Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE UNIVERSITY OF KENTUCKY 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.

Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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

The University of Kentucky Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program

Why OIG Did This Review

According to the Centers for Disease Control and Prevention (CDC), opioids were involved in more than 48,000 deaths in 2017, and opioid deaths were 6 times higher in 2017 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 reviews of States that received CDC funding to enhance their prescription drug monitoring programs (PDMPs). We selected Kentucky for review because it had the second highest age-adjusted drug overdose fatality rate in the United States in 2013.

Our objectives were to (1) identify actions the University of Kentucky (the University) has taken to achieve Prescription Drug Monitoring Program (PDMP) goals of improving safe prescribing practices and preventing prescription drug abuse and misuse and (2) ensure that it used Federal funds in accordance with Federal requirements.

How OIG Did This Review

Our audit covered actions the University proposed for CDC's "Prescription Drug Overdose: Prevention for States" grant for September 1, 2015, through August 31, 2017. We examined the University's status for completing its proposed activities as of our onsite review in August 2018.

What OIG Found

We identified actions the University 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 our onsite review in August 2018. The University also complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and publicly reported two of the five CDC-directed indicators.

Additionally, the University used the grant funds that we reviewed in accordance with Federal regulations. Finally, the University provided information on the actions it plans to take in future grant years to achieve the program goals of improving the PDMP.

What OIG Recommends

We are making no recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

As a result of the national opioid epidemic, Federal funding to U.S. Department of Health and Human Services (HHS) 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 48,000 deaths in 2017, and opioid deaths were 6 times higher in 2017 than in 1999. CDC 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 to 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 reviews of States that received CDC funding to enhance their PDMPs. We selected Kentucky for review because it had the second highest age-adjusted drug overdose fatality rate[1] in the United States according to 2013 CDC data.

OBJECTIVES

Our objectives were to (1) identify actions the University of Kentucky has taken to achieve PDMP goals of improving safe prescribing practices and preventing prescription drug abuse and misuse and (2) ensure that it used Federal funds in accordance with Federal requirements.

BACKGROUND

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

Prior to the "Prescription Drug Overdose: Prevention for States" (PfS) program, CDC's initial overdose prevention program was the Prescription Drug Overdose: Boost for State Prevention (Prevention Boost). This program equipped five state health departments, one of which was Kentucky, with resources and scientific assistance to prevent prescription drug overdose. This 1-year funding was provided to advance three key areas: (1) maximizing the use of PDMPs; (2) improving public insurance mechanisms to protect patients; and (3) evaluating policies to identify prevention that works. CDC created the current PfS program to continue this work and to help States increase their efforts.

[1] Age-adjusted drug overdose fatality rates are the number of deaths per 100,000 population and are calculated by applying age-specific death rates to the 2000 U.S. standard population age distribution.

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

To combat the ongoing prescription drug overdose epidemic, States may advance four prevention strategies: two are required and two are optional.[2] 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. The State agency's notice of award for the CDC grant required that the State agency submit to CDC both 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.[3]

University of Kentucky, the University of Kentucky Research Foundation, and the Kentucky Injury Prevention and Research Center

State Governments are eligible to receive CDC's PfS grant. In Kentucky, CDC awarded PfS grant funds to the University of Kentucky Research Foundation (Foundation), a unit of the University of Kentucky. The Foundation receives all grants awarded to the University of Kentucky, including this PfS grant. The Kentucky Injury Prevention and Research Center (KIPRC), located at the University of Kentucky's College of Public Health, carries out an agreement between the University of Kentucky and the Kentucky Cabinet for Health and Family Services, Department for Public Health. KIPRC serves as the agent of the Department for Public Health. For purposes of this report, we refer collectively to the University of Kentucky, the Foundation, and KIPRC as the "University."

[2] PfS grantees are expected to advance two required prevention strategies. In addition, PfS grantees must also address one of 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.

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

In 1999, Kentucky implemented the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program (a controlled substance prescription drug monitoring system) allowing prescribers, pharmacists, and law enforcement officials to request reports that provide detailed information regarding an individual's controlled substance prescription history. In 2005, an update to the KASPER system allowed pharmacists and prescribers to receive KASPER reports in real-time, permitting them to use a patient's controlled substance prescription history to make treatment decisions at the point of care. Essentially, KASPER shows the prescriber, the dispenser, and all prescriptions for an individual over a specified period.

