Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NEW YORK ACHIEVED PROGRAM GOALS FOR ENHANCING ITS PRESCRIPTION DRUG MONITORING PROGRAM

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Office of Inspector General

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Report in Brief

Date: August 2019 Report No. A-02-18-02001

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

Why OIG Did This Review

According to the Centers for Disease Control and Prevention (CDC), opioids were involved in more than 47,000 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 have received CDC funding to enhance their prescription drug monitoring programs (PDMPs). We selected New York for review 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 New York 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) determine whether New York complied with certain Federal requirements.

How OIG Did This Review

Our review covered actions that New York has taken to enhance and maximize its PDMP and that it proposed for CDC's "Prescription Drug Overdose: Prevention for States" grant for March 2016, through August 2017. We examined New York's status of completing 13 proposed activities and reviewed documentation to determine whether it submitted reports and used funds in compliance with certain Federal requirements.

New York Achieved Program Goals For Enhancing Its Prescription Drug Monitoring Program

What OIG Found

We identified actions that New York has taken, using Federal funds for improving PDMPs, to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse. As of August 2018, New York had completed the 13 federally-funded activities it proposed to enhance and maximize its PDMP. Specifically, New York completed four activities related to the integration of its PDMP with electronic health records, four activities related to the use of mobile technology for the PDMP, and five activities related to public health surveillance.

New York complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and reporting CDC-directed indicators (for awardees using PDMPs for public health surveillance). Additionally, with respect to the selected financial transactions we reviewed, New York used grant funds in accordance with Federal requirements.

What OIG Recommends

This report contains no recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

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 2017, and opioid deaths were 6 times higher in 2017 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 PDMPs operate independently, PDMP capabilities and usage vary from State to State. PDMP data may be used 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 have received CDC funding to enhance their PDMPs.¹ We selected New York for review because it experienced a significant increase in the rate of drug overdose deaths during 2016 and 2017.

OBJECTIVES

Our objectives were to (1) identify actions that New York 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) determine whether New York complied with certain 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 resources and support needed for preventing overdoses.

¹ We previously issued Washington State Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program (A-09-18-01001, issued April 2019) and The University of Kentucky Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program (A-04-18-02012, issued May 2019).

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, States should publicly report five indicators, known as CDC-directed indicators, as specified in the funding opportunity announcement.³ (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. New York's notice of award for the CDC grant required that New York 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.⁴

New York's Prescription Drug Monitoring Program

In New York, the Department of Health (DOH) is responsible for maintaining and enhancing the PDMP to provide practitioners with access to view patients' controlled substance prescription histories.⁵ Health Research, Inc. (HRI), a not-for-profit corporation, assists DOH by evaluating, soliciting, and administering external financial support for DOH projects. For purposes of this report, we refer collectively to DOH and HRI as the "State agency."

Effective August 2013, most prescribers in New York are required to consult patient prescription histories via the PDMP when writing prescriptions for Schedule II, III, and IV controlled substances.⁶ Patient prescription histories include all controlled substances dispensed in New York and reported by the pharmacy or dispenser during the past year. This information allows practitioners to better evaluate their patients' treatment with controlled substances and determine whether there may be abuse or non-medical use.

² 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 and/or 2) develop and implement Rapid Response Projects.

³ CDC has deferred to the States' discretion as to whether these CDC-directed indicators will be publicly reported.

⁴ The Annual Performance Report consists of New York'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.

⁵ DOH calls its PDMP the Prescription Monitoring Program.

⁶ The requirement to check the PDMP does not apply to veterinarians or in certain qualifying circumstances such as practitioners administering a controlled substance in the emergency department of a hospital or to a patient in hospice care.

The State agency received a CDC grant for the PfS program with a project period March 1, 2016, through August 31, 2019. From March 1, 2016, through August 31, 2017 (audit period), the State agency was awarded \$2,238,224 for work on all 4 prevention strategies (grant number 6NU17CE002742-01) and proposed 13 activities related to the first required strategy (for enhancing and maximizing its PDMP). In its Work Plan, the State agency said that it would:

- 1. Review and rectify obstacles to the integration of the PDMP with electronic health records (EHRs) by:
 - evaluating previous EHR integration attempts to identify obstacles and address outstanding issues;
 - evaluating advances in current technology and policy which may overcome obstacles:
 - proposing technical solutions to overcome previous obstacles and obtain conceptual agreement; and
 - drafting service definitions, functional specifications, web specifications, and implementation guides for PDMP queries.
- 2. Enhance access to the PDMP via mobile technology by:
 - purchasing mobile devices for testing,
 - testing its PDMP on each mobile device purchased,
 - modifying its PDMP programing to accommodate the use of the application on mobile devices, and
 - improving the appearance of PDMP search results on mobile devices.
- 3. Collect, analyze, and interpret public health surveillance data by:
 - adopting an agency-wide definition of an opioid poisoning,
 - accessing and analyzing core datasets using CDC's list of indicators and explore using additional indicators to apply to these core datasets,
 - exploring access to additional datasets and possible indicators to apply to these additional datasets,

- using surveillance data to produce maps and data tables that demonstrate the alignment of program activities in geographic areas most impacted by prescription drug overdoses, and
- disseminating and communicating surveillance results.

