

approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Persons unable to download an electronic copy of "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1825 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: September 26, 2014.

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: 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: Common Data Platform (CDP)—NEW

The Common Data Platform (CDP) includes new instruments for the Substance Abuse and Mental Health Services Administration (SAMHSA). The CDP will replace separate data collection instruments used for reporting Government Performance and Results Act of 1993 (GPRA) measures: The Transformation Accountability (TRAC) Reporting System (OMB No. 0930–0285) used by the Center for Mental Health Services (CMHS); the Prevention Management Reporting and Training System (PMRTS—OMB No. 0930–0279) used by the Center for Substance Abuse Prevention (CSAP); and the Services Accountability and Improvement System (SAIS—OMB No. 0930–0208) used by the Center for Substance Abuse Treatment (CSAT).

The CDP will also include two grantee-level data collection forms approved by consensus of offices and Centers within SAMHSA as well as the Department of Health and Human Services (HHS): the Infrastructure, Prevention, and Mental Health Promotion (IPP) Form used by a subset of CMHS grantees and the Aggregate Tool used by CSAT's Addiction Technology Transfer Center (ATCC) grantees.

Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRAMA) reporting requirements and analyses of the data will help SAMHSA determine whether progress is being made in achieving its

mission. The primary purpose of this data collection system is to promote the use of common data elements among SAMHSA grantees and contractors. The common elements were recommended by consensus among SAMHSA Centers and Offices. Analyses of these data will allow SAMHSA to quantify effects and accomplishments of its discretionary grant programs which are consistent with the OMB-approved GPRA measures and address goals and objectives outlined in the Office of National Drug Control Policy's Performance Measures of Effectiveness and the SAMHSA Strategic Initiatives.

The CDP will be a real-time, performance management system that captures information on substance abuse treatment and prevention and mental health services delivered in the United States. A wide range of client and program information will be captured through CDP for approximately 3,000 grants (2,224 for CMHS; 642 for CSAT; 122 for CSAP; and 33 for HIV Continuum of Care). Substance abuse treatment facilities, mental health service providers, and substance abuse prevention programs will submit their data in real-time or on a monthly or a weekly basis to ensure that the CDP is an accurate, up-to-date reflection on the scope of services delivered and characteristics of the clients.

In order to carry out section 1105(a) (29) of GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity. This plan must:

- Establish performance goals to define the level of performance to be achieved by a program activity;
- Express such goals in an objective, quantifiable, and measurable form;
- Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;
- Provide a basis for comparing actual program results with the established performance goals; and
- Describe the means to be used to verify and validate measured values.

This CDP data collection supports the GPRAMA, which requires overall organization management to improve agency performance and achieve the mission and goals of the agency through the use of strategic and performance planning, measurement, analysis, regular assessment of progress, and use of performance information to improve the results achieved. Specifically, this

data collection will allow SAMHSA to have the capacity to report on a consistent set of performance measures across its various grant programs that conduct each of these activities.

SAMHSA's legislative mandate is to increase access to high quality substance abuse and mental health prevention and treatment services and to improve outcomes. Its mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA's vision is to provide leadership and devote its resources—programs, policies, information and data, contracts and grants—toward helping the Nation act on the knowledge that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

In order to improve the lives of people within communities, SAMHSA has many roles:

- Providing Leadership and Voice by developing policies; convening stakeholders; collaborating with people in recovery and their families, providers, localities, Tribes, Territories, and States; collecting best practices and developing expertise around behavioral health services; advocating for the needs of persons with mental and substance use disorders; and emphasizing the importance of behavioral health in partnership with other agencies, systems, and the public.

- Promoting change through Funding and Service Capacity Development. Supporting States, Territories, and Tribes to build and improve basic and proven practices and system capacity; helping local governments, providers, communities, coalitions, schools, universities, and peer-run and other organizations to innovate and address emerging issues; building capacity across grantees; and strengthening States', Territories', Tribes', and communities' emergency response to disasters.

