



Department of Health

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Executive Deputy Commissioner

November 16, 2015

Mr. John F. Buyce, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street, 11th Floor
Albany, NY 12236-0001

Dear Mr. Buyce:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Follow-Up Audit Report 2015-F-6 entitled, "Selected Operating and Administrative Practices of the Bureau of Narcotic Enforcement." (Report 2011-S-19).

Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure

cc: Michael J. Nazarko
Dan Sheppard
Keith Servis
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**Department of Health
Comments on the
Office of the State Comptroller's
Follow-Up Audit Report 2015-F-6 entitled,
Selected Operating and Administrative Practices
of the Bureau of Narcotic Enforcement**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Follow-Up Audit Report 2015-F-6 entitled, "Selected Operating and Administrative Practices of the Bureau of Narcotic Enforcement." (Report 2011-S-19).

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.

Response #1

The Bureau of Narcotic Enforcement (Bureau, BNE) maintains it has fully implemented Recommendation 1 and reviewed prescription data identified by the audit to isolate instances and patterns that warrant formal investigation.

The Bureau informed OSC that "review of that data revealed lower percentage numbers of the most often-diverted types of drugs at the time, suggesting they were not the product of diversion or other criminal activity," as claimed by OSC. Moreover, "the data discrepancies identified by OSC are consistent with the Bureau's decades of experience with routine clerical and data entry errors." The Bureau further informed OSC that "The overwhelming majority of scripts OSC identified represent legitimate prescription fills free of criminal activity." OSC's claims that "Bureau officials indicate that other efforts were not made because they strongly disagree with the premise of the recommendation" is inaccurate.

OSC mischaracterizes the Bureau's position in stating that Bureau officials "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."

Bureau officials expressed no such concern. The Bureau provided details of two patterns in which it investigated, and received credit from OSC for following up on those two. The Bureau explained the review it conducted on the other patterns OSC had identified, but which the Bureau independently determined that investigations were unwarranted. In those instances, the Bureau followed up, but no investigation was warranted.

The follow-up audit report statement that, “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” appears to be at odds with what OSC communicated to the Bureau during the audit follow up. Then, OSC requested “Investigative Case Files” on specific examples it previously identified from its review of certain data, as well as “Any other cases derived from the potential issues identified in the previous audit.”

When asked for clarification, a member of the OSC audit team stated in an email communication to the Bureau in April 2015 that OSC sought “actual evidence that any referenced investigative cases in connection with recommendations 1 and 2 have actually taken place. Providing summaries of what data analysis was done and how that lead to an investigation may be helpful in providing context of how the case was initiated and the results, but it will not show that cases were actually worked on.”

OSC’s measurement of the Bureau’s implementation of its recommendations was based on whether the Bureau “initiated any investigations as a result” and could provide “actual evidence” that the investigations “have actually taken place”. This does not recognize follow-up in cases where an investigation was not warranted. Law enforcement units must continue to exercise independent judgment about their investigations, and the Bureau intends to continue to use its best experienced-based, independent judgment about which ones to pursue.

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.

Response #2

The Bureau strongly asserts that Recommendation 2 is fully implemented.

The OSC acknowledges in its report the significant enhancements implemented by the Bureau to expand its data analysis since the original audit. The Department's actions and the initiatives it has implemented achieve the "full intent of the recommendation". BNE is working to implement additional initiatives, as part of a continuous effort to strengthen its data analysis and investigative capabilities.

BNE staff conduct extensive and wide-ranging analyses. The initiatives implemented by the Bureau, including enhancements to the Prescription Monitoring Program (PMP) and the implementation of I-STOP, have improved its data analysis efforts. Moreover, in evaluating the data analysis aspect of the program, the focus should be on the appropriateness of the queries used and their effectiveness in achieving program goals. The Department's expanded data analyses effectively support its diversion identification and investigation mission, the actions implemented since the original audit have enhanced effectiveness, and additional initiatives, including the SAS software, will strengthen BNE's ability to prevent, identify and respond to diversion.

New York is the recognized national leader in PMP development and implementation. New York is one of only two states currently mandating that prescribers check its PMP database every time before prescribing a controlled substance. Other states will soon be following suit, in part because of the significant impact demonstrated by New York's program. The Bureau has educated national audiences, at the request of the U.S. Dept. of Health and Human Services (HHS), on New York's prescription monitoring program and how it has helped to significantly reduce prescription drug diversion and abuse. HHS turned to the Bureau when they wanted to give a presentation to state governors about the benefits to public health of law enforcement use of prescription monitoring programs to help curb opioid abuse. Bureau efforts have been endorsed by the Expert Panel of the Prescription Drug Monitoring Program Center for Excellence at Brandeis University, and Bureau staff give several presentations per year at the request of various law enforcement, medical, and academic groups.

The Bureau described several steps it took and continues to take to expand the use and analysis of its data. Since the original OSC Audit Report, the PMP has become virtually real-time (requiring reporting to the Bureau within 24 hours of dispensing) in comparison to the previous 10- to 15-day-long pharmacy reporting requirements which hampered investigative activity. The Bureau also implemented the Internet System for Tracking Over-Prescribing (I-STOP), which requires providers to check the PMP system prior to every issuance of a controlled substance prescription to a patient to ensure that multiple prescriptions for the same substance are not issued, and to deter doctor-shopping. Since its inception on August 27, 2013, doctor-shopping for opioids in New York State has decreased by over 80%. The Bureau documented to OSC several examples of how the use of data mining resulted in investigative cases and how data-mining is used.

