Substance Abuse and Mental Health Services Administration
SAMHSA
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TO: Rod McClure, MBBS, Ph.D., FAFPHM, FAICD
Director, Division of Analysis, Research, and Practice Integration (DARPI)

FROM: Division Director, Division of Systems Development

SUBJECT: Memorandum of Understanding (MOU) between the Substance Abuse and Mental Health Services Administration (SAMHSA)/ Center for Substance Abuse Prevention (CSAP) and the Centers for Disease Control and Prevention (CDC) for the Prescription Drug Overdose (PDO) program.

Attached is the MOU between SAMHSA and CDC that has been developed to outline the joint oversight of the evaluation and program monitoring for the PDO program. The purpose of this MOU is to enable the development and implementation of a rigorous monitoring and evaluation of the PDO program.

The objective of the multi-site monitoring and evaluation initiative is to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among individuals 18 years of age and older by training first responders and other key community sectors on secondary prevention strategies, including the purchase and distribution of naloxone. Both monitoring and evaluation data will be critical for interpreting the effectiveness of the PDO program and will inform future policy and programmatic initiatives related to PDO.

The attached MOU outlines the respective responsibilities of each agency between (FY 2016-FY 2021). Please sign each of the three MOUs. Keep one original and return the remaining two originals to Linda Crawford, Staff Assistant, 5600 Fishers Lane, 16E37B, Rockville Maryland 20857.

Jorielle Brown, Ph.D.

Attachments

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Memorandum of Understanding
between
Centers for Disease Control and Prevention (CDC) and
Substance Abuse and Mental Health Services Administration
(SAMHSA)

1. **Title:** Evaluation of SAMHSA's Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO) Cooperative Agreement. (*State based naloxone education and distribution program)*

2. **Purpose:** To enter into an agreement between CDC and SAMHSA to monitor and evaluate the PDO (state based naloxone distribution and education) program. The aim of the PDO program is to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among individuals 18 years of age and older by training first responders and other key community sectors on secondary prevention strategies, including the purchase and distribution of naloxone. Both monitoring and evaluation data will be critical for interpreting the effectiveness of the PDO program and will inform future policy and programmatic initiatives related to PDO.

3. **Period of Agreement**: This Memorandum of Understanding (MOU) will begin upon execution, approximately 9/1/2016, and will continue to 9/30/2021. However, the MOU may be revised at the end of each fiscal year in the event that CDC or SAMHSA needs to make amendments to the agreement. There are no funds being transferred between SAMHSA and CDC under this agreement.

4. **Authority**: SAMHSA Authority for this agreement is authorized under Public Health Service (PHS) Act, Section 301(a) (42 U.S.C. 241(a)); Sections 341(a) and 344(d) (42 U.S.C. 257(a) and 260(d)); Sections 503 and 515 (42 U.S.C. 290aa-2 and 290cc). These sections authorize the conduct of research in all areas of drug abuse. The SAMHSA authority for this agreement is Section 520(b) (14) and (15) of the PHS Act.

5. **Program Contacts:**

CDC:
Project Officer:
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Health Scientist
Evaluation and Integration Team
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SAMHSA/CSAP:
Project Officer:
Tonia F. Gray, MPH
Sr. Public Health Advisor
Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
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6. **Travel**: Any Federal travel for grantee meetings and/or site visits will be determined each fiscal year, depending on available funding.

7. **Description of work:** The objectives of this initiative are to conduct a program evaluation of up to 12 states funded through SAMHSA's naloxone education and distribution program, to describe and understand the effectiveness among different sub-populations, across settings, and to increase understanding of the barriers and facilitators to program implementation in these populations and settings. Potential key evaluation questions that may be considered for the evaluation include:

    - What are the differences in distribution/up-take of naloxone kits from first responders vs. those in the broader community?
    - How is the variability in factors (implementation, infrastructure, geography, demography, Training/TA, barriers to implementation) relate to outcomes across funded communities?
    - How does the saturation level of naloxone in a community affect health outcomes?

CDC or the CDC awarded contractor with CDC oversight will perform the following tasks for the evaluation:

a. *Project management:* CDC shall provide management and oversight of the evaluation, including meeting preparation, accurate and timely reports, comprehensive work plans, timelines, and coordination and communications for the various tasks and activities.

b. *Develop Evaluation Plan*: CDC and the awarded contractor shall provide a strategy for carrying out the task of evaluating the naloxone distribution and education program, including developing and implementing the program evaluation plan. The evaluation plan shall include methods for data collection, a data analysis plan [both qualitative and quantitative] for analyzing grantee data, and timelines for delivering reports on yearly analyses.

c. *Develop State Evaluation Plan Template and Provide Evaluation Technical Assistance (TA):* The CDC awarded contractor shall develop an evaluation plan template to be provided to SAMHSA awardees to create state specific evaluation plans. The contractor shall provide technical assistance to awardees around the evaluation plan template, development of an evaluation plan, and all other evaluation related TA as necessary.

