

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**OHIO MADE PROGRESS TOWARD
ACHIEVING PROGRAM GOALS
FOR ENHANCING ITS
PRESCRIPTION DRUG
MONITORING PROGRAM**

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



Amy J. Frontz
Deputy Inspector General
for Audit Services

December 2020
A-05-18-00004

Office of Inspector General

<https://oig.hhs.gov>

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The designation of financial or management practices as questionable,
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operating divisions will make final determination on these matters.

Report in Brief

Date: December 2020

Report No. A-05-18-00004



Why OIG Did This Audit

According to the Centers for Disease Control and Prevention (CDC), opioids were involved in more than 47,000 deaths in 2018, and opioid deaths were 6 times higher in 2018 than in 1999. CDC has awarded funding to States to address the nonmedical use of prescription drugs and to address opioid overdoses. We are conducting a series of audits of States that have received CDC funding to enhance their prescription drug monitoring programs (PDMPs). We selected Ohio for audit because it experienced a significant increase in the rate of drug overdose deaths during 2016 and 2017.

Our objectives were to: (1) identify actions that Ohio has taken, using Federal funds for improving PDMPs, to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse and (2) ensure that Ohio used Federal funds in accordance with Federal requirements.

How OIG Did This Audit

Our audit covered actions Ohio has taken to enhance and maximize its PDMP. In addition, we selected financial transactions, including contracts and payroll costs, that Ohio and subrecipients charged to its grants, and we reviewed the associated supporting documentation to determine whether Ohio used funds in accordance with Federal requirements.

Ohio Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program

What OIG Found

We identified actions that Ohio has taken, using Federal funds for improving PDMPs, to achieve program goals of improving safe prescribing practices and preventing prescription drug abuse and misuse as of August 2019. Ohio also complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and publicly reported the five CDC-directed indicators.

The Ohio Department of Health made improvements in its PDMP related to two required strategies of CDC's "Prescription Drug Overdose: Prevention for States" (PFS) program: (1) enhance and maximize a State PDMP and (2) implement community or insurer health system interventions aimed at preventing prescription drug overdose and abuse. It also made improvements in its PDMP related to the two optional PFS program strategies: (1) conduct policy evaluations to reduce prescription drug overdose morbidity and mortality and (2) develop and implement Rapid Response Projects.

Further, Ohio improved access and strengthened the State's PDMP using Substance Abuse and Mental Health Services Administration grant funding. Ohio's Board of Pharmacy (BoP) improved real-time access to PDMP data by integrating Ohio's PDMP with existing technologies such as electronic health records to improve the ability of Ohio's PDMP to reduce the nature, scope, and extent of prescription drug abuse. BoP also strengthened Ohio's PDMP by providing resources to make the changes necessary to increase interoperability with other States' PDMPs.

Additionally, Ohio used the grant funds that we reviewed in accordance with Federal regulations. Therefore, we are making no recommendations.

What OIG Recommends and Ohio's Comments

This report contains no recommendations.

In response to our draft report, Ohio stated that they are continually improving their strategies and methodologies in combating the drug overdose crisis that has occurred in Ohio within the last five years. We included Ohio's comments as appendices to this report.

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INTRODUCTION

WHY WE DID THIS AUDIT

As a result of the national opioid epidemic, Federal funding to the U.S. Department of Health and Human Services' (HHS's) prevention and treatment programs has increased to help curb opioid abuse and misuse. According to the Centers for Disease Control and Prevention (CDC), opioids were involved in more than 47,000 deaths in 2018, and opioid deaths were 6 times higher in 2018 than in 1999. CDC has awarded funding to States as part of HHS's strategic effort to address the nonmedical use of prescription drugs and to address opioid overdoses. States use these funds for prevention strategies to improve safe prescribing practices and prevent prescription drug overuse, misuse, abuse, and overdoses.

To track the prescribing and dispensing of prescription drugs, States use prescription drug monitoring programs (PDMPs), which are State-run electronic databases. Because each State's PDMP operates independently, PDMP capability and usage varies from State to State. States may use PDMP data to identify patients at risk of misusing prescription opioids and clinicians with inappropriate prescribing and dispensing practices.

We are conducting a series of audits of States that have received CDC and Substance Abuse and Mental Health Services Administration (SAMHSA) funding to enhance their PDMPs. (Appendix C lists related Office of Inspector General reports.) We selected for audit the State of Ohio because it experienced a significant increase in the rate of drug overdose deaths during 2016 and 2017. The Ohio Department of Health (ODH) and Ohio Board of Pharmacy (BoP) administered the CDC and SAMHSA grants for the State of Ohio. For purposes of this report, we refer collectively to ODH and BoP as "Ohio."