The University received a CDC PfS grant for the award period of September 1, 2015, through August 31, 2019. For the project period of September 1, 2015, through August 31, 2017 (audit period), CDC awarded the University $2,786,456 (Year 1—$940,000 and Year 2—$1,846,456) for work on three[4] of the four prevention strategies (grant number 1U17CE002732-01).

HOW WE CONDUCTED THIS REVIEW

Our audit covered actions that the University proposed for CDC's PfS grant and has taken to enhance and maximize its PDMP for the audit period. Specifically, we examined the University's status for completing its proposed activities as of our onsite review in August 2018. In addition, we selected financial transactions that the University charged to this CDC grant during the audit period and reviewed the associated supporting documentation to determine whether the University used funds in accordance with Federal requirements. In addition, we reviewed the University's documentation to determine whether the University complied with Federal requirements for submitting reports and reporting the five CDC-directed indicators.

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 identified actions the University 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 our onsite review in August 2018. The University also complied with

[4] The University conducted work on the following three strategies: 1) enhance and maximize a State PDMP; 2) implement community or insurer health system interventions aimed at preventing prescription drug overdose and abuse; and 3) conduct policy evaluations.

Federal requirements for submitting its Federal Financial Report and Annual Performance Report and publicly reported two of the five CDC-directed indicators.[5]

Additionally, the University used the grant funds that we reviewed in accordance with Federal regulations. Finally, the University provided information on the actions it plans to take in future grant years to achieve the program goals of improving the PDMP. Therefore, we are making no recommendations.

THE UNIVERSITY ENHANCED THE STATE'S PRESCRIPTION DRUG MONITORING PROGRAM

As of August 2018, the University had made improvements to the State's PDMP related to the 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 to the State's PDMP related to one optional PfS program strategy: conducting policy evaluations.

Activities Related to Enhancing and Maximizing the Kentucky Prescription Drug Monitoring Program

The University proposed the following activities related to the first required strategy of enhancing and maximizing the PDMP: (1) integrate KASPER with electronic health records, (2) develop and deliver prescriber continuing education training, (3) establish a multi-source drug overdose fatality surveillance system (DOFSS),[6] and (4) conduct nonfatal prescription drug overdose surveillance.

Some examples of the University's successful implementation of these four activities, during the audit period, included the following:

- integrating KASPER reports with a large commercial pharmacy chain's electronic health records;
- developing and providing to physicians and nurse practitioners training focused on KASPER access; and
- developing a DOFSS that centralizes death investigation information by combining data from various data sources such as vital statistics death certificates, autopsy reports, coroner reports, and post-mortem toxicology reports.

[5] As of August 2018, the University reports all five CDC-directed indicators to CDC in the Annual Performance Report and publicly published two of the CDC-directed indicators within the quarterly KASPER issued reports. As of April 2019, the University reported all five indicators publicly on http://www.mc.uky.edu/kiprc/Files/drug/2019/KASPER%20Indicator%20Report.pdf.

[6] Kentucky's DOFSS is a comprehensive database that utilizes multiple sources to enhance the Commonwealth's analytical capacity to identify and characterize drug overdose fatalities.

In addition to these successes, the University identified some barriers and challenges to enhancing and maximizing PDMPs. Specifically, one barrier was healthcare facility costs related to adopting electronic medical records. Another challenge the University faced during the audit period, was the transition from ICD-9 to ICD-10[7] coding drug dependence and overdose. This slowed the production of timely reporting.

Activities Related to Implementing Community Interventions

The University proposed the following activities related to the second required strategy of implementing community interventions: (1) create a multidisciplinary, data-focused, drug overdose prevention group; (2) establish the KIPRC Drug Overdose Technical Assistance Center (DOTAC);[8] (3) enhance the local health department's use of drug abuse and overdose data results; and (4) enhance prevention education on overdose risk, appropriate prescribing, and naloxone use in the State and especially in high drug overdose counties.

