1**SUPPORTING STATEMENT A FOR ELECTRONIC HEALTH RECORD DATA**

Center for Mental Health Services (CMHS)

CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINIC - EXPANSION

(CCBHC-E) GRANT PROGRAM EVALUATION

Check which applies:

☒ New

☐ Revision

☐ Reinstatement with Change

☐ Reinstatement without Change

☐ Extension

☐ Emergency

☐ Existing

A. JUSTIFICATION

A1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval from the Office of Management and Budget (OMB) to conduct the national cross-site evaluation of Certified Community Behavioral Health Clinic-Expansion (CCBHC-E) Planning, Development, and Implementation (PDI) grants and Improvement and Advancement (IA) grants.

SAMHSA is requesting clearance for the submission of grantees' Electronic Health Record data related to the implementation and impact studies that will be conducted as part of the evaluation.

a. Statement of need for a rigorous evaluation of the CCBHC-E grant program

The CCBHC model was authorized by section 223 of the Protecting Access to Medicare Act of 2014 (PAMA), which directed the Department of Health and Human Services to establish a Medicaid Demonstration program aimed at improving the availability, quality, and outcomes of community-based outpatient mental health and substance use disorder services. PAMA established a federal definition and criteria for CCBHCs and stipulated that they may receive an enhanced Medicaid reimbursement rate based on their anticipated costs of care. These criteria fall into six areas: (1) staffing, (2) availability and accessibility of services, (3) care coordination, (4) scope of services, (5) quality and other reporting, and (6) organizational authority. The criteria within this document address each of these areas, including the nine core services under the scope of services. The full CCBHC certification criteria are available at https://www.samhsa.gov/sites/default/files/programs_campaigns/ccbhc-criteria.pdf.

The CCBHC model offers states an opportunity to improve the behavioral health of their citizens in the following ways:

- Ensure that behavioral health services are responsive to the needs of the communities served.
- Promote improved access to high-quality care.
- Provide comprehensive, community-based mental and substance use disorder services.
- Advance the integration of mental health and substance use disorder treatment with primary care screening and monitoring.
- Assimilate and apply evidence-based and other effective practices more consistently.
- Ensure that care coordination is the linchpin holding together all aspects of CCBHC care and ensuring it is an improvement over existing services.
- Expand access to care and improve the quality of behavioral health services through enhanced federal matching funds available via the demonstration for services delivered to Medicaid beneficiaries.

In FY 2022, SAMHSA awarded two new cohorts under the CCBHC-E program, which are the subject of this evaluation. One cohort, awarded under the CCBHC-PDI Notice of Funding Opportunity (NOFO), is for clinics interested in becoming CCBHCs and in need of planning and support to come into compliance with the CCBHC certification criteria. The other cohort, awarded under the CCBHC-IA NOFO, is for clinics that are already established CCBHCs and are seeking to expand, improve, and advance their services.

The evaluation presents an opportunity to provide SAMHSA, policymakers, and the wider behavioral health community with new information about how these grants support adoption of the CCBHC model, how they influence sustainable expansion of CCBHC capacities beyond the grant period, and how implementation of the model influences client-level outcomes. An evaluation of the IA and PDI grantees specifically provides an opportunity to examine implementation successes and challenges within each area of the certification criteria among a larger and more diverse group of clinics operating in different state and community contexts. By carefully measuring these contexts and how they change over time, the evaluation can provide new information about how factors such as alternative sources of funding and state/community support for the model influence implementation and outcomes. Finally, this evaluation will assess changes in the quality of care and longitudinal client-level health, behavioral health, and functional outcomes.

In accordance with the current evaluation contract timeline, the evaluation will span 60 months, beginning June 5, 2023, and ending June 4, 2028. Primary data collection for the evaluation will not begin until SAMHSA receives final OMB approval. The data collection described in this request will build upon previous CCBHC evaluations and provide essential data on the implementation and development of CCBHCs, along with rigorous estimates of their effects on key client outcomes. The findings will support SAMHSA's work to improve access to high-quality, community-based care; identify best practices to support implementation and adoption of the CCBHC model; and provide actionable information to help SAMHSA, Congress, and state and community leaders guide decisions about future investments in the model.

b. Overview of study design and evaluation questions

The Evaluation Team will conduct its evaluation using a mixed-methods approach.

