Attachment 7

OMB Number: XXXX-XXXX Expiration Date: XX/XX/XXXX

Substance Abuse and Mental Health Services Administration (SAMHSA)

Center for Substance Abuse Prevention (CSAP) Online Reporting Tool (CORT)

Improving Access to Overdose Treatment (ODTA)

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is XXXX-XXXX. Public reporting burden for this collection of information is estimated to average 25 hours per respondent per year, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E45, Rockville, Maryland, 20857.

Center for Substance Abuse Prevention (CSAP) Online Reporting Tool (CORT) **Improving Access to Overdose Treatment (ODTA)**

I. Annual Targets Report (ATR)

[TO BE ENTERED IN THE "WORK PLAN" SECTION OF SPARS FOR THE APPROPRIATE FEDERAL FISCAL YEAR.]

Note

<u>e</u> : C	efini	tion of Terms can be found in <u>Appendix A</u> .
Α.	Rec	ipient Information
	[THI	S SECTION WILL BE PRE-POPULATED IN SPARS.]
	1.	Organization name:
	2.	Grant number:
	3.	Federal fiscal year:
В.	Per	formance Measures
	1.	Estimated number of individuals expected to complete Training of Trainers (ToT) <u>primary</u> training:
		[IF I.B.1 = 0, THEN SKIP TO I.B.4]
	2.	Estimated number of individuals expected to complete ToT <u>primary</u> training by participant type
		a. Prescribing health care providers
		(1) Physicians:
		(2) Physician assistants:
		(3) Nurse practitioners:
		(4) Dentists:
		b. Pharmacists:
		c. Non-prescribing service providers:
		d. Other individuals:
		[IF I.B.2.d = 0, THEN SKIP TO I.B.4]
	3.	Estimated number of <i>other</i> individuals expected to complete the ToT <u>primary</u> training by specified type
		a. (Specified other type 1):
		b. (Specified other type 2):
		x. (Specified other type X):

4.	Estimated number of individuals expected to complete ToT <u>secondary</u> training:
5.	Estimated number of individuals expected to complete ToT <u>secondary</u> training by participant type
	a. Prescribing health care providers
	(1) Physicians:
	(2) Physician assistants:
	(3) Nurse practitioners:
	(4) Dentists:
	b. Pharmacists:
	c. Non-prescribing service providers:
	d. Other individuals:
	[If I.B.5.d = 0, then skip to I.B.7]
6.	Estimated number of <i>other</i> individuals expected to complete ToT <u>secondary</u> training by specified type
	a. (Specified other type 1):
	b. (Specified other type 2):
	c. (Specified other type X):
7.	Estimated number of service providers to be trained on prescribing naloxone by service provider type
	a. Physicians:
	b. Physician assistants:
	c. Nurse practitioners:
	d. Pharmacists:
	e. Dentists:
	f. Other service providers:
	[IF I.B.7.F = 0 , THEN SKIP TO I.B.9]
8.	Estimated number of other service providers to be trained on prescribing naloxone by specified type
	a. (Specified other type 1):
	b. (Specified other type 2):
	c. (Specified other type X):

Projected naloxone-related spending and distribution

II. Q

TO BE E

A.

B.

For reporting purposes, "**naloxone**" refers to naloxone or other FDA-approved opioid overdose-reversing medication or device.

over	dose-reversing medication or device.
9.	Estimated amount of award funds to be spent on naloxone purchases by type
	a. Injectable: \$
	b. Intranasal: \$
	c. Auto-injector: \$
10.	Estimated amount of award funds to be spent on
	a. Co-payments: \$
	b. Other cost sharing: \$
11.	Estimated number of naloxone kits to be distributed:1
uarte	rly Performance Report (QPR)
NTERED	IN THE "PERFORMANCE REPORTS" SECTION OF SPARS FOR THE APPROPRIATE REPORTING PERIOD.]
Recip	ient Information
[THIS SE	ECTION WILL BE PRE-POPULATED IN SPARS.]
1.	Organization name:
2.	Grant number:
3.	Federal fiscal year/quarter:
Perfo	rmance Measures
	ach performance indicator, enter a numeric value. If your grant program did not implement a specific ty or service identified during this reporting period, enter "0" for the corresponding performance ator.
<u>Char</u>	acteristics of ToT program participants and trainings
1.	Number of trainings conducted by ToT type
	a. Primary trainings:
	b. Secondary trainings:
	c. Tertiary trainings:
	[IF II.B.1.a = 0 AND II.B.1b \neq 0, THEN SKIP TO II.B.5]
	[IF II.B.1.a = 0 AND II.B.1b = 0 , THEN SKIP TO II.B.7]