OBJECTIVES

Our objectives were to: (1) identify actions that Ohio has taken, using Federal funds for improving PDMPs, to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse and (2) ensure that Ohio used Federal funds in accordance with Federal requirements.

BACKGROUND

CDC's "Prescription Drug Overdose: Prevention for States" Program

CDC provided grant funds to 29 States under the program entitled "Prescription Drug Overdose: Prevention for States" (PFS). The PFS program helps States combat the ongoing prescription-drug-overdose epidemic (particularly the abuse, misuse, and inappropriate prescribing of opioid pain relievers) by providing State health departments with the resources and support needed for preventing overdoses.

To combat the ongoing prescription drug epidemic, States may advance four prevention strategies: two are required, and two are optional.¹ All applicants for funding are required to propose two or more substrategies to enhance the use of PDMPs. If one of these substrategies is public health surveillance, the State must publicly report five indicators, known as CDC-directed indicators, as specified in the funding opportunity announcement. (Appendix B lists the five indicators.) For each strategy, the State submits to CDC a Work Plan listing the proposed activities to be completed.

All HHS grant recipients, including States receiving CDC grant funding, must comply with all terms and conditions outlined in the notice of award. ODH's notice of award for the CDC grant required that ODH submit to CDC the Annual Performance Report no later than 120 days before the end of the budget period and the annual Federal Financial Report no later than 90 days after the end of the budget period.²

SAMHSA's "Electronic Health Record Integration and Interoperability Expansion" Program

In addition to the CDC PFS grant funding, the State of Ohio received SAMHSA grant funds under the Electronic Health Record Integration and Interoperability Expansion (PEHRIIE). The PEHRIIE grant is administered by BoP; the purpose of the program is to: (1) improve real-time access to PDMP data by integrating PDMPs into existing technologies such as electronic health records (EHRs) to improve the ability of State PDMPs to reduce the nature, scope, and extent of prescription drug abuse and (2) strengthen State PDMPs that are currently operational by providing resources to make the changes necessary to increase interoperability of State PDMPs.

PEHRIIE grant funds must be used to support integrating PDMPs into EHRs and expanding interoperability, including but not limited to the following types of activities:

- Modifying the PDMP system to alert dispensers and prescribers of information that will help identify and prevent misuse or unlawful diversion of controlled substances. Dispensers and prescribers could create a threshold within their EHR health information exchange that would alert them when patients receive a certain number of prescriptions for controlled substances.

¹ PFS grantees are expected to advance two required strategies. In addition, PFS grantees must also address one of the two optional prevention strategies. The two required strategies are: (1) enhance and maximize a State PDMP and (2) implement community or insurer health system interventions aimed at preventing prescription drug overdose and abuse. The two optional strategies are: (1) conduct policy evaluations to reduce prescription drug overdose morbidity and mortality and (2) develop and implement Rapid Response Projects.

² The Annual Performance Report consists of ODH's progress on each strategy, population data, and PDMP indicators. The Federal Financial Report includes information on funds authorized and disbursed during the timeframe covered by the report. Budget periods usually are 12 months long; however, shorter or longer periods may be established for programmatic or administrative reasons.

- Developing capability of PDMP data to be integrated into EHR pharmacy dispensing systems, and other health information technologies, with appropriate privacy protections so that PDMP information is presented to users within their normal workflow.
- Providing a plan on how to achieve interoperability with at least eight other State PDMPs including two geographically bordering States.
- Enabling PDMP users to automatically sign on to the PDMP system based on their User System. Authentication should not interfere with the user’s workflow.

Ohio’s Prescription Drug Monitoring Program

Ohio established its PDMP, known as the Ohio Automated Rx Reporting System (OARRS), to monitor the prescribing and dispensing of controlled substances and drugs identified as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense these substances. OARRS was established in 2006 and is maintained by BoP. OARRS collects information on all outpatient prescriptions for controlled substances and one non-controlled substance (gabapentin) dispensed by Ohio-licensed pharmacies and personally furnished by Ohio prescribers. This data is reported every 24 hours and is maintained in a secure database. OARRS is a tool that can be used to address prescription drug diversion and abuse. It serves multiple functions, including as a patient care tool, drug epidemic early warning system, and drug diversion and insurance fraud investigative tool. OARRS also helps prescribers and pharmacists avoid potentially life-threatening drug interactions as well as identify individuals fraudulently obtaining controlled substances from multiple health care providers, a practice commonly referred to as “doctor shopping.” It can also be used by professional licensing boards to identify or investigate clinicians with patterns of inappropriate prescribing and dispensing and to assist law enforcement in cases of controlled substance diversion.

