



New York State Office of the State Comptroller
Thomas P. DiNapoli

Division of State Government Accountability

Opioid Prescriptions for Medicaid Recipients in an Opioid Treatment Program

**Medicaid Program
Department of Health**



Report 2017-S-66

November 2018

Executive Summary

Purpose

To determine if the Department of Health has taken sufficient steps to safeguard Medicaid recipients who are receiving opioids while also in a Treatment Program for opioid use disorder. This audit covered the period October 1, 2013 through September 30, 2017.

Background

The United States currently faces an opioid misuse epidemic, which began in the 1990s with the over-prescribing of opioid drugs for pain-related conditions. Opioid treatment programs (Treatment Programs) provide medication-assisted treatment, which includes certain opioid medications, coupled with counseling and behavioral therapies for people diagnosed with an opioid use disorder. New York State maintains a database to monitor prescription drug use, known as the Internet System for Tracking Over-Prescribing (I-STOP), which contains records of controlled substance prescriptions. I-STOP is a tool to assist prescribers in determining the most appropriate prescription(s) for an individual. To maximize safety of patient care, Treatment Programs should check I-STOP and, with a patient's consent (as required by federal law), seek coordination of care with the patient's other opioid prescriber(s). Per federal and State laws, opioid medications dispensed by Treatment Programs are not included in I-STOP for review by other practitioners. At the time of our audit, federal lawmakers were considering a series of bills aimed at addressing the opioid crisis, including a bill to modify federal law to allow Treatment Programs to contact other providers to coordinate patient care even without patient consent, and to remove the federal confidentiality restrictions that prevent Treatment Program opioid medications from being included in I-STOP. Although those modifications were not included in the opioids package recently passed by the U.S. Senate and the U.S. House of Representatives, the debate over the sharing of substance use disorder treatment information among different health care providers is expected to continue.

Key Findings

- During our audit period, 33 percent of Medicaid recipients in Treatment Programs also received prescription opioids outside of their Treatment Programs. Recipients may have received inappropriate, unnecessary, and/or dangerous opioid prescriptions if Treatment Programs did not check I-STOP and, where authorized, coordinate care with other prescribers to ensure the controlled substances prescribed to their patients were medically warranted.
- We identified 18,786 Medicaid recipients who received 208,198 opioid prescriptions through the Medicaid program while also in a Treatment Program for opioid use disorder. Of those recipients, 493 needed medical care as a result of 691 opioid or narcotic overdoses that occurred within a month of receiving a prescription opioid. Twelve of those individuals died during the time of their medical care involving the overdose.
- We reviewed medical records for a sample of 25 recipients who received 1,065 opioid prescriptions while in a Treatment Program for their opioid use disorder.
 - We determined Treatment Programs were not consistently checking I-STOP. We found that I-STOP was checked a total of 18 times for the 25 recipients. Further, we did not find that I-STOP was checked prior to every instance that a medication-assisted opioid was

dispensed for take-home use, as required by State law.

- We found that 13 of the 25 recipients were asked at least once during treatment to sign a consent form to coordinate care with the recipient's opioid prescriber. However, 3 of the 13 recipients declined to sign a consent form. We found care coordination with regard to opioid prescriptions occurred for 59 of the 1,065 prescriptions (6 percent).

Key Recommendations

- Take steps to ensure Treatment Programs appropriately check I-STOP.
- Evaluate steps to improve scrutiny over opioid prescriptions for Medicaid recipients who are being treated for opioid use disorder, including determining whether managed care controls over opioid prescriptions for these recipients should be consistent with fee-for-service controls.

Other Related Audits/Reports of Interest

[Department of Health: Medicaid Managed Care Premiums for Recipients With Comprehensive Third-Party Insurance \(2016-S-60\)](#)

[Department of Health: Maximizing Medicaid Drug Rebates for Health and Recovery Plans \(2017-S-61\)](#)

**State of New York
Office of the State Comptroller**

Division of State Government Accountability

November 20, 2018

Howard A. Zucker, M.D., J.D.
Commissioner
Department of Health
Corning Tower
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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 doing so, 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 *Opioid Prescriptions for Medicaid Recipients in an Opioid Treatment Program*. 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,

*Office of the State Comptroller
Division of State Government Accountability*

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Background

The New York State Medicaid program is a federal, state, and locally funded program that provides a wide range of medical services, including substance use disorder treatment and medically appropriate pharmacy benefits, to those who are economically disadvantaged and/or have special health care needs. The Medicaid program is administered by the State's Department of Health (Department). For the fiscal year ended March 31, 2018, New York's Medicaid program had approximately 7.3 million recipients and Medicaid claim costs totaled about \$62.9 billion. The federal government funded about 55.7 percent of New York's Medicaid claim costs and the State and the localities (the City of New York and counties) funded the remaining 44.3 percent.