- Supporting the field with Information/Communications by conducting and sharing information from national surveys and surveillance (e.g., National Survey on Drug Use and Health [NSDUH], Drug Abuse Warning Network [DAWN], Behavioral Health Service Information System [BHSIS]); vetting and sharing information about evidence-based practices (e.g., National Registry of Evidence-based Programs and Practices [NREPP]); using the Web, print, social media, public appearances, and the press to reach the public, providers (e.g., primary, specialty,

guilds, peers), and other stakeholders; and listening to and reflecting the voices of people in recovery and their families.

- Protecting and promoting behavioral health through Regulation and Standard Setting by preventing tobacco sales to minors (Synar Program); administering Federal drug-free workplace and drug-testing programs; overseeing opioid treatment programs and accreditation bodies; informing physicians' office-based opioid treatment prescribing practices; and partnering with other HHS agencies in regulation development and review.

- Improving Practice (i.e., community-based, primary care, and specialty care) by holding State, Territorial, and Tribal policy academies; providing technical assistance to States, Territories, Tribes, communities, grantees, providers, practitioners, and stakeholders; convening conferences to disseminate practice information and facilitate communication; providing guidance to the field; developing and disseminating evidence-based practices and successful frameworks for service provision; supporting innovation in evaluation and services research; moving innovations and evidence-based approaches to scale; and cooperating with international partners to identify promising approaches to supporting behavioral health.

Each of these roles complements SAMHSA's legislative mandate. All of SAMHSA's programs and activities are geared toward the achievement of its mission, and performance monitoring is a collaborative and cooperative aspect of this process. SAMHSA will strive to coordinate its efforts to further its mission with ongoing performance measurement development activities.

Reports, to be made available on the SAMHSA Web site and by request, will inform staff on the grantees' ability to serve their target populations and meet their client and budget targets. SAMHSA CDP data will also provide grantees with information that can guide modifications to their service array. Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

Based on current funding and planned fiscal year 2015 notice of funding announcements (NOFA), SAMHSA programs will use these measures in fiscal years 2015 through 2017.

CSAP will use CDP measures for the HIV Minority AIDS Initiative (MAI),

Strategic Prevention Framework State Incentive Grants (SPF SIG), and Partnerships for Success (PFS).

CMHS will use the CDP measures to collect client-level data for the following programs: Comprehensive Community Mental Health Services for Children and their Families (CMHI); Healthy Transitions (HT); National Child Traumatic Stress Initiative (NCTSI) Community Treatment Centers; Mental Health Transformation State Incentive Grants (MH SIG); Minority AIDS/HIV Services Collaborative Program; Primary and Behavioral Health Care Integration (PBHCI); Services in Supportive Housing (SSH); Systems of Care (SoC); and Transforming Lives Through Supportive Employment. In addition, grantees in the PBHCI program will complete an additional data collection tool that is specific to their program.

CMHS programs that will use the CDP to collect grantee-level IPP indicators include: Advancing Wellness and Resiliency in Education (Project AWARE); Circles of Care; Comprehensive Community Mental Health Services for Children and their Families (CMHI); Garrett Lee Smith Campus Suicide Prevention Program; Garrett Lee Smith State/Tribal Suicide Prevention Program; Healthy Transitions Program; Linking Actions for Unmet Needs in Children's Mental Health (LAUNCH); National Suicide Prevention Lifeline; NCTSI Treatment and Service Centers; NCTSI Community Treatment Centers; NCTSI National Coordinating Center; Mental Health Transformation Grant Program; Minority AIDS/HIV Services Collaborative Program; Minority Fellowship Program; PBHCI; Safe Schools/Healthy Students; Services in Supportive Housing; State Mental Health Data Infrastructure Grants for Quality Improvement; Statewide Consumer Network Grants; Statewide Family Network Grants; Suicide Lifeline Crisis Center Follow Up; Systems of Care; Transforming Lives Through Supported Employment; Native Connections; Now is the Time: Minority Fellowship Program- Youth; Cooperative Agreements to Implement the National Strategy for Suicide Prevention, Historically Black Colleges and Universities Center for Excellence in Behavioral Health; and Statewide Peer Networks for Recovery and Resilience.

