Billing Code: 4162-20 P

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: Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence (CFE) Screening and Brief Intervention (SBI) Project and Project CHOICES Evaluation (OMB No. 0930-0302) — Reinstatement

Since 2001, SAMHSA's Center for Substance Abuse Prevention has been operating the SAMHSA Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence (CFE). The purpose of the FASD Center for Excellence is to prevent alcohol-exposed pregnancies among women of childbearing age and pregnant women and to improve the quality of life for individuals affected by FASD. Data will be collected from women served across approximately 10 sites in local/community-based agencies. Women will be screened for alcohol use, and provided appropriate interventions based on their pregnancy status.

The FASD CFE will be integrating Screening and Brief Intervention (SBI) for pregnant women

and Project CHOICES for non-pregnant women through service delivery organizations and will monitor the results. Approximately 10 sites will implement the SBI program and/or Project CHOICES.

At baseline, an assessment form will be administered by the counselor to screen women at the participating sites or health care delivery programs. Basic demographic data will be collected for all women screened (age, race/ethnicity, education, and marital status) at baseline by participating sites but no personal identification information will be transmitted to SAMHSA. Both quantity and frequency of drinking will be assessed for all women. Pregnant women will be assessed for risk of alcohol use using the TWEAK screening instrument, which has been used successfully with pregnant women. Non-pregnant women will be assessed for ability to conceive and use of effective birth control.

SBI focuses on 10- to 15-minute counseling sessions, conducted by a counselor who will use a scripted manual to guide the program. Participants in SBI will be assessed throughout their pregnancy to monitor alcohol use, referred for additional services to support their efforts to stop drinking, and will be provided with the 10–15 minute program until the client abstains from alcohol. Clients will be followed up until their 36th week of pregnancy. At each process visit, the quantity and frequency of drinking will be assessed and the client's goals for drinking will be recorded. In addition, process level variables will be assessed to understand how the program is being implemented (e.g., whether SBI was delivered; duration of the program; what referrals were made; client satisfaction). At the 36th week of pregnancy quantity and frequency of drinking will be assessed, and the client's satisfaction with the program will be recorded.

For those who screen positive for Project CHOICES (non-pregnant women 18–44 years who are at risk for an alcohol-exposed pregnancy), the program will provide two Motivational Interviewing (MI) sessions related to alcohol use, plus one contraceptive counseling session. The goal is to help these women prevent an alcohol-exposed pregnancy by abstaining from alcohol and using contraceptive methods of their choice consistently and correctly. At the end of the Project CHOICES program, women are assessed on their alcohol consumption and contraceptive use in the past 30 days, and their satisfaction with the program is recorded. At 3 months and 6 months after the end of the program, women are assessed on 30-day alcohol consumption and contraceptive use using the same core assessment form that was used at baseline.

All participating sites will maintain personally identifiable information of their clients for service delivery purposes, but the sites will keep such information private to the maximum extent allowable by laws. Data will be collected at the site level and sites will be instructed to keep personal data secure in a specified location. To further ensure privacy of individual responses, all data will be reported at the aggregate level so that individual responses cannot be identified; no data will be reported at the individual participant level. Furthermore, data will be collected to meet the criteria of a "limited data set" as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (HIPAA), (HIPAA Privacy Rule, 45 C.F.R. _ 164.501) [45 C.F.R. 164.514(e)(4)(ii)]. A computer generated coding system will be used to identify the records, and access to records will be limited only to authorized personnel. In addition, the identifiers will be stored separately from the data. No direct identifiers will be included in order for the data to be considered a "limited data set." A summary of the actions the

contractors will take in order to comply with HIPAA follows:

- Ensure that the personal health information respondents disclose to outside entities does not violate the Privacy Rule.
- When creating a unique identification code, ensure that the code does not contain information that can be used to identify the individual.
- Sign a data agreement that states all HIPAA requirements will be adhered to consistent with a limited data set.
- Agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

The data collection is designed to monitor the implementation of the proposed programs by measuring whether abstinence from alcohol is achieved, and for Project CHOICES by measuring whether effective birth control practices are performed. Furthermore, the program will include process measures to monitor how the interventions were provided.

Estimated annualized burden hours

Instrument/Activity	No. of Respondents	No. of Responses per Responden	Total No. of Responses	Average Burden per Response	Total Burden Hours per Collection
Pregnant Women (SBI)					
Baseline Assessment (Form A)	9,273	1	9,273	.25	2,318
Process Assessment for all Eligible women (Forms A and B) (26.6% of baseline)	2,468	2	4,936	.21	1,037
Process Assessment for women actively drinking (Forms A and B) (16% of 2,468 eligible women)	395	1	395	.21	83
End of Program Assessment (Forms A and C) (50% of eligible women)	1,234	1	1,234	.16	197
SBI Sub Total	**9,273**	**---**	**15,838**	**---**	**3,635**

Non-Pregnant Women (Project CHOICES)					
Baseline Assessment (Form A)	1,220	1	1,220	.25	305
End of program Assessment (Forms A and C) (50% of 629 eligible women)	314	1	314	.25	79
Follow-up Assessment (Form A) (50% of 629 eligible women)	314	2	628	.25	157
Project CHOICES Sub Total	**1,220**	**---**	**2,162**	**---**	**541**
TOTALS	**10,493**	**---**	**18,000**	**---**	**4,176**

Written comments and recommendations concerning the proposed information collection should be sent by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

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Statistician

[FR Doc. 2013-22958 Filed 09/20/2013 at 8:45 am; Publication Date: 09/23/2013]