

Department of Health

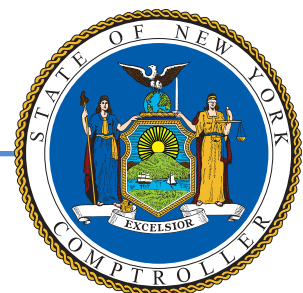
Patient Safety Center Activities and Handling of Revenues

Report 2019-S-15 | March 2021

OFFICE OF THE NEW YORK STATE COMPTROLLER

Thomas P. DiNapoli, State Comptroller

Division of State Government Accountability



Audit Highlights

Objectives

To determine whether the Department of Health (Department) is meeting the goals and objectives of the Patient Safety Center (PSC) and is collecting and utilizing designated revenue for that purpose. Our audit covered the period from April 1, 2015 through May 16, 2019.

About the Program

The Patient Health Information and Quality Improvement Act of 2000 (Act), enacted October 6, 2000 and known as Lisa's Law, was named after Lisa Smart, a 30-year-old woman who died in 1997 as a result of a medical error introduced during surgery by a physician with a history of negligence unknown to the patient.

Pursuant to the Act's amendments to the Public Health Law (PHL), a PSC was established within the Department for the purpose of maximizing patient safety, reducing medical errors, and improving the quality of health care through data reporting, collection, analysis, and dissemination as well as improving public access to health care information. PHL also identified several other areas of PSC quality improvement, including safety goals and best practices.

The Department is responsible for monitoring compliance with applicable federal and State laws and regulations and, through its Bureau of Administrative Hearings (Legal), for enforcing violations. Regulatory enforcement occurs through a formal resolution process, which may culminate in stipulated settlement agreements (Orders) with violators, including penalty amounts. Pursuant to PHL, a portion of the penalties imposed against facilities or individuals found to be in violation of certain sections of law are allocated to a special revenue fund created specifically to support PSC expenditures. The Department's Bureau of Accounts Management (Revenue) is responsible for overseeing the PSC special revenue account, including the collection of penalties and the allocation of funds into the account.

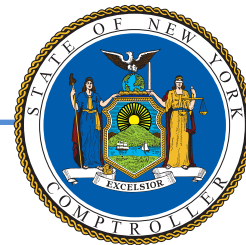
Key Findings

- The Department has generally met the primary objectives of the PSC regarding data reporting, collection, and analysis and the dissemination of health care information, including public access to such information. However, we found a lack of formal guidance governing certain enforcement and recordkeeping practices. By not adequately enforcing and administering such responsibilities, the Department undermines achievement of PSC goals.
- The Department needs to improve its oversight of PSC revenues and related activities to ensure that the PSC account is receiving all revenue due. Specifically, we found:
 - A lack of formalized policies and procedures and poor internal communications contributed to PSC revenue either not being collected or not being properly allocated to the PSC account for PSC-related activities.
 - In some cases, Legal allows payment plans for penalties but does not monitor respondents' compliance with payment terms. There is a risk that respondents who are not adhering to these legally binding payment plans are not being held accountable for the full extent of the penalty imposed for their misconduct.

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- Notably, while the enacted State budget has provided the Department with an appropriation to spend from the PSC fund for non-personal service expenditures, PSC costs have been paid for by the General Fund – the major operating fund of the State – and federal funding.

Key Recommendations

- Develop procedures to ensure Revenue is informed of all Order codes that are applicable to the PSC account.
- Take steps to enhance accountability over PSC account activities.
- Develop formal policies and procedures documenting the basis for approving Order terms including fine amounts, payment plans, and referrals to licensing authorities.



Office of the New York State Comptroller Division of State Government Accountability

March 10, 2021

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

Dear Dr. Zucker:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit entitled *Patient Safety Center Activities and Handling of Revenues*. The audit was performed 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.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

Division of State Government Accountability

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Glossary of Terms

Term	Description	Identifier
Act	Patient Health Information and Quality Improvement Act of 2000, also known as Lisa's Law	<i>Key Term</i>
AG	State attorney general	<i>Key Term</i>
ARBI	Accounts Receivable and Billing Invoice module	<i>Key Term</i>
BHS	Bureau of Hospital Services	<i>Violation Code</i>
BNE	Bureau of Narcotics Enforcement	<i>Division</i>
CLA	Clinical Laboratories	<i>Violation Code</i>
CNA	Certified nurse aide	<i>Key Term</i>
CS	Controlled Substances	<i>Violation Code</i>
Department	Department of Health	<i>Auditee</i>
Facility	Hospitals, nursing homes, home health care agencies, emergency medical service operators, diagnostic and treatment centers, and x-ray facilities	<i>Key Term</i>
FMR	Financial Management Reporting system	<i>Key Term</i>
HHC	Home health care agencies	<i>Violation Code</i>
Individual	Facility health care staff, and in the case of nursing homes, visitors and security personnel	<i>Key Term</i>
Legal	Bureau of Administrative Hearings	<i>Division</i>
LPN	Licensed practical nurse	<i>Key Term</i>
NH	Nursing homes	<i>Violation Code</i>
OP	SED's Office of the Professions	<i>Division</i>
Orders	Refers collectively to Stipulation and Order, Decision Order, and Order issued by Legal	<i>Key Term</i>
PA	Patient abuse	<i>Violation Code</i>
PHL	New York State Public Health Law	<i>Law</i>
PSC	Patient Safety Center	<i>Key Term</i>
PSC account	Patient Safety Center special fund account	<i>Key Term</i>
QOCI account	Quality of Care Improvement special fund account	<i>Key Term</i>
Revenue	Bureau of Accounts Management	<i>Division</i>
RN	Registered professional nurse	<i>Key Term</i>
SED	State Education Department	<i>Agency</i>
SFS	Statewide Financial System	<i>Key Term</i>
Surveillance	Refers to both the Center for Health Care Provider Services and Oversight and the Wadsworth Center	<i>Unit</i>
Tax and Finance	Department of Taxation and Finance	<i>Agency</i>

Background

New York State's Patient Health Information and Quality Improvement Act of 2000 (Act) was enacted in October 2000 to support New Yorkers' right to information about health care providers and facilities, including malpractice and disciplinary histories. Known as Lisa's Law, the Act was named after Lisa Smart, a 30-year-old woman who died in 1997 as a result of a medical error introduced during surgery by a physician with a history of negligence unknown to the patient.