The Department pays health care providers either directly through fee-for-service (FFS) arrangements (for example, the Department makes payments directly to health care providers for services rendered to Medicaid recipients) or through monthly premium payments to managed care organizations (MCOs). Under managed care, the Department pays MCOs a monthly premium for each Medicaid recipient enrolled in the plan, and the MCO is responsible for ensuring the enrollees have access to a comprehensive range of medical services. MCOs report encounter claims (claims from providers that MCOs paid) to inform the Department of the services provided to their members. The Department is responsible for ensuring that services provided under managed care are in compliance with Medicaid standards and for assessing the quality and appropriateness of care and services furnished to Medicaid enrollees.

The United States currently faces an opioid misuse epidemic, which began in the 1990s with the over-prescribing of opioid drugs for pain-related conditions. The high potential for misuse of opioids has led to alarming trends across the country, including record numbers of people developing opioid use disorders, overdosing on opioids, and dying from overdoses.¹ Overdose deaths involving prescription opioids in New York State have risen from 754² in 2010 to 1,382³ in 2015, an increase of 83 percent.

Symptoms of opioid use disorders include strong desire for opioids; inability to control or reduce use; continued use despite interference with major obligations or social functioning; use of larger amounts over time; development of tolerance; spending a great deal of time to obtain and use opioids; and withdrawal symptoms that occur after reducing or stopping use, such as negative mood, nausea or vomiting, muscle aches, diarrhea, fever, and insomnia.

Opioid treatment programs (Treatment Programs) provide medication-assisted treatment coupled with counseling and behavioral therapies for people diagnosed with an opioid use disorder. Methadone and buprenorphine are opioid medications used in Treatment Programs to relieve the withdrawal symptoms and psychological cravings that cause chemical imbalances in the body.

¹ [Centers for Medicare & Medicaid Services: Opioid Misuse Strategy 2016 \(January 2017\)](#).

² [Department of Health: New York State Opioid Poisoning, Overdose and Prevention - 2015 Report to the Governor and NYS Legislature](#).

³ [Department of Health: Overdose Deaths Involving Any Opioid Pain Reliever \(as of May 2017\)](#).

New York State maintains a database to monitor prescription drug use, known as the Internet System for Tracking Over-Prescribing (I-STOP), which contains records of all controlled substances (paid by Medicaid, other insurers, cash purchases, etc.) that were dispensed in New York State and reported by a pharmacy/dispenser. I-STOP is a tool to assist prescribers in determining the most appropriate treatment for an individual. Federal guidance from the Health and Human Services' Substance Abuse and Mental Health Services Administration encourages Treatment Programs to use prescription monitoring programs such as I-STOP as a resource to maximize safety of patient care. For example, checking I-STOP can aid Treatment Programs in identifying undisclosed opioid prescriptions or drug abuse. Federal guidance suggests consulting I-STOP at admission and periodically thereafter, and State law requires that Treatment Programs consult I-STOP when controlled substances are dispensed for off-premises use. Federal guidance also encourages Treatment Programs to coordinate care with patients' other prescribers of controlled substances. Per the New York Codes, Rules and Regulations, Title 14, providers shall seek to obtain consent from the patient so that the provider practitioner may consult with the prescribing practitioner and discuss: the patient's total medical condition and situation; the prescribed medicine and available alternatives; and the best plan of services to be rendered by each practitioner, given the patient's concurrent treatment.

Federal Title 42 C.F.R. Part 2 (Part 2) prevents information about a patient's participation in a Treatment Program from being disclosed without the patient's written consent. Part 2 was promulgated in the 1970s to encourage individuals with substance use disorders who feared negative consequences, such as possible criminal prosecution, loss of housing, and loss of child custody, to seek treatment. In 1996, the federal Health Insurance Portability and Accountability Act (HIPAA) was passed. HIPAA sets the minimum standard privacy rules addressing the use and disclosure of a patient's health information by organizations. Under HIPAA, medical providers can share patient information for treatment purposes without the written consent of a patient.

During our audit, the U.S. Senate and the U.S. House of Representatives were considering a series of bills to address the opioid crisis, including the Overdose Prevention and Patient Safety Act (H.R. 6082) and the SUPPORT for Patients and Communities Act (H.R. 6). Among the differences between the bills, the Overdose Prevention and Patient Safety Act would authorize the disclosure of patient records without the patient's written consent to a covered entity for purposes of treatment, payment, and health care operations, so long as such disclosure is made in accordance with HIPAA, which would include allowing Treatment Programs to contact other providers to coordinate patient care. After passing the House, H.R. 6082 was received in the Senate and referred to the Committee on Health, Education, Labor and Pensions.