Some examples of the University's successful implementation of these four activities, during the audit period, included the following:

- establishing relationships with key community stakeholders to develop the Kentucky Drug Overdose Prevention Advisory group;[9]

- establishing the DOTAC, which completed 20 data requests from a range of stakeholders including local health departments, media outlets, law enforcement, governmental agencies, and treatment providers between January 1, and March 28, 2016;

[7] ICD 9 was used to code and classify mortality data from death certificates until 1999 when use of ICD-10 for mortality coding started. ICD-10CM is a clinical modification of the World Health Organization's ICD-10, which consists of a diagnostic system. ICD-10CM includes the level of detail needed for morbidity classification and diagnostic specificity. It also provides code titles and language that complement accepted clinical practice.

[8] DOTAC supports local health departments, community coalitions, and State and local agencies in their efforts to address substance misuse, abuse, and overdose. DOTAC's goal is to support and enhance local agency and community organization access to timely local data and analytical results on controlled substance prescribing, drug related morbidity, and mortality trends.

[9] The Drug Overdose Prevention Advisory Group is an action team that provides input on ongoing KASPER enhancements and analytical projects. The Drug Overdose Prevention Advisory Group also serves as overseers of the drug overdose prevention and enhanced opioid overdose surveillance programs CDC awarded to KIPRC.

- providing awareness of the KIPRC website[10] to all 120 counties in Kentucky;[11] and

- conducting in-person workshops[12] at state-wide and national conferences to over 1,000 participants including the Kentucky Department of Criminal Justice Training staff.

In addition to these successes, the University identified some barriers and challenges to implementing community interventions. Specifically, the University noted that implementing drug overdose prevention programs and policies in rural communities was difficult due to the lack of integration capacity among the local community and organizations. In addition, the University noted that connecting individuals with substance use disorder (SUD) to treatment facilities based on the type of facility desired and expected payment type was challenging.

Activities Related to Conducting Policy Evaluation

The University proposed the following activities related to an optional strategy of conducting policy evaluation: (1) evaluation of KASPER querying and prescribing regulations by profession; (2) cost-benefit analysis of KASPER querying and prescribing laws by profession; (3) evaluation of the decedent control substance testing law;[13] (4) cost-benefit analysis of the decedent control substance testing law; and (5) additional activities funded by supplemental funds.

Some examples of the University's successful implementation of some of these five activities during the audit period included the following:

- completing a content analysis of laws and regulations and creating a focus group with key stakeholders to develop surveys;[14]

[10] The KIPRC website provides information to the State's population to increase knowledge and awareness of the injury prevalence in Kentucky and to impart skills and strategies to reduce this issue. Specifically, the website covers various resources and topics related to injury (for example, community safety, drug overdose), programs (for example, links to DOTAC, prevention programs, trauma registry), education and training (for example, trainings provided by the College of Public Health and Injury Prevention Centers), and publications and reports (such as links to the KASPER Threshold Analysis and Drug Overdose database).

[11] In addition, 120 coalition and data presentations were delivered in 14 counties, of which, 10 counties used the coalition and drug-related data to establish calls to action, set outcomes, and establish additional drug overdose prevention-related workgroups.

[12] These workshops consisted of training on addiction and pain management for prescribers in high burden regions and training on best prescribing practices and naloxone use for clinical professions.

[13] According to the Kentucky Revised Statutes (KRS) chapter 72.026, "In cases requiring a post-mortem examination under KRS 72.025, the coroner or medical examiner shall take a biological sample and have it tested for the presence of any controlled substances which were in the body at the time of death and which at the scene may have contributed to the cause of death."

[14] A survey of elected coroners provided an assessment of the impact KRS chapter 72.026 had on death investigations, including identification of barriers and facilitators to implementation of the mandate.

- collecting data on the PDMP administration and identifying the cost bearers of KASPER querying and prescribing laws;[15]

- surveying elected coroners, with the assistance of the Chief Medical Examiner and the Kentucky Coroners Association, to understand the impact of controlled substance testing laws on drug overdose investigations;[16]

- preparing a cost-benefit analysis of the evaluation of the decedent control substance testing law, which would be included in a final report that would be ready during budget year three; and

- testing of ICD-10CM definitions, validating cases, and establishing consensus on indicators for surveillance and reporting.[17]

The University did not specifically identify any significant barriers or challenges relating to the optional strategy of conducting policy evaluation.

