Substance Abuse and Mental Health Administration
Primary and Behavioral Health Care Integration Grant Program
OMB Supporting Statement

A. Justification

1. Circumstance for Information Collection

The Substance Abuse and Mental Health Services Administration/Center for Mental Health Services (SAMHSA/CMHS) is requesting a revision from the Office of Management and Budget (OMB) for data collection activities associated with the Primary and Behavioral Health Care Integration (PBHCI) grant program. Specifically, SAMHSA is requesting approval to only collect information on physical health indicators through a supplemental module to the TRansforming ACcountability (TRAC) System and grantee quarterly reports. This data collection has been transferred from HHS/ASPE to SAMHSA. The current data collection (OMB No. 0930-0340) expires on September 30, 2014.

SAMHSA launched the PBHCI program in FY 2009 with the understanding that adults with serious mental illness (SMI) experience heightened rates of morbidity and mortality, in large part due to elevated incidence and prevalence of risk factors such as obesity, diabetes, hypertension, and dyslipidemia. These risk factors are influenced by a variety of factors, including inadequate physical activity and poor nutrition; smoking; side effects from atypical antipsychotic medications; and lack of access to health care services. Many of these health conditions are preventable through routine health promotion activities, primary care screening, monitoring, treatment and care management /coordination strategies and/or other outreach programs. Much of the national effort towards achieving the triple aim of improved health, enhanced care, and reduced costs are associated with developing person-centered systems of care that address an individual's holistic health.

Collection of the information included in this request is authorized by Section 505 of the Public Health Service Act (42 USC 290aa-4) – Data Collection. Authorization for the PBHCI program is provided under Section 5604 of H.R. 3590, the Affordable Care Act (ACA), which authorizes SAMHSA to provide awards for the co-location of primary and specialty care in community-based mental health settings.

2. Purpose and Use of Information

The purpose of the PBHCI grant program is to improve the overall wellness and physical health status of people with serious mental illnesses (SMI), including individuals with co-occurring substance use disorders, by supporting communities to coordinate and integrate primary care services into publicly-funded community mental health and other community-based behavioral health settings. The program's goal is to improve the physical health status of adults with serious mental illnesses (and those with co-occurring substance use disorders) who have or are at risk for co-occurring primary care conditions and chronic diseases. The program's objective is to support the triple aim of improving the health of those with SMI; enhancing the client's experience of

care (including quality, access, and reliability); and reducing/controlling the per capita cost of care.

The information collected through this request will allow SAMHSA to monitor grantee performance and provide information indicating whether the provision of integrated primary care services produces improvements in the physical health of the SMI population receiving services from community-based behavioral health agencies.

Physical Health Indicators: Client-level data on physical health indicators will be reported to SAMHSA through the TRAC as part of SAMHSA's ongoing performance measurement and monitoring activities.

TRAC is the web-based system through which all grants funded by the SAMHSA Center for Mental Health Services (CMHS) report performance measurement data (OMB Approval No. 0930-0285). Through TRAC, each grantee is required to collect and report data on behavioral health outcomes for each person receiving services as a result of the grant, using a standard protocol. These data are collected by grantee staff members who interview each service participant at initial entry into the program, every six months while enrolled in services, and when discharged from the program. In order to accommodate program-specific performance monitoring needs, the system allows individual grant programs to add a small number of OMB-approved data elements that are critical for assessing core outcomes for the program. In addition to client-level data, grantees also report grant-level infrastructure changes through TRAC.

SAMHSA is requesting that OMB provide clearance for SAMHSA to continue to collect PBHCI-specific physical health indicators through the TRAC system. The Office of Management and Budget previously approved SAMHSA's request for this project to collect six required physical health indicators, and two optional physical health indicators. The required indicators included height, weight, HgBA1c or blood glucose, blood pressure, triglycerides, and cholesterol, which are biomarkers for obesity, diabetes, hypertension, hyperlipidemia, and hypercholesterolemia, respectively. The optional indicators included waist circumference and breath carbon monoxide, which are indicators of metabolic syndrome and smoking status, respectively. We are now requesting that all eight physical health indicators be required. We are also requesting clearance to collect two additional indicators: one question indicating the date that the blood draw occurred, and an optional question, to determine whether an eight hour fast occurred prior to the blood tests.

