

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE SUBSTANCE ABUSE AND MENTAL
HEALTH SERVICES ADMINISTRATION
FOLLOWED GRANT REGULATIONS
AND PROGRAM-SPECIFIC
REQUIREMENTS WHEN AWARDING
STATE TARGETED RESPONSE TO THE
OPIOID CRISIS GRANTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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Office of Inspector General

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Report in Brief

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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

The Substance Abuse and Mental Health Services Administration (SAMHSA) awarded State Targeted Response to the Opioid Crisis (Opioid STR) grants to States and territories to use for programs that address opioid addiction. The 21st Century Cures Act allowed SAMHSA to award \$1 billion in funding, half in Federal fiscal year (FY) 2017 and the other half in FY 2018 based on a formula developed by agencies and offices within the Department of Health and Human Services (HHS).

Our objective was to determine whether SAMHSA followed HHS grant regulations and program-specific requirements when awarding Opioid STR grants authorized under the 21st Century Cures Act.

How OIG Did This Review

Our audit covered SAMHSA's Opioid STR grant award process for FY 2017 (October 1, 2016, through September 30, 2017). During FY 2017, SAMHSA awarded 57 Opioid STR grants totaling \$484.5 million. We reviewed documentation provided by SAMHSA pertaining to the grant award process. We also evaluated whether SAMHSA's funding formula was based on the 21st Century Cures Act, reviewed the funding formula elements, and obtained SAMHSA's explanation for why the elements were chosen. We reviewed the formula calculation methodology that SAMHSA used to determine the funding amounts for each of the 57 grants.

The Substance Abuse and Mental Health Services Administration Followed Grant Regulations and Program-Specific Requirements When Awarding State Targeted Response to the Opioid Crisis Grants

What OIG Found

We found that SAMHSA followed HHS grant regulations and program-specific requirements when awarding Opioid STR grants authorized under the 21st Century Cures Act. Specifically, SAMHSA performed an adequate review of all 57 grant applications and adequately followed up with applicants to address their concerns. As part of the pre-award process, SAMHSA created teams of expert staff members to review the applications and evaluate the information.

We also determined that SAMHSA's funding formula elements (unmet need for opioid use disorder and drug poisoning deaths) were based on the 21st Century Cures Act. According to SAMHSA, these funding elements provided the most comparable and uniform data on a national scale to assess the prevalence of the opioid crisis. Lastly, we found that the 2018 State Opioid Response grant legislation provides an additional 15-percent set-aside for the 10 States with the highest mortality rates related to drug poisoning deaths.

What OIG Recommends

This report contains no recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

The 21st Century Cures Act authorized State Targeted Response to the Opioid Crisis (Opioid STR) grants to provide supplemental funding to States and territories to address the opioid crisis. The grants are to be used to carry out activities that increase access to treatment; reduce unmet treatment need; and reduce opioid overdose (drug poisoning) deaths through the provision of prevention, treatment, and recovery activities for opioid use disorder (OUD).¹

The Substance Abuse and Mental Health Services Administration (SAMHSA) awarded Opioid STR grants for States and territories to use for programs that address opioid addiction. The 21st Century Cures Act provided \$1 billion in funding, half in Federal fiscal year (FY) 2017 and the other half in FY 2018, that SAMHSA awarded using a formula developed by agencies and offices within the Department of Health and Human Services (HHS).

As part of its oversight activities, the Office of Inspector General is conducting a series of reviews of opioid-related grants because adequate controls are necessary to ensure that award money is used appropriately. This is the first report in the series. We conducted this review to verify that SAMHSA awarded the grants in accordance with Federal requirements.

OBJECTIVE

Our objective was to determine whether SAMHSA followed HHS grant regulations and program-specific requirements when awarding Opioid STR grants authorized under the 21st Century Cures Act.