Ultimately, the House and Senate voted to pass the SUPPORT for Patients and Communities Act, which does not include the proposed modifications to federal confidentiality restrictions contained in the Overdose Prevention and Patient Safety Act. However, the debate over the alignment between Part 2 and HIPAA is expected to continue. The debate centers around concerns that some people in need will avoid treatment for fear of negative consequences associated with disclosure of their substance use disorder. Part 2 currently prevents opioid medications (e.g., methadone and buprenorphine) dispensed by Treatment Programs from being included in I-STOP, and State law does not require Treatment Programs to report this information on I-STOP. Those in

favor of changes to Part 2 believe the benefits of allowing physicians to freely share information for treatment purposes (including sharing via prescription monitoring programs) will greatly improve patient care. Advocates for keeping Part 2 intact believe that changing the law will result in individuals forgoing treatment.

For the period October 1, 2013 through September 30, 2017, Treatment Programs provided services to 57,032 Medicaid recipients. Medicaid paid approximately 18 million claims totaling \$916 million in combined FFS and encounter claims for these recipients during the same period.

Audit Findings and Recommendations

For the four-year period October 1, 2013 to September 30, 2017, we identified 18,786 Medicaid recipients who received 208,198 prescriptions for opioids through the Medicaid program while also receiving opioids as part of a Treatment Program for opioid use disorder. These recipients may have received inappropriate, unnecessary, and/or dangerous prescriptions if Treatment Programs did not check I-STOP and, where authorized, coordinate care with other prescribers to ensure the controlled substances prescribed to their patients were medically warranted. Prescribers may also be unaware their patients are already receiving opioid medications from a Treatment Program because Part 2 prohibits disclosure of Treatment Program activity in I-STOP.

During our audit period, 33 percent of Medicaid recipients in Treatment Programs also received prescription opioids outside of their Treatment Program. Three percent of these individuals who received opioid prescriptions while in a Treatment Program received medical care for an overdose within 30 days of obtaining a prescription. More specifically, of the 18,786 recipients, 493 needed medical care as a result of 691 opioid or narcotic overdoses that occurred within a month of receiving a prescription opioid. Twelve of those individuals died during the time of their medical care involving the overdose. The Department should consider providing additional scrutiny over prescription drugs for Medicaid recipients with opioid use disorder to ensure any opioids obtained are medically necessary and in the best interest of the recipient's overall health and safety.

We reviewed medical records for a sample of 25 recipients who received 1,065 opioid prescriptions while in a Treatment Program for their opioid use disorder and determined that Treatment Programs were not checking I-STOP, in accordance with State requirements, to identify undisclosed opioid use. We also found that care coordination occurred for 59 of the 1,065 prescriptions (6 percent).

Opioid Prescriptions for Medicaid Recipients in a Treatment Program

Almost all of the 18,786 recipients were provided methadone as part of their medication-assisted treatment from Treatment Programs, and less than 1 percent were provided with buprenorphine. Both methadone and buprenorphine are opioid medications.

Methadone, which is commonly used to treat opioid use disorder, can be dangerous when taken in unsupervised combination with other opioids. Patient care may need to be coordinated when medication-assisted treatment for opioid use disorder and prescriptions for opioid pain medication outside of a Treatment Program are provided concurrently. Federal guidance encourages Treatment Programs to coordinate care with patients' other prescribers of controlled substances. Patients are expected to disclose their drug prescriptions to their Treatment Program. Also, Treatment Programs should check for a patient's other opioid use on I-STOP. Federal guidance suggests consulting I-STOP at admission and periodically thereafter, and State law requires that Treatment Programs consult I-STOP when controlled substances are dispensed for off-premises use. If a Treatment Program becomes aware of outside prescriptions, patient consent can be requested and, if provided, the health care providers involved can discuss the patient's medical condition and situation, the prescribed medicine, and available alternatives to determine the

best comprehensive plan. However, per federal regulations, Treatment Programs are required to obtain consent from the patient prior to sharing treatment information with other practitioners. Nevertheless, if there is a lack of care coordination or Treatment Programs are not aware of the outside prescriptions, patient safety may be endangered. Providing opioid medications without a comprehensive understanding of a patient's medical conditions and treatments may put the patient at risk of continued abuse, overdose, and death. There is also risk that some individuals will divert prescriptions (i.e., transfer drugs to an unintended recipient for illicit use).