Public Health Law (PHL) Article 29-D, Title 2, established a Patient Safety Center (PSC) within the Department of Health (Department) for the purpose of maximizing patient safety, reducing medical errors, and improving the quality of health care. The Department's Office of Quality and Patient Safety does this through systems of data reporting, collection, analysis, and dissemination as well as improving public access to health care information. PHL charged the PSC with developing a system for the voluntary reporting of medical errors and identified several other areas of PSC quality improvement, including safety goals, best practices, and reporting of adverse events in office-based surgery.

PHL authorizes penalties to be imposed against facilities or individuals found to be in violation of certain sections of law. Until March 31, 2008, such funds were allocated to a special revenue Quality of Care Improvement (QOCI) account. Funds from this account are earmarked for improving care at residential health care facilities. In April 2008, to support the Department's increasing PSC expenditures, the Legislature created a special revenue PSC account and directed a portion of the penalties – amounts in excess of \$2,000 per violation – be deposited into this account.

Within the Department, the Center for Health Care Provider Services and Oversight is responsible for monitoring health care facilities (e.g., hospitals, nursing homes, home health care agencies, emergency medical service operators, and diagnostic and treatment centers), while the Wadsworth Center is responsible for monitoring clinical laboratories. Collectively, these centers, referred to as Surveillance, ensure facility compliance with applicable federal and State laws and regulations. Also, Surveillance is responsible for ensuring that facility staff (e.g., registered professional nurses [RNs], licensed practical nurses [LPNs], certified nurse aides [CNAs]) and other individuals (e.g., emergency medical technicians) are complying with requirements for controlled substances and patient protection. Surveillance fulfills these responsibilities through surveys (inspections) and complaint investigations and issuing applicable violations that are enforced through assessments according to PHL Section 12(1) and Section 12-b(2), based on the schedule of related categories shown in Table 1.

**Table 1 – PHL Section 12(1) and Section 12-b(2)
Violation Code Categories**

Category	Code
Bureau of Hospital Services	BHS
Clinical Laboratories	CLA
Controlled Substances	CS
Miscellaneous – Diagnostic and Treatment Centers	D&T
Emergency Medical Service Operators or Emergency Medical Technicians	EMS
Home Health Care Agencies	HHC
Nursing Homes	NH
Patient Abuse	PA
Miscellaneous – X-Ray	X-Ray

Regulatory violations are referred to the Department’s Bureau of Administrative Hearings (Legal) for enforcement. Regulatory enforcement occurs through a formal resolution process, generally as follows:

- Surveillance provides violation information to Legal to determine whether sufficient evidence exists to enforce the violations and impose penalties allowed under PHL Section 12. If sufficient evidence does not exist, Legal informs Surveillance and takes no actions on the violations.
- If sufficient evidence exists, Legal attempts to work with the facility or individual respondent to reach a settlement agreement, known as a Stipulation and Order. As part of the Order, Legal, with approval of Surveillance, may suspend a portion of the penalty and allow for payment plans.
- If a settlement cannot be reached, the violations may be brought to the Department’s Bureau of Adjudication for a hearing and Decision Order by an administrative law judge.
- If the respondent is issued a Notice of Hearing and Statement of Charges and fails to answer the Department, Legal will proceed with supporting the violations through Orders. Additionally, in the case of nursing home PHL 2803-d violations, the Commissioner’s designee makes a formal preliminary finding and the accused has an opportunity to request, within 30 days of receipt of the finding, an opportunity to challenge it. If the accused does not respond to the finding, the designee can issue a final Order in the matter.

Orders define the respondent’s legal responsibility to make payment to resolve penalties resulting from regulatory violations.

Legal refers finalized Orders, which may include one or more violations, to the Department’s Bureau of Accounts Management (Revenue) for accounts receivable processing. Revenue is responsible for overseeing the PSC account, including:

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- Recording and tracking Orders as accounts receivable;
 - Tracking accounts receivable balances;
 - Depositing Order payments to the PSC account; and
 - Preparing an aging of accounts receivable, issuing past due notification letters, and coordinating with Legal for those past due accounts receivable that require referral to the State Attorney General (AG) or the Department of Taxation and Finance (Tax and Finance) for collection.

Violations that may be criminal in nature are referred to the AG's office for investigation and enforcement if applicable.

Audit Findings and Recommendations

Generally, we found that the Department is meeting PSC objectives related to data reporting, collection, and analysis; and dissemination of health care information, including public access to such information. However, it is also responsible for ensuring its enforcement practices are sufficiently robust to support the PSC goals of maximizing patient safety, reducing medical errors, and improving quality of health care. Our analysis found a lack of formal guidance and follow-up within these activities that may hinder accomplishment of these goals.

The Department also needs to improve its oversight of PSC revenues to ensure that the PSC account is receiving all revenue due. For instance, Revenue was unaware that certain violation categories and criminal penalties were applicable to PSC and thus had not taken steps to ensure that appropriate amounts from these sources were deposited to the PSC account. We also note that the Department's use of PSC funds was restricted due to spending caps in place during our scope, and the General Fund – the major operating fund of the State – and federal funding were used to cover PSC expenses.