¹ This count should include the estimated number of grant-funded naloxone kits that the grantee and grantee partner(s) plan to distribute during the reporting federal fiscal year, as well as the estimated number of naloxone kits provided/purchased by another entity that the grantee plans to distribute as part of the ODTA grant program during the reporting federal fiscal year.

2.	Number of individuals who completed ToT <u>primary</u> trainings:
3.	Number of individuals who completed ToT <u>primary</u> trainings by participant type
	a. Prescribing health care providers
	(1) Physicians:
	(2) Physician assistants:
	(3) Nurse practitioners:
	(4) Dentists:
	b. Pharmacists:
	c. Non-prescribing service providers:
	d. [OTHER TYPE 1 SPECIFIED IN ATR]:
	e. [OTHER TYPE 2 SPECIFIED IN ATR]:
	X. [OTHER TYPE X SPECIFIED IN ATR]:
	y. Other individuals:
	[IF II.B.3.y = 0 AND II.B.1.b $\neq 0$, Then skip to I.B.5]
	[IF II.B.3.y = $0 \text{ and } \text{II.B.1.b} = 0$, then skip to I.B.8]
4.	Number of other individuals who completed ToT <u>primary</u> trainings by specified type
	a. (Specify other type 1):
	b. (Specify other type 2):
	x. (Specify other type X):
	[IF II.B.1.b = 0 , then skip to I.B.8]
5.	Number of individuals who completed ToT <u>secondary</u> trainings by participant type
	a. Prescribing health care providers
	(1) Physicians:
	(2) Physician assistants:
	(3) Nurse practitioners:
	(4) Dentists:
	b. Pharmacists:
	c. Non-prescribing service providers:
	d. [OTHER TYPE 1 SPECIFIED IN ATR]:
	e. [OTHER TYPE 2 SPECIFIED IN ATR]:
	X. [OTHER TYPE X SPECIFIED IN ATR]:
	y. Other individuals:
	[IF II.B.5.Y = 0 , then skip to II.B.7]

6.	Number of other individuals who completed ToT <u>secondary</u> trainings by specified type
	a. (Specify other type 1):
	b. (Specify other type 2):
	c. (Specify other type X):
7.	Number of service providers trained on prescribing naloxone by service provider type
	a. Prescribing health care providers
	(1) Physicians:
	(2) Physician assistants:
	(3) Nurse practitioners:
	(4) Dentists:
	b. Pharmacists:
	c. [OTHER TYPE 1 SPECIFIED IN ATR]:
	d. [OTHER TYPE 2 SPECIFIED IN ATR]:
	X. [OTHER TYPE X SPECIFIED IN ATR]:
	y. Other service providers:
	[IF II.B.7.Y = 0 , THEN SKIP TO II.B.9]
8.	Number of other service providers trained on prescribing naloxone by specified type
	a. (Specify other type 1):
	b. (Specify other type 2):
	x. (Specify other type #):
Nalo	oxone-related spending and distribution
	reporting purposes, " naloxone " refers to naloxone or other FDA-approved opioid erdose-reversing medication or device.
9.	Amount of award funds spent on naloxone product purchases by type
	a. Injectable: \$
	b. Intranasal: \$
	c. Autoinjector: \$
10.	Amount of award funds spent on
	a. Co-payments: \$
	b. Other cost sharing: \$