BACKGROUND

The 21st Century Cures Act State Targeted Response to the Opioid Crisis Grants

The 21st Century Cures Act, P.L. 114-255 (enacted Dec. 13, 2016) provided SAMHSA two appropriations of \$500 million, one in FY 2017 and one in FY 2018.² Grants funded with these appropriations must be used for activities that supplement the opioid crisis activities of the State agency that administers the Substance Abuse Prevention and Treatment block grant. The grants aim to address the opioid crisis by increasing access to treatment, reducing unmet treatment need, and reducing opioid drug poisoning-related deaths through the provision of prevention, treatment, and recovery activities for OUD. The legislation stipulates that when

¹ OUD occurs when the recurrent use of opioids, including prescription opioids and illicit drugs such as heroin, causes clinically and functionally significant impairment.

² Appendix B contains a list of the Opioid STR grant awards for FY 2017.

awarding the grants, SAMHSA must give preference to States with an incidence or prevalence of OUD that is substantially higher relative to other States.³

Following the 21st Century Cures Act, Congress passed the Consolidated Appropriations Act, 2018, to support a comprehensive response to the opioid crisis. The Consolidated Appropriations Act, 2018, made available an additional \$1 billion in grants for States and territories to provide additional funding for opioid crisis activities already undertaken by State agencies. These grants, known as State Opioid Response (SOR) grants, are awarded using a formula similar to the Opioid STR grant formula plus an additional 15 percent set aside for the 10 States hardest hit by the crisis.⁴ Those 10 States, which have the highest mortality rates related to drug poisoning deaths, are West Virginia, Ohio, New Hampshire, District of Columbia, Pennsylvania, Kentucky, Maryland, Massachusetts, Delaware, and Rhode Island.⁵

SAMHSA's Grant Award Process for State Targeted Response to the Opioid Crisis Grants

Within HHS, SAMHSA is the agency that leads public health efforts to advance the behavioral health of the Nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on communities in the United States. As part of its activities, SAMHSA awards grants to States and territories for substance abuse prevention and treatment. Within SAMHSA, the Center for Substance Abuse Treatment and the Center for Substance Abuse Prevention accepted the applications for the FY 2017 Opioid STR grants.

When awarding grants, SAMHSA must follow the pre-award grant regulations in the Office of Management and Budget's (OMB's) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (commonly called Uniform Guidance). HHS codified the Uniform Guidance at 45 CFR part 75, which prescribes instructions and other pre-award matters⁶ for the granting agency to use in the announcement and application process for awards made on or after December 26, 2014. The Uniform Guidance stipulates that the use of certain sections is required only for competitive Federal awards but may also be used by the HHS awarding agency for non-competitive awards where appropriate or required by Federal statute. The Opioid STR grants are non-competitive, and the HHS awarding agency, SAMHSA, chose to use these additional sections.

In addition, the *HHS Grants Policy Statement* provides the general terms and conditions for HHS discretionary grant and cooperative agreement awards. It describes the roles of HHS operating divisions and other HHS organizations in HHS grants, specifies recipient and HHS staff

³ Section 1003(c)(1) of the 21st Century Cures Act.

⁴ These 10 States received allocations totaling \$142.5 million in additional SOR grant funding.

⁵ State Opioid Response Grants Funding Opportunity Announcement No. TI-18-015.

⁶ Other pre-award matters include the funding agency's standard application requirements and review of both the merit of proposals and the risk posed by applicants.

responsibilities, outlines the grant application and review processes, and explains the various resources available to those interested in the HHS grants process.

The funding amounts for the Opioid STR grants were determined by a weighted formula consisting of two elements: unmet need for OUD treatment⁷ and drug poisoning deaths.⁸ Specifically, the formula assigns a 70-percent weight to the number of people who meet the criteria for dependence on or abuse of heroin or opioid pain relievers and have not received treatment and assigns a 30-percent weight to the number of drug poisoning deaths. These percentages were then multiplied by the Opioid STR funding amount available and adjusted to ensure that each State and territory was awarded a minimum of \$2 million and \$250,000, respectively.