PSC Goals and Objectives

The PSC functioned within the Office of Health Systems Management, and as of 2009, had eight staff with PSC responsibilities. However, this structure changed drastically over the years, and at the time we began our audit, PSC functions had been delegated across several different areas within the Department. With the PSC broadly diffused, and its responsibilities integrated into other programs, it is difficult to discern PSC's unique contribution to its goals of maximizing patient safety, reducing medical errors, and improving quality of health care. Nonetheless, we were able to determine that the Department has generally met the primary objectives of the PSC, which were to promote:

- Data-driven surveillance of regulated health care facilities;
- Quality improvement through health information analysis and reporting of quality data;
- System changes and clinical practices that reduce unintended harm to patients; and
- Quality health care for all citizens of New York.

Department activities to support the PSC objectives include identifying, analyzing, and reporting health care quality measurements; recommending statewide medical safety goals and best practices and making them available to stakeholders and the public; and establishing voluntary and collaborative reporting systems of medical errors and adverse event data at office-based surgery facilities.

PSC Account Revenue

The PSC fund, which was created by the Legislature to support PSC activities, is financed by penalties for violations of various sections of the PHL according to the schedule shown in Table 2.

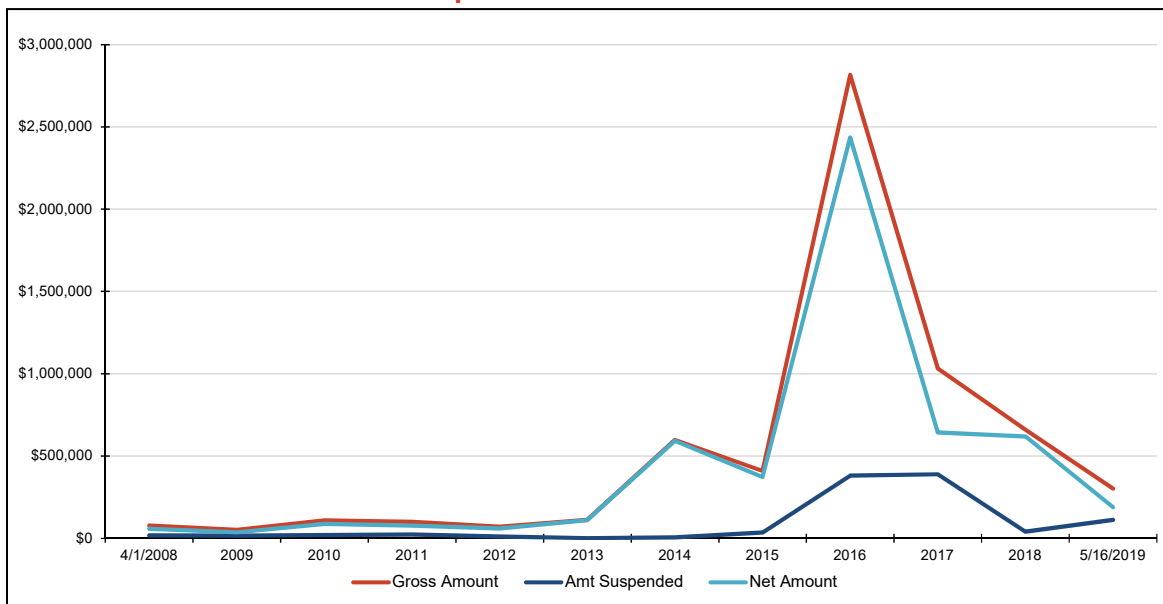
Table 2 – Allocation of Penalties Pursuant to PHL Section 12(1) and Section 12-b(2)

PHL Section	Penalty per Violation	Amount Allocated to QOCI Account	Amount Allocated to PSC Account
12(1)(a)	≤ \$2,000	≤ \$2,000	\$0
12(1)(b)	≤ \$5,000	\$2,000	≤ \$3,000
12(1)(c)	≤ \$10,000	\$2,000	≤ \$8,000
12-b(2)*	≤ \$10,000	\$2,000	≤ \$8,000

* In cases where a penalty is imposed in lieu of a one-year imprisonment.

During the period April 1, 2015 through May 16, 2019, the Department issued 454 violations on Orders issued on or after April 1, 2008, totaling \$4,377,788 in fines. The following figure depicts gross, suspended, and net penalty amounts for Orders issued April 1, 2008 or later that were open at some point between the period April 1, 2015 to May 16, 2019.

Gross/Net/Suspension Amounts: All Codes



As identified in a prior audit (Report [2015-S-26 Nursing Home Surveillance](#)), the large spike in enforcements in 2016 and resulting drop-off in 2017 stem from the Department's action to correct a backlog of enforcement cases. Despite the 2017

decline in enforcement processing, Legal’s penalty suspension amounts remained near constant between 2016 and 2017. Data analysis revealed that this trend was largely attributable to three large suspensions of Orders, one in 2016 and two in 2017, authorized by Legal (see Table 3).

Table 3 – Summary of Three Suspension Orders

Order	Total Penalty Amount	Suspended Amount	Net Penalty
CLA-16-002	\$292,000	\$262,000	\$30,000
CLA-17-002	\$200,000	\$100,000	\$100,000
CLA-17-008	\$230,000	\$202,000	\$28,000

The Department collected over 88 percent of the revenues associated with Section 12(1)(b) and (c) violations that were open during this period. However, the Department could benefit from more formalized policies and procedures and better internal communications to ensure penalties are collected and properly allocated to the PSC account for PSC-related activities.

Penalty Suspensions

Orders define the respondent’s legal responsibility to make payment to resolve penalties resulting from regulatory violations. As part of an Order, Legal, with approval by Surveillance, may suspend a portion of the penalty. Surveillance’s enforcement matrix includes the significance of infractions and suspensions for facilities and individuals and for criminal violations. However, the matrix does not include Surveillance’s recommended penalty range per violation, which is part of the basis for Legal’s decisions regarding the amount to be suspended. Furthermore, the recommended range to suspend per violation and whether suspensions are being offered to repeat violators or violators that have defaulted on prior agreements is not defined or quantified in either of the two enforcement policy and procedure documents provided to us (for nursing homes and home health care agencies) or the Referral to Medicaid Fraud Control Unit policy and procedure. The home health care policy and procedure discusses only the potential, in some instances, for a suspension of a portion of the assessed fine should the facility maintain compliance with requirements.