Medicaid MCOs paid for 195,048 of the 208,198 opioid prescriptions we identified. The remaining 13,150 were paid via Medicaid FFS. The number of opioid prescriptions obtained by these Medicaid recipients while in treatment for opioid use disorder ranged from 1 to 177, as follows:

Number of Opioid Prescriptions	Number of Recipients	Average Months in Treatment
1	5,783	30
2	2,558	31
3 to 4	2,393	31
5 to 9	2,267	31
10 to 19	1,965	32
20 to 36	1,928	37
37 to 177	1,892	44
Totals	18,786	

Sample Review

When Treatment Programs become aware of recipients taking prescribed medications, they are required to document the medication name and purpose. Treatment Programs must request consent from the patient in order to consult with the prescriber and ensure the medications are medically necessary and in the best interest of the recipient's overall health and safety. Part 2 prevents Treatment Programs from discussing patient care with another provider without written consent from the patient. If a recipient wishes to preserve the confidentiality of the treatment relationship, the Treatment Program is required to discuss probable risks and consequences of uncoordinated care. If the individual continues to refuse consent to coordinate care and continues taking the prescribed medication, the Treatment Program may consider discharging the individual from their treatment.

We reviewed medical records for a sample of 25 Medicaid recipients from three Treatment Programs. On average, these recipients were in their Treatment Programs for 41 months. These individuals received 1,065 Medicaid opioid prescriptions while they were in treatment for their opioid use disorder.

- We found evidence that I-STOP was checked a total of 18 times for the 25 recipients. Further, we did not find that I-STOP was checked prior to every instance that a medication-

assisted opioid was dispensed for take-home use, as required by State law.

- We found that 13 of the 25 recipients were asked at least once during treatment to sign a consent form to coordinate care with the recipient's opioid prescriber. However, 3 of the 13 recipients declined to sign a consent form.
- We found indications that the Treatment Programs were aware of 566 of the 1,065 opioid prescriptions (53 percent).
 - We found evidence that consent to coordinate care was obtained regarding 85 of the 1,065 prescriptions (8 percent).
 - We found evidence that care coordination with regard to opioid prescriptions occurred for 59 of the 1,065 prescriptions (6 percent).

Our record review included group and individual counseling notes, internal and external communications regarding the recipients' care, treatment plans, treatment goals, medical assessments, and toxicology results. In reviewing these documents, we looked for indications that the provider was aware of opioid prescriptions via the use of toxicology tests, patient's voluntary disclosure, or the use of I-STOP. We also looked for evidence that providers sought care coordination with the outside prescribers.

Our record review included an individual who received 66 prescriptions (which, on average, were each a 30-day supply) for fentanyl, morphine, or hydrocodone/acetaminophen while receiving medication-assisted treatment (methadone) from a Treatment Program. We determined the Treatment Program was generally aware that the individual was receiving these drugs. However, while the prescriptions were recurring since 2013, there were no documented attempts to coordinate care with the opioid prescribers until 2017. When asked in 2017, the recipient declined to allow the Treatment Program to contact other prescribers. Therefore, pursuant to Part 2, the Treatment Program could not collaborate with the prescribing practitioner regarding the individual's concurrent care.

In another case, an individual received 49 prescriptions (which, on average, were each a 30-day supply) for hydrocodone/acetaminophen, oxycodone, oxymorphone, or methadone while also receiving medication-assisted treatment from a Treatment Program. We found that the Treatment Program was not aware of the other prescriptions, and, therefore, there was no coordination of care between the Treatment Program and the prescribing practitioners.

Department officials stated that coordination of care for a patient in a Treatment Program consists of much more than obtaining patient consent, as providers are attempting to develop trust with the patients and keep them engaged in the treatment. We acknowledge there may be challenges to developing patient relationships; however, consistently seeking a patient's consent and coordinating their care can help ensure that medications are medically necessary and in the best interest of the recipient's overall health and safety. Furthermore, due to limitations placed on the Treatment Programs by Part 2, which requires patient consent to coordinate with other providers, the Department should consider increasing monitoring efforts and integrating system-wide controls regarding opioid prescriptions for recipients with opioid use disorder, as follows.