HOW WE CONDUCTED THIS REVIEW

Our review covered actions that the State agency has taken to enhance and maximize its PDMP and that it proposed for CDC's PfS grant for the audit period. We examined the State agency's status of completing the 13 proposed activities as of August 2018 (i.e., before the end of the project period). We also selected financial transactions that the State agency charged to this CDC grant during the audit period and reviewed the associated supporting documentation to determine whether the State agency used the funds in accordance with Federal requirements. In addition, we reviewed the State agency's documentation to determine whether the State agency complied with Federal requirements for submitting reports and reporting the 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 that the State agency has taken, using Federal funds for improving PDMPs, to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse. As of August 2018, the State agency had completed the 13 activities it proposed for the audit period to enhance and maximize its PDMP. The State agency also complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and reporting CDC-directed indicators. Additionally, with respect to the selected financial transactions we reviewed, the State agency used the grant funds in accordance with Federal regulations.

⁷ The State agency reported the five CDC-directed indicators to CDC in the Annual Performance Report, but only publicly reported three indicators. The State agency published on its website the following three indicators: (1) decrease in the percentage of patients receiving more than an average daily dose of greater than 100 morphine milligram equivalents (across all opioid prescriptions); (2) 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; and (3) decrease in the percentage of prescribed opioid days that overlap with benzodiazepine prescriptions.

THE STATE AGENCY ENHANCED ITS PRESCRIPTION DRUG MONITORING PROGRAM

As of August 2018, the State agency had completed 13 activities related to reviewing and rectifying obstacles to the integration of the PDMP with EHRs, enhancing access to the PDMP via mobile technology, and public health surveillance.

Activities Related to Reviewing and Rectifying Obstacles to the Integration of the Prescription Drug Monitoring Program with Electronic Health Records

EHR integration allows health care providers to review patient medical records while also seeing PDMP data for controlled substance drug transactions. This rapid access means that providers no longer need to disrupt their workflow by logging into a separate system to query the PDMP.

The State agency said that it would (1) evaluate previous EHR integration attempts to identify obstacles and address outstanding issues; (2) evaluate advances in current technology and policy which may overcome obstacles; (3) propose technical solutions to overcome previous obstacles and obtain conceptual agreement; and (4) draft service definitions, functional specifications, web specifications, and implementation guides for PDMP queries.

In April 2016, the State agency formed a workgroup that met monthly to evaluate integration attempts nationally to learn how other States integrated their PDMPs with EHRs, identify obstacles the States encountered, and determine how the States overcame those obstacles.

The workgroup determined that the HHS Office of National Coordinator for Health Information Technology (ONC)⁸ had not established technical standards governing PDMP queries via EHRs. The State agency overcame this obstacle by using a messaging standard previously established for inter-state data exchange of electronic healthcare information.⁹

The workgroup also determined that while PDMP user agreements were in place between the State agency and healthcare providers, similar agreements needed to be in place with Regional Health Information Organizations (RHIOs)¹⁰ when the PDMP is accessed through EHRs. The State agency has begun developing these user agreements. In addition, because the PDMP contains highly confidential information, individuals must attest that they will use information

⁸ ONC is the principal Federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

⁹ Messaging standards define the technical aspects of sending information so that one system can exchange information with another and have that information understood by the receiving system.

¹⁰ A RHIO is a local data hub where a region's electronic health information is stored and shared. RHIOs provide the services that make statewide access to a patient's health information possible.

appropriately before they are allowed to perform a query and must re-attest every 4 hours.¹¹ To overcome the obstacles of performing this attestation when a query is performed through an EHR, the State agency created software that displays the required attestation in the EHR application before allowing the PDMP to be queried.

The State agency also evaluated the technical capabilities for exchanging data between the Statewide Health Information Network for New York (SHIN-NY) and the Universal Public Health Node (UPHN). The State agency drafted implementation guides to outline the technical details for secure data exchange services over the internet between UPHN and PDMP, for associating a prescriber's identity with a query, and for establishing attestation standards. In March 2018, the State agency began a pilot study designed to determine whether modifications to the UPHN platform are needed.

