

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report	4	1	4	5	20

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR).

Dated: July 24, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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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–NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for 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 and performance. Data will be collected on 26 service systems, and approximately 5,541 children and families.

Data collection for this evaluation will be conducted over a five-year period. Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The length of time that individual families will participate in the study ranges from 12 to 24 months depending upon when they enter the evaluation. The outcome measures include the following: Child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The core of service system data will be collected every 18–24 months throughout the 5-year evaluation period, with a sustainability survey conducted in years 3 and 5. Service utilization and cost data will be tracked and submitted to the national evaluation every six 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. We will also conduct a comprehensive evaluation of the CMHI's data driven technical assistance; this component of the evaluation will employ a mixed-methods approach, combining qualitative and quantitative data to provide a comprehensive assessment of the continuous quality improvement (CQI) process in funded system of care communities. Specifically, data will be gathered through three complementary activities: A baseline survey of key

constituents in all funded communities; a subsequent monitoring survey administered every two years to the same constituents; and biennial case studies of four selected communities.

In addition, the evaluation will include three special studies: (1) The sector specific assessment and quasi-experimental comparison study will examine in more detail the outcomes and service experience of children from multiple child-serving sectors and, through child-level matching, compare these outcomes with those not receiving system of care services; (2) The Alumni Network Study will examine the effectiveness of the system of care Alumni Network Web site by evaluating end-user satisfaction and usability of the Web site and will also assess the collaboration between communities via a Web-based Networking and Collaboration Survey that will measure the nature and extent of the interaction between communities; (3) The Study of State Strategies for Sustainability will examine the state's role in sustaining communities after federal funding ceases and describe effective strategies for sustaining funded systems of care. A short version of the sustainability survey developed for this evaluation will be used to gather this information.

Internet-based technology such as Web-based surveys and data entry and management tools will be used in this evaluation. The measures of the national evaluation address the national outcome measures for mental health programs as currently established by SAMHSA.

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.

## PHASE VI ESTIMATE OF RESPONDENT BURDEN

[Note: Total burden is annualized over a 5-year period]

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-year average annual burden hours
<b>System of Care Assessment</b>						
Interview Guide A. Core Agency Representative.	Key site informants .....	1,598	3	1.00	1,794	359
Interview Guide B. Project Director.						
Interview Guide C. Family Representative/Representative of Family/Advocacy Organizations.						
Interview Guide D. Program Evaluator.						
Interview Guide E. Intake Worker.						
Interview Guide F. Care Coordinator.						
Interview Guide G. Direct Service Delivery Staff.						
Interview Guide H. Care Review Participant.						
Interview Guide I. Caregiver of Child or Youth Served by the Program.						
Interview Guide L. Direct Service Staff from Other Public Child-Serving Agencies.						
Interview Guide M. Care Record/Chart Review.						
Interview Guide N. Other Staff.						
Interview Guide O. Debriefing Document.						
Interview Guide P. Youth Respondent.						
Interview Guide Q. Youth Coordinator.						
Interview Guide R. Cultural and Linguistic Competence Coordinator.						
Interview Guide S. Social Marketing Communications Manager.						
<b>Child and Family Outcome Study</b>						
Caregiver Information Questionnaire, Revised: Caregiver—Intake (CIQ-RC-I).	Caregiver .....	2,541	1	0.37	2,032	406
Caregiver Information Questionnaire, Revised: Staff as Caregiver—Intake (CIQ-RS-I).	Staff as Caregiver.					
Caregiver Information Questionnaire, Revised: Caregiver—Follow-Up (CIQ-RC-F).	Caregiver .....	5,541	3 <sup>4</sup>	0.28	6,280	1,256
Caregiver Information Questionnaire, Revised: Staff as Caregiver—Follow-Up (CIQ-RS-F).	Staff as Caregiver.					
Caregiver Strain Questionnaire (CGSQ).	Caregiver .....	5,541	5	0.17	4,627	925
Child Behavior Checklist 1½-5 (CBCL 1½-5).	Caregiver .....	5,541	5	0.33	9,226	1,845