Of the nine Order categories related to PSC, we analyzed three that had very high-dollar-value suspensions, and found that suspended amounts frequently constitute a large percentage of the respondent’s overall penalty (see Table 4) – reaching 90 percent of the total penalty for one Clinical Laboratories Order.

Table 4 – Penalties and Suspensions for Three Order Categories

Order Category	No. of Orders	No. of Orders With Suspensions	%	Total Penalty Amount (All Orders)	Total Suspended Amount	%
BHS	20	2	10%	\$250,000	\$43,000	17%
CLA	17	10	59%	1,579,000	748,900	47%
CS	72	55	76%	593,150	258,500	44%
Totals	109	67	61%	\$2,422,150	\$1,050,400	43%

In addition to high suspension amounts, we found widely varying suspension amounts offered to repeat violators. Notably, in one case, Legal gave an individual a 40 percent penalty suspension on their first Controlled Substances Order. Despite having violated the terms of this Order, this repeat violator was granted an 81 percent penalty suspension on their second Controlled Substances Order.

Payment Collection Issues: Payment Plans

Legal indicated that, while some Orders (e.g., Nursing Homes and Bureau of Hospital Services) almost always require businesses to pay the full amount due within 30 days, others (e.g., Controlled Substances and Patient Abuse) may contain payment plan provisions. Payment plans disburse the amount owed into smaller payments over a defined time period to ease the burden for individual respondents. While payment plans are a helpful option for certain respondents, the Department does not have formalized policies and procedures in place to ensure they are properly implemented and monitored.

Delinquent Installment Payments

Orders with payment plans include binding language indicating that lack of timely payment may result in the entire fine amount becoming due and payable upon demand as well as the restoration of any previously suspended amounts. Orders require Legal to monitor the cases by proactively requesting updated payment information from Revenue, which is responsible for collecting payments, issuing past due notifications, or coordinating with Legal regarding the referral of overdue debts to the AG or Tax and Finance for collection.

We analyzed a random sample of seven Orders (six Controlled Substances and one Nursing Homes), dated April 1, 2008 or later and open at some point between April 1, 2015 through May 16, 2019, with payment plans in Revenue's Financial Management Reporting (FMR) system. We found that, for all seven, the respondents had violated payment plan terms. We found one of the seven instances in which Revenue informed the respondent about their \$3,855 delinquency, but no evidence to the extent Legal was notified or considered whether it should take action to collect the entire outstanding balance due of \$30,800 on all seven Orders at the time of default as well as the granted

suspension amount of \$7,600 on all seven Orders, for a total of \$38,400. As of May 16, 2019, \$5,930 was still owed to the Department for the seven Orders.

In response, Legal officials stated they often fail to track these Orders because of the important and time-consuming work that attorneys and support staff handle on a day-to-day basis. Staff workload notwithstanding, there is a risk that respondents who are not adhering to legally binding payment plans are not being held accountable for the full extent of the penalty imposed for their misconduct, which, in turn, can minimize the value of penalties as a deterrent. Violation of payment plans also negatively impacts funding of the PSC account and, by extension, the Department's patient safety activities.

Additionally, during our audit, we learned Legal did not have formalized policies and procedures for tracking payment plans. However, in April 2019 (at the start of our audit), Legal implemented a new policy and procedure to track payment plans and formalized it in October 2019. Under this policy, Revenue is required to inform Legal if a scheduled payment becomes delinquent by more than five business days. According to Legal officials, as of January 2020, Revenue had yet to inform them of a late payment instance.

Inconsistent Payment Plan Terms

According to Department officials, each case involving PHL Section 12 violations is processed independently by attorneys, with payment plans considered when the respondent is apparently unable to make payment in full. Proposed Orders also go through a series of reviews before being approved for issuance. Despite this review process, we found that payment plan terms varied significantly both across Order categories and within a category, without clear documentation why. For example, of a sample of seven Orders, six Controlled Substances Orders with similar net penalty amounts (ranging from \$2,400 to \$4,500) had payments plans that ranged from 10 to 160 monthly installments.

Improper Allocation of PSC Funds

For the period October 2009 through September 2015, Revenue had deposited \$392,000 in the PSC account. However, it wasn't until early 2016 that Revenue realized it had been mistakenly depositing the majority of the regulatory penalty amounts collected in excess of \$2,000 per violation to the QOCI account instead of the PSC account.

Once aware of the regulatory penalty oversight, in early 2016, Revenue began a two-year manual process to analyze and reclassify monies from the QOCI account to the PSC account for all Nursing Homes and Nursing Home Administrator Orders issued since April 1, 2008. Through this process, Revenue determined that, for this eight-year period, over \$3.6 million in penalties for Nursing Homes violations had been erroneously deposited into the QOCI account. Revenue took corrective action and transferred this amount to the PSC account. However, despite identifying the error in 2016, Revenue did not take immediate steps to ensure future penalties received

would be allocated properly. As a result, Revenue continued to improperly deposit PSC funds into the QOCI account until its reclassification efforts covering past years were completed in July 2018. Revenue officials stated they continued this practice because the FMR system could not accommodate “split transactions,” or amounts from one Order deposited into multiple special revenue accounts.

Furthermore, according to Revenue, only the Nursing Homes and Nursing Home Administrator Order codes were related to the PSC account. However, we identified eight other Order codes related to the PSC account that had also been overlooked and erroneously deposited to the QOCI account. We also determined that Nursing Home Administrator was not applicable to the PSC account. Revenue officials stated they were unaware that additional Order codes were applicable to the PSC account while Nursing Home Administrator was not, indicating a lack of communication between Revenue and Legal. Were it not for this audit, the misallocation of penalties collected under these other eight Order codes may have gone undetected. While the allocation of funds can be corrected, the PSC account has lost out on the interest earned due to misdirected deposits. Revenue presented us with proposed reclassifications to correct the misallocation on the eight newly identified Order codes. However, we found the document was incomplete and inconsistent and returned it to Revenue.