The evaluation consists of three components: (1) a process evaluation, which will focus on the organizations/infrastructure and services changes clinics make to meet and maintain the CCBHC certification criteria, (2) an outcome evaluation, which will focus on the impact of these organizational/infrastructure and service changes on health, behavioral health, and functional outcomes for individuals receiving CCBHC services, and (3) a synthesis of these two components, aimed at determining the specific features of the CCBHC model that contribute to improvements in outcomes over time and the features that could be strengthened.

The evaluation will address a set of key questions (Exhibit 1) to help SAMHSA understand how the activities implemented by clinics to meet and maintain the certification criteria lead to the desired outcomes. These questions will also align with specific components of the certification criteria to facilitate analysis focused on the implementation of each component.

Exhibit 1. Evaluation questions

Process Evaluation Questions
Organizational and infrastructure changes
1a. What infrastructure and staffing changes do grantees make to implement the CCBHC model? How does this infrastructure differ from that of non-CCBHC clinics?
1b. To what extent are CCBHCs able to implement specific components of the certification criteria? Which certification criteria are the most challenging for CCBHCs to implement? How does the availability of the local workforce affect model implementation?
1c. To what extent do CCBHCs engage people with lived experience in the development, implementation, and monitoring of the model? To what extent do these individuals reflect the diversity of people served by CCBHCs in each community?
1d. What methods did CCBHCs use to conduct their community needs assessments? To what extent were people with lived experience and other community members engaged in the community needs assessment process? How do CCBHCs use the community needs assessment to identify and implement evidence-based practices and services aligned with the needs of the communities they serve?
1e. To what extent do CCBHCs address disparities in care?
1f. To what extent do CCBHCs establish and maintain formal and informal collaborative relationships with health, social service, and other providers, including DCOs? How quickly are those relationships developed and formalized?
1g. To what extent do CCBHC data systems support population health management, measurement-based care, electronic prescribing, care coordination, and clinical decision support?
1h. What investments do states and communities make to support and sustain the CCBHC model?
1i. To what extent are grantees able to sustain the model, including through other state CCBHC programs? Which components of the CCBHC model are difficult for clinics to maintain after grant funding ends? What infrastructure changes may be necessary to sustain the model?
Service-level changes
2a. What processes do CCBHCs implement to increase access to care, including for the uninsured and underinsured? What creative strategies do grantees develop to increase access to care? To what extent do the characteristics of CCBHC clients change over time?
2b. To what extent are CCBHC clients able to get care when needed? What processes do CCBHCs implement to support timely comprehensive evaluations and connect people with appropriate services?
2c. To what extent do CCBHCs offer and maintain all services included in the certification criteria? Which services were added because of CCBHC certification?
2d. To what extent do CCBHCs deliver EBPs? Which EBPs were added because of CCBHC certification?
2e. To what extent are peer support staff-integrated into the delivery of care across the nine core CCBHC services?
2f. To what extent do CCBHC staff provide culturally and linguistically appropriate services?
2g. To what extent do CCBHCs engage consumers, family members, or caregivers in treatment planning?
2h. Does the quality of CCBHC services improve over time?
2i. To what extent do CCBHCs integrate mental health and SUD treatment?

