medicine practice and specific questions related to possible revision of the CLIA standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

Matters To Be Discussed: The agenda will include agency updates from the CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). Presentations and discussions will include improving laboratory quality in diverse settings, to include sites that perform waived testing as well as laboratories implementing telehealth initiatives such as digital pathology. Advancing laboratory interoperability in health information technology will also be discussed.

Agenda items are subject to change as priorities dictate.

Webcast: The meeting will also be Webcast. Persons interested in attending the in-person meeting or viewing the Webcast can access information about doing so at this URL: *http://wwwn.cdc.gov/cliac/default.aspx*

Online Registration Required: All in-person CLIAC attendees are required to register for the meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for international registrants. Register at *http://wwwn.cdc.gov/cliac/default.aspx* by scrolling down and clicking the appropriate link under ''Meeting Registration'' (either U.S. Citizen Registration or Non-U.S. Citizen Registration) and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than August 14, 2013 for U.S. registrants and August 7, 2013 for international registrants.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible. *Oral Comments:* In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date. *Written Comments:* For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting's Summary Report.

Availability of Meeting Materials: To support the green initiatives of the federal government, the CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIAC Web site on the day of the meeting for materials. Note: If using a mobile device to access the materials, please verify the device's browser is able to download the files from the CDC's Web site before the meeting. Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An internet connection, power source and limited hard copies may be available at the meeting location, but cannot be guaranteed. *http://wwwn.cdc.gov/cliac/cliac_meeting_all_documents.aspx*

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Science and Standards, Laboratory Science, Policy and Practice Program Office, Office of Surveillance, Epidemiology and Laboratory Services, CDC, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone (404) 498–2741; fax (404) 498–2210; or via email at *NAnderson@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–17868 Filed 7–24–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 10, 2013, the Agency submitted a proposed collection of information entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0312. The approval expires on July 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17835 Filed 7–24–13; 8:45 am]

BILLING CODE 4160–01–P

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.