The pre-award process for the Opioid STR grants begins with SAMHSA preparing the Funding Opportunity Announcement (FOA). The FOA contains information related to the funding opportunity, requirements, submission timeframes, and evaluation criteria. SAMHSA then obtains approvals from OMB and posts the FOA on HHS's Grants.gov website.⁹ In response, the applicants prepare and submit applications through Grants.gov, which feeds the information into the National Institutes of Health's (NIH's) electronic Research Administration (eRA) Commons.¹⁰

Once SAMHSA receives the applications, the Division of Grant Review contacts each applicant organization to inform its officials that its application has been successfully submitted. The applications are reviewed by a committee of Federal employees who are experts in a field related to the requirements in the FOA. The reviewers record their results on checklists. SAMHSA reviews both the technical and the financial aspects of each application. At the end of the pre-award phase, SAMHSA makes award decisions, announces those decisions, and issues the Notice of Award (NoA), which is the legal document notifying the recipient that an award has been granted and containing information about the terms and conditions of the award.

⁷ To determine unmet need, SAMHSA used survey results from the National Survey on Drug Use and Health (NSDUH), which uses unmet treatment need as a standard measure. The NSDUH calculates unmet need based on a series of approximately 21 questions related to use, frequency of use, feelings during use, attempt to cut down, and other measures.

⁸ For drug poisoning deaths, SAMHSA used CDC's Surveillance System, which is a collection of databases that CDC uses to gather data. One of those databases is the National Vital Statistics System (NVSS). CDC's National Center for Health Statistics uses the NVSS to monitor deaths due to drug poisoning. NVSS collects mortality information from death certificates in all 50 States and the District of Columbia.

⁹ Grants.gov is a website for Federal agencies to post discretionary funding opportunities and for grantees to find and apply to those funding opportunities.

¹⁰ eRA Commons is NIH's information technology infrastructure used to process and manage grants awarded by NIH and other grantor agencies, including SAMHSA. The eRA Commons systems provide an online interface where grant applicants, grantees, and grantor agency staff can access and share administrative information related to grants.

HOW WE CONDUCTED THIS REVIEW

Our audit covered SAMHSA's Opioid STR grant award activity for FY 2017 (October 1, 2016, through September 30, 2017). During FY 2017, SAMHSA awarded 57 Opioid STR grants totaling \$484.5 million.¹¹ To determine whether SAMHSA awarded the grants in accordance with Federal requirements, we reviewed documentation provided by SAMHSA pertaining to the grant award process. This documentation included the FOA, grant applications, checklists for review of Opioid STR grant proposals, resolutions of identified concerns, and NoAs.

To determine whether SAMHSA's grant calculations were reasonable, we evaluated whether SAMHSA's funding formula was based on the 21st Century Cures Act, reviewed the funding formula elements, and obtained SAMHSA's explanation for why the elements were chosen. We reviewed the formula calculation methodology that SAMHSA used to determine the funding amounts for each of the 57 grants. Specifically, we used the unmet need and drug poisoning deaths data as the basis for our recalculation of the grant funding amounts. We applied the percentages and considered SAMHSA's minimum grant amounts.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

RESULTS OF REVIEW

We found that SAMHSA followed HHS grant regulations and program-specific requirements when awarding Opioid STR grants authorized under the 21st Century Cures Act. Specifically, SAMHSA performed an adequate review of all 57 grant applications and adequately followed up with applicants to address their concerns. As part of the pre-award process, SAMHSA created teams of expert staff members to review the applications and evaluate the information. We also determined that SAMHSA's funding formula elements were based on the 21st Century Cures Act. Lastly, the 2018 SOR grant legislation provides an additional 15-percent set-aside for the 10 States hardest hit by the opioid crisis.

SAMHSA ADEQUATELY REVIEWED STATE TARGETED RESPONSE TO THE OPIOID CRISIS GRANT APPLICATIONS

We found that SAMHSA's policies were adequate and enabled SAMHSA to identify and resolve application deficiencies. When reviewing applications, SAMHSA performed the steps detailed in its Guidance for Conducting Internal Merit Reviews for Non-Competitive Grants. For example, the Guidance for Conducting Internal Merit Reviews for Non-Competitive Grants

¹¹ SAMHSA used the other \$15.5 million of this appropriation for technical assistance and SAMHSA administration.

requires SAMHSA to establish committees consisting of three reviewers each to go through each application to identify any deficiencies or missing information and create a consolidated assessment form and checklist based on the final reviewer consensus. To meet this requirement, SAMHSA assigned each application to a three-reviewer committee which produced consolidated assessment forms and checklists that identified all application deficiencies. SAMHSA's FOA for these grants followed Federal guidance and contained programmatic and financial requirements that each applicant was required to address in its grant application and would be required to comply with during the grant period.