In addition, Revenue was unaware of the requirement for the AG to deposit criminal penalties in excess of \$2,000 into the PSC account. As a result, Revenue never followed up with the AG about referred alleged criminal violations for which the AG may have collected penalties. Surveillance officials stated 6,605 alleged nursing home criminal violations were referred to the AG from April 1, 2015 through May 16, 2019. In response to our preliminary report, the Department stated that the AG’s office has not recovered any fines assessed pursuant to PHL Section 12-b(2) that meet the threshold required for distribution into the PSC account.

Department officials also responded that Legal is implementing new procedures to improve communication with Revenue regarding the proper allocation of penalty amounts, based on the types of violations in each Order.

Accounts Receivable Tracking

The PHL sets forth a “per violation” distribution of funds between the QOCI and PSC accounts. However, Revenue’s method for recording accounts receivable makes it difficult to ensure funds are accurately allocated between them.

For instance, in FMR, Revenue categorized receivables by their associated Order number. Although one Order may include multiple violations, Revenue entered only each Order’s total amount – rather than multiple delineated violations – in FMR as the accounts receivable.

On July 1, 2018, the Department began using the Statewide Financial System (SFS) Accounts Receivable and Billing Invoice (ARBI) module to record Orders and their associated receivables. In ARBI, Revenue categorizes receivables by

their associated Order number, but only records the Order's total penalty amount associated with the QOCI account and the total penalty amount associated with the PSC account; it does not record individual violations and associated receivable amounts, both of which factor into the distribution of funds between the QOCI and the PSC accounts. Under the current SFS ARBI module, the Department should develop allocation methodology to ensure partial payments are correctly and promptly allocated.

For example, in ARBI, for an Order with one violation and a total penalty of \$10,000, \$2,000 would be allocated to the QOCI account and the remaining \$8,000 to the PSC account. Alternatively, if the total penalty stemmed from two violations of \$5,000 each, \$4,000 ($\$2,000 \times 2$) would be allocated to the QOCI account and the remaining \$6,000 ($\$3,000 \times 2$) to the PSC account. However, Revenue would post these three violations in ARBI as one \$2,000 receivable and one \$4,000 receivable to the QOCI account, and one \$8,000 receivable and one \$6,000 receivable to the PSC account without designating the related violations. Without delineated violations and associated amounts, Revenue as well as internal and external audit entities cannot verify whether penalties have been appropriately allocated without running additional reports on each Order.

Because of the way Revenue entered accounts receivable into its FMR and SFS ARBI module systems, we were unable to determine how much of a given penalty should have been allocated to the PSC account versus the QOCI account. As such, for our calculation purposes, we assigned the first \$2,000 from each Order to the QOCI account and the remainder to the PSC account.

Use of PSC Funds

For each year in our audit scope, the enacted State budget provided the Department with a \$949,000 appropriation, or the authority to spend \$949,000 from the PSC fund provided such funds exist and are spent on non-personal service expenditures for PSC purposes. Despite this authority, for each year in our audit scope, the Division of Budget instituted \$0 cash ceilings (spending limitations) on the PSC fund to offset Medicaid and State Education Department (SED) spending increases. Because of the cash ceilings, patient safety initiatives during our audit scope were paid by the State's General Fund and federal funding, rather than the PSC fund.

Other Matters

Various State laws and regulations provide a basis for the actions the Department is to take for certain violations, but does not impose an obligation:

- PHL Sections 3397(1)(a) and (b), 3302(12), and 3304(1), in part, prohibit individuals from fraudulently or deceitfully obtaining, diverting, or possessing controlled substances.

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- PHL Section 2803-c, which addresses the rights of patients in certain medical facilities, establishes that every patient shall be free from mental and physical abuse and from physical and chemical restraints.
 - PHL Section 2803-d(6)(g) states, in part, the Department shall report instances of physical abuse, mistreatment, neglect, or misappropriation of resident property by a CNA or other unlicensed individual, and any brief statement by the CNA or other unlicensed individual disputing the finding to the nursing home Nurse Aide Registry when a determination has been made after the Department has provided an opportunity to be heard.
 - PHL Section 2803-j(3) states the Nurse Aide Registry shall include findings of physical abuse, mistreatment, neglect, or misappropriation of resident property by a CNA in a nursing home and any brief statement by the nurse aide disputing the findings.
 - New York Codes, Rules and Regulations, Title 10, subsections 415.31(a)(8) and (10) require the Nurse Aide Registry to include final findings of resident abuse, mistreatment, or neglect against a CNA with a date of hearing or finding, and a record of criminal conviction for resident abuse, mistreatment, neglect, or misappropriation of resident property against a CNA and the date of conviction.
 - Education Law Sections 6905(7) and 6906(7) require RNs and LPNs to be of good moral character. While the Law does not require the Department to notify SED's Office of the Professions (OP), it was the Department's practice to do so.

Enforcement strives to encourage successful implementation of policies by promoting sustained compliance with the law, maximizing social benefits, and protecting the public interest. However, inconsistencies in policies and procedures related to enforcement and interagency communication decrease the effectiveness of the process.

Settlement Agreements

According to the Department, Surveillance provides violation information to Legal, including its recommended penalty amount per violation, and Legal then works with the respondent to negotiate a settlement agreement. Legal considers a variety of factors when setting terms, including: type of facility and operating costs, history of enforcement and non-compliance, strength and sufficiency of evidence, financial position of individuals, and the strain on the Department's administrative law judge to hear hundreds of enforcement matters.

Patient Abuse Referrals to Nurse Aide Registry

Federal and State regulations prohibit nursing homes from employing CNAs who have been convicted or have a documented finding of physical abuse, neglect, mistreatment, or misappropriation of resident property recorded in the Department's Nurse Aide Registry. To determine whether the Department was referring findings of

CNA patient abuse to its Nurse Aide Registry, we reviewed 20 Patient Abuse Orders, 10 of which were for CNAs. All ten were identified through our review of repeat offender Orders.