Ohio received a CDC PFS grant for the award period of September 1, 2015, through August 31, 2019. For the project period September 1, 2015, through August 31, 2017 (audit period), CDC awarded Ohio \$2,880,000, \$940,000 for the first year and \$1,940,000 for the second year, for work on all four prevention strategies (grant number 1U17CE002738-01). The total funds actually obligated during our audit period was \$2,487,223, with the remaining \$392,777 carried over into the 2018 budget year.

In addition to the CDC PFS grant, Ohio received a SAMHSA PEHRIIE grant (grant number TI024494-01) for the award period of September 30, 2012, through September 29, 2016. The total amount awarded for all years of the grant was \$449,382. We limited our audit to the final year of the PEHRIIE grant, September 30, 2015, through September 29, 2016. Ohio obligated \$115,993 during the final year of the PEHRIIE grant. The majority of these funds was put toward payroll and PDMP-related contracts.

HOW WE CONDUCTED THIS AUDIT

Our audit covered actions Ohio has taken to enhance and maximize its PDMP and that it proposed for CDC's PfS and SAMHSA's PEHRIIE grant funding. Specifically, we examined Ohio's status for completing its proposed PfS and PEHRIIE activities as of August 2019. In addition, we selected financial transactions, including contracts and payroll costs, that Ohio and subrecipients charged to both the PfS and PEHRIIE grants, and we reviewed the associated supporting documentation to determine whether Ohio used funds in accordance with Federal requirements.

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 AUDIT

We identified actions that Ohio has taken, using CDC and SAMHSA Federal funds for improving PDMPs, to achieve program goals of improving safe prescribing practices and preventing prescription drug abuse and misuse as of August 2019. Ohio also complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and publicly reported the five CDC-directed indicators.

Additionally, Ohio used the grant funds that we reviewed in accordance with Federal regulations. Therefore, we are making no recommendations.

OHIO ENHANCED ITS PRESCRIPTION DRUG MONITORING PROGRAM USING CDC GRANT FUNDING

ODH made improvements in its PDMP related to two required strategies of the PfS program: (1) enhance and maximize a State PDMP and (2) implement community or insurer health system interventions aimed at preventing prescription drug overdose and abuse. It also made improvements in its PDMP related to the two optional PfS program strategies: (1) conduct policy evaluations to reduce prescription drug overdose morbidity and mortality and (2) develop and implement Rapid Response Projects.

Activities Related to Enhancing and Maximizing the Prescription Drug Monitoring Program

ODH proposed the following activities related to the first required strategy of enhancing and maximizing the PDMP: (1) enhance PDMP functionality to increase PDMP utilization by prescribers to manage patients, (2) expand and improve proactive reporting, and (3) conduct

public health surveillance with PDMP data and publicly disseminate reports on CDC-directed metrics quarterly or semiannually.

Examples of ODH's successful implementation of these three activities during the audit period include the following:

- ODH coordinated with BoP to upgrade the State's PDMP. The upgrade allowed for batch uploading, which allows a prescriber or its delegate to request and generate reports for multiple patients at a time.
- ODH expanded and improved proactive reporting. This includes the implementation of a platform that provides a score that could indicate a patient's risk of overdose or addiction, red flags to alert prescribers to a potential patient safety issue, visualizations of data, search functions, and the ability to communicate via messaging to other providers. In addition, ODH upgraded the PDMP to collect the diagnosis and surgical codes for the reason for the prescription as part of the comprehensive upgrades. Other activities related to promoting adherence to mandatory reporting laws include adding functionality to the OARRS to allow for augmented monitoring of compliance on mandatory use.
- ODH used PDMP data for public health surveillance reports and provided information to local community projects to identify, implement, and evaluate interventions.

Activities Related to Implementing Community or Insurer/Health System Interventions Aimed at Preventing Prescription Drug Overdose and Abuse

ODH proposed the following activities related to the second required strategy of implementing community or insurer/health system interventions: (1) identify and provide technical assistance to high-burden communities and counties, especially efforts to address problematic prescribing, and (2) enhance uptake of evidence-based opioid prescribing guidelines.