CSAT will use the CDP measures with the following programs: Assertive Adolescent and Family Treatment (AAFT); Access to Recovery 3 (ATR3); Adult Treatment Court Collaboratives (ATCC); Enhancing Adult Drug Court Services, Coordination and Treatment (EADCS); Offender Reentry Program

(ORP); Treatment Drug Court (TDC); Office of Juvenile Justice and Delinquency Prevention—Juvenile Drug Courts (OJJDP–JDC); Teen Court Program (TCP); HIV/AIDS Outreach Program; Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services (TCE–HIV); Addictions Treatment for the Homeless (AT–HM); Cooperative Agreements to Benefit Homeless Individuals (CABHI); Cooperative Agreements to Benefit Homeless Individuals—States (CABHI–States); Recovery-Oriented Systems of Care (ROSC); Targeted Capacity Expansion- Peer to Peer (TCE–PTP); Pregnant and Postpartum Women (PPW); Screening, Brief Intervention and Referral to Treatment (SBIRT); Targeted Capacity Expansion (TCE); Targeted Capacity Expansion- Health Information Technology (TCE–HIT);

Targeted Capacity Expansion Technology Assisted Care (TCE–TAC); Addiction Technology Transfer Centers (ATTC); International Addiction Technology Transfer Centers (I–ATTC); State Adolescent Treatment Enhancement and Dissemination (SAT–ED); Grants to Expand Substance Abuse Treatment Capacity in Adult Tribal Healing to Wellness Courts and Juvenile Drug Courts; and Grants for the Benefit of Homeless Individuals—Services in Supportive Housing (GBHI).

SAMHSA will also use the CDP to collect CMHS client-level measures and IPP information from the HIV Continuum of Care program, which is funded by CSAP, CMHS, and CSAT.

SAMHSA uses performance measures to report on the performance of its discretionary services grant programs. The performance measures are used by

individuals at three different levels: the SAMHSA administrator and staff, the Center administrators and government project officers, and grantees.

SAMHSA and its Centers will use the data for annual reporting required by GPRA, for grantee performance monitoring, for SAMHSA reports and presentations, and for analyses comparing baseline with discharge and follow-up data. GPRA requires that SAMHSA’s report for each fiscal year include actual results of performance monitoring. The information collected through the CDP will allow SAMHSA to report on the results of these performance outcomes. Reporting will be consistent with specific SAMHSA performance domains to assess the accountability and performance of its discretionary grant programs.

ESTIMATES OF ANNUALIZED HOUR BURDEN—COMMON DATA PLATFORM CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS

SAMHSA program title	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours
HIV Continuum of Care (CSAP, CMHS, CSAT funding)—specific Form	200	2	400	0.67	268