11. Total number of naloxone kits distributed using ODTA grant-funded resources: 2
a. Number of ODTA grant-purchased naloxone kits distributed:
b. Number of non-ODTA grant-purchased naloxone kits distributed:
12. Number of events where naloxone was administered by ToT-trained individuals
a. Opioid overdose reversal:
b. Death:
c. Not an opioid overdose:
d. Unknown:
[IF II.B.12.d = 0, THEN SKIP TO II.B.13]
d.1. Please explain why outcomes are unknown:
13. Number of patients <u>linked</u> to treatment services following opioid overdose reversal by service type
a. Medication for opioid use disorder (MOUD):
b. Counseling:
c. Behavioral therapies:
d. Recovery support services:
e. Other types of treatment services:
14. Number of patients who <u>initiated</u> treatment services following an opioid overdose reversal by service type
a. Medication for opioid use disorder (MOUD):
b. Counseling:
c. Behavioral therapies:
d. Recovery support services:
e. Other types of treatment services:

² Total number of grant-funded naloxone kits distributed using ODTA grant-funded resources (e.g., ODTA grant-funded staff time, ODTA grant-funded distribution/delivery costs). This should include grant-funded naloxone kits distributed by the grantee or grantee partner(s) during the reporting period, as well as naloxone kits provided/purchased by another entity that were distributed by the grantee or grantee partner(s) during the reporting period using ODTA grant-funded resources.

C. Progress Report Overview Updates

Please share updates for grant-funded activities during the reporting period related to overall programmatic implementation and to approved goals and objectives.

1. Overall progress

Please share an update on progress completed during the reporting period related to overall programmatic implementation and to approved goals and objectives. (Suggested, but not limited to 1-2 paragraphs) [OPEN TEXT FIELD]

2. Challenges/barriers

If applicable, please share challenges faced during the reporting period related to overall programmatic implementation and to approved goals and objectives and identified strategies to overcome them. (Suggested, but not limited to 1-2 paragraphs) [OPEN TEXT FIELD]

3. Successes

If applicable, please share accomplishments achieved during the reporting period related to overall programmatic implementation and to approved goals and objectives. (Suggested, but not limited to 1-2 paragraphs) [Open text field]

4. Innovations

If applicable, please share innovations developed and/or implemented during the reporting period related to program initiatives. (Suggested, but not limited to 1-2 paragraphs) [OPEN TEXT FIELD]

D. Comments (Optional):	OPEN TEXT FIELD
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III. Work Plans

[TO BE ENTERED IN THE "WORK PLAN" SECTION OF SPARS]

A. Needs Assessment

Upload and provide a brief description of your document, *if required*. Once you upload your document, you will only update this section if you revise your needs assessment.

B. Strategic Plan

Depending upon your grant cohort, you may be required to submit one or more individual components of a strategic plan and/or a complete comprehensive strategic plan. If you are unsure of your requirements, consult your government project officer (GPO).

Strategic plan components

1. Annual work plan

Upload and provide a brief description of your document. Once you upload your document, you will only update this section if you revise your plan.

2. Implementation plan

Upload and provide a brief description of your document. Once you upload your document, you will only update this section if you revise your plan.

3. Sustainability plan

Upload and provide a brief description of your document. Once you upload your document, you will only update this section if you revise your plan.

4. Other strategic plan component not listed above

Upload and provide a brief description of your document, *if required*. Once you upload your document, you will only update this section if you revise your plan.

Full strategic plan

5. Strategic plan

Upload and provide a brief description of your document, *if required*. Once you upload your document, you will only update this section if you revise your plan.

C. Evaluation

1. Evaluation plan

Upload and provide a brief description of your document, *if required*. Once you upload your document, you will only update this section if you revise your plan.

2. Evaluation report

Upload and provide a brief description of your document, if required.

APPENDIX A - List of Definitions

Definitions

Assessment: Assessment is the first step in the Strategic Prevention Framework (SPF) process and helps prevention planners understand prevention needs for the population of focus based on a careful review of data gathered from a variety of sources. Specifically, assessment involves collection and analysis of available data sources to identify substance use consumption patterns, related consequences, and risk and protective factors impacting the population of focus. A comprehensive assessment also involves the examination of available resources to identify gaps, examines readiness to address problems identified, and prioritizes problems based on specific criteria (e.g., magnitude, trends, severity). See A Guide to SAMHSA's Strategic Prevention Framework for more details. Also, see definition for needs assessment.

Behavioral therapies: Behavioral therapies are variety of different types of mental health treatment approaches that focus on complex issues over a long period of time.