We found that SAMHSA performed an adequate review of all 57 grant applications and adequately followed up with applicants to address their concerns. As part of the pre-award process, SAMHSA created teams of expert staff members to review the applications and evaluate the information. The teams recorded their reviews on assessment forms and checklists based on the FOA criteria sections. After SAMHSA completed this process, it prepared and issued the NoAs to the grantees.

THE FUNDING FORMULA SAMHSA USED TO CALCULATE STATE TARGETED RESPONSE TO THE OPIOID CRISIS GRANTS WAS BASED ON THE AUTHORIZING STATUTE

HHS's *Grants Policy Administration Manual* specifies that program requirements, like funding formulas, must be based on an authorizing statute.¹² The 21st Century Cures Act stipulates that in awarding grants, preference must be given to States with an incidence or prevalence of OUD that is substantially higher relative to other States.¹³

We determined that SAMHSA's grant formula is based on the 21st Century Cures Act. According to SAMHSA officials, the Assistant Secretary for Financial Resources, the Assistant Secretary for Planning and Evaluation, the Office of the Secretary, and SAMHSA collaboratively determined the elements of the funding formula. These agencies and offices selected unmet need and drug poisoning deaths as the basis for the formula because these provide the most comparable and uniform data on a national scale to assess the prevalence of the opioid crisis. In addition, HHS officials stated that they felt that the gap in treatment need and the mortality rate were critical aspects of assessing the prevalence of the opioid crisis in each State. The elements were approved by the Office of National Drug Control Policy, OMB, and the Drug Program Coordinator. The information for unmet need and drug poisoning deaths came from SAMHSA's NSDUH survey results and CDC's drug poisoning deaths statistics.

¹² HHS, *Grants Policy Administration Manual*, part C, chapter 1(b) (Dec. 31, 2015).

¹³ Section 1003(c)(1) of the 21st Century Cures Act.

HHS officials assigned a 70-percent weight to unmet need and a 30-percent weight to drug poisoning deaths.¹⁴ These weights were chosen by HHS officials, who stated that they felt strongly that a primary aspect of addressing the crisis was reducing the treatment gap.

2018 STATE OPIOID RESPONSE GRANTS INCLUDED AN ADDITIONAL SET-ASIDE FOR THE 10 STATES HARDEST HIT BY THE OPIOID CRISIS

We found that SAMHSA's Opioid STR grant funding formula is based on the 21st Century Cures Act; however, the SOR grants legislation contained in the Consolidated Appropriations Act, 2018, provides an additional \$1 billion funding to States, territories, and Tribes to support a comprehensive response to the opioid crisis. For the SOR grants, SAMHSA used a formula similar to the Opioid STR grant formula, but unlike the Opioid STR grants, the SOR grant funding included an additional 15-percent set-aside for the 10 States hardest hit by the crisis. The 15-percent set-aside provides an additional \$142.5 million in funding for those States with the highest mortality rates related to drug poisoning deaths.

While the same funding formula elements were used for the Opioid STR and SOR grants, the STR and SOR grant formulas weighted the elements differently. The Opioid STR grant formula assigned a 70-percent weight for unmet need and a 30-percent weight for drug poisoning deaths, whereas the SOR grant formula assigned a 50-percent weight for unmet need and a 50-percent weight for drug poisoning deaths.

According to SAMHSA officials, Congress did not have concerns about SAMHSA's formula elements but did want to give more money to less populated States with a higher percentage of deaths.¹⁵ The 15-percent set-aside provides additional funding to those States.

CONCLUSION

SAMHSA followed HHS grant regulations and program-specific requirements when awarding Opioid STR grants authorized under the 21st Century Cures Act. Specifically, SAMHSA had a process in place to ensure that Opioid STR grants were awarded appropriately to the States and territories. We also found that the funding formula used for Opioid STR grants was based on the 21st Century Cures Act. In addition, 2018 SOR grants legislation provided an additional 15-percent set-aside for those States with a higher percentage of opioid-related deaths. Accordingly, this report does not contain recommendations.