Oversight Controls, Tools, and Challenges

Medicaid Controls

The Department requires prior approvals for certain opioids prescribed to FFS recipients already receiving buprenorphine or other opioids from a pharmacy. The prior approval process allows the Department to review medical justifications from prescribers prior to recipients receiving drugs. After we initiated our audit, the Department expanded the prior approval process to include opioids prescribed to recipients with a previous diagnosis of opioid use disorder. However, Department officials noted that, per Part 2, an individual's treatment for opioid use disorder may not be disclosed by the State during the prior approval process, thereby limiting the State's ability to discuss patient care with prescribers. Despite the potential limitations to this control, the Department should evaluate the benefits of coordinating with and monitoring MCOs to ensure opioid prescriptions provided to recipients enrolled in MCOs are controlled similarly to FFS. As previously stated, the 18,786 Medicaid recipients received 208,198 prescriptions for opioids through the Medicaid program while also receiving opioids as part of a Treatment Program – Medicaid MCOs paid for 195,048 of those 208,198 opioid prescriptions while the remaining 13,150 were paid via Medicaid FFS. Department outreach is key as Medicaid MCOs are not always required to have the same controls as FFS Medicaid (for instance, unless statutorily mandated) and are not required to inform the Department of each specific control they have implemented.

Under its Recipient Restriction Program (RRP), Medicaid can restrict an individual's access to care and services if it is determined that unnecessary, duplicative, contraindicated, or conflicting services have been received. For example, recipients could be required to obtain care and services through designated primary physicians and pharmacies. As part of the RRP, the Office of the Medicaid Inspector General (OMIG) periodically runs reports to assess risks. For example, certain reports are used to identify recipients who have unnecessary emergency room services or excessive inpatient services and diagnosis codes related to substance use disorder. They also run reports to identify recipients with questionable controlled substance claim patterns. After OMIG runs the reports, a medical review is performed on selected high-risk recipients to determine whether a restriction is warranted. Some of the recipients identified in this audit may have been reviewed under the RRP based on these processes. However, the RRP does not include risk assessments specific to individuals receiving medication-assisted treatment for opioid use disorder concurrently with opioid prescriptions.

I-STOP

As previously stated, federal guidance encourages Treatment Programs to use prescription monitoring programs like I-STOP to maximize patient safety by identifying undisclosed opioid prescriptions or drug abuse. Federal guidance suggests consulting I-STOP at admission and periodically thereafter. Additionally, State law requires that I-STOP be consulted when controlled substances are dispensed by practitioners for off-premises use. This requirement applies to Treatment Programs when they dispense "take-home" doses of methadone or buprenorphine. Medications are dispensed for off-premises use on days when a Treatment Program is closed or

when patients have earned privileges that allow it. When prescriptions for controlled substances are found in I-STOP, Treatment Programs can seek coordination of care with the other practitioner(s), provided that they have obtained consent from the patient, to ensure the controlled substances are medically warranted and monitor patients to ensure the medications are taken as directed. Absent such data, treatment is potentially compromised because Treatment Programs may not have a full understanding of a patient's medical conditions and treatments. Although Treatment Programs use toxicology screens (such as urine tests to look for traces of drugs) to help assess recipient compliance with treatment rules and goals, toxicology results can incorrectly indicate compliance because standard tests do not screen for all substances that might be abused, substances can be taken and metabolized between tests, and not all samples are supervised.

We found that I-STOP was underutilized by the Treatment Programs we visited. I-STOP was created to monitor the abuse of controlled substance prescriptions and to help the medical community provide better care by allowing practitioners to see all prescribed controlled substances. The Treatment Programs we visited reported that they use I-STOP, and it is a good resource to corroborate recipients' reported abstinence from outside prescriptions for controlled substances. However, the records we reviewed for the 25 recipients did not have evidence showing the Treatment Programs were reviewing I-STOP consistently. In fact, as previously stated, we found evidence indicating that I-STOP was only checked a total of 18 times for the 25 recipients in our sample. We also did not find evidence that Treatment Programs were checking I-STOP prior to every instance a medication-assisted opioid was dispensed for take-home use, as required by State law.

In response to our findings, officials at the Office of Alcoholism and Substance Abuse Service (OASAS) and the Department agreed to work together to develop guidance to providers regarding the obligation to check I-STOP prior to dispensing. According to officials, the guidance will also state that Treatment Programs should check I-STOP for patients upon admission. Officials noted that the guidance will be clinically appropriate and consistent with regulatory intent.

One Treatment Program we visited cited the amount of time and resources needed to search I-STOP for a large number of recipients as a barrier to its use. According to Department officials, I-STOP allows users to upload a file containing information (i.e., name and date of birth) for multiple patients (according to Department officials, information on 30 patients can be uploaded at a time). However, this provider was manually entering each patient's information. At the time of our visits, each Treatment Program was treating 576 to 761 recipients, which is near each clinic's maximum capacity. Statewide, Treatment Programs treat approximately 40,000 patients daily. Additionally, OASAS officials stated that Treatment Programs are rather unique when compared to a typical provider with regard to the high volume of daily patients. Considering the volume of recipients being treated at these Treatment Programs, the statutory duty to consult I-STOP prior to dispensing a controlled substance, and the value of the I-STOP information to Treatment Programs, the Department should explore ways to improve the ease of access to the I-STOP data and ensure providers are aware of the ability to upload files.

