and the number of respondents. Additionally, CSAP is adding a new data collection component titled the Participants Survey, which is the data collection instrument for the participants (or attendees) of the THM events.

Changes

Under the current approval, SAMHSA/CSAP distributes a brief Town Hall Meeting Feedback Form to all CBOs participating in THM events. This paper-and-pencil based form includes 14 items about the THM event, among which—

- Where, when, and who conducted the meeting;
- Number of attendees;

- Format of the meeting;
- Participants in the presentations;
- Actions planned;
- Media coverage;
- Composition of the audience;
- Responses of the attendees;
- Materials provided;
- Indications of increased awareness;

and

- Indications of increased involvement.

Under this revision, SAMHSA/CSAP will provide organizers of THM events with password-protected login information to access the Organizers Survey via the Internet. The Organizers Survey includes 36 items about the THM event. Listed below is a summary of the revisions that were made—

Reworded Topics/Questions

- Date of THM event.
- Location of THM event.
- Organization(s) coordinating the THM event.
- Format/Features of the THM event.
- Promotion of the THM event.
- Participants in the THM event presentations.
- Major actions planned as a result of the THM event.
- Overall satisfaction with the THM event.
- Sharing of any other important features of reactions to the THM event.
- Number/Composition of THM attendees.

Deleted Topics/Questions

- Description of meeting.
- Organization affiliation.
- Overall response of THM event attendees.
- Use of materials from the THM resource kit.
- Indications of increased awareness.
- Indications of increased involvement.

New Topics/Questions

- Indication of whether a THM event was not held and reason why the event was not held.
- Venue in which THM event was held.
- Characterization of the THM event location.
- Duration of the THM event (in hours and minutes).
- Youth involvement in the THM event.
- Topic of THM event, if other than underage drinking.
- Demographics of the participants (age, race, gender).
- Language of the THM event.
- Use of materials from the <http://www.stopalcoholabuse.gov> Web site.
- Participation in THM-related webinars.
- Viewing of online training and requests for technical assistance (TA).
- Satisfaction with training and/or TA received.
- Improved capacity to provide effective UAD services due to training and/or TA received.
- Implementation of training and/or TA recommendations.

- Indication of whether data were collected about the THM event and willingness to share those data with CSAP.

New Data Collection Component

SAMHSA/CSAP will provide organizers of THM events with a unique URL to make available to participants of their THM event. This unique URL provides access to the Participants Survey.

The Participants Survey includes 17 items about the THM event, among which—

- When and where the THM event was held;
- Estimation of the number of attendees at the THM event;
- Perception of increased awareness;
- Indication of reach of the underage drinking prevention messages from the THM event;
- Perception of increased involvement;
- Indication of the most important underage drinking issues facing the community;
- Perception of how well the THM event addressed those issues;
- Appropriateness of the THM event in terms of length and duration;
- Overall assessment of the THM event; and
- Demographics of the participants.

The Organizers Survey will be completed by an estimated 3,400 THM event organizers and will require only one response per respondent. It will take an average of 30 minutes (0.500 hours) to review the instructions and complete the survey. This burden estimate is based on comments from several potential respondents who reviewed the survey and provided comments on how long it would take them to complete it.

The Participants Survey will be completed by an estimated nine participants per THM event and will require only one response per respondent. The estimated number of participant respondents is based on 21 percent of the average of the sum of adult (66,519) and youth (53,554) participants, as reported on the 2008 THM events feedback forms (1,492 forms reported adults as participants and 1,316 forms reported youth as participants) $[(120,073/2,808 = 42.76) \times 0.21 = 8.9798]$. It will take an average of 10 minutes (0.167 hours) to review the instructions and complete the survey. This burden estimate is based on comments from several potential respondents who reviewed the survey and provided comments on how long it would take them to complete it.

Form name	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
Organizers Survey	3,400	1	0.500	1,700.00
Participants Survey	¹ 30,600	1	0.167	5,110.20
Totals	34,000	6,810.20

¹ 9 responses per THM event [3,400].

SAMHSA/CSAP intends to support THM events every other year. The information collected will be used by SAMHSA/CSAP to help plan for these biennial events, to provide technical assistance and training to organizations that sponsor the events, and to comply with the reporting requirements of the Government Performance Results Act of 1993. The information collected will also provide a descriptive picture of the nationwide initiative, and it will indicate how the THM events were received by the community and factors that may be associated with well-received events.

Written comments and recommendations concerning the proposed information collection should be sent by September 1, 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: July 20, 2010.

Elaine Parry,

Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [September 1, 2010].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0302. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Tissue Intended for Transplantation—(OMB Control Number 0910-0302)—Extension

Under section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA issued regulations under part 1270 (21 CFR part 1270) to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Section 1270.31(a) through (d) requires written procedures to be prepared and followed for the following

steps: (1) All significant steps in the infectious disease testing process under § 1270.21; (2) all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as prescribed in § 1270.21; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Section 1270.31(a) and (b) also requires recording and justification of any deviation from the written procedures. Section 1270.33(a) requires records to be maintained concurrently with the performance of each significant step in the performance of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and such records required under § 1270.21. Section 1270.33(h) requires all records to be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35(a) through (d) requires specific records to be maintained to document the following: (1) The results and interpretation of all required infectious disease tests; (2) information on the identity and relevant medical records of the donor; (3) the receipt and/or distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, FDA estimates that there are approximately 257 tissue establishments of which 145 are conventional tissue banks and 112 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,959,270 conventional tissue products and 82,741 eye tissue products recovered per year with an average of 25% of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 57,275 donors of conventional tissue and 54,115 donors of eye tissue each year.