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September 23, 2015

Howard A. Zucker, M.D., J.D.
Commissioner
New York State Department of Health
Corning Tower, Empire State Plaza
Albany, NY 12237

Re: Selected Operating and Administrative Practices of the Bureau of Narcotic Enforcement
Report 2015-F-6

Dear Dr. Zucker:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we have followed up on the actions taken by officials of the Department of Health (Department) to implement the recommendations contained in our audit report, *Selected Operating and Administrative Practices of the Bureau of Narcotic Enforcement* (Report 2011-S-19), issued November 21, 2012.

Background, Scope, and Objective

The Department's Bureau of Narcotic Enforcement (Bureau) is responsible for combating the illegal use and trafficking of prescription controlled substances by: issuing Official New York State Prescriptions to practitioners; issuing licenses to manufacturers, distributors, hospitals, nursing homes, and researchers; providing educational material for parents, educators, and health care professionals; and investigating suspected drug diversion or illegal sales involving theft, forgery, and fraudulent visits to practitioners' offices. The Bureau is headquartered in Albany, with additional investigators in New York City, Syracuse, Rochester, and Buffalo.

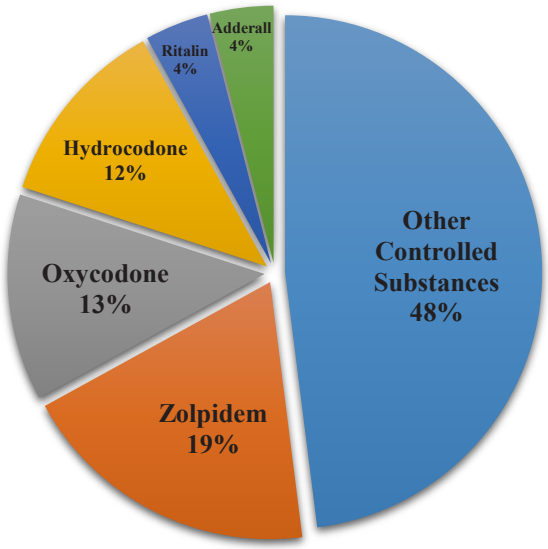
New York State regulations require all pharmacy providers, dispensing practitioners, and manufacturers and distributors of controlled substances to electronically submit controlled substance prescription data to the Department. The prescription data collected resides on the Bureau's Prescription Monitoring Program (PMP) Registry. The Bureau uses this data to support investigations into abusive prescribing. In August 2013, subsequent to our original audit, the Legislature approved the new Internet System to Track Over-Prescribing (I-STOP), which, among other provisions, enhanced the PMP by making additional data available while requiring real-time submission of controlled substance prescription information within 24 hours of substance delivery.

Our initial audit report examined whether the Bureau was effectively and efficiently combating prescription drug diversion and abuse in New York State, in large part through the analysis and use of PMP data. We found several areas, ranging from prevention and deterrence to detection and prosecution, where the Bureau could improve its ability to ensure resources are used effectively to stem drug diversion and abuse through a range of efforts, including better utilization of existing data. For example, our analysis of prescription data identified patterns of errors or inconsistencies affecting more than 325,000 prescriptions for controlled substances that were filled over 565,000 times. In several of these situations, the Bureau's then Chief Investigator agreed that further investigation was warranted.

Three medications accounted for almost half of the drugs acquired with these prescriptions:

- Zolpidem - a hypnotic drug used to treat insomnia and sometimes marketed as Ambien (19 percent);
- Oxycodone - a popular painkiller commonly marketed as OxyContin (13 percent); and
- Hydrocodone - another pain medicine sometimes marketed as Vicodin (12 percent).

Breakdown of Top Drugs Acquired



Two other medications each accounted for 4 percent of the drugs acquired:

- Methylphenidate Hydrochloride - a central nervous system stimulant, such as Ritalin, often used to treat attention deficit disorders; and
- Amphetamines - powerful psychostimulant drugs, such as Adderall, which produce effects like increased energy and euphoria.

