Dated: July 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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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: 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 CFR _ 164.501) [45 CFR 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	Number of respondents	Number of responses per respondent	Total number 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

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received by September 23, 2013.

Summer King,

Statistician.

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DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: BioWatch Filter Holder Log, Filter Holder Log DHS Form 9500

AGENCY: Office of Health Affairs, DHS.

ACTION: 60-Day Notice and request for comments; Extension without change of a currently approved collection.

SUMMARY: The Department of Homeland Security, Office of Health Affairs/OCMO Early Detection Division, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until September 23, 2013. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Office of Health Affairs/OCMO Early Detection Division, DHS Attn.: Daniel Yereb, *djy1@dhs.gov* 703–647–8052.

SUPPLEMENTARY INFORMATION: Following collection, the filter samples are transported to a local Laboratory Response Network (LRN) laboratory for analysis. Should laboratory analysis determine the presence of one or more of the organisms of concern, additional analysis, collection, and response activities are conducted to determine the risk to public health, and to take appropriate public health, emergency response, and law enforcement actions.

The BioWatch Program provides funding to participating jurisdictions for the cost of collection and laboratory analysis activities, including the preparation and maintenance of required documentation. The filter holder log form is part of the documentation required by federal law enforcement for the BioWatch Program.

The filter holder log is required to create a unique record of the filter installed plus give a written chain-of-custody record tied to each collected filter sample. In the event of a positive laboratory result and subsequent determination of the presence of an organism of concern, a variety of law enforcement organizations may become engaged in the process of determining if any criminal activity has taken place. The Federal Bureau of Investigation (FBI) instructed the BioWatch Program to maintain a written record for each collected filter sample to support law enforcement activities, including criminal prosecution in the case of a deliberate release of a biological warfare agent. In addition, filter holder logs (chain-of-custody records) should be consistent nationwide for all BioWatch jurisdictions.

Written records are required to meet FBI evidentiary standards for establishing the chain of custody for any filter samples used for criminal prosecution (chain of custody is the tracking and documentation of the physical control of evidence at all stages in the collection and analysis process). The memorandum from the FBI to DHS directing the creation of written records is included in Attachment 1.

Collection of written records establishing chain of custody for samples containing biological agents and toxins for the purpose of evidence in a criminal proceeding is consistent with the ''Best Evidence Rule'', Section 1002, of the federal Rules of Evidence (Attachment 2).

The FBI requirement levied on the BioWatch Program is consistent with Section 7 of the FBI Quality Assurance Guidelines for Laboratories Performing Microbial Forensic Work, produced by the members of the Scientific Working Group on Microbial Genetics and Forensics (SWGMGF) Attachment 3. Such record keeping supports mandatory reporting requirements directed by The APHIS Interim Final Rule 7 CFR Part 331, repeated at 9 CFR