## PHASE VI ESTIMATE OF RESPONDENT BURDEN—Continued

[Note: Total burden is annualized over a 5-year period]

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-year average annual burden hours
Child Behavior Checklist 6–18 (CBCL 6–18).						
Education Questionnaire, Revision 2 (EQ–R2).	Caregiver .....	5,541	5	0.33	9,226	1,845
Living Situations Questionnaire (LSQ).	Caregiver .....	5,541	5	0.08	2,300	460
Behavioral and Emotional Rating Scale—Second Edition, Parent Rating Scale (BERS–2C).	Caregiver .....	4,909	5	0.17	4,099	820
Columbia Impairment Scale (CIS).	Caregiver .....	<sup>5</sup> 5,348	5	0.08	2,219	444
Parenting Stress Index (PSI).	Caregiver .....	<sup>6</sup> 2,030	5	0.08	846	169
Devereux Early Childhood Assessment for Infants (DECA 1–18M). Devereux Early Childhood Assessment for Toddlers (DECA 18–36M). Devereux Early Childhood Assessment (DECA 2–5Y).	Caregiver .....	<sup>7</sup> 1,528	5	0.08	637	127
Preschool Behavioral and Emotional Rating (PreBERS).	Caregiver .....	1,528	5	0.10	764	153
Delinquency Survey, Revised (DS–R).	Youth .....	<sup>8</sup> 3,624	5	0.13	2,416	483
Behavioral and Emotional Rating Scale—Second Edition, Youth Rating Scale (BERS–2Y).	Youth .....	3,624	5	0.17	3,026	605
Gain Quick–R: Substance Problem Scale (GAIN).	Youth .....	3,624	5	0.08	1,504	301
Substance Use Survey, Revised (SUS–R).	Youth .....	3,624	5	0.10	1,812	362
Revised Children’s Manifest Anxiety Scales (RCMAS).	Youth .....	3,624	5	0.05	906	181
Reynolds Adolescent Depression Scale—Second Edition (RADS–2).	Youth .....	3,624	5	0.05	906	181
Youth Information Questionnaire, Revised—Intake (YIQ–R–I).	Youth .....	3,624	1	0.25	906	181
Youth Information Questionnaire, Revised—Follow-Up (YIQ–R–F).	Youth .....	3,624	4	0.25	3,624	725
<b>Service Experience Study</b>						
Multi-Sector Service Contacts, Revised: Caregiver—Intake (MSSC–RC–I).	Caregiver .....	5,541	1	0.25	1,385	277

## PHASE VI ESTIMATE OF RESPONDENT BURDEN—Continued

[Note: Total burden is annualized over a 5-year period]

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-year average annual burden hours
Multi-Sector Service Contacts, Revised: Staff as Caregiver—Intake (MSSC-RS-I).	Staff as Caregiver.					
Multi-Sector Service Contacts, Revised: Caregiver—Follow-Up (MSSC-RC-F).	Caregiver .....	5,541	4	0.25	5,541	1,108
Multi-Sector Service Contacts, Revised: Staff as Caregiver—Follow-Up (MSSC-RS-F).	Staff as Caregiver.					
Cultural Competence and Service Provision Questionnaire, Revised (CCSP-R).	Caregiver .....	5,541	<sup>9</sup> 4	0.13	2,955	591
Youth Services Survey for Families (YSS-F).	Caregiver .....	5,541	4	0.12	2,593	519
Youth Services Survey (YSS).	Youth .....	3,624	4	0.08	1,203	241
<b>Comparison and Sector Study: Juvenile Justice</b>						
Court Representative Questionnaire (CRQ).	Court representatives .....	<sup>10</sup> 212	5	0.50	530	106
Electronic Data Transfer of Juvenile Justice Records.	Key site personnel .....	212	5	0.03	35	7
<b>Comparison and Sector Study: Education</b>						
Teacher Questionnaire (TQ)	Teacher .....	212	5	0.50	530	106
School Administrator Questionnaire (SAQ).	School administrators .....	212	5	0.50	530	106
Electronic Data Transfer of Education Records.	Key site personnel .....	212	5	0.03	35	7
<b>Comparison and Sector Study: Child Welfare</b>						
Child Welfare Sector Study Questionnaire—Intake (CWSQ-I).	Care coordinators .....	212	1	0.50	106	21
Child Welfare Sector Study Questionnaire—Follow-Up (CWSQ-F).	Care coordinators .....	212	4	0.50	424	85
Electronic Data Transfer of Child Welfare Records.	Key site personnel .....	212	5	0.03	35	7
<b>Sustainability Study</b>						
Sustainability Survey: Brief Form.	Project Director .....	79	2	0.17	26	5
Sustainability Survey .....	Providers <sup>11</sup> .....	126	2	0.75	189	38
	Caregiver <sup>11</sup> .....	42	2	0.75	63	13