Restrictions to Information Included in I-STOP

State law⁴ only allows controlled substances to be prescribed, administered, or dispensed to an individual with an opioid use disorder in certain circumstances, such as: during emergency medical treatment; when a patient is suffering from an incurable and fatal disease; or if the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of a person with a serious illness or injury.

Accordingly, information that recipients are diagnosed with and receiving treatment for opioid use disorder may be critical to practitioners considering prescribing or dispensing controlled substances. While I-STOP's purpose is to curb the abuse of controlled substance prescriptions and assist practitioners in determining the most appropriate treatment, it does not include medications provided by Treatment Programs, in accordance with State and federal laws and regulations. Therefore, prescribers and dispensers of controlled substances outside of Treatment Programs may not be aware of a patient's opioid use disorder and the treatment thereof.

In addition to the 18,786 Medicaid recipients who received opioid prescriptions outside of their Treatment Program, we found another 933 recipients who received 4,642 buprenorphine prescriptions outside of the Treatment Program while also receiving methadone from a Treatment Program. These prescriptions were buprenorphine formulations indicated for opioid dependence treatment. However, individuals may experience withdrawal symptoms if they take both methadone and buprenorphine concurrently. We also determined 40 recipients received 68 buprenorphine prescriptions outside of the Treatment Program while also receiving buprenorphine from the Treatment Program. As a result of the exclusion of Treatment Program medications from I-STOP (in accordance with State and federal laws), practitioners may prescribe and/or dispense drugs that could be in conflict with other medications or duplicative. Additionally, diversion of these drugs is a possibility.

Both State and federal laws would require changes in order for drugs provided by Treatment Programs to be included in I-STOP. Part 2 prohibits this data from being included because doing so would disclose a person's substance use disorder without written consent. As of the conclusion of our audit, federal lawmakers had not passed legislation to remove this restriction.

Recommendations

1. Evaluate the benefits of the following actions to improve scrutiny over opioid prescriptions for Medicaid recipients who are being treated for opioid use disorder:
 - a. Developing a report that can be used to notify Treatment Programs when I-STOP indicates recipients are receiving potentially dangerous prescriptions (such as opioids);
 - b. Taking steps to ensure Treatment Programs are aware of the option to upload patient information when querying I-STOP;
 - c. Taking steps to ensure Medicaid MCOs have controls requiring medical appropriateness

⁴ New York State Public Health Law, Sections 3350 and 3351.

- reviews prior to dispensing opioids to recipients with opioid use disorder consistent with Medicaid FFS controls; and
- d. Including a risk assessment within the Recipient Restriction Program that is specific to individuals receiving medication-assisted treatment for opioid use disorder concurrently with opioid prescriptions.
2. Issue guidance to remind Treatment Programs of the statutory and regulatory requirement to check I-STOP when Treatment Programs dispense take-home doses of opioid medications. Evaluate the benefits of establishing additional guidance for Treatment Programs to make other checks of I-STOP when clinically appropriate.
 3. Formally remind Treatment Program providers of the importance of seeking to coordinate care with prescribers of opioids outside of the Treatment Programs.

Audit Scope, Objective, and Methodology

The objective of our audit was to determine if the Department has taken sufficient steps to safeguard Medicaid recipients who are receiving opioids while also in a Treatment Program for opioid use disorder. This audit covered the period October 1, 2013 through September 30, 2017.

To accomplish our audit objective and assess relevant internal controls, we interviewed Department officials to confirm our understanding of applicable Medicaid policies and processes. We met with OMIG officials to discuss their processes for identifying recipients with claim patterns indicative of potentially dangerous care or abuse of services. We met with OASAS officials to gain an understanding of Treatment Programs and how they operate. We reviewed applicable State and federal laws, rules, and regulations.

We extracted claim data from the Medicaid Data Warehouse (MDW) to identify recipients in a Treatment Program. We then obtained a list of opioid National Drug Codes (NDCs) from the Centers for Disease Control and Prevention website and extracted Medicaid pharmacy claims with opioid NDCs from the MDW. We merged the Treatment Program claims with the pharmacy claims to identify opioid prescriptions during the time of a recipient's opioid use disorder Treatment Program. We provided the Department and OMIG with the computer code we used to extract data from the MDW as well as our detailed methodology for analyzing claims.

