

general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (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 For Discussion:** The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on laboratory information exchange in health information technology; and laboratory safety and quality: lessons learned through the Ebola response.

Agenda items are subject to change as priorities dictate.

**Webcast:** The meeting will also be Webcast. Persons interested in viewing the Webcast can access information at: <http://wwwn.cdc.gov/cliac/default.aspx>

**Online Registration Required:** All people attending the CLIAC meeting in-person 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/Meetings/MeetingDetails.aspx#>

Register by scrolling down and clicking the "Register for this Meeting" button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than April 8, 2015 for U.S. registrants and April 1, 2015 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 oral comments 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, speakers should 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, and 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 that the device's browser is able to download the files from the CDC's Web site before the meeting. [http://wwwn.cdc.gov/cliac/cliac\\_meeting\\_all\\_documents.aspx](http://wwwn.cdc.gov/cliac/cliac_meeting_all_documents.aspx) 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.

**Contact Person For Additional Information:** Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Programs, Standards, and Services, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, CDC, 1600 Clifton Road NE., Mailstop F-11, Atlanta, Georgia 30329-4018; telephone (404) 498-2741; or via email at [NAAnderson@cdc.gov](mailto:NAAnderson@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 CDC and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

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

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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: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase VI (OMB No. 0930-0307)—REVISION

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center of Mental Health Services is responsible for the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (Children's Mental Health Initiative—CMHI) that will collect data on child mental health outcomes, family life, and service system development. Data will be collected on nine (9) service systems, and approximately 2,106 children and families and providers/administrators, using 26 instruments. Data collection will be decreased by 26,960 hours due to program changes resulting from the closing of 19 communities funded in FY 2009 that no longer require data collection and data collection for the Sector and Comparison Study.

Data collection for this evaluation will be conducted over the next 3-year period. Child and family outcomes of interest will be collected at intake and at 6-month follow-up. The individual families will participate in the study for the remaining 12 months. The outcome measures include the following: Child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The service system data will be collected every 6 months during the remaining 3 years of the evaluation. Service utilization and cost data will be tracked and submitted to the national evaluation every 6 months using two tools—the Flex Fund Tool and the Services and Costs Data Tool—to estimate average cost of treatment per child, distribution of costs, and allocation of costs across service categories. Service delivery and system variables of interest include the

following: Maturity of system of care development in funded system of care communities, adherence to the system of care program model, and client service experience.

Internet-based technology such as data entry and management tools will be used in this evaluation. The measures of the national evaluation address annual Congressional reporting requirements of the program's authorizing legislation, and the national outcome measures for mental health programs as currently established by SAMHSA.

#### Changes

The previously approved Phase VI evaluation is composed of six core study components: (1) The System of Care Assessment that documents the development of systems of care through site visits conducted every 12–18 months; (2) the Cross-Sectional

Descriptive Study that collects descriptive data on all children and families who enter the CMHS-funded systems of care throughout the funding period; (3) the Child and Family Outcome Study that collects data longitudinally on child clinical and functional status, and family outcomes; (4) the Service Experience Study that collects data on family experience and satisfaction with services from a sample of children and families; (5) the Services and Costs Study that assesses the costs and cost-effectiveness of system of care services; and (6) the Sustainability Study, as well as and three special studies: The Alumni Networking Study, the Continuous Quality Improvement (CQI) Initiative Evaluation, and the Sector and Comparison Study. Earlier revisions eliminated one of the core studies, the Sustainability Study, and two of the special studies: The Alumni

Networking Study and the Continuous Quality Improvement (CQI) Initiative Evaluation.

This revision requests the elimination of the Sector and Comparison Study. The eliminated studies have provided data to the program and are no longer needed. The Sector and Comparison Study was conducted with a subsample of the FY 2008-funded CA awardees, which are not included in this revision.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take to complete each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

