

vehicle sold by respondent. Part V requires dissemination of the order, now and in the future, to persons with responsibilities relating to the MINI Division and the subject matter of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates that respondent submit an initial compliance report to the FTC, and make subsequent reports available to the FTC, upon request. Part VIII is a provision “sunsetting” the order after twenty (20) years, within certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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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: Community Mental Health Services Block Grant and Substance Abuse and Prevention Treatment Block Grant FY 2016–2017 Plan and Report Guidance and Instructions (OMB No. 0930-0168)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), is requesting approval from the Office of Management and Budget (OMB) for a revision of the 2016 and 2017 Community Mental Health Services Block Grant (MHBG) and Substance Abuse Prevention and Treatment Block Grant (SABG) Plan and Report Guidance and Instructions.

Currently, the SABG and the MHBG differ on a number of their practices (e.g., data collection at individual or aggregate levels) and statutory authorities (e.g., method of calculating MOE, stakeholder input requirements

for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these block grants have had different approaches to application requirements and reporting. To compound this variation, states have different structures for accepting, planning, and accounting for the block grants and the prevention set aside within the SABG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by block grant and by state.

Increasingly, under the Affordable Care Act, more individuals are eligible for Medicaid and private insurance. This expansion of health insurance coverage will continue to have a significant impact on how State Mental Health Authorities (SMHAs) and Single State Agencies (SSAs) use their limited resources. In 2009, more than 39 percent of individuals with serious mental illnesses (SMI) or serious emotional disturbances (SED) were uninsured. Sixty percent of individuals with substance use disorders whose treatment and recovery support services were supported wholly or in part by SAMHSA block grant funds were also uninsured. A substantial proportion of this population, as many as six million people, will gain health insurance coverage in 2014 and will have various outpatient and other services covered through Medicaid, Medicare, or private insurance. However, these plans will not provide access to the full range of support services necessary to achieve and maintain recovery for most of these individuals and their families.

Given these changes, SAMHSA has conveyed that block grant funds be directed toward four purposes: (1) To fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and targeted prevention activities and services; and (4) to collect performance and outcome data to determine the ongoing effectiveness of behavioral health prevention, treatment and recovery support services and to plan the implementation of new services on a nationwide basis.

To help states meet the challenges of 2016 and beyond, and to foster the implementation of an integrated physical health and mental health and

addiction service system, SAMHSA must establish standards and expectations that will lead to an improved system of care for individuals with or at risk of mental and substance use disorders. Therefore, this application package includes fully exercising SAMHSA’s existing authority regarding states’, territories’ and the Red Lake Band of the Chippewa Tribe’s (subsequently referred to as “states”) use of block grant funds, and a shift in SAMHSA staff functions to support and provide technical assistance for states receiving block grant funds as they fully integrate behavioral health services into health care.

Consistent with previous applications, the FY 2016–2017 application has sections that are required and other sections where additional information is requested. The FY 2016–2017 application requires states to submit a face sheet, a table of contents, a behavioral health assessment and plan, reports of expenditures and persons served, an executive summary, and funding agreements and certifications. In addition, SAMHSA is requesting information on key areas that are critical to the states success in addressing health care integration. Therefore, as part of this block grant planning process, SAMHSA is asking states to identify their technical assistance needs to implement the strategies they identify in their plans for FY 2016 and 2017.

To facilitate an efficient application process for states in FY 2016–2017, SAMHSA convened an internal workgroup to develop the application for the block grant planning section. In addition, SAMHSA consulted with representatives from SMHAs and SSAs to receive input regarding proposed changes to the block grant. Based on these discussions with states, SAMHSA is proposing several changes to the block grant programs, discussed in greater detail below.

Changes to Assessment and Planning Activities

The revisions reflect changes within the planning section of the application. The most significant of these changes relate to evidenced based practice for early intervention for the MHBG, participant directed care, medication assisted treatment for the SABG, crisis services, pregnant women and women with dependent children, community living and the implementation of Olmstead, and quality and data readiness collection.