These ten Orders originally contained allegations of patient abuse (neglect) – per PHL Section 2803-d, a reportable finding on the Nurse Aide Registry that precludes continued nursing home employment. The Department entered into settlement agreements with nine (90 percent) respondents that ultimately reduced the charges to patient rights violations (which the Department reports to the Nurse Aide Registry but does not preclude continued nursing home employment) and included a suspension of penalties, ranging from 25 percent to 60 percent of the original penalty amount. These nine Orders also contained violations similar to those of another PHL 2803-d Order that was reported to the Nurse Aide Registry and that precluded continued nursing home employment.

As with other Order category settlement agreements, Department officials stated they do not have specific written policies for patient abuse settlement agreements. They also informed us that some CNA care plan violations are treated as lesser violations (e.g., violations of patients' rights, PHL Section 2803-c). This practice allows qualified staff whose error is not representative of their general quality of work to avoid being listed on the Nurse Aide Registry and permanently barred from working in nursing homes. In response to our finding, Department officials indicated they are working with Surveillance to propose legislative changes that would allow CNA patient abuse findings downgraded to patient rights violations to be placed on the Nurse Aide Registry in a qualified manner (e.g., probation) that would allow them to continue working in nursing homes with the provision that a subsequent patient abuse violation within three years from the date of the Order would result in their placement on the Nurse Aide Registry, liability for any prior suspended portion of penalty, and ineligibility for an administrative hearing to challenge the finding.

Penalties for Patient Abuse and Controlled Substance Orders

Based on our analysis of all Orders with PSC-related violations that were issued on or after April 1, 2008 and that were open between April 1, 2015 and May 16, 2019, we determined that Orders that involve patient abuse are seemingly treated far more leniently than those involving theft and misuse of controlled substances, with net penalties per Order averaging \$251 versus \$2,398, respectively. This treatment is a result of Legal's enforcement practices, which vary depending on the circumstances of each Order and the financial position of the individual who committed the violation. We expanded our sample population of 454 for this particular analysis, because it included only one Patient Abuse Order. For this analysis, we included orders of all dollar amounts, issued on or after April 1, 2008, and open between April 1, 2015 and May 16, 2019.

Legal considers numerous variables when setting fines and works closely with respondents, both facilities and individuals, to reach settlement agreements. Officials

pointed to CNAs with patient abuse violations as an example, saying these lower-earning individuals may also suffer a monetary burden from employment suspension or termination as well as associated legal expenses, and any fines imposed only worsen their economic distress and do not serve the public interest. Officials also maintain that evidence or other mitigating factors (e.g., a respondent's cooperation with the investigation, inadequate assistance from supervisors or colleagues during the alleged violation) can result in different penalties assessed for incidents that appear to have similar findings.

In addition, the Department states that fines for controlled substance violations are generally higher than those for patient abuse violations because controlled substance cases involve RNs and LPNs, who earn higher salaries. The associated penalties are therefore proportional to the respondents' higher salaries and their likely ability to pay. The Department also considers that controlled substance violations usually involve multiple instances of misconduct and are usually premeditated, willful, and capable of causing serious harm to patients. Officials stated patient abuse violations, on the other hand, while intolerable, may involve single violations by lower-wage CNAs that are often reactive and the result of stressful encounters. These CNAs also run the risk and repercussions of having their names placed on the Nurse Aide Registry should the patient abuse (PHL 2803-d) charge not be reduced to a patient rights (PHL 2803-c) violation. Placement on the Nurse Aide Registry would prohibit them from continuing to work as a CNA in a nursing home.

Even though some patient abuse violations may lack intent, they still may involve patient suffering. Based on the findings of this audit, the Department is currently considering increasing patient abuse violation fines, which have remained at similar levels for many years.

Controlled Substance Referrals for RNs and LPNs

RNs and LPNs are licensed by SED and provide patient care services at facilities surveilled by the Department. According to Department officials, current State law does not require the Department to notify SED's OP when licensees incur controlled substance violations at Department-licensed facilities. Initially, Legal officials informed us that, in the interest of patient health and safety and as a matter of practice, they provide copies of all Controlled Substances Orders to the Department's Bureau of Narcotics Enforcement (BNE), which in turn submits them to OP, but they later expressed uncertainty about this. We later learned no one was, in fact, reporting these violations. In response, Department officials attributed the mishandling of this duty to a period of miscommunication between BNE and Legal, during which each thought the other was reporting controlled substance violations to SED.

For our risk-based sample of seven Controlled Substances Orders for RNs and LPNs licensed by SED, the Orders did not indicate whether the Department had notified BNE or OP of these matters. Only five of the seven Orders contained language informing the respondent that SED would be notified.

The overlap of SED and Department oversight responsibilities necessitates clear communication between the two agencies regarding not only violations but also actions that contravene good moral character, as the Education Law prescribes. For SED to make this determination, the Department needs to report violations by RNs and LPNs. Failure to communicate misconduct by RNs and LPNs prevents SED, the licensing authority, from taking appropriate disciplinary action where warranted, potentially jeopardizing the health and safety of these individuals' patients. In response to our preliminary findings, Department officials stated they frequently bring these matters to the attention of SED during the course of their investigation – prior to Order issuance – and that OP takes action prior to Order issuance. However, we question OP's ability to take action before the matter has been formally resolved. We note that, as a result of this audit, the Department implemented a new policy to ensure SED is notified of controlled substance violations.

Order Tracking Weaknesses

An effective system for tracking violations and individual and facility Orders is essential to ensure that all Orders are recorded and repeat offenders are identified. However, we found that Legal does not have a system for assigning a unique identifier to each facility or individual or an electronic database to record and historically track all violations enforced, including Order numbers assigned to respondents, their corresponding license or certificate number, and a summary of Order information. The lack of such controls increases the risk that Legal is unable to: identify and act on repeat CNA patient abuse offenders, or any patient abuse offenders, and ensure they are referred to the Nurse Aide Registry; take into account prior enforced violations when developing new settlement agreements; and enforce previously granted suspensions should prior Order terms be violated.