All of these valuable drugs carry significant demand on the street and through "black market" operations.

In addition to our analytical results, our prior audit also found:

- Returned and unused prescription forms were not always properly secured and accounted for in the Bureau's offices or at its suppliers' locations;
- Inconsistent approaches to investigating prescription drug diversion were employed among regional offices, whose caseloads and performance results differed significantly;
- State funding was used to purchase equipment that was not deployed and put to use, and to pay for staff who were not working in the Bureau, while other employees who were working in the Bureau were funded by other programs; and

- A failure to address some important issues previously reported by the State Inspector General's office. Among these issues were ensuring that investigators do not abuse State time due to outside employment and updating its Peace Officer's Manual.

The objective of our follow-up was to assess the extent of implementation, as of July 8, 2015, of the five recommendations included in our initial report.

Summary Conclusions and Status of Audit Recommendations

We engaged this follow-up in November 2014. Throughout the course of our fieldwork, Department officials were substantially less than forthcoming in responding to our requests for information about the nature and extent of their implementation efforts. In February 2015, after repeated delays and limited response from Bureau officials, we made several specific written requests for information to support implementation of the five recommendations, and supplied the Bureau with guidance on what types of information it could provide to satisfy our follow-up requirements. We then re-requested this information in March and again in April 2015. We also followed up via telephone several times during this period. Despite the extensive series of requests, it was not until May 2015 – six months after our follow-up began and after a new Bureau Director was hired – that we received any substantive information from the Department. The majority of the requested information was not provided until June and July 2015. In addition, some of the information that we requested still had not been provided at the time we concluded our fieldwork.

Moreover, most of the information we sought should have been readily available and accessible to management in the normal course of their oversight and operation of the Bureau. For example, one of the key recommendations from our prior audit (Recommendation 2) dealt with modernizing the Bureau's use of technology and expanding its data analysis capabilities. Through independent inquiries outside the Department, our auditors learned that, in 2013, the Bureau had contracted to purchase a specialized software tool (SAS Fraud Framework) designed to analyze large amounts of data for fraud indicators. However, officials did not mention this purchase to our staff until June 2015 (nearly seven months after we engaged the follow-up) and did not provide any supporting documentation about it until July. We took these actions and delays into consideration in determining the implementation status of our prior recommendations and in assessing the adequacy and reliability of the information provided.

Overall, we found the Bureau made progress in enhancing its PMP data in anticipation of the full implementation of I-STOP. In addition, the Bureau has revamped some of the routine doctor shopping analyses that it had previously performed, thus allowing for more efficient analysis. Further, the Department strengthened its accountability over returned prescription forms and has improved its monitoring of expenditures to some extent. However, the Bureau has reviewed only a limited portion of the potential errors and inconsistencies in prescription data identified in the prior audit, and has not clearly established the broad organizational goals and performance measures necessary to monitor the performance of its investigators. Of the five prior audit recommendations, two were fully implemented, two were partially implemented, and one was not implemented.

Follow-Up Observations

Recommendation 1

Further review the prescription data identified by our audit to isolate instances and patterns that warrant formal investigation.

Status - Partially Implemented

Agency Action - Since our prior audit was issued, the Bureau followed up on only two of the specific patterns of errors and inconsistencies outlined in the prior audit report, which accounted for only about 1,200 prescriptions. Bureau officials indicate that other efforts were not made because they strongly disagree with the premise of the recommendation. They assert that, as a law enforcement entity, they must base their decisions to conduct investigations on their independent judgment and evaluation of evidence. They expressed concern that, were they to follow up on the issues identified by our audit, they would be subordinating their judgment to that of the auditors. However, in our opinion, this explanation lacks merit.

Our recommendation does not state explicitly or otherwise imply that the Bureau should open formal investigations on all of the higher risk prescriptions we identified. Rather, it proposes that officials evaluate the data we provided and then, using their own judgment, isolate those instances that warrant more formal investigation based on the new evidence and analysis. Although the Bureau has reviewed a limited amount of the patterns and inconsistencies we identified, the open items still account for more than 250,000 of the 325,000 prescriptions identified by our prior audit.