Some examples of ODH's successful implementation of these activities during the audit period include the following:

- ODH identified high-burden communities and counties and provided technical assistance to them, especially efforts to address problematic prescribing. ODH supported 11 communities in the State with subgrants from the PfS to implement comprehensive, multifaceted, population-based Prescription Drug Overdose Prevention

Programs.³ ODH coordinated these programs and provided technical assistance to local projects on implementation of strategy.⁴

- ODH enhanced uptake of evidence-based opioid prescribing guidelines. ODH conducted a survey to assess the implementation of the Ohio Emergency Department Opioid Prescribing guidelines and used the results in its prevention efforts. ODH implemented a Primary Care Setting Quality Improvement project for Pain Management Guidelines. The project will develop and test a toolkit for physician practices and health care organizations to use to implement the prescribing guidelines (Chronic Pain and Acute Pain in nonemergency settings) in their organizations.

Activity Related to Conducting Policy Evaluations

ODH proposed the following major activity related to the first optional strategy of conducting policy evaluation: conducting a rigorous evaluation on a law, policy, or regulation designed to prevent opioid overuse, misuse, abuse, and overdose.

An example of ODH's successful implementation of this activity during the audit period includes identifying two legislative policies related to prescription drug overdose prevention for a rigorous evaluation. In years 1 and 2, ODH completed an evaluation of House Bill (HB) 341.⁵ ODH is in the process of conducting an evaluation of HB 4.⁶

Activity Related to Developing and Implementing Rapid Response Projects

ODH proposed the following major activity related to the second optional strategy of conducting policy evaluation: develop and implement rapid response projects.

³ The overarching goal of these subgrants is to decrease the unintentional overdose deaths in communities by implementing evidence-based Policy, Systems, and Environmental Change (PSEC) strategies. Projects coordinate county coalitions and task forces, overdose fatality reviews, community response plans, and PSECs, including increasing the use of OARRS, adopting pain management guidelines, and expanding access to naloxone.

⁴ In 2018, ODH funded 18 additional contracts (covering 23 counties) to assist other counties (not currently funded) in building capacity to better address prescription drug abuse prevention.

⁵ HB 314 became effective on September 16, 2014. This legislation requires opioid prescribers and dispensers to register in OARRS upon renewing their license, request an OARRS report for the previous 12 months before initially prescribing a controlled substance to a patient, and documenting the OARRS query in the patient's medical record.

⁶ HB 4 became effective on July 16, 2015. This legislation allows a physician to authorize individuals to furnish naloxone pursuant to physician protocol to a person at risk of overdose or to someone in a position to assist him or her. It also authorizes a pharmacist or pharmacy intern to dispense naloxone without a prescription to a person at risk of overdose or to a friend or family or community member who may intervene.

An example of ODH's successful implementation of this activity during the audit period is implementing a rapid response project to advance an innovative prevention approach. The rapid response project (supported with supplemental funding) implements community and clinical linkages to people reentering communities after release from jail, substance use disorder treatment facilities, and emergency departments to prevent overdoses.

OHIO IMPROVED ACCESS AND STRENGTHENED THE STATE'S PRESCRIPTION DRUG MONITORING PROGRAM USING SAMHSA GRANT FUNDING

BoP improved real-time access to PDMP data by integrating Ohio's PDMP with existing technologies such as EHRs to improve the ability of Ohio's PDMP to reduce the nature, scope, and extent of prescription drug abuse. BoP also strengthened Ohio's PDMP by providing resources to make the changes necessary to increase interoperability with other States' PDMPs. BoP addressed EHRs PEHRIIE grant goals through the following activities:

- completing integration of NARxCHECK⁷ risk summary tools with the MetroHealth EHR system and all Ohio Kroger pharmacies,
- providing funding to Kroger for the PDMP Access Project,⁸
- expanding interstate data sharing of PDMP data with 17 States, and
- implementing a pilot program allowing single sign-on access to patient data to the PDMP using CliniSync's Community Health Record service.

CONCLUSION

Ohio had made improvements to the PDMP program goals of improving safe prescribing practices and preventing prescription drug abuse and misuse. For the selected financial transactions we reviewed, Ohio followed Federal regulations applicable to the use of grant funds. Therefore, this report contains no recommendations.

In response to our draft report, Ohio stated that they are continually improving their strategies and methodologies in combating the drug overdose crisis that has occurred in Ohio within the last five years. We included Ohio's comments as (appendices D and E) to this report.