Client-Level Services Forms

CSAP:					
HIV-Minority AIDS Initiative (MAI)	18,041	4	72,164	0.38	27,422
SPF SIG/Community Level	122	4	488	0.38	185
SPF SIG/Program Level	510	4	2,040	0.38	775
PFS/Community Level	550	4	2,200	0.38	836
PFS/Program Level	111	4	444	0.38	169
CMHS:					
Comprehensive Community Mental Health Services for Children and their Families Program (CMHI)	3,431	2	6,862	0.45	3,088
HIV Continuum of Care (CoC)	1,500	2	3,000	0.45	1,350
Healthy Transitions (HT)	1,600	2	3,200	0.45	1,440
NCTSI Community Treatment Centers (NCTSI)	1,856	1	1,856	0.45	835
Mental Health Transformation State Incentive Grant (MH SIG)	2,975	1	2,975	0.45	1,339
Minority AIDS/HIV Services Collaborative Program	2,844	2	5,688	0.45	2,560
Primary and Behavioral Health Care Integration (PBHCI)	14,000	2	28,000	0.50	14,000
Services in Supportive Housing (SSH)	4,975	2	9,950	0.45	4,478
Systems of Care (SoC)	1,164	1	1,164	0.45	524
Transforming Lives Through Supported Employment ..	1,500	2	3,000	0.45	1,350
CSAT:					
Assertive Adolescent and Family Treatment (AAFT) ...	303	3	909	0.47	427
Access to Recovery 3 (ATR3)	239,186	1	239,186	0.47	112,417
Adult Treatment Court Collaboratives (ATCC)	1,078	3	3,234	0.47	1,520
Enhancing Adult Drug Court Services, Coordination, and Treatment (EADCS CT)	4,664	3	13,992	0.47	6,576
Offender Reentry Program (ORP)	1,843	3	5,529	0.47	2,599
Treatment Drug Court (TDC)	5,996	3	17,988	0.47	8,454
Office of Juvenile Justice and Delinquency Prevention—Juvenile Drug Courts (OJJDP–JDC)	392	3	1,176	0.47	553
Teen Court Program (TCP)	5,996	3	17,988	0.47	8,454
HIV/AIDS Outreach Program (HIV-Outreach)	4,352	3	13,056	0.47	6,136
Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services (TCE–HIV)	4,885	3	14,655	0.47	6,888
Addictions Treatment for Homeless (AT–HM)	10,636	3	31,908	0.47	14,997
Cooperative Agreements to Benefit Homeless Individuals (CABHI)	2,702	3	8,106	0.47	3,810

ESTIMATES OF ANNUALIZED HOUR BURDEN—COMMON DATA PLATFORM CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS—Continued

SAMHSA program title	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours
Cooperative Agreements to Benefit Homeless Individuals—States (CABHI-States)	142	3	426	0.47	200
Recovery-Oriented Systems of Care (ROSC)	846	3	2,538	0.47	1,193
Targeted Capacity Expansion—Peer to Peer (TCE-PTP)	827	3	2,481	0.47	1,166
Pregnant and Postpartum Women (PPW)	1,719	3	5,157	0.47	2,424
Screening Brief Intervention Referral and Treatment* (SBIRT)	59,419	3	178,257	0.47	83,781
Targeted Capacity Expansion—Health Information Technology (TCE-HIT)	5,295	3	15,885	0.47	7,466
Targeted Capacity Expansion Technology Assisted Care (TCE-TAC)	346	3	1,038	0.47	488
Addiction Technology Transfer Centers (ATTC)	32,676	3	98,028	0.47	46,073
International Addiction Technology Transfer Centers (I-ATTC)	1,789	3	5,367	0.47	2,522
State Adolescent Treatment Enhancement and Dissemination (SAT-ED)	925	3	2,775	0.47	1,304
Grants to Expand Substance Abuse Treatment Capacity In Adult Tribal Healing to Wellness Courts and Juvenile Drug Courts	240	3	720	0.47	338
Grants for the Benefit of Homeless Individuals-Services in Supportive Housing (GBHI)	1,960	3	5,880	0.47	2,764
Total Services—Client Level Instruments	443,596	829,710	383,169
CMHS Infrastructure, Prevention, and Mental Health Promotion (IPP) Form:					
Project AWARE	120	4	480	2	960
Circles of Care	11	4	44	2	88
Comprehensive Community Mental Health Services for Children and their Families Program (CMHI)	69	4	276	2	552
Garrett Lee Smith Campus Suicide Prevention Grant Program	123	4	492	2	984
HIV Continuum of Care	33	4	132	2	264
Garrett Lee Smith State/Tribal Suicide Prevention Grant Program	102	4	408	2	816
Healthy Transitions (HT)	16	4	64	2	128
Historically Black Colleges and Universities Center for Excellence in Behavioral Health	1	4	4	2	8
Linking Actions for Unmet Needs in Children's Mental Health (LAUNCH)	54	4	216	2	432
National Suicide Prevention Lifeline	2	4	8	2	16
NCTSI Treatment & Service Centers	32	4	128	2	256
NCTSI Community Treatment Centers	81	4	324	2	648
NCTSI National Coordinating Center	2	4	8	2	16
Mental Health Transformation Grant	30	4	120	2	240
Minority AIDS/HIV Services Collaborative Program	17	4	68	2	136
Minority Fellowship Program	9	4	36	2	72
Primary and Behavioral Health Care Integration	70	4	280	2	560
Safe Schools/Healthy Students Initiative	7	4	28	2	56
Services in Supportive Housing	5	4	20	2	40
State Mental Health Data Infrastructure Grants for Quality Improvement	2	4	8	2	16
Statewide Consumer Network Grants	42	4	168	2	336
Statewide Family Network Grants	53	4	212	2	424
Suicide Lifeline Crisis Center FUP Grants	27	4	108	2	216
Systems of Care	31	4	124	2	248
Transforming Lives Through Supported Employment ..	6	4	24	2	48
Native Connections	20	4	80	2	160
Now Is the Time: Minority Fellowship Program-Youth ..	5	4	20	2	40
Cooperative Agreements to Implement the National Strategy for Suicide Prevention	4	4	16	2	32
Statewide Peer Networks for Recovery and Resiliency ..	8	4	32	2	64
Total IPP	982	3,928	7,856
CSAP Aggregate Tool:					
Adult Treatment Court Collaborative (ATCC)	6	4	24	.25	6