TABLE 1—ESTIMATE OF RESPONDENT BURDEN

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours
<b>System of Care Assessment</b>					
Interview Guides A–I, L–S .....	Key site informants .....	207	1	1.00	207
<b>Child and Family Outcome Study</b>					
Caregiver Information Questionnaire, Revised—Intake (CIQ–R–I).	Caregiver .....	1,099	1	0.37	407
Caregiver Information Questionnaire, Revised—Follow-Up (CIQ–R–F).	Caregiver .....	1,099	1	0.28	308
Caregiver Strain Questionnaire (CGSQ) .....	Caregiver .....	1,099	2	0.17	374
Child Behavior Checklist (CBCL)/Child Behavior Checklist 1½–5/6–18.	Caregiver .....	1,099	2	0.33	725
Education Questionnaire, Revision 2 (EQ–R2) ....	Caregiver .....	1,099	2	0.33	725
Living Situations Questionnaire (LSQ) .....	Caregiver .....	1,099	2	0.08	176
Behavioral and Emotional Rating Scale—Second Edition, Parent Rating Scale (BERS–2C).	Caregiver .....	1,781	2	0.17	606
Columbia Impairment Scale (CIS) .....	Caregiver .....	1,989	2	0.08	318
Parenting Stress Index (PSI) .....	Caregiver .....	536	2	0.08	86
Deveraux Early Childhood Assessment (DECA)	Caregiver .....	504	2	0.08	81
Preschool Behavioral and Emotional Rating Scale—Second Edition, Parent Rating Scale (PreBERS).	Caregiver .....	504	2	0.10	101
Delinquency Survey—Revised (DS–R) .....	Youth .....	1,504	2	0.13	391
Behavioral and Emotional Rating Scale—Second Edition, Youth Rating Scale (BERS–2Y).	Youth .....	1,504	2	0.17	511
GAIN Quick—R: Substance Problem Scale .....	Youth .....	1,504	2	0.08	241
Substance Use Survey, Revised (SUS–R) .....	Youth .....	1,504	2	0.10	301
Revised Children's Manifest Anxiety Scales, Second Edition (RCMAS–2).	Youth .....	1,504	2	0.07	211
Reynolds Adolescent Depression Scale, Second Edition (RAD5–2).	Youth .....	1,504	2	0.05	150
Youth Information Questionnaire, Revised—Baseline (YIQ–R–I).	Youth .....	1,504	.....	0.25	376
Youth Information Questionnaire, Revised—Follow-Up (YIQ–R–F).	Youth .....	1,504	.....	0.25	376
<b>Service Experience Study</b>					
Multi-Sector Service Contacts, Revised—Intake (MSSC–R–I).	Caregiver .....	2,257	1	0.25	564
Multi-Sector Service Contacts, Revised—Follow-Up (MSSC–R–F).	Caregiver .....	2,257	2	0.25	1,129

TABLE 1—ESTIMATE OF RESPONDENT BURDEN—Continued

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours
Cultural Competence and Service Provision Questionnaire, Revised (CCSP-R).	Caregiver .....	2,257	1	0.13	293
Youth Services Survey—Family (YSS-F) .....	Caregiver .....	2,257	1	0.12	271
Youth Services Survey (YSS) .....	Youth .....	1,504	1	0.08	120
<b>Services and Costs Study</b>					
Flex Funds Data Dictionary/Tool .....	Local programming staff compiling/entering administrative data on children/youth.	275	3	0.03	25
Services and Costs Data Dictionary/Data Entry Application.	Local evaluator, staff at partner agencies, and programming staff compiling/entering service and cost records on children/youth.	2,257	20	0.05	2,257

SUMMARY OF ANNUALIZED BURDEN ESTIMATES FOR 1 YEAR

	Number of distinct respondents	Number of responses per respondent	Total annual burden (hours)
Caregivers .....	2,257	1.5	9,059
Youth .....	1,504	1.6	2,682
Providers/Administrators .....	275	24.0	1,333
<b>Total Summary .....</b>	<b>4,036</b>	<b>27</b>	<b>13,074</b>

Written comments and recommendations concerning the proposed information collection should be sent by April 23, 2015 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 email to: *OIRA\_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, 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, DC 20503.

**Summer King,**  
Statistician.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

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**Project: Substance Abuse and Mental Health Data Archive (SAMHDA) Data Portal Applications—In Use Without Approval**

The Substance Abuse and Mental Health Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ) funded the SAMHDA contract to promote the access and use of the nation's substance abuse and mental health data on December 3rd, 1997. This includes public-use data files, file

documentation, and access to restricted-use data files to support a better understanding of this critical area of public health. As a part of the SAMHDA initiative, the Data Portal was created and launched in January of 2013. The Data Portal provides researchers that need access to restricted-use data remote access to confidential data via a virtual desktop from a secure, approved location. Completions of an application process and project approval are required for Data Portal access. The information being collected in this needs assessment will provide CBHSQ the information required to determine whether a researcher is qualified to obtain access to the Data Portal, and restricted-use data collected under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA).

Description of Forms: Applications will include 18 questions and require the submission of CV's. The application asks for information including the name of the organization that the researcher belongs to, name, title and contact information of the researcher and all subsequent researchers on the team, summaries of each applicants experience with restricted data and their CV's, descriptions of the proposed