Reporting of physical health indicators through TRAC will facilitate standardized reporting and consolidation of the physical health data from all 70 grantees. Physical health data will be extracted from grantees' clinical registries and/or electronic medical records and entered into the TRAC system every 6 months. This interval coincides with the TRAC-required bi-annual client-level interviews so that all TRAC data can be entered simultaneously and grantees' data management burden can be minimized.

Quarterly Reports: Quarterly reports will be submitted to SAMHSA throughout the life of the grant for ongoing performance measurement and monitoring purposes.

Quarterly reports will be used by program staff to monitor grantee performance. The reports will allow program staff to assess key accomplishments and barriers, staffing changes, infrastructure activities, and implementation of specific program components. It will help program staff understand which patients are deemed eligible for the program and how funding is being used to support the program, as well as allow for relevant training and technical assistance to be directed to grantees per their report narrative.

Changes

SAMHSA/CMHS is requesting the deletion of the following tools:
1. Site Visit Interviews
2. Client Physical Exam and Survey
3. Client-level Service Utilization Report

SAMHSA/CMHS is requesting only the Physical Health Indicators collected through TRAC and Quarterly Reports be approved by OMB for continued collection.

3. Use of Information Technology

***Physical Health Indicators*:** Information technology will be used to reduce program respondent burden. The existing TRAC System is a web-based data entry and reporting system designed to support web-based data collection efforts for CMHS. The system will be updated to incorporate proposed changes to the client-level data collection and the infrastructure development, prevention, and mental health promotion performance indicators. 100% of responses are expected to be submitted electronically through the web-based system. The TRAC System also provides a data repository service that includes methods for receiving the data, data quality checks, storage, and data presentation in reports by individual performance indicator or grouped with other performance indicators. The TRAC system complies with the requirements of Section 508 of the Rehabilitation Act to permit accessibility to people with disabilities.

This web-based system is intended to allow for easy data entry and access to reports for grantees that are required to submit TRAC data to CMHS. Entering and accessing data and viewing reports will be limited to those individuals with a username and password. A user's level of access to the data and reports will be defined based on his or her authority and responsibilities.

Electronic submission of the data promotes enhanced data quality. With built-in data quality checks and easy access to data outputs and reports, users of the data can feel confident about the quality of the output. The electronic submission also promotes immediate access to the dataset. Once the data are put into the web-based system, it will be available for access, review, and reporting by all those with access to the system from Center staff to the grantee staff.

***Quarterly Reports*:** Quarterly reports will be submitted electronically to Government Project Officers (GPOs) in the form of Word and Excel (or other database) documents.

4. <u>Efforts to Identify Duplication</u>

Physical Health Indicators: While entering this information into TRAC may represent some duplication of effort since results will likely also be entered into an electronic medical record, chart or registry, it is critical to collect this information in a standardized way that is also connected with the SAMHSA-required client-level TRAC data. The data will be entered concurrently with the entry of the client's other TRAC data and is only expected to add up to 5 minutes of data entry time.

*Quarterly Reports***:** Information collected in the Quarterly Reports is not collected elsewhere, and thus does not represent a duplication of effort.

5. <u>Involvement of Small Entities</u>

Individual grantees vary from small entities through large provider organizations. Every effort has been made to reduce the number of data items collected from grantees to the least number required to accomplish the objectives of the effort and to meet performance monitoring requirements and therefore, there is no significant impact involving small entities in general.

6. <u>Consequences If Information Collected Less Frequently</u>

*Physical Health Indicators***:** Mental health programs typically collect client-level data at admission and then conduct periodic reassessments of consumers while the individual remains in services. When feasible, mental health providers also conduct an assessment when the consumer is discharged. The data collection schedule for the client-level physical health indicators parallels this model. All CMHS programs that provide direct services, including the PBHCI program, collect data every six months while the consumer is receiving services.

The baseline data collection point is critical for measuring changes. Extending the interval for the periodic reassessment beyond the requested intervals could lead to loss of contact with consumers, significantly diminishing the response rates and lowering the value of the data for performance reporting use by losing measurement of intermediate effects.