THE UNIVERSITY'S PLANNED ACTIONS FOR IMPROVING THE PRESCRIPTION DRUG MONITORING PROGRAM

The University plans to continue to make improvements to the PDMP program by carrying out the activities outlined in its Work Plan for project years 3 and 4 (through August 31, 2019). Specifically, the University stated that it would:

- monitor the use of the morphine milligram equivalents (MME) warning flag to determine the extent of the decline of opioid prescribing;

- explore additional options for the integration of KASPER, including direct connections from electronic health records and the use of the RxCheck[18] hub;

- convert prior KASPER training to web-based modules, providing a broader accessibility to training;

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[15] Kentucky requires prescribers to query KASPER before initially prescribing opioids, as well as quarterly when long term opioid prescribing is occurring. The goal is to measure if querying within KASPER is conducted prior to dispensing a prescription.

[16] Historical toxicology invoice data was collected, cleaned, and linked to death certificate data.

[17] The University also developed the medical coder abstraction and physician abstraction form to test effectiveness of drug overdose coding definitions and case validation and distributed the results to key stakeholders.

[18] RxCheck is a fully operational hub that enables States to securely and efficiently share PDMP data while maintaining ownership, direct control, and access to their data.

- continue DOFSS analysis of drug overdose fatality data collection and identify risk factors;

- update reporting of State- and county-level profiles and dashboards;

- promote FindHelpNowKY.org, the go-to site for matching available SUD treatment slots with individuals' needs, to build public awareness;

- complete the analysis of physicians' ICD10 coding review and share results with CDC;

- continue Naloxone training to law enforcement professionals;

- work with the Kentucky State Police to obtain drug interdiction data;

- obtain additional toxicology data to include coroner's decision to have decedents tested for controlled substances to determine the impact of the State's mandate requiring postmortem toxicology testing or coroner cases;

- conduct a second economic analysis on the incremental cost effectiveness of cases with and without toxicology testing; and

- assess the economic impact of dental prescribing guidelines.

CONCLUSION

As of our onsite review in August 2018, the University had made improvements to the PDMP program goals of improving safe prescribing practices and preventing prescription drug abuse and misuse. The University also has planned actions related to future grant years to achieve the program goals of improving the PDMP. For the selected financial transactions we reviewed, the University followed Federal regulations applicable to the use of grant funds. In addition, the State agency complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and for publicly reporting the five CDC-directed indicators.

This report contains no recommendations.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

Our audit covered actions that the University proposed for CDC's PfS grant and has taken to enhance and maximize its PDMP for the audit period. Specifically, we examined the University's status for completing its proposed activities as of our onsite review in August 2018. In addition, we selected certain financial transactions charged to this CDC grant during our audit period and reviewed the associated supporting documentation to determine whether the University used funds in accordance with Federal requirements.

We did not review the University's overall internal control structure. Rather, we limited our review to determining whether it had completed its proposed activities and whether it used grant funds in accordance with Federal requirements.

We performed our fieldwork from May 2018 through January 2019, which included visiting the University's office in Lexington, Kentucky.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- interviewed University officials to identify actions that they had taken to enhance and maximize its PDMP;
- reviewed documentation to determine actions that the University had taken to complete its proposed activities and each activity's current status;
- reviewed 37 selected financial transactions totaling $215,376 and all supporting documentation for those transactions to determine whether the transactions were allowable based on Federal regulations; and
- discussed the results of our review with University 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 five indicators:

- decrease in the percentage of patients receiving more than an average daily dose of greater than 100 MMEs[19] (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-naive (i.e., who had not taken prescription opioids in 60 days);
- decrease in the percentage of prescribed days overlap between opioid prescriptions; and
- decrease in the percentage of prescribed opioid days that overlap with benzodiazepine prescriptions.[20]

[19] The number of milligrams of morphine an opioid dose is equal to when prescribed.

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