Recommendation 2

Modernize the Bureau's use of technology and information resources by expanding routine data analysis to assist in more effectively identifying and investigating prescription drug diversion and abuse.

Status - Partially Implemented

Agency Action - Preparation for the implementation of I-STOP has improved the quality of, and access to, prescription data in the PMP. With more information now available more timely, the Bureau has expanded its use to more effectively identify doctor shoppers. In addition, Bureau investigators indicate they have used the data to identify practitioners who fail to check the prescription drug monitoring registry prior to prescribing or dispensing a controlled substance, as well as to identify abusive prescribing habits of practitioners and other health care providers. While these efforts have enhanced the Bureau's use of data analysis since our prior engagement, the full intent of the recommendation has not yet been implemented. Bureau staff are still limited in the types of queries they run, mainly utilizing only one standard query which they modify slightly as needed.

In March 2015, four months after our follow-up began, the Bureau finalized a contract to begin training its staff to use the SAS Fraud Framework software that had been purchased in 2013. According to Bureau officials, once finally implemented, the software should allow for faster and easier analysis of prescription data based on preset parameters with specifically built data models to systemically identify inappropriate prescribing behavior that could warrant further investigation. Officials indicate that once Bureau staff have been trained and are routinely using this software to identify potentially abusive prescribing, it may significantly modernize the Bureau's data analysis capabilities. However, at the time we concluded our fieldwork, the Bureau had not yet begun to use the software.

Recommendation 3

Properly account for, safeguard, and monitor the destruction or other disposition of prescription forms returned to both the Bureau and its contracted supplier.

Status - Implemented

Agency Action - The Bureau stores returned prescription forms in a locked cabinet within a secured room. The room is equipped with swipe card access as well as an alarm that must be disabled upon entry. Access to the room is limited to selected Bureau employees. Within the room there is a scanner and shredder, which a Bureau employee uses to scan and destroy returned prescription forms. The scanner logs all scanned prescriptions. In addition, the Bureau now receives a weekly log from its prescription form supplier to account for any forms that have been returned and destroyed.

Recommendation 4

Establish and communicate clearly defined and consistent priorities, objectives, and goals to guide regional investigations. Monitor outcomes to determine whether investigators and offices are meeting expectations.

Status - Not Implemented

Agency Action - The Bureau did not provide adequate documentation to support that it established clearly defined and consistent priorities, objectives, and goals for its investigations. However, the current Bureau Director, shortly after his appointment in April 2015 (and well after our follow-up began), made changes to the Bureau's monthly report to show investigation data by investigator. The Bureau Director plans to use the new report format to assist in case reviews with individual investigators to assess their performances and to identify regional trends.

Recommendation 5

Monitor and reconcile expenditures to ensure that funding is used as intended.

Status - Implemented

Agency Action - Department officials were correct in stating that they implemented this recommendation, given the Fiscal Management Group's (FMG) reconciliation of the Bureau's use of State appropriations for the 2012-13 fiscal year, soon after our prior report was issued. However, no such reconciliations were performed for either of the two subsequent years (2013-14 and 2014-15) prior to this review. In response to the original audit, the Department indicated FMG would not commit to annual reconciliations due to limited staff resources. Nevertheless, we question why Department officials would not prioritize efforts to monitor the actual use of the Bureau's State appropriations, particularly given the findings of our prior report. Subsequently, in a memo dated May 15, 2015 (near the end of our follow-up's fieldwork), the Department indicated that bi-annual reconciliations will be performed in the future.

Major contributors to this report were Heather Pratt, Scott Heid, Cheryl Glenn, and Christi Martin. We would appreciate your response to this report within 30 days, indicating any actions planned to address the unresolved issues discussed in this report.

Very truly yours,

Brian Reilly
Audit Manager

cc: Division of the Budget
Diane Christensen, Director of Internal Audit