The FY 2014–2015 application sections on the Affordable Care Act, health insurance marketplace,

enrollment and primary and behavioral health care integration have been consolidated into a Health Care System and Integration section moving the emphasis to implementation of health care systems rather than preparation of the Affordable Care Act. Additionally, the FY 2014–2015 Quality, Data and Information Technology sections have been consolidated into one section in the FY 2016–2017 application. SAMHSA has provided a set of guiding questions to stimulate and direct the dialogue that states may engage in to determine the various approaches used to develop their responses to each of the focus areas.

The proposed revisions are described below:

- *Health Care System and Integration*—This section is a consolidation of the FY 2014–2015 sections on the Affordable Care Act, health insurance marketplace, enrollment and primary and behavioral health care integration. It is vital that SMHAs and SSAs programming and planning reflect the strong connection between behavioral and physical health. Fragmented or discontinuous care may result in inadequate diagnosis and treatment of both physical and behavioral conditions, including co-occurring disorders. Health care professionals, consumers of mental, substance use disorders, co-occurring mental, and substance use disorders treatment recognize the need for improved coordination of care and integration of primary and behavioral health care. Health information technology, including electronic health records (EHRs) and telehealth are examples of important strategies to promote integrated care. Use of EHRs—in full compliance with applicable legal requirements—may allow providers to share information, coordinate care and improve billing practices.

Implementation by SMHAs, SSAs and their partners of the Affordable Care Act is an important part of efforts to ensure access to care and better integrate care. In a recent report, the Congressional Budget Office estimates that by 2018, 25 million persons will have enrolled in the Affordable Care Act Marketplace and 12 million in Medicaid and the State Children's Health Insurance Program (SCHIP). The Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) estimates that 32 million Americans will acquire coverage for mental and substance use disorder treatment as a result of the Affordable Care Act, including both previously uninsured persons and those enrolled in plans that lacked adequate coverage. In

2014, non-grandfathered health plans sold in the individual or the small group health insurance markets offered coverage for mental and substance use disorders as an essential health benefit.

- *Evidenced-Based Practices for Early Intervention for the MHBG*—In its FY 2014 appropriation, SAMHSA was directed to require that states set aside 5 percent of their MHBG allocation to support evidence-based programs that provide treatment to those with early SMI including but not limited to psychosis at any age. SAMHSA worked collaboratively with the National Institutes of Health, National Institute on Mental Health (NIMH) to review evidence showing efficacy of specific practices in ameliorating SMI and promoting improved functioning. NIMH has released information on Components of Coordinated Specialty Care (CSC) for First Episode Psychosis. Results from the NIMH funded *Recovery After an Initial Schizophrenia Episode (RAISE)* initiative, a research project of the NIMH, suggest that mental health providers across multiple disciplines can learn the principles of CSC for First Episode of Psychosis (FEP), and apply these skills to engage and treat persons in the early stages of psychotic illness.

States can implement models across a continuum, which have demonstrated efficacy, including the range of services and principles identified by NIMH. Utilizing these principles, regardless of the amount of investment, and with leveraging funds through inclusion of services reimbursed by Medicaid or private insurance, every state will be able to begin to move their system toward earlier intervention, or enhance the services already being implemented.

- *Participant Directed Care*—As states implement policies that support self-determination and improve person-centered service delivery, one option that states can consider is the role that vouchers may play in their overall financing strategy. Many states have implemented voucher and self-directed care programs to help individuals gain expanded access to care and to enable individuals to play a more significant role in the development of their prevention, treatment and recovery services. The major goal of a voucher program is to ensure individuals have a genuine, free, and independent choice among a network of eligible providers. The implementation of a voucher program expands mental and substance use disorder treatment capacity and promotes choice among clinical treatment and recovery support providers, providing individuals with the ability to secure the best treatment options available to meet their specific

needs. A voucher program facilitates linking clinical treatment with critical recovery support services, such as care coordination, childcare, motivational development, early/brief intervention, outpatient treatment, medical services, housing support, employment/education support, peer resources, family/parenting services or transportation.

States interested in utilizing a voucher system should create or maintain a voucher management system to support vouchering and the reporting of data to enhance accountability by measuring outcomes. Meeting these voucher program challenges by creating and coordinating a wide array of service providers, leading them through the innovations and inherent system change processes results in the building of an integrated system that provides holistic care to individuals recovering from mental and substance use disorders.