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.

Response #3

The Department agrees with the report.

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.

Response #4

The Department maintains that BNE has fully implemented Recommendation 4 and has established and communicated clearly defined and consistent priorities, objectives, and goals to guide regional investigations, and effectively monitor investigator performance. The Bureau also monitors outcomes to determine whether investigators and offices are meeting expectations. The Bureau submitted a wealth of documentation including goals, objectives, and performance measures in writing as of February 24, 2014, to OSC.

For example, the Bureau documented that the director and chief investigator communicate central office priorities, objectives, and goals directly to investigators in the regional offices through e-mail, a biweekly conference call with all of the senior investigators in the regional offices, and a monthly conference call involving all investigators.

The Bureau submitted documentation of its annual training of all investigators, which emphasizes Bureau priorities, objectives, and goals through classroom instruction; of how it prioritizes investigations to prevent the greatest potential for harm to patients and the general public, and based upon frequency of occurrence; of its investigation-tracking software, and how it permits supervisors to assign investigations statewide and review investigators' progress; of monthly reports and how it has used the statistics to issue directives to the regions with three specific examples; of a sample PowerPoint presentation to the New York City office, which was used to provide guidance to investigators in the region in connection with case reviews there; and of Annual Performance Evaluations.

The documentation included schedules listing the courses and course materials themselves used in investigator training. It included a description of how supervisors use its investigation-tracking software to assign investigations statewide, review investigators' progress, and assign the investigation a corresponding time priority for the investigator. It included examples, such as monthly reports, to demonstrate how senior management uses data from the system to make regional or statewide recommendations or directives regarding case prioritization. The Bureau also described how it conducts semi-annual in-person reviews with each investigator, and reviews of all investigations.

The Bureau supplied a copy of a sample Annual Performance Evaluation, used to ensure investigators are conducting their investigations in accordance with the clearly defined and consistent priorities, objectives, and goals set by the Bureau. The annual "performance appraisal and rating" is, as its name suggests, a review of the quality of performance over time.

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.

Response #5

While the Status of the Recommendation is noted as "Implemented", we would like to clarify the agency action described. Specifically,

1. The report states that no reconciliations were performed for either of the two subsequent years (2013-14 and 2014-15) prior to this review. Please note a formal reconciliation was already scheduled for the 2014-15 SFY, but since the lapse period did not occur until June 30, 2015, the formal reconciliation would not have been undertaken before that date.

While a formal reconciliation for the 2013-14 SFY was not conducted, several steps were taken to correct any issues with expenditures on that account.

- A) Monthly disbursement reports were sent to program staff by staff in the Bureau of Budget Management to ensure expenditures were being recorded properly.
 - B) Training was provided to staff in the Bureau of Narcotic Enforcement on the proper coding of expenditures and on uses of the State's Accounting System.
 - C) A brochure on the Department's Time and Activity Reporting System that explains the system and its importance in properly recording expenditures was provided to staff in the Bureau of Narcotic Enforcement.
 - D) Subsequently, a formal review of the 2013-14 fiscal year for this account was performed which showed no deficiencies in the proper recording of expenditures.
2. Since significant corrective action was taken to ensure the Narcotic Enforcement Account was operating in accordance with proper fiscal procedures, and subsequent reviews prove this to be correct, the Department was correct in scheduling only bi-annual formal reviews for this account, thus allowing fiscal staff to concentrate on other high priority areas to minimize overall potential fiscal problems.

Other Issues

Initially, OSC Audit 2014-S-68 was not solely a follow-up audit. It was paired with a new audit of the BNE's implementation of the electronic prescribing mandate (e-prescribing), a component of the Internet System to Track Over-Prescribing (I-STOP) legislation passed in August 2013.

OSC described it as both a follow-up audit and a new audit to "assess the progress the Bureau has made both in implementing the new I-STOP prescription monitoring program and in utilizing the data generated by the new system to combat illegal drug activity." The original scope of this audit included a program – e-prescribing – that had yet to be implemented. The effective date of the electronic prescribing program would not be fully implemented until four months later, on March 27, 2015.¹ The program affects over 140,000 prescribers, hundreds of facilities, over 5,000 pharmacies, and any patient in New York State who needs a prescription.

The Department's Executive Deputy Commissioner, citing this and several other issues with elements of the proposed audit, requested a temporary postponement of the audit because the Bureau could not be as responsive as it normally would, due to a) the upcoming implementation of the mandatory electronic prescribing program and b) the imminent departure of the Bureau Director, leaving the Bureau without one for a time. OSC denied the request, but stated that it would be mindful of the Bureau's time constraints associated with the implementation of electronic prescribing. OSC requested information at the start of the most resource-intensive period of e-prescribing implementation. The Bureau provided substantive responses as early as January 2015, both face-to-face and by e-mail. The initial request for information included 18 different, extensive requests, three of which OSC withdrew and two of which were for data that did not

¹ On March 13, 2015, Governor Andrew M. Cuomo and the New York State Legislature amended the Public Health Law and the Education Law to extend the implementation date for mandatory electronic prescribing to March 27, 2016.

exist. The Bureau responded to seven of the remaining thirteen requests from January-March 2015. In April 2015, OSC changed its remaining requests, and imposed deadlines, which the Bureau met. The Department has striven to comply with all OSC deadlines.

The Department strongly urges future audits recognize the importance of data confidentiality. During the audit, OSC requested patient-identifiable information. BNE sharing of protected health information can only be justified in certain limited circumstances, and permission to release such is required by law.