Process Evaluation Questions
2j. How well do CCBHCs coordinate care with other services and supports, including 988 and local crisis services? What creative strategies do CCBHCs use to support care coordination?
2k. How does the implementation of the CCBHC model impact other service sectors and the criminal justice system?
Outcome Evaluation Questions
Client-level changes
3a. To what extent do CCBHC clients experience improvements in physical health, behavioral health status, and functioning? To what extent do CCBHC clients remain engaged in care?
3b. To what extent do CCBHC clients experience improvements in their quality of life?
3c. What grantee or clinic characteristics are associated with client-level improvements? What broad types of services or combinations of services are associated with client-level improvements?
3d. To what extent do CCBHC clients and family members have positive perceptions of the care received from CCBHCs? To what extent do they have a usual source of care and know where to get care?
3e. To what extent do CCBHC clients experience fewer behavioral health crises?
3f. To what extent do CCBHC clients experience fewer ED visits and hospitalizations?

A2. Purposes and Use of Information

The purpose of the CCBHC-E grants is to address problems of access, coordination, and quality of behavioral healthcare by establishing a standard definition and criteria for organizations certified as CCBHCs. This ensures that all service recipients have access to a common set of comprehensive, coordinated services, with the ultimate goal of decreasing disparities in care and outcomes across communities. Data collected in this evaluation will help SAMHSA assess the degree to which activities at the clinic level and systems levels affect the development, implementation, and sustainment of CCBHCs consistent with the certification criteria, as well as the impacts of model adoption on client outcomes. The proposed data collection activity is described below.

Exhibit 2. Evaluation data collection and analysis strategy

Data collection or analysis	Mode, timing, and respondent	Relevant evaluation questions	Domains	Analytic technique
EHR data	In OYs 2 and 4, the study team will ask grantees to upload EHR data from all clients who received CCBHC services that supplemented the outcomes measured by NOMs.	3a-c	(1) substance use; (2) mental health symptoms and functioning.	Descriptive, HLM

a. Quantitative Data

Electronic Health Record (EHR) data

At two points during the evaluation, we will ask grantees to upload de-identified client-level EHR data. This data will include client demographics and interview information, the Patient Health Questionnaire (PHQ-9), the Columbia-Suicide Severity Rating Scale (C-SSRS), the Generalized Anxiety Disorder 7-item (GAD-7), the Alcohol Use Disorders Identification Test, and the Drug Abuse Screening Test (DAST-10), which the Evaluation Team has identified as tools grantees commonly use to collect client data. Grantees will upload these data during Quarter 4, 2025, and during Quarter 3, 2026. All client data will be uploaded during these periods to reduce the burden of determining duplicates. These data will provide SAMHSA with further data about client outcomes.

b. Timeline for data collection

The evaluation is expected to be completed in 5 years, with 4 years of data collection. We will request that grantees submit these data to the Evaluation Team twice: once in September 2025 and again in July of 2026.

A3. Use of Information Technology

We will provide grantees with a secure location through which they can share their data files. This location will be hosted on Microsoft SharePoint, which is HIPAA-compliant. Grantees will be required to log in using accounts we will provide, and all data will remain password protected. Once logged in, grantees will only have access to data they have uploaded. Access to uploaded data will be given only to the individual who uploaded the data and to members of the Evaluation Team who need direct access to raw data.

A4. Efforts to Identify Duplication

In formulating the evaluation design, SAMHSA has carefully considered ways to minimize burden by supplementing existing data sources with targeted primary data collection. To this end, the evaluation will rely on existing data that grantees already submit to SAMHSA. These include various documents (applications, disparities impact statements, attestation documents, and midyear and annual reports), IPP indicators, and client-level NOMs and service use information. SAMHSA also plans to require IA and PDI grantees to submit a subset of clinical quality measures used in the CCBHC demonstration.[i] Other existing data sources that will inform the evaluation include the National Substance Use and Mental Health Services Survey (N-SUMHSS) and Medicaid claims. However, the level of detail and consistency of the information provided in these source documents and other data sources will likely vary from state to state and may not fully address the requirements. To supplement these data sources, SAMHSA is requesting OMB clearance to survey all grantee project directors and to conduct qualitative interviews and/or focus groups with community stakeholders, grantees, their partners, and people receiving CCBHC services, including youth and parents/caregivers.