¹⁴ HHS officials set minimum grant amounts for States and territories that applied for an Opioid STR grant. The minimum was \$2 million for a State and \$250,000 for a territory. Because data was less complete for the territories, HHS officials calculated territory grants using the national average percentages for unmet need and drug poisoning deaths.

¹⁵ In April 2017, Senators from New Hampshire, a less populated State with a higher rate of drug poisoning deaths, stated that the Opioid STR grant formula does not adequately take the prevalence of the problem into account and favors more populous States over less populated States because of the heavy weight that population plays in the grant funding formula. The Senators expressed disappointment that the Opioid STR grant formula used mortality numbers instead of per capita death rates to determine funding allocations.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit focused on the Opioid STR grant award process that SAMHSA used when it issued to States and territories the Opioid STR grants for FY 2017 (audit period). In April 2017, SAMHSA awarded 57 grants ranging from \$250,000 to \$44.7 million and totaling \$484.5 million during the audit period. We reviewed the grant applications and relevant documents for SAMHSA's Opioid STR grant pre-award process.

We limited our review of internal controls to those related to our objective. We performed fieldwork from October 2017 to October 2018 at the SAMHSA office in Rockville, Maryland.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, HHS guidance, and SAMHSA policies and procedures;
- interviewed SAMHSA officials to gain an understanding of the Opioid STR grant program and SAMHSA's grant award process;
- reviewed information obtained from SAMHSA officials to determine the funding formula process, the FOA procedures, application submission and review processes, and NoA issuance process;
- reviewed the elements used in the formula and information regarding those elements;
- interviewed SAMHSA officials about the formula, its development, and any alternative elements considered in creating the formula;
- reviewed the formula calculation steps and determined the calculation's reasonableness and accuracy;
- obtained and reviewed States and territories' grant application packages and NoA documents;
- reviewed all available SAMHSA documents, including SAMHSA's official pre-award files and FOA, for each of the 57 grant applications for compliance with HHS's and SAMHSA's internal policies for awarding Federal funds; and
- discussed the results of our review with SAMHSA officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: STATE TARGETED RESPONSE TO THE OPIOID CRISIS GRANTS

State/Territory ¹⁶	FY 2017 Grant Award
California	\$44,749,771
Texas	27,362,357
Florida	27,150,403
Pennsylvania	26,507,559
Ohio	26,060,502
New York	25,260,676
Michigan	16,372,680
Illinois	16,328,583
North Carolina	15,586,724
Tennessee	13,815,132
New Jersey	12,995,621
Arizona	12,171,518
Washington	11,790,256
Georgia	11,782,710
Massachusetts	11,742,924
Indiana	10,925,992
Kentucky	10,528,093
Maryland	10,036,843
Missouri	10,015,898
Virginia	9,762,332
Louisiana	8,167,971
Alabama	7,967,873
Colorado	7,869,651
Wisconsin	7,636,938
Oklahoma	7,283,229
South Carolina	6,575,623
Oregon	6,564,425
West Virginia	5,881,983
Nevada	5,663,328
Utah	5,537,458
Connecticut	5,500,157
Minnesota	5,379,349
Puerto Rico	4,811,962
New Mexico	4,792,551
Arkansas	3,901,295
Mississippi	3,584,702
New Hampshire	3,128,366
Kansas	3,114,402

¹⁶ Guam and the Marshall Islands, although eligible, did not apply for grants.

State/Territory¹⁶	FY 2017 Grant Award
Iowa	2,728,077
Rhode Island	2,167,007
Maine	2,039,029
Alaska	2,000,000
Delaware	2,000,000
District of Columbia	2,000,000
Hawaii	2,000,000
Idaho	2,000,000
Montana	2,000,000
Nebraska	2,000,000
North Dakota	2,000,000
Vermont	2,000,000
Wyoming	2,000,000
South Dakota	1,999,997
American Samoa	250,000
Federated States of Micronesia	250,000
Northern Marianas	250,000
Palau	250,000
Virgin Islands	250,000
Total	\$484,491,947