- *Medication Assisted Treatment (MAT)*—There is a voluminous literature on the efficacy of Food and Drug Administration (FDA)-approved medications for the treatment of substance use disorders. However, many treatment programs in the U.S. still offer only abstinence-based treatment for these conditions. The evidence base for medication assisted treatment of these disorders is described in several of SAMHSA's Treatment Improvement Protocol Series (TIPS) publications numbered 40, 43, 45, and 49. SAMHSA strongly encourages the states to require that treatment facilities providing clinical care to those with substance use disorders be required to either have the capacity and staff expertise to utilize MAT or have collaborative relationships with other providers such that these MATs can be accessed as clinically indicated for patient need. Individuals with substance use disorders who have a disorder for which there is an FDA-approved medication treatment should have access to those treatments.

- *Crisis Services*—In the on-going development of efforts to build an evidence-based robust system of care for adults diagnosed with an SMI, children with a serious emotional disturbance (SED) and persons with addictive disorders and their families via a coordinated continuum of treatments, services and supports, growing attention is being paid across the country to how states and local communities identify and effectively respond to behavioral health crises. SAMHSA has taken a leadership role in deepening the understanding of what it means to be in crisis and how to effectively respond to crisis as experienced by people with behavioral health conditions.

- A crisis response system will have the capacity to recognize and respond to crises across a continuum, from crisis planning, to early stages of support and respite, to crisis stabilization and intervention, to post-crisis follow-up and support for the individual and their family. SAMHSA expects that states will build on the emerging and growing body of evidence for effective community-based crisis response systems. Given the multi-system involvement of many individuals with behavioral health issues, the crisis response system approach provides the infrastructure to improve care coordination and outcomes, manage costs and better invest resources.

- *Pregnant Women and Women With Dependent Children*—Substance-abusing pregnant women have been a leading priority population throughout the history of the SABG (Section 1922(b) of Title XIX, Part B, Subpart II, of the PHS Act (42 U.S.C. 300x–22(b)). The authorizing legislation required states to expend not less than 5 percent of the FY 1993 and FY 1994 SABG to increase the availability of treatment services designed for pregnant women and women with dependent children. The purpose of these programs is to expand the availability of comprehensive, residential substance use disorder treatment, and recovery support services for pregnant and postpartum women and their minor children, including services for non-residential family members. This population continues to be of utmost concern, since by helping such women along their recovery journey, additional benefits may result: Fetal alcohol spectrum disorder may be prevented; a normal birth-weight may be achieved; and intergenerational transmission of addiction may be interrupted. Women with dependent children are also identified as a priority for specialized treatment (as opposed to treatment as usual) in the implementing regulations governing the SABG. In 1995 and subsequent fiscal years states are required to expend no less than an amount equal to that spent by the state in prior fiscal years for treatment services designed for pregnant women and women with dependent children.

- *Community Living and the Implementation of Olmstead*—The community living and Olmstead section was included in the environmental factors/background section of the FY 2014–2015 application and has been added to the planning section of the FY 2016–2017 application. The integration mandate in Title II of the Americans with Disabilities Act (ADA) and the Supreme Court's decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999), provide

legal requirements that are consistent with SAMHSA's mission to reduce the impact of substance abuse and mental illness on America's communities. Being an active member of a community is an important part of recovery for persons with behavioral health conditions. Title II of the ADA and the regulations promulgated for its enforcement require that states provide services in the most integrated arrangement appropriate and prohibit needless institutionalization and segregation in work, living, and other settings. In response to the tenth anniversary of the Supreme Court's *Olmstead* decision, then HHS Secretary Sebelius directed the creation of the Coordinating Council on Community Living at the HHS. SAMHSA has been a key member of the Coordinating Council on Community Living and has funded a number of technical assistance opportunities to promote integrated services for people with behavioral health needs, including a policy academy to share effective practices with states.

Community living has been a priority across the federal government with recent changes to Section 811 and other housing programs operated by the Department of Housing and Urban Development (HUD). HUD and HHS collaborate to support housing opportunities for persons with disabilities, including persons with mental/substance use disorders. The Department of Justice (DOJ) and HHS Office of Civil Rights (OCR) cooperate on enforcement and compliance measures. DOJ and HHS OCR have expressed concern about some aspects of state mental health systems including use of traditional institutions and other settings that have institutional characteristics to serve persons whose needs could be better met in community settings. More recently, there has been litigation regarding certain employment services such as sheltered workshops. States should ensure Block Grant funds are allocated to support treatment and recovery services in community settings whenever feasible and remain committed, as SAMHSA is, to ensuring services are implemented in accordance with *Olmstead* and Title II of the ADA.