## PHASE VI ESTIMATE OF RESPONDENT BURDEN—Continued

[Note: Total burden is annualized over a 5-year period]

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-year average annual burden hours
<b>CQI Initiative Evaluation</b>						
CQI Baseline Survey, Web-Based.	Key site personnel .....	208	1	0.50	104	21
CQI Monitoring Survey, Web-Based.	Key site personnel .....	208	2	0.50	208	42
CQI Local Focus Group Guide.	Key site personnel .....	30	2	1.00	60	12
CQI National Focus Group Guide.	National TA providers .....	20	2	1.00	40	8
<b>Alumni Networking Study</b>						
Networking and Collaboration Survey.	Key site personnel .....	248	2	0.50	248	50
Alumni Network Web Site Satisfaction Survey.	Key site personnel, National TA providers, Branch staff.	458	2	0.25	229	46
<b>Services and Costs Study</b>						
Flex Funds Data Dictionary/ Tool.	Local programming staff compiling/entering administrative data on children/youth.	<sup>12</sup> 1,306	<sup>13</sup> 3	0.03	129	26
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.	5,541	<sup>14</sup> 100	0.05	27,705	5,541
<b>Summary of Annualized Burden Estimates for 5 Years</b>						
	Number of distinct respondents	Number of responses per respondent	Average 5-year burden per response (hours)	Total annual burden (hours)		
Caregivers .....	5,541	0.9	2.2	10,959		
Youth .....	3,624	0.9	1.0	3,261		
Providers/Administrators .....	598	10.8	1.0	6,593		
Total Summary .....	9,763	13	.....	20,812		

<sup>1</sup> An average of 23 stakeholders in up to 26 grant communities will complete the System of Care Assessment interview. These stakeholders will include site administrative staff, providers, agency representatives, family representatives, and youth.

<sup>2</sup> Number of respondents across 26 grantees (5223), in addition to 318 children/families from the comparison sample. Average based on a 5 percent attrition rate at each data collection point.

<sup>3</sup> Number of responses per respondent is five over the course of the study (once every 6 months for 24 months, with one baseline/intake response, and 4 follow-up responses).

<sup>4</sup> Approximate number of caregivers with children over age 5, based on Phase IV data submitted as of 12/08. Also includes 318 children/families from the comparison sample.

<sup>5</sup> Approximate number of caregivers with children 3 and older, based on Phase IV data submitted as of 12/08. Also includes 318 children/families from the comparison sample.

<sup>6</sup> Approximate number of caregivers with either: (1) children served at the roughly 7 early childhood-focused communities, for whom the instrument is required; or (2) children aged 0 to 12 at other communities, where the instrument is optional (we estimate that 1/3 of caregivers will be administered the instrument when it is optional). Estimates are based on Phase IV data submitted as of 12/08.

<sup>7</sup> Approximate number of caregivers with either: (1) children served at the roughly 7 early childhood-focused communities, for whom the instrument is required; or (2) children aged 0 to 5 at other communities, where the instrument is optional (we estimate that 1/3 of caregivers will be administered the instrument when it is optional). Estimates are based on Phase IV data submitted as of 12/08.