We visited three Treatment Programs. We selected two Treatment Programs with a high percentage of recipients who received opioid prescriptions and a third with a low percentage. We interviewed administrative, clinical, and medical personnel at each location. We also reviewed treatment records for a sample of recipients judgmentally selected because they had a high number of opioid prescriptions during our audit period.

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. In addition, the Comptroller appoints members to certain boards, commissions, and public authorities, some of whom have minority voting rights. 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.

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.

Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in their entirety at the end of the report. In their response, Department officials generally concurred with many of the audit recommendations and indicated that certain actions will be taken to address them. Our responses to certain Department misunderstandings are included in the report's State Comptroller's Comments.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department 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 where recommendations were not implemented, the reasons why.

Contributors to This Report

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Vision

A team of accountability experts respected for providing information that decision makers value.

Mission

To improve government operations by conducting independent audits, reviews, and evaluations of New York State and New York City taxpayer-financed programs.

Agency Comments and State Comptroller's Comments



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
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SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

September 21, 2018

Mr. Christopher Morris, Audit Manager
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, New York 12236-0001

Dear Mr. Morris:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2017-S-66 entitled, "Opioid Prescriptions for Medicaid Recipients in an Opioid Treatment Program."

Thank you for the opportunity to comment.

Sincerely,

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

Enclosure

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**Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2017-S-66 entitled,
Opioid Prescriptions for Medicaid Recipients in an
Opioid Treatment Program**

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2017-S-66 entitled, "Opioid Prescriptions for Medicaid Recipients in an Opioid Treatment Program."

General Comments:

The Department agrees with OSC that New York State, like the nation, is in the midst of an opioid epidemic. During this epidemic we are confronted with the fact that only one of every 10 people in need of treatment seeks help¹ due in great part to the stigma associated with addiction. Therefore, we must be mindful of the State's obligation to develop policies and procedures that protect the integrity of the program while also maintaining patient safety and confidentiality. Not doing so runs the risk of fewer individuals seeking or sustaining treatment.

The Office of Alcoholism and Substance Abuse Services' (OASAS) system of treatment and more specifically, Opioid Treatment Programs (OTPs), are at the forefront of battling this epidemic; serving some of the most vulnerable and difficult to engage individuals in the OASAS system of care. Further, the OASAS OTP system is one of the largest in the nation, currently serving over 41,000 individuals daily. Given the volume of individuals served, it is reassuring to know OSC identified relatively few concerns in a such a sizeable system that has saved countless New Yorkers.

OSC reviewed data on 25 patients selected from three programs with a combined 18,786 recipients. These 25 patients were not randomly selected, but were chosen specifically because "they had a high number of opioid prescriptions during (their) site visit." OSC also points out Medicaid paid for 208,198 opioid prescriptions for the 18,786 Medicaid recipients for the audit period for patients in an OTP. To characterize a system as inadequate based on an unrepresentative, non-randomized sample of the some of the highest users of prescription opioids in the OASAS treatment system is misleading. Further, the aggregate numbers only equate to an average of one prescription per person every three months over the term of the audit. For the 25 highest users receiving 1,065 prescriptions, the average is one prescription per month. However, the Department takes seriously its obligation to prevent inappropriate dispensing of opioid medications and is reviewing alternatives to strengthen existing requirements and procedures.

State Comptroller's Comment - The Department's statement that we characterized the system as inadequate based only on a review of 25 patient records is misleading. In addition to extensive

¹ Vivek Murthy, 19th US Surgeon General, <https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf>

reviews of 25 patient files (detailed on page 10 of our report), our audit conclusions were based on in-depth interviews we conducted at all three Treatment Programs – interviews that were conducted with officials and staff who oversaw and took part in the day-to-day care of thousands of Medicaid recipients, including: Program Directors, Medical Directors, Clinic Supervisors, Nurses, and other pertinent staff at the Treatment Programs. Further, we met with OASAS officials, including the Medical Director, as well as officials from the Department’s Bureau of Narcotic Enforcement. These and various other comprehensive audit steps, including detailed opioid prescription and other data reviews, contributed to our audit conclusions. We are pleased the Department states it takes seriously its obligation to prevent inappropriate dispensing of opioid medications and that the Department is reviewing alternatives to strengthen existing requirements and procedures.