⁷ NARxCHECK is an add-on feature for EHRs when querying the PDMP. It uses a proprietary algorithm to calculate a relative overdose risk score for a given patient based on their PDMP records. This score is then displayed in an EHR to help the provider quickly decide whether to review the patient's full PDMP record before prescribing a controlled substance.

⁸ The primary purpose of the PDMP Access Project is to automate and integrate access to the PDMP.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered actions that Ohio has taken to enhance and maximize its PDMP using CDC and SAMHSA grant funding. Specifically, we examined Ohio's status for completing its proposed activities as of August 2019. In addition, we selected certain financial transactions charged to the PfS and PEHRIIE grants during our audit period and reviewed the associated supporting documentation to determine whether ODH and BoP used funds in accordance with Federal requirements.

We did not review ODH and BoP's overall internal control structures. Rather, we limited our audit to determining whether they had completed their proposed activities and whether they used grant funds in accordance with Federal requirements.

We performed our fieldwork remotely and at the State offices in Columbus, Ohio.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- interviewed ODH and BoP officials to identify actions that Ohio has taken to enhance and maximize its PDMP;
- reviewed documentation to determine the actions that Ohio has taken to complete the proposed activities and each activity's current status;
- reviewed 24 selected financial transactions totaling \$1,157,303 and all supporting documentation for those transactions to determine whether the transactions were allowable based on Federal regulations; and
- discussed the results of our audit with ODH and BoP 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: FIVE CDC-DIRECTED INDICATORS

CDC requires that awardees using PDMPs for public health surveillance publicly report the following 5 indicators:

- decrease in the percentage of patients receiving more than an average daily dose of greater than 100 morphine milligram equivalents⁹ (across all opioid prescriptions);
- decrease in the rate of multiple provider episodes for prescription opioids (5 or more prescribers and 5 or more pharmacies in a 6-month period) per 100,000 residents;
- decrease in the percentage of patients prescribed long-acting/extended-release opioids who were opioid-naïve (i.e., who have not taken prescription opioids in 60 days);
- decrease in the percentage of prescribed days that overlap between opioid prescriptions; and
- decrease in the percentage of prescribed opioid days that overlap with benzodiazepine prescriptions.¹⁰

⁹ The number of milligrams of morphine an opioid dose is equal to when prescribed.

¹⁰ Benzodiazepines are a class of agents that work in the central nervous system and are used for a variety of medical conditions.

APPENDIX C: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>California Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-09-18-01006</u>	12/10/2019
<i>New York Achieved Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-02-18-02001</u>	8/19/2019
<i>The University of Kentucky Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-04-18-02012</u>	5/30/2019
<i>Washington State Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-09-18-01001</u>	4/15/2019

APPENDIX D: OHIO DEPARTMENT OF HEALTH COMMENTS



Mike DeWine, Governor
Jon Husted, Lt. Governor

Stephanie McCloud, Director

December 11, 2020

Sheri L. Fulcher
Regional Inspector General for Audit Services
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: File ID No. A-05-18-00004, November 20, 2020 Report – Ohio Department of Health Agency Response

Dear Regional Inspector Fulcher:

The Office of Inspector General's November 20, 2020 report has made no recommendations. The Ohio Department of Health would like to express our sincere appreciation in the accountability and transparency that was provided from the review of the Prescription Drug Overdose Monitoring Program.

We are continually improving our strategies and methodologies in combating the drug overdose crisis that has occurred in Ohio within the last five years. Again, we thank you for the review and if you have any questions, please contact Will McHugh, Assistant Director, at [REDACTED].

Sincerely,

Stephanie McCloud/w.m

Stephanie McCloud
Director

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APPENDIX E: OHIO BOARD OF PHARMACY COMMENTS



December 9, 2020

Attn: Tate Clark
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Report Number A-05-18-00004

The State of Ohio Board of Pharmacy (Board) acknowledges receipt of the draft audit report *Ohio Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program*, report number A-05-18-00004. As the report contains no recommendations, the Board has no substantive response to the report's content.

The Board appreciates the opportunity to partner with the U.S. Department of Health and Human Services (HHS) for funding and programmatic support of its work to ensure the proper use of controlled substances and dangerous drugs. We also appreciate the acknowledgement of the sound practices and programmatic effectiveness of the Board's use of federal resources.

Please feel free to reach out to me at [REDACTED] with any questions or if additional information is needed.

Sincerely,

Matt Corlett
Director of Administration

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