

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>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 12, 2012.

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: Transformation Accountability Reporting System—(OMB No. 0930-0285)—Extension

The Transformation Accountability (TRAC) Reporting System is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through TRAC for approximately 700 grantees. This request includes an extension of the currently approved data collection effort.

This information collection will allow SAMHSA to continue to meet the Government Performance and Results Act (GPRA) of 1993 reporting requirements that quantify the effects and accomplishments of its programs, which are consistent with OMB guidance. 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.

In addition, this data collection supports the GPRA Modernization Act of 2010 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 CMHS 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 improve the quality and availability of treatment and prevention services for substance abuse and mental illness. To support this mission, the Agency's overarching goals are:

- **Accountability**—Establish systems to ensure program performance measurement and accountability
- **Capacity**—Build, maintain, and enhance mental health and substance abuse infrastructure and capacity
- **Effectiveness**—Enable all communities and providers to deliver effective services

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

The total annual burden estimate is shown below:

ESTIMATES OF ANNUALIZED HOUR BURDEN—CMHS CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage cost	Total hour cost
Client-level baseline interview	15,681	1	15,681	0.48	7,527	1 \$15	\$112,903
Client-level 6-month reassessment interview	10,637	1	10,637	0.367	3,904	15	58,557
Client-level discharge interview ²	4,508	1	4,508	0.367	1,776	15	26,644
Client-level baseline chart abstraction ³	2,352	1	2,352	0.1	235	15	3,528
Client-level reassessment chart abstraction ⁴	8,703	1	8,703	0.1	870	15	13,055
Client-level discharge chart abstraction ⁵	8,241	1	8,241	0.1	824	15	12,362

ESTIMATES OF ANNUALIZED HOUR BURDEN—CMHS CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS—
Continued

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage cost	Total hour cost
Client-level Subtotal ⁶	15,137	15	227,048
Infrastructure development, prevention, and mental health promotion quarterly record abstraction	942	4	3,768	4	15,072	⁷ 35	527,520
Total	16,623	29,298	885,135

¹ Based on minimum wage.

² Based on an estimate that 35 percent will leave the program annually, and it will be possible to conduct discharge interviews on 40 percent of those who leave the program.

³ Based on 13 percent non-response for those eligible at baseline (18,033); baselines are required for all consumers served or an admin baseline for non-responders.

⁴ Based on 40 percent non-response for those eligible for six-month reassessment.

⁵ Based on 60 percent non-response for those discharged.

⁶ This is the maximum burden if all consumers complete the baseline and periodic reassessment interviews.

⁷ To be completed by grantee Project Directors, hence the higher hourly wage.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2-1057, One Choke Cherry Road, Rockville, MD 20857 or email a copy to summer.king@samhsa.hhs.gov. Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Summer King,
Statistician.

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Proposed Project: Services Accountability Improvement System—(OMB No. 0930-0208)—Extension

This is an extension to the previously OMB approved instrument. The Services Accountability Improvement System (SAIS), which is a real-time, performance management system that captures information on the substance

abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through SAIS for approximately 600 grantees. Substance abuse treatment facilities submit their data on a monthly and even a weekly basis to ensure that SAIS is an accurate, up-to-date reflection on the scope of services delivered and characteristics of the treatment population. Over 30 reports on grantee performance are readily available on the SAIS Web site. The reports inform staff on the grantees' ability to serve their target populations and meet their client and budget targets. SAIS data allow grantees information that can guide modifications to their service array. Continued 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.

Note that there are no changes to the instrument or the burden hours from the previous OMB submission.

ESTIMATES OF ANNUALIZED HOUR BURDEN ¹—CSAT GPRA CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS

Center/Form/Respondent type	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Added burden proportion ²
Clients						
Adolescents	3,900	4	15,600	.5	7,800	.34
Adults						
General (non ATR or SBIRT)	28,000	3	84,000	.5	42,000	.34
ATR	53,333	3	159,999	.5	80,000	.34