Recommendation #1

Evaluate the benefits of the following actions to improve scrutiny over opioid prescriptions for Medicaid recipients who are being treated for opioid use disorder:

- a. Developing a report that can be used to notify Treatment Programs when I-STOP indicates recipients are receiving potentially dangerous prescriptions (such as opioids);
- b. Taking steps to ensure Treatment Programs are aware of the option to upload patient information when querying I-STOP;
- c. Taking steps to ensure Medicaid MCOs have controls requiring medical appropriateness reviews prior to dispensing opioids to recipients with opioid use disorder consistent with Medicaid FFS controls; and
- d. Including a risk assessment within the Recipient Restriction Program that is specific to individuals receiving medication-assisted treatment for opioid use disorder concurrently with opioid prescriptions.

Response #1

- a. OASAS programs, by Federal law, cannot disclose to the Department Prescription Monitoring Program (PMP) the identity of any patient who is in a program. Thus, the PMP has no way to identify who is in an OASAS OTP treatment program at any given time, making this recommendation difficult, if not impossible, to implement.

State Comptroller’s Comment - We recognized, throughout our report, that federal law prevents information about a recipient’s participation in a Treatment Program from being disclosed to I-STOP (i.e., PMP). As detailed on page 12 of our report, officials from the Treatment Programs we visited stated I-STOP is a good resource to verify recipients’ reported abstinence from controlled substances (and to identify undisclosed drug use). However, we found that I-STOP was underutilized by the Treatment Programs we visited. More critically, none of the Treatment Programs we visited were checking I-STOP in accordance with the State law requirement that Treatment Programs consult I-STOP each time a take-home dose of opioid medication is dispensed. One Treatment Program cited the time and resources needed to search I-STOP for

many recipients as a barrier to its use. The Department can help ease this burden. Using the Department's Medicaid and I-STOP data, the Department can determine which Medicaid recipients are participating in a Treatment Program while simultaneously receiving opioid prescriptions. The Department could develop a report that could be used to notify Treatment Programs of recipients in their care who are also receiving potentially dangerous opioid prescriptions. Developing such a report would also avoid disclosing a recipient's participation in a Treatment Program on I-STOP.

As a constructive alternative, the Department and OASAS will develop guidance for OASAS programs/practitioners who treat patients with opioid use disorder (OUD) about best practices for treating patients that have been prescribed a controlled substance and CDC guidelines, and, as stated below, OASAS will remind OTPs of obligations to continue to check the PMP prior to dispensing and at other times as clinically appropriate.

- b. OTPs do not upload patient information into I-STOP because they do not prescribe. Further, as noted above, Federal law prohibits OASAS programs from disclosing to the Department Prescription Monitoring Program (PMP) the identity of any patient who is in a program. .

State Comptroller's Comment - The Department misinterpreted the word "upload" in this recommendation. As stated on page 12 of our report, one Treatment Program was manually entering patient information (i.e., name and date of birth) to check I-STOP for a patient's controlled substance use. At the time of our site visits, each Treatment Program was treating 576 to 761 recipients, which was near each clinic's maximum capacity. According to Department officials, I-STOP allows users to "upload" batches of recipient information (information on as many as 30 recipients at once), as opposed to manually entering each person's information one at a time. As this could be a more efficient way for Treatment Programs to check I-STOP, the Department should promote this functionality.

- c. The Department will share the clinical criteria for patients on opioid dependence therapy with the Medicaid Managed Care plans. The Department will also encourage the Managed Care plans to develop similar prior authorization editing.
- d. OMIG's Recipient Restriction Program utilizes a comprehensive medical review by the State Medical Review Team (SMRT). The SMRT consists of pharmacists, nurses, and a medical doctor, who assess risk and makes appropriate recommendations for restriction.

Recommendation #2

Issue guidance to remind Treatment Programs of the statutory and regulatory requirement to check I-STOP when Treatment Programs dispense take-home doses of opioid medications. Evaluate the benefits of establishing additional guidance for Treatment Programs to make other checks of I-STOP when clinically appropriate.

Response #2:

A survey of OTPs by OASAS indicated the clear majority do check I-STOP at various times during a treatment episode in their programs as a clinical tool. OASAS will work with Department to coordinate issuance of such guidance that is consistent with the regulatory intent, not unduly onerous, and clinically appropriate.

State Comptroller's Comment - We remind officials that State law requires Treatment Programs to consult I-STOP each time a take-home dose of opioid medication is dispensed. None of the Treatment Programs we visited were checking I-STOP in accordance with this legal requirement. Department guidance to Treatment Programs should be consistent with this requirement.

Recommendation #3

Formally remind Treatment Program providers of the importance of seeking to coordinate care with prescribers of opioids outside of the Treatment Programs.

Response #3:

OASAS will issue guidance to OTP's reminding them to use clinical judgment and best practices when treating patients who may be prescribed other opioids, including seeking consent and consulting with other prescribers.