d. *Prepare Human Subjects and OMB/PRA Package for Evaluation Instruments*: The CDC awarded contractor shall develop and submit IRB and OMB/PRA packages for the naloxone PDO evaluation study, including the administration of surveys, and focus groups for site visits as well as the collection of administrative data. An IRB package is required when the evaluation plan is considered to be research, contributes to generalizable knowledge, and includes collection of data from human subjects. CDC will submit the PDO evaluation OMB/PRA package for clearance and approval.

e. *Data Collection and Data Analysis Plans and Implementation:* CDC will collect quantitative data around short and long terms outcomes documented in the PDO Funding Opportunity Announcement (FOA) through templated awardee reporting bi-annually. The CDC awarded contractor will collect qualitative evaluation data to inform the program evaluation. The contractor will conduct an in-person focus group with at least five awardees (focus group sites may not be repeated) and annual phone interviews with all sites. CDC may propose methods for new data collection, methods for obtaining existing administrative data, or a combination of both.

f. *Reporting:* CDC and the awarded contractor shall develop an annual aggregate evaluation report describing evaluation findings from the previous program year (beginning in year 2). State specific evaluation reports showing trends over time for an individual state will be developed starting in year 2. A final evaluation report will also be developed describing evaluation findings across the 5 year program period. All reports should incorporate data collected by CDC, SAMHSA, and awarded contractors. As needed, the CDC evaluation contractor will handle ad hoc information reporting requests. These requests will be limited to qualitative and quantitative data collected as part of the program evaluation. Additionally, the CDC contractor will develop an annual report outlining the magnitude and type of evaluation TA provided to awardees. This report should be arranged by state awardee and by TA subject matter.

g. *Dissemination:* CDC shall provide annual, state-specific, and final reports with timely and user-friendly evaluation findings to SAMHSA, grantees, and other prevention stakeholders as appropriate. Reports should developed and ready for dissemination no later than 3 months following the end of the annual reporting period.

h. *Coordination, consultation, and transfer:* Coordination shall be made between SAMHSA's COR and CDC will collaborate to transfer evaluation data from CDC and its awarded contractor to SAMHSA.

SAMHSA/CSAP will perform the following tasks:

a. *Management*: SAMHSA shall provide oversight of the performance monitoring and implementation data, including meeting preparation, accurate and timely reports, comprehensive work plans, and timeliness of all monitoring activities.

b. *Develop Performance Monitoring Plan*: SAMHSA shall provide a strategy for carrying out the task of monitoring the implementation of the naloxone distribution and education program. The plan shall include systems development, data analysis plan for analyzing grantee data, and timelines for delivering reports on an annual basis. The plan should focus on monitoring how funding is being spent and the strategies/activities being implemented by awardees.

c. *Prepare Human Subjects and OMB/PRA Package for the Monitoring Data collection:* SAMHSA shall manage the development of the PDO Monitoring and Reporting tools and obtain all necessary IRB/OMB approvals prior to data collection. In addition, an IRB package is required when the evaluation plan is considered to be research, contributes to generalizable knowledge, and includes collection of data from human subjects. SAMHSA will explore the option of including the monitoring OMB package with the evaluation OMB package that CDC submits, so there can be a joint submission for both data collections.

d. *Data Collection and Data Analysis Plans and Implementation:* SAMHSA shall include a plan for the systems development, data processing, cleaning, analysis, and reporting for the Prescription Drug Overdose monitoring data. Data collection should focus on the implementation of state strategies and activities intended to achieve outcomes identified in the FOA.

e. *Reporting:* SAMHSA shall provide monitoring and implementation data to CDC and its awarded contractor annually no later than 4 weeks following the end of the project reporting period. The content and format of this data shall be determined by SAMHSA and the CDC awarded contractor. This data will inform the development of annual and final evaluation reports developed by the CDC contractor. Annual reports will link programmatic activities being implemented with both process and outcome findings based on current and trend data. The final report shall reflect the totality of implementation activities and the program's progress over time. Additional analyses may be requested on an ad hoc basis as needed by SAMHSA or CDC.

f. *Dissemination:* SAMHSA shall provide CDC and grantees with performance monitoring and implementation data on an annual basis. Data format and content will be determined by SAMHSA and CDC.

g. *Coordination, consultation, and transfer:* Coordination shall be made between SAMHSA's COR and CDC will coordinate to transfer monitoring data from SAMHSA to CDC and its awarded contractor. SAMHSA's contractor for the PDO monitoring contract will be involved in the direct transfer of data to CDC.

8. **Modification and Cancellation Clause:** The agreement may be amended by mutual consent or terminated by either party with a 45-day written notice.

Acceptance:

Approved for the Centers for Disease Control and Prevention

Rod McClure, MBBS, Ph.D., FAFPHM, FAICD
Director, Division of Analysis, Research, and Practice Integration (DARPI)
Injury Center
Centers for Disease Control and Prevention

8/8/16
Date

Approved for the Substance Abuse and Mental Health Services Administration:

Jorielle Brown, Ph.D.
Director, Division of Systems Development
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration

8/2/16
Date