- *Quality and Data Collection*—The FY 2014–2015 Quality, Data and Information Technology sections have been consolidated into one section in the FY 2016–2017 application and is part of the planning section. SAMHSA is moving forward on the task of advancing a system for the collection of client level substance abuse and mental health treatment data. As such, SAMHSA is undertaking a series of

efforts designed to develop a set of common core performance, quality, and cost measures to demonstrate the impact of SAMHSA's discretionary and block grant programs and guide SAMHSA's evaluation activities.

The foundation of this effort is National Quality Behavioral Health Framework, which derives from the National Quality Strategy and seeks to improve the delivery of health care services, individual patient health outcomes, and the overall health of the population. The overarching goals are to ensure that services are evidence-based and effective; that they are person/family-centered; that care is coordinated across systems; that services promote healthy living; and that they are safe, accessible and affordable.

For the FY 2016–2017 MHBG and SABG reports, achieving these goals will result in a more coordinated behavioral health data collection program that complements other existing systems (e.g., Medicaid administrative and billing data systems; and state mental health and substance abuse data systems), ensures consistency in the use of measures that are harmonized across various agencies and reporting systems, and provides a more complete understanding of the delivery of mental health and substance abuse services. Both goals can only be achieved through continuous collaboration with and feedback from SAMHSA's state partners.

SAMHSA anticipates this movement is consistent with the current state authority's movement toward system integration and will minimize challenges associated with changing operational logistics of data collection and reporting. SAMHSA understands some modifications to data collection systems may be necessary, but will work with the states to minimize the impact of these changes.

Other Changes

The overall format has been streamlined to integrate the environmental factors throughout the behavioral health assessment and plan narrative. This has reduced the length of the application by 10 pages.

While the statutory deadlines and block grant award periods remain unchanged, SAMHSA encourages states to turn in their application as early as possible to allow for a full discussion and review by SAMHSA. Applications for the MHBG-only is due no later than September 1, 2015.

The application for SABG-only is due no later than October 1, 2015. A single application for MHBG and SABG is due no later than September 1, 2015.

Estimates of Annualized Hour Burden
 The estimated annualized burden for a uniform application is 37,429 hours. Burden estimates are broken out in the

following tables showing burden separately for Year 1 and Year 2. Year 1 includes the estimates of burden for the uniform application and annual

reporting. Year 2 includes the estimates of burden for the application update and annual reporting. The reporting burden remains constant for both years.

TABLE 1—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 1

Application element	Number respondents	Responses/ respondents	Burden/ response (hours)	Total burden
Application Burden				
Yr One Plan (separate submissions)	30 (CMHS)	1	282	16,920
	30 (SAPT)			
Yr One Plan (combined submission)	30	1	282	8,460
<i>Application Sub-total</i>	60			25,380
Reporting Burden				
MHBG Report	59	1	186	10,974
URS Tables	59	1	35	2,065
SAPTBG Report	60 ¹	1	186	11,160
Table 5	15 ²	1	4	60
<i>Reporting Subtotal</i>	60			24,259
Total	119			49,639

¹ Redlake Band of the Chippewa Indians from MN receives a grant.
² Only 15 States have a management information system to complete Table 5.

TABLE 2—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 2

Application element	Number respondents	Responses/ respondents	Burden/ response (hours)	Total burden
Application Burden				
Yr Two Plan	24	1	40	960
<i>Application Sub-total</i>	24			960
Reporting Burden				
MHBG Report	59	1	186	10,974
URS Tables	59	1	35	2,065
SAPTBG Report	60	1	186	11,160
Table 5	15	1	4	60
<i>Reporting Subtotal</i>	60			24,259
Total	119			25,219

The total annualized burden for the application and reporting is 37,429 hours (49,639 + 25,219 = 74,858/2 years = 37,429).

Link for the application: <http://www.samhsa.gov/grants/block-grants>.

Written comments and recommendations concerning the proposed information collection should be sent by April 27, 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

Centers for Disease Control and Prevention

[30Day-15-0963]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for