In developing our sample related to repeat offenders, we identified three individuals who each received different Orders for the same violation. In each case, multiple Orders were entered into because of various administrative processing errors.

Furthermore, Legal's practices did not ensure that all Orders for individuals contain their professional license number or registration number – critical information that would create greater accuracy and efficiency in the enforcement and collections processes, for example, by preventing processing delays that occur when Orders for new respondents are confused with those for similarly named respondents and accurately identifying repeat offenders.

Recommendations

1. Develop procedures to ensure Revenue is informed of all Order codes that are applicable to the PSC account, both currently and as new codes develop.
2. Take steps to enhance accountability over PSC account activities. At a minimum, this should include:

-
- Finalizing and processing outstanding reclassifications to the PSC account for the eight newly identified Order codes.
 - Implementing a process to improve the tracking of expected revenues and improve the process to disburse revenues to the appropriate account.
 - Developing procedures to track payments and enforce Orders when respondents fail to pay according to an Order's terms.
 - Improving the communication between Legal and Revenue regarding Order payment plan terms and improving enforcement efforts when payment plan terms have been violated.
3. Develop formalized policies and procedures documenting the basis for approving Order terms including fine amounts, payment plans, and referrals to licensing authorities.
 4. Institute a process whereby the Nurse Aide Registry is formally notified about Orders that contain qualified findings of sufficient and credible evidence of patient rights violations, and enhance the tracking and accountability efforts for those individuals who have a history of repeat patient rights incidents.

Audit Scope, Objectives, and Methodology

The objectives of our audit were to determine if the Department is meeting the goals and objectives of the PSC and collecting and utilizing designated revenue for that purpose. Our audit covered the PSC activities during the period April 1, 2015 through May 16, 2019.

To achieve our objectives, we interviewed officials from the Department; reviewed and gained an understanding of the Department's policies and procedures; and became familiar with, and assessed the adequacy of, internal controls related to the Department's PSC activities and monitoring of the PSC account. For PSC activities, we also reviewed the Department website and various documents supporting PSC initiatives as required by legislation. For PSC revenues, we analyzed FMR and SFS data received from the Department. In total, we identified 454 Orders with PSC-related violations that were issued on or after April 1, 2008, and open during the period April 1, 2015 through May 16, 2019. Using this as our population, we performed a range of testing, as discussed next.

We reviewed a random sample of seven Orders to determine whether the respondent made timely payments on their payment plan as described within the Order. Additionally, we judgmentally reduced this sample of seven Orders to six Controlled Substances Orders to determine the consistency among payment plan terms within an Order category. We also reviewed a judgmental sample of seven Controlled Substances Orders pertaining to RNs and LPNs with the highest net penalties (above \$2,000). We reviewed a separate judgmental sample of six individuals who had more than one Patient Abuse or Controlled Substances Order associated with their name to ascertain how Legal responded to individuals with multiple Orders where the provisions outlined in the suspension terms of those Orders were violated. We based our selection on several factors, including: number of Orders, time elapsed between Orders, penalty amounts associated with Orders, difference in penalty amounts between Orders, and suspensions offered. For our final analysis, we reviewed another judgmental sample of ten Orders that detailed patient abuse violations involving CNAs. Of 2,876 Orders issued on or after April 1, 2008 that were open at some point between April 1, 2015 and May 16, 2019, we judgmentally selected a sample of ten CNAs whose names appeared more than once for patient abuse violations. Our analyses made use of both judgmental and random sampling; however, none of our results can be projected to the population of 454 as a whole, nor the greater population of SFS and FMR data from which the 454 originated.

Statutory Requirements

Authority

The audit was performed 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 conducted our 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

Reporting Requirements

A draft copy of the report was provided to Department officials for their review and comment. Their comments were considered in preparing this final report and are attached in their entirety to the end of it, along with our own State Comptroller's Comments addressing certain Department statements. In general, Department officials agreed with our recommendations and indicated actions they would take to implement them.

Within 180 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and if the recommendations were not implemented, the reasons why.

Agency Comments



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

December 16, 2020

Mr. Brian Reilly, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Mr. Reilly:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2019-S-15 entitled, "Patient Safety Center Activities and Handling of Revenues".

Thank you for the opportunity to comment.

Sincerely,

Lisa J. Pino, M.A., J.D.
Executive Deputy Commissioner

Enclosure

cc: Diane Christensen
Theresa Egan
Brett Friedman
Geza Hrazdina
James Dematteo
James Cataldo
Jonah Bruno
Jill Montag
Robert Schmidt
Lori Conway
Daniel Oliver
Jeremy Hayes
Mark Fleischer
Anne Schettine
Michael Bass
Rossini Maitre

Empire State Plaza, Corning Tower, Albany, NY 12237 | health.ny.gov

**Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2019-S-15 entitled,
Patient Safety Center Activities and Handling of Revenues**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2019-S-15 entitled, "Patient Safety Center Activities and Handling of Revenues."

Recommendation #1

Develop procedures to ensure Revenue is informed of all Order codes that are applicable to the PSC account, both currently and as new codes develop.

Response #1

In December 2019, the Division of Legal Affairs (Legal) and Revenue Unit started to use a cover letter for Legal to communicate how STIP Order fines are to be allocated for PHL § 12. This cover letter includes all order codes and the amount that is to be allocated to each order code along with amounts for PHL § 12.

[Comment 1](#)

Recommendation #2

Take steps to enhance accountability over PSC account activities. At a minimum, this should include:

- Finalizing and processing outstanding reclassifications to the PSC account for the eight newly identified Order codes.
- Implementing a process to improve the tracking of expected revenues and improve the process to disburse revenues to the appropriate account.
- Developing procedures to track payments and enforce Orders when respondents fail to pay according to an Order's terms.
- Improving the communication between Legal and Revenue regarding Order payment plan terms and improving enforcement efforts when payment plan terms have been violated.