Counseling: Counseling is a type of mental health therapy and considered to be a short-term treatment. It is goal-oriented and tends to focus on a specific issue or life challenge.

Dentists: Dentists are individuals with advanced dental-related degrees such as DDS (Doctor of Dental Surgery) or DMD (Doctor of Medicine in Dentistry or Doctor of Dental Medicine) including general dentists, endodontists, periodontists, and oral and maxillofacial surgeons who are licensed to practice dentistry (which may involve oral surgery and prescribing pain medication).

Evaluation: Evaluation is the fifth step in the SPF process and is about enhancing prevention practice. It is the systematic collection and analysis of information about prevention activities to reduce uncertainty, improve effectiveness, and facilitate decision-making. See <u>A Guide to SAMHSA's Strategic Prevention Framework</u> for more details.

Evaluation plan: An evaluation plan is a written document that describes how grant-funded prevention strategies will be assessed and establishes outcome and/or impact measures tied to the original problem that the grant-funded program plans to address.

Evaluation report: An evaluation report is a written document that summarizes the purpose, methodologies, findings, and conclusions of grantee evaluations efforts and offers recommendations for program improvements. As part of the findings section, the evaluation report should examine whether prevention activities were successful in achieving the grant program's goals and objectives as laid out in the evaluation plan. Ideally, evaluation reports should include both process and outcome evaluation.

Family members: Family members are individuals who have a relative (e.g., spouse, child, parent, sibling, grandparent, or other familial relation) that has experienced an opioid overdose.

Federal fiscal year: Federal fiscal year (FY) is the annual period established for government accounting purposes. It begins on October 1 and ends on September 30 of the following year. For program monitoring purposes, the federal FY is further broken down into four quarters.

- Federal FY/Quarter 1: October 1 December 31
- Federal FY/Quarter 2: January 1 March 31
- Federal FY/Quarter 3: April 1 June 30
- Federal FY/Quarter 4: July 1 September 30

Goal: A goal is a broad statement about the long-term expectation of what should happen because of your program (the desired result). It serves as the foundation for developing your program objectives. Goals should align with the statement of need that is described. Goals should only be one sentence. The characteristics of effective goals include:

- Goals address outcomes, not how outcomes will be achieved.
- Goals are concise.
- Goals describe the behavior or condition in the community expected to change.
- Goals describe who will be affected by the project.
- Goals lead clearly to one or more measurable results.

Health care providers: Health care providers are licensed medical professionals authorized to prescribe medications (e.g., physicians, physician assistants, nurse practitioners, dentists) and other individuals certified to provide medical-related services in a health care setting.

Innovation/innovative strategy: An innovative prevention strategy is a method, idea, or approach that departs from the common ways of addressing a problem by applying adaptations, new processes, or new techniques to accomplish a goal.

Known or suspected opioid overdose events: For the purpose of grantee reporting, known or suspected opioid overdose events refer to situations where one or more doses of naloxone or other FDA-approved opioid overdose-reversing medication are administered in response to a known or suspected opioid overdose. Individuals administering naloxone must have received training or been equipped with naloxone funded by the grant. The known or suspected overdose event concludes once the person experiencing the known or suspected opioid overdose leaves the location where naloxone was administered (e.g., walks away) or is transferred into the care of others assuming responsibility for medical care (e.g., transported to hospital, care transferred to emergency department attending physician). If naloxone is administered to more than one individual at the same location, grantees should consider these as separate events.

Lead trainer: The lead trainer is the key personnel responsible for curriculum development and dissemination. The lead trainer will directly train health care providers and pharmacists to become certified ToT trainers.

Linkage/linked: Linkage or linked is defined as a confirmed encounter with a support service for which an individual was provided information through verbal or written referral. See also definition of for referral.

Medication for opioid use disorder (MOUD): Medication for opioid use disorder is an evidence-based pharmacological treatment for opioid use disorder and is most used in combination with counseling. There are 3 approved medications to treat opioid use in the U.S.: <u>methadone</u>, <u>buprenorphine</u>, and <u>naltrexone</u>.