Activities Related to Enhancing Access to the Prescription Drug Monitoring Program Via Mobile Technology

The State agency said that it would (1) purchase mobile devices for testing, (2) test its PDMP on each mobile device purchased, (3) modify its PDMP programming to accommodate the use of the application on mobile devices, and (4) improve the appearance of the PDMP search results on mobile devices.

According to the State agency, the PDMP was cumbersome to access and navigate on mobile devices. Therefore, the State agency redesigned the PDMP programming to improve its appearance on mobile devices and simplified the process for searching a patient's controlled substance prescription history. The State agency purchased mobile devices of differing brands (Android, Apple, etc.) and tested the capability of each device to access the PDMP during the redesign process. The mobile-friendly version of the PDMP was launched in June 2017. The State agency indicated that it has seen an increase in mobile traffic and has received generally positive feedback from users since the launch of the mobile-friendly PDMP.

Activities Related to Public Health Surveillance

The State agency said that it would (1) adopt an agency-wide definition of an opioid poisoning, (2) access and analyze core datasets using CDC's list of indicators and explore using additional indicators, (3) explore access to additional datasets and possible indicators, (4) use surveillance data to produce maps and data tables which demonstrate the alignment of program activities

¹¹ Individuals attest that they will ensure that the information obtained from the PDMP is only used in the treatment of a person or dispensing of a controlled substance to a person, and that they will safeguard the confidential information.

¹² SHIN-NY allows healthcare professionals to connect and electronically exchange patient clinical information statewide. UPHN is a subset of SHIN-NY and consists of a collection of web-based services that serve as a platform for enabling queries of the PDMP through EHRs.

in geographic areas most impacted by prescription drug overdoses, and (5) disseminate and communicate surveillance results.

The State agency adopted an agency-wide definition of an opioid poisoning by implementing the use of CDC indicators for analyzing and reporting opioid-related data. The State agency used the CDC indicators to analyze core datasets, including death records, hospital discharge data, and emergency room data. The State agency also explored accessing additional datasets, including Naloxone¹³ Administration reports by law enforcement and community members, treatment admissions to certified treatment programs, pre-hospital care reports, and PDMP data. The State agency used the datasets to generate and distribute opioid surveillance data in the form of tables, maps, bar charts, trend graphs, and choropleth maps¹⁴ beginning in October 2016, with continual quarterly and annual updates. The opioid surveillance data was reported at the county, regional, and State levels for all opioid overdoses, heroin overdoses, opioids excluding heroin overdoses, and neonatal abstinence syndrome hospitalization.

CONCLUSION

As of August 2018, the State agency had completed the 13 federally-funded activities it proposed for the audit period. For the selected financial transactions we reviewed, the State agency followed Federal requirements 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 reporting CDC-directed indicators.

This report contains no recommendations.

¹³ Naloxone is a medication designed to rapidly reverse opioid overdose.

¹⁴ A choropleth map is a thematic map in which areas are shaded or patterned in proportion to the measurement of the statistical variable being displayed on the map.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered actions that the State agency has taken to enhance and maximize its PDMP and that it proposed for CDC's PfS grant for March 1, 2016, through August 31, 2017. We examined the State agency's status for completing the 13 proposed activities as of August 2018 (i.e., before the end of the project period). We also selected financial transactions that the State agency charged to this CDC grant during our audit period and reviewed the associated supporting documentation to determine whether the State agency used the funds in accordance with Federal requirements. In addition, we reviewed the State agency's documentation to determine whether the State agency complied with Federal requirements for submitting reports and reporting CDC-directed indicators.

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

We performed our fieldwork from August 2018 through May 2019, which included visiting the State agency's office in Albany, New York.

METHODOLOGY

To accomplish our objectives, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- interviewed State agency officials to identify actions that the State agency has taken to enhance and maximize its PDMP;
- reviewed documentation to determine actions that the State agency has taken to complete the proposed activities and each activity's current status;
- reviewed 65 selected financial transactions totaling \$236,656 and all supporting documentation for those transactions to determine if the transactions were allowable based on Federal requirements;
- reviewed grant documents and reports to determine whether the State agency submitted the Federal Financial Report and Annual Performance Report and reported the CDC-directed indicators according to Federal requirements; and
- discussed the results of our review with State agency officials.

We provided the State agency with a draft audit report on July 15, 2019. The State agency elected not to provide written comments.

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: CDC-DIRECTED INDICATORS

States that advance a prevention substrategy for public health surveillance should publicly report CDC-directed indicators.

- decrease in the percentage of patients receiving more than an average daily dose of greater than 100 morphine milligram equivalents¹⁵ (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 have 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.¹⁶

¹⁵ The amount of milligrams of morphine an opioid dose is equal to when prescribed.

¹⁶ Benzodiazepines are a class of agents that work in the central nervous system and are used for a variety of medical conditions.