Response #2

- Finalizing and processing outstanding reclassifications to the PSC account for the eight newly identified Order codes.

The Department has put together a reclassification for the order codes that should have been included from April 1, 2008 for allocation to PHL § 12. On page 14 of the Audit Findings Report OSC states that the Department did submit a reclassification to OSC. OSC returned the document to the Department calling it "incomplete and inconsistent." We disagree with this assertion as the documentation provided clearly states the amounts from each order that should have been allocated to PHL § 12. The Department asked

OSC for clarification on what they found to be incomplete and inconsistent and OSC has provided no further response or information on this matter.

[Comment 2](#)

- Implementing a process to improve the tracking of expected revenues and improve the process to disburse revenues to the appropriate account.

The Department has implemented a tracking process whereby we track expected revenues for fines of all order types through the Statewide Financial System (SFS). Each individual order is entered into the system under the category according to the cover letter submitted by Legal. If an order is related to a PHL § 12 fine, it is coded into SFS as PSC or QOCL. When the payment is received it is immediately allocated to the proper fund. If an individual STIP order designates 2 different types of fines, the account is set up in SFS to allocate the proper amounts to each fund associated with the STIP order.

- Developing procedures to track payments and enforce Orders when respondents fail to pay according to an Order's terms.

The Department has implemented a tracking process utilizing an Accounts Receivable report monthly in SFS. This report details which orders were not paid and how many days past due the payment is. The Department then sends out a collection letter to the delinquent party named in the STIP order. If the order is set up in installment payments the collection letter states that the payment terms were not met on the order and the total amount of the fine is now due. If no payment is made after that, the Department sends out a second collection letter to the party demanding payment in full. If the Department still receives no payment, the Department sends the amount still owed by the party to the Tax and Finance Department for collection through the Statewide Offset Program (SWOP). The amount due will remain on the SFS system until full payment is collected.

[Comment 3](#)

- Improving the communication between Legal and Revenue regarding Order payment plan terms and improving enforcement efforts when payment plan terms have been violated.

Legal now sends a cover letter detailing the fine types on the STIP order for the Revenue Unit. If the order has installment payments it is clearly designated in the STIP order. Also now stated in the STIP orders are: 1) does the entire fine become due if an installment payment is missed? 2) does the suspended amount (if any) become due when an installment payment is missed? If the Revenue Unit has any questions regarding a STIP order, Revenue will ask Legal for clarification.

The Revenue unit also will send a copy of the Accounts Receivables analysis to Legal for their review. This report will notify Legal which STIP orders are past due and how many days past due the party is.

Recommendation #3

Develop formalized policies and procedures documenting the basis for approving Order terms including fine amounts, payment plans, and referrals to licensing authorities.

Response #3

- The Division of Legal Affairs has already developed and implemented comprehensive written policies relating to all aspects of its enforcement responsibilities, including approval process, terms of settlement, and referrals to licensing authority.
- The written policies include a settlement matrix that sets forth the methodology for determining appropriate settlement amount and requires documentation to explain the basis for the settlement amount, and also requires managerial review and approval.
- The policy discourages the use of payment plans and limits the number of installments and length of payment period.
- The policy requires that appropriate referrals be made to licensing authorities. In addition, the internal distribution forms that are used to identify individuals who should receive a copy of Orders have been updated to include representatives of the licensing authorities.

[Comment 4](#)

Recommendation #4

Institute a process whereby the Nurse Aide Registry is formally notified about Orders that contain qualified findings of sufficient and credible evidence of patient rights violations and enhance the tracking and accountability efforts for those individuals who have a history of repeat patient rights incidents.

Response #4

- The Division of Legal Affairs had, prior to the audit, implemented a process whereby all Stipulations and Orders, including those based on findings of patient right's violations were sent to the Nurse Aid Registry.
- The Division of Legal Affairs, as part of its new written formal settlement policies, implemented a requirement that Stipulations and Order include a provision that requires that future findings against the same Aide will result in automatic referral to the State Nurse's Aide Registry, and that the Aide is ineligible to challenge said finding in a hearing or lawsuit.
- The Division of Legal Affairs is working on ways to add unique qualifiers to better identify and track subjects of enforcement to ensure that referrals against prior offenders can be readily identified and handled appropriately.

State Comptroller's Comments

1. We are pleased the Department is taking action to develop procedures in response to our audit.
2. We have no record of the Department requesting clarification on the inconsistencies and incomplete information found. The intent of our review was to determine if reclassifications were being undertaken. As stated in the report, during our review, we noted flaws in the Department's proposed reclassification and informed them of these issues.
3. Our audit found the Department had not been consistently tracking expected revenues and developing procedures to track payments and enforce Orders. Thus, we are pleased the Department is implementing processes to improve these activities. Further, as a result of our audit, the Department has now improved communication between Legal and Revenue.
4. We are pleased the Department is taking action to develop policies based on the audit's findings.

Contributors to Report

Executive Team

Tina Kim - *Deputy Comptroller*
Ken Shulman - *Assistant Comptroller*

Audit Team

Brian Reilly, CFE, CGFM - *Audit Director*
Ed Durocher, CIA - *Audit Manager*
Theresa Podagrosi, CGAP - *Audit Manager*
Ann Marsh, CPA - *Audit Supervisor*
Cheryl Glenn - *Examiner-in-Charge*
Christian Butler - *Senior Examiner*
Brian Supple, CFE - *Senior Examiner*
Ritika Baxi - *Staff Examiner*
Mary McCoy - *Supervising Editor*

Contact Information

(518) 474-3271

StateGovernmentAccountability@osc.ny.gov

Office of the New York State Comptroller
Division of State Government Accountability
110 State Street, 11th Floor
Albany, NY 12236



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