A5. Involvement of Small Entities

Grantees vary in size, from small entities to large provider organizations. The qualitative data collection protocols have been designed to minimize burden on these entities and their clients. We will make every effort to schedule telephone interviews and site visits at the convenience of these respondents and participants. The Evaluation Team will request the minimum amount of information from grantees necessary to evaluate the CCBHC-E IA and PDI grants effectively.

A6. Consequences if Information Is Collected Less Frequently

Each of the data sources provides information needed for the evaluation. If the data are not collected, the Evaluation Team will not have adequate information to answer the evaluation questions. The inclusion of all planned data sources is necessary to obtain information about CCBHC implementation and outcomes.

EHR data will be uploaded no more than twice during the evaluation period. If data are not uploaded at both periods, the Evaluation Team will not have adequate ability to assist grantees in ensuring that data are properly uploaded. These data are essential to obtain, as they provide further information about the physical and mental well-being and substance use of CCBHC clients, which are not reflected in NOMs data or collected via client interviews. Since these data are already collected by grantees, their use imposes no additional burden to grantees or clients.

A7. Special Circumstances

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

A8. Consultation Outside of Agency

This is a new data collection. The 60-day notice was published in the Federal Register on 04/21/2026 (91 FR 21299). Comments were not received. The 30-day notice published in the Federal Register on 06/30/2026 (91 FR 39629).

The CCBHC-E evaluation plan was developed in consultation with a nine-member evaluation advisory panel (EAP) made up of specialists in evaluation design and implementation, mental health services research, and behavioral healthcare delivery design, along with providers of mental health services who have evaluation experience. The EAP met once via webinar to review the evaluation and data collection plan and to respond to questions related to the evaluation design. Select members of the EAP also met with a member of the Evaluation Team to review and provide feedback on the client interview protocol and procedures. Exhibit 3 lists the EAP members.

Exhibit 3. EAP Members

Name	Title and affiliation
Rinad Sary Beidas, Ph.D.	Chair and professor, Department of Medical Social Sciences, Feinberg School of Medicine at Northwestern University
Stephanie Jordan Brown, M.A.	Founder and principal, Behavioral Healthcare Delivery Redesign, Strategy and Financing Consultancy
Patrick Corrigan, Psy.D.	Distinguished professor, Department of Psychology, Illinois Institute of Technology (IIT) Director, CHEER
Jonah Cunningham, B.S., MPP	President and CEO, National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD) Executive director, National Association for Rural Mental Health (NARMH)
Aisha Ellis, M.S.N., RN, ANP-BC	Adult nurse practitioner and Ph.D. student, Johns Hopkins School of Nursing
Paul Frankel, Ph.D., M.S., B.S.	Program evaluator, Centerstone
Lisa Razzano, Ph.D.	Professor, Department of Psychiatry, College of Medicine at the University of Illinois at Chicago (UIC) Deputy director, UIC Center on Mental Health Services Research & Policy
Margaret Swarbrick, Ph.D.	Research professor and associate director of Center for Alcohol and Substance Use Studies, Graduate School of Applied and Professional Psychology, Rutgers University's Director, Wellness Institute, Collaborative Support Programs of New Jersey, Inc.
Gwen Whigham, LADC	Outreach worker and recovery coach, Volunteers of America of Massachusetts

A9. Explanation of Any Payment or Gift to Respondents

The grantees will not receive additional payments for sharing their EHR data.

A10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. The Privacy Act does not apply to this data collection. Participants will not be asked about, nor will they provide, individually identifiable health information. The data produced through this project will not contain, nor be retrievable by, personal identifiers. The Evaluation Team staff are trained on handling sensitive data and the importance of privacy.