Naloxone: For the purpose of grantee reporting, naloxone refers to naloxone or any other FDA-approved opioid overdose-reversing medication or device. Naloxone is a medication approved by the <u>Food and Drug Administration</u> (FDA) designed to rapidly reverse opioid overdose. It is an opioid antagonist—meaning that it binds to opioid receptors and can reverse and block the effects of other opioids, such as heroin, morphine, and oxycodone. Administered when a patient is showing signs of <u>opioid overdose</u>, naloxone is a temporary treatment and its effects do not last long. Therefore, it is critical to obtain medical intervention as soon as possible after administering/receiving naloxone. The medication can be given by intranasal spray (into the nose), intramuscular (into the muscle), subcutaneous (under the skin), or intravenous injection.

Naloxone administration: Naloxone administration refers to an event where naloxone or any other FDA-approved opioid overdose-reversing medication is administered to a person known or suspected to be experiencing an opioid overdose.

Naloxone dose: A naloxone dose is the measured quantity delivered in a single administration. One naloxone kit includes two doses. See also definition for naloxone kit.

Naloxone kit: One naloxone kit includes two doses of naloxone or other FDA-approved opioid-reversing medication, including all FDA-approved delivery devices (e.g., auto-injector, intranasal spray).

Needs assessment: A needs assessment uses data to define the nature and extent of substance abuse problems, identifies affected populations, identifies underlying causal factors that lead to consumption patterns, and uses findings to select appropriate strategies. Also, see definition for assessment.

Non-prescribing service providers: A non-prescribing service provider is an individual working in a health care or service role that does not have the ability to prescribe or dispense medications. This may include, but is not limited to, medical assistants, nurses, behavioral health technicians, behavioral health therapists and counselors, pharmacy technicians, social workers, or substance use treatment providers. Students pursuing an advanced degree in health-related fields, such as dental, pharmacy, or medical students, are also included here.

Nurse practitioners: Nurse practitioners are registered nurses with an advanced degree (master's or doctoral degree) and additional clinical training who are licensed to practice medicine (including prescribing medication) autonomously or in collaboration with other health care providers.

Objectives: Objectives describe the results to be achieved and the manner in which they will be achieved. Multiple objectives are generally needed to address a single goal. Well-written objectives help set program priorities and targets for progress and accountability.

Outcomes: Outcomes reported should be based on the results of naloxone administration delivered and reported by individuals who received grant-funded naloxone training or were equipped with grant-funded naloxone. Grantees are not expected to report outcomes that occur after the person experiencing a known or suspected opioid overdose leaves the location where naloxone was administered (e.g., walks away) or is transferred into the care of others assuming responsibility for medical care (e.g., transported to hospital via ambulance, care transferred to emergency department attending physician).

- a. Opioid overdose reversal: Regardless of the number of naloxone doses administered to a person known or suspected to be experiencing an opioid overdose, if the person becomes responsive and their respiration returns to normal within a few minutes of naloxone administration, the outcome is considered to be an "opioid overdose reversal."
- **b. Death:** If the administration of one or more doses of naloxone does not result in the return to normal respiration, and it is determined by someone with authority that the person suspected of experiencing an opioid overdose is deceased, the outcome is considered to be "death."
- c. Not an opioid overdose: If the administration of one or more doses of naloxone does not result in the return to normal respiration, and it is discovered that the person suspected of experiencing an opioid overdose is actually suffering from the effects of another health issue that mimics symptoms of opioid overdose (e.g., experiencing a heart attack, reacting to toxic levels of another substance), the outcome is considered to be "not an opioid overdose."
- **d. Unknown:** If a person experiencing a suspected opioid overdose is showing signs of life and remains unresponsive after receiving one or more doses of naloxone, but the naloxone administrator is unsure if the person is experiencing an opioid overdose or another health emergency when transferred to others assuming responsibility for medical care (e.g.,

transported to hospital, care transferred to emergency department attending physician), the outcome is considered to be "unknown."

Pharmacists: Pharmacists are individuals with an advanced degree (PharmD) who are licensed to dispense medication and provide patient consultation regarding medications. Many states allow pharmacists to prescribe certain medications, including naloxone.

Physician assistants: Physician assistants are individuals with a master's level medical-related degree who are licensed to practice medicine (including prescribing medication) through an agreement with a physician.