Quarterly Reports: Information collected in the quarterly reports is required for SAMHSA GPOs to effectively monitor the performance of grantees. Collecting the information less often would interfere with each GPO's ability to effectively monitor each program and to provide additional training needed to improve grantee performance.

7. Consistency with the Guidelines in 5 CFR 1320.5(d) (2)

This information collection fully complies with the guidelines in 5 CFR 1320.5(d) (2).

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on June 17, 2014 (79 FR 34544).

Both external and internal stakeholders were consulted by CMHS in the development of these indicators and the data collection methodology. CMHS obtained feedback and consultation regarding the availability of data, methods and frequency of collection, and the appropriateness of data elements.

9. Payment to Respondents

No monetary incentives will be provided to grantees.

10 .Assurance of Confidentiality

Grantees will not report any individually identifiable client-level information as part of this data collection effort. Only de-identified client-level data will be reported by grantees, therefore, SAMHSA and its contractors will not receive identifiable client records.

Provider-level data (e.g. information contained in the grantee quarterly reports) will be aggregated to, at the least, the level of the grant/cooperative agreement-funding announcement.

The TRAC System does collect a limited amount of personally identifiable information (PII) from grantee staff members who enter client data into the TRAC System. In consultation with HHS, SAMHSA concluded that the TRAC System does not require a Systems of Records Notice (SORN). However, a Privacy Impact Assessment (PIA) for the TRAC system was submitted to HHS on August 15th, 2014.

11. Questions of a Sensitive Nature

No questions of a sensitive nature being collected.

12. Estimate of Annualized Hour Burden

Table 1 provides the basis of the annualized estimates of hour burden of collection of the proposed information.

Physical Health Indicators: SAMHSA estimates that entry of the physical health indicators into TRAC will require approximately 5 additional minutes of burden. Data will be collected every six months from an average of 200 clients per site at 70 PBHCI sites. Data will be entered into TRAC by administrative-level personnel, at an estimated hourly rate of $10 per hour.

Quarterly Reports: SAMHSA estimates that the completion of Quarterly Reports will require approximately two hours of additional burden. Quarterly Reports will be completed every three months by Project Directors, at an estimated hourly burden of $35 per hour.

Table 1. Estimates of Annualized Hour Burden

Type of Response	Number of Sites	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Hour Burden	Hourly Wage Cost	Total Hour Cost
Client-level interview – Physical Health Indicators	70	14,000	2	28,000	.08	2,240	$10	$22,400
Grantee Quarterly Report	70	70	4	280	2	560	$35	$19,600
Total	70	14,070		**28,280**		**2,800**		**$42,000**

13. Estimates of annualized Cost Burden to Respondents

There will be no capital, start-up, operation, maintenance, nor purchase costs incurred by the sites participating in this this data collection.

14. Estimate of Annualized Costs to the Federal Government

Costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of data collection. It is estimated that three CMHS employees will each be involved for 25 percent of their time. Costs of CMHS staff time will approximate $68,000 annually.

15. Changes in Burden

Currently there are 10,057 burden hours in the OMB inventory. The Program is requesting 2,800 burden hours. This reduction in burden is due to the elimination of several data collection instruments that were collected as part of a previous evaluation, but are no longer included in the current data collection request.

16. Plans for Tabulation and Publication

Physical health indicator data will be collected by individual grantee sites, and will be stored by Westat, the contractor that manages SAMHSA's TRAC data collection system. At the end of the

current Westat contract, or at the request of SAMHSA, Westat will transfer de-identified data to SAMHSA or another designated contractor.

Physical Health Indicator data and information from grantee Quarterly Reports will be reviewed for monitoring and program management. Information will be used internally by the agency for performance monitoring purposes. Data will also be used to inform periodic data reports that will be distributed internally and externally.

The time frame for submission of the reporting requirements varies by grant cycle and grant program period of performance throughout the year.

Table 2. Schedule for Activities

Activity	Date
OMB approval	September, 2014
Data collection continues	September, 2014
Data collection ends	September, 2018
Data analysis	Ongoing

17. Display of Expiration Date

The expiration date of the OMB approval will be displayed.

18. Exceptions to the Certification Statement

The certifications are included in this submission.