EHR data: EHR data will be uploaded by grantees into a web-based, password-protected data entry system. Prior to upload, grantees will strip identifying information from the data and provide clients with unique identifiers that do not correspond with other identifiers which may have been assigned to clients. The Evaluation Team will provide training to all grantees regarding appropriate procedures for meeting and maintaining privacy protection. These trainings will include information on obtaining IRB approval, obtaining appropriate releases from participants that comply with state and federal law (including the Health Insurance Portability and Accountability Act [HIPAA]), and ensuring privacy protection by grantee staff. In addition to the training, the Evaluation Team will provide the grantees with materials that cover all the information presented in the training, with the intention that these materials be used by

current grantee staff for their own reference and to train any new staff regarding privacy protection procedures. Because the data to be shared will consist of data already collected or planned to be collected from clients by grantees, the Evaluation Team will be seeking approval for a waiver of consent.

A11. Questions of a Sensitive Nature

The Evaluation Team will not be collecting any additional information not already collected by grantees.

A12. Estimates of Annualized Hour Burden

Exhibit 4 provides estimates of the average annual burden for collecting the proposed information. Below, we provide details on the total time and cost burdens for each of the separate data collection activities.

- **EHR data:** In each of the two rounds of data uploading, SAMHSA estimates that it will take approximately eight hours for EHR data to be exported from grantee's EHR, documented as instructed, and uploaded to the secure portal.

Exhibit 4. Estimated annualized burden hours

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Average Hourly Wage	Total Hour Cost Burden[a]
EHR data collection	298	2	8	4,768	$59.07	$281,645.76
TOTAL	298	2	8	4,768	$59.07	$281,645.76

[a]Total respondent cost is calculated as the number of respondents x number of responses per respondent x average burden per response in hours x average hourly wage.

A13. Estimates of Annualized Cost Burden to Respondents

There will be no capital, start-up, operational, maintenance, or purchase costs incurred by the respondents participating in data collection for the evaluation.

A14. Estimates of Annualized Cost to the Government

The Contractor will coordinate, monitor, analyze, and report the CCBHC-E Grant Program Evaluation data provided by the grantees to the Government Contracting Officer Representative. The Federal Government employee (GS-14, $162,629) spends 5% of their time overseeing the CCBHC-E Grant Program Evaluation, equaling $8,131 per year ($40,657 total). Additional costs include the contract awarded for these evaluation activities by SAMHSA ($9.15 million over five years, or an annualized cost of $1.83 million). The total estimated average cost to the government per year is $1,838,131.

A15. Explanation for Program Changes or Adjustment

This is a new data collection request.

A16. Plans for Tabulation and Publication and Project Time Schedule

The evaluation contract for the CCBHC-E PDI and IA grant programs anticipates that aggregate results from the national evaluation will be incorporated into text and charts in the following publications:

- Four annual reports due May 2024, 2025, 2026, and 2027
- A final evaluation report describing evaluation data collection, analysis, and findings, due May 5, 2028
- Brief analytic reports of no more than five pages to be distributed through the SAMHSA Center for Behavioral Health Statistics and Quality Short Report mechanism or similar vehicles; these short reports are designed to provide brief updates using bullet points, figures, charts, and tables that are easily understood by a wide range of audiences
- Two ad hoc data requests (such as presentations and blog postings) per year in 2025 through 2028, as well as additional optional publications, presentations, and trainings as directed by SAMHSA

Exhibit 5 provides an overview of the evaluation tasks and the years in which the Evaluation Team will conduct them.

SAMHSA may also incorporate the aggregate results from the cross-site evaluation into journal articles, scholarly presentations, and congressional testimony related to the outcomes of the CCBHC-E PDI and IA grant programs.

Exhibit 5. Evaluation tasks timeline

Data collection timeline	Base Year	OY1	OY2	OY3	OY4
EHR data collection			X	X	

A17. Display of OMB Expiration Date

The expiration date for OMB approval will be displayed.

A18. Exceptions to Certificate Statement

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

[i] Substance Abuse and Mental Health Services Administration. (February 2023). *Certified community behavioral health clinic (CCBHC) certification criteria* [PDF]. https://www.samhsa.gov/sites/default/files/revised-ccbhc-criteria-dec-2022.pdf