ESTIMATES OF ANNUALIZED HOUR BURDEN—COMMON DATA PLATFORM CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS—Continued

SAMHSA program title	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours
Total SAMHSA	444,584	833,662	389,901

Notes:

1. Screening, Brief Intervention, Treatment and Referral (SBIRT) grant program: The estimated number of respondents is 10% of the total respondents, 742,740.
2. Numbers may not add to the totals due to rounding.

Written comments and recommendations concerning the proposed information collection should be sent by November 3, 2014 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

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: National System of Care Expansion Evaluation—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) is requesting approval from the Office of Management and Budget (OMB) for the new collection of data for the National System of Care (SOC) Expansion Evaluation.

Evaluation Plan and Data Collection Activities. The purpose of the National SOC Expansion Evaluation is to assess the success of the SOC expansion planning and implementation grants in expanding the reach of SOC values, principles, and practices. These include maximizing system-level coordination and planning, offering a comprehensive array of services, and prioritizing family and youth involvement. In order to obtain a clear picture of SOC expansion grant activities, this longitudinal, multi-level evaluation will measure activities and performance of grantees at three levels essential to building and sustaining effective SOC. The three levels are: jurisdiction, local system, and child and family levels.

Data collection activities will occur through four evaluation components. Each component includes data collection activities and analyses involving similar topics. Each component has multiple instruments that will be used to address various aspects. Thus, there are a total of eight new instruments that will be used to conduct this evaluation. All four evaluation components involve collecting data from implementation grantees, but only the Implementation

assessment includes data collection from planning grantees as well.

The four studies with their corresponding data collection activities are as follows:

(1) The Implementation assessment will document the development and expansion of SOC. Data collection activities include: (a) Stakeholder Interviews with high-level administrators, youth and family representatives, and child agencies to describe the early implementation and expansion efforts of planning and implementation grants, (b) the web-based Self-Assessment of Implementation Survey to assess SOC implementation and expansion at the jurisdictional level over time, and (c) the SOC Expansion Assessment (SOCEA) administered to local providers, managers, clients, and their caregivers to measure SOC expansion strategies and processes implemented related to direct service delivery at the local system level. Implementation grantees will participate in all three of the Implementation assessment data collection activities. Planning grantee participation will be limited to the Stakeholder Interview and the Self-Assessment of Implementation Survey.

(2) The Network Analysis will use Network Analysis Surveys to determine the depth and breadth of the SOC collaboration across agencies and organization. Separate network analysis surveys will be administered at the jurisdiction and local service system levels. The Geographic Information System (GIS) Component will measure the geographic coverage and spread of the SOC, including reaching underserved areas and populations. At the jurisdictional and local service system levels, the GIS component will use office and business addresses of attendees to key planning, implementation and expansion events. At the child/youth and family level, Census block groups (derived from home addresses) will be used to depict the geographic spread of populations served by SOC.