<sup>8</sup> Based on Phase IV finding that approximately 63 percent of the children in the evaluation were 11 years old or older. Also includes 318 children/families from the comparison sample.

<sup>9</sup> With the exception of the MSSC-R, respondents only complete Service Experience Study measures at follow-up points. See Footnote #3 for the explanation about the average number of responses per respondent.

<sup>10</sup> Approximate number of children/families in each sector, for the Sector and Comparison Study. This includes cases within the communities, as well as within the comparison sample.

<sup>11</sup> For each community, 1 respondent will be a caregiver and 3 respondents will be administrators/providers.

<sup>12</sup> Assumes that each community will use flexible funds expenditures on average for approximately one quarter of the children/youth enrolled.

<sup>13</sup> Assumes that three expenditures, on average, will be spent on each child/youth receiving flexible fund benefits.

<sup>14</sup> Assumes that each child/youth in system of care communities and in the comparison sample will have 100 service episodes, on average.

Written comments and recommendations concerning the proposed information collection should be sent by August 28, 2009 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: 202-395-6974.

Dated: July 27, 2009.

**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**

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**Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase V (OMB No. 0930-0280)—Revision**

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) is responsible for the

National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program, which collects data on child mental health outcomes, family life, and service system development and performance. Data will be collected on 30 service systems and roughly 8,810 children and families.

The data collection for this evaluation will be conducted for a 3-year period. The core of service system data will be collected twice (every 18 to 24 months) during the 3-year evaluation period. A sustainability survey will be conducted in selected years. Service delivery and system variables of interest include the following: Maturity of system of care development; adherence to the system of care program model; services received by youth and their families, and the costs of those services; and consumer service experience.

The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation. Child and family outcomes of interest will be collected at intake and during subsequent follow-up interviews at six-month intervals. Client service experience information is collected at these follow-up interviews. Measures included in an outcome interview are determined by the type of assessment (intake or follow-up), child's age, and whether the respondent is the caregiver or a youth.

The outcome measures include the following: Child symptomatology and functioning, family functioning, material resources, and caregiver strain. The caregiver interview package includes the Caregiver Information Questionnaire, Child Behavior Checklist, Behavioral and Emotional Rating Scale (BERS), Education Questionnaire, Columbia Impairment Questionnaire, Living Situations

Questionnaire, Family Life Questionnaire, and Caregiver Strain Questionnaire at intake, and also includes the Multi-service Sector Contacts Form, Cultural Competence and Service Provision Questionnaire and the Youth Services Survey (a national outcome measurement tool) at follow-up assessments. Caregivers of children under age 6 complete the Vineland Screener to assess development, and do not complete the BERS. The Youth Interview package includes the Youth Information Questionnaire, Revised Children's Manifest Anxiety Scale, Reynolds Depression Scale, BERS (youth version), Delinquency Survey, Substance Use Survey, GAIN-Quick: Substance Dependence Scale, and Youth Services Survey (youth version).

The evaluation also includes three special studies: (1) An evidence-based practices study that examines the effects of various factors on the implementation and use of evidence-based treatments and approaches in system of care communities; (2) A cultural and linguistic competence study that examines the extent to which the cultural and linguistic characteristics of communities influence program implementation and provider adaptation of evidence-based treatments, and provider service delivery decisions based on provider culture and language; and (3) an evaluation of the communities' use of reports produced by the national evaluation for continuous quality improvement. The national evaluation measures address the national outcome measures for mental health programs as currently established by SAMHSA.

Table 1 summarizes which national evaluation components are unchanged from the original 2006 submission and which are new or changed.

TABLE 1—STUDY COMPONENT AND INSTRUMENT REVISIONS FOR PHASE V RE-SUBMISSION

	New or changed for 2009 resubmission	No change	Nature of change
<b>System of Care Assessment</b>			
Site Visit Tables .....	.....	X	
Interview Protocols .....	.....	X	
Inter-Agency Collaboration Scale (IACS) .....	.....	X	