Physicians: Physicians are individuals with advanced medical degrees such as an MD (Doctor of Medicine) or DO (Doctor of Osteopathic Medicine) who are licensed to practice medicine, including general practitioners and doctors with advanced training in medical specialties (e.g., urology, pediatrics, psychiatry, oncology, obstetrics, and gynecology). Excludes individuals with advanced dental-related degrees such as DDS (Doctor of Dental Surgery) or DMD (Doctor of Dental Medicine).

Policy: Policy is a set of organizational rules (including but not limited to laws) intended to promote healthy behavior and prevent unhealthy behavior.

Population of focus: Population of focus refers to a group of individuals that prevention efforts are intended to reach or serve.

Practice: A practice is a type of approach, technique, or strategy that is intended to promote wellbeing and reduce the onset and progression of substance use and its related problems.

Prescribing health care providers: A prescribing health care provider is a health care professional with the ability to prescribe mediations to patients. This includes physicians, physician assistants, nurse practitioners, and dentists.

Prevention: Prevention is the active, assertive process of creating conditions and/or personal attributes that promotes the wellbeing of people. A proactive process designed to empower individuals and systems to meet the challenges of life events and transitions by creating and reinforcing conditions that promote healthy behaviors and lifestyles. Substance use prevention is intended to promote wellbeing and reduce the onset and progression of substance use and related problems.

Prevention strategies: Prevention strategies are practices, policies, or programs intended to promote wellbeing and reduce the onset and progression of substance use and its related problems.

Primary training: The primary training is provided by the funded organization to health care providers, pharmacists, and community partners enrolled in the ToT program. The primary training will prepare trainees to present the information effectively, respond to participant questions, and lead activities that reinforce the learning material. Recipients of the primary training will commit to providing the training material in their respective regions.

Program: A program is a set of predetermined, structured, and coordinated activities intended to promote wellbeing and reduce the onset and progression of substance use and its related problems. It can incorporate different practices; guidance for implementing a specific practice can be developed and distributed as a program.

Recovery support services: Recovery support services refers to a broad range of non-clinical services, that are culturally and linguistically designed to support individuals with mental health and/or substance use disorders seeking recovery. Recovery support services may include, but are not limited to, employment coaching, linkages to housing, recovery housing services, care navigation services, support groups, and peer support services that foster health, wellness, and resilience. Recovery support services, assisting both individuals and

families, are offered in various settings and help individuals enter and navigate care systems, remove obstacles to recovery, stay engaged in the recovery process, and lead fulfilling lives in their chosen communities.

Referral: A referral is defined as the act of providing information about, or direction to, support services. A referral may be provided verbally or in writing.

Secondary training: The secondary training is provided by certified ToT trainers and provides information on policies, procedures, and models of care for prescribing, co-prescribing, and expanding access to naloxone and other FDA-approved overdose reversal medications to the specified population of focus (rural or urban).

SPARS: SPARS is the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Performance Accountability and Reporting System. It is an online data entry, reporting, technical assistance request, and training system to support grantees in reporting timely and accurate data to SAMHSA.

Strategic plan: Strategic planning is the fifth step in the SPF process and increases the effectiveness of prevention efforts by ensuring prevention planners select and implement the most appropriate programs/strategies for the population(s) of focus. A strategic plan is a written document that prioritizes substance use problems identified in the assessment process (SPF Step 1), selects appropriate programs/practices to address each priority, combines programs/practices to ensure a comprehensive approach, and builds/shares a logic model with key stakeholders. See <u>A Guide to SAMHSA's Strategic Prevention Framework</u> for more details.

Targeted geographic area: Targeted geographic area refers to the catchment area where grant-funded services are being provided.

Tertiary training: Tertiary training is provided by recipients of the secondary training. Recipients of tertiary training may include colleagues, patients, family members, friends, students, and community level partners.

Training of Trainers (ToT) trainer: A ToT trainer has completed the ToT program provided by the lead trainer. The ToT program will include a curriculum that covers training topics and materials as well as instruction on how to deliver the training topics and materials to others. ToT trainers will master facilitative skills and demonstrate subject matter expertise in the training topic areas.