NEW YORK STATE OF OPPORTUNITY. Department of Health

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Executive Deputy Commissioner

February 8, 2019

Mr. Kenneth Shulman
Assistant Comptroller
New York State Office of the State Comptroller
110 State Street, 10th Floor
Albany, New York 12236

Dear Mr. Shulman:

Pursuant to the provisions of Section 170 of New York State Executive Law, I hereby transmit to you a copy of the New York State Department of Health's comments related to the Office of the State Comptroller's final audit report 2017-S-66 entitled, "Opioid Prescriptions for Medicaid Recipients in an Opioid Treatment Program."

Please feel free to contact Estibaliz Alonso, Assistant Commissioner, Office of Governmental and External Affairs at (518) 473-1124 with any questions.

Sincerely,

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

Enclosure

cc: Estibaliz Alonso

Department of Health
Comments on the
Office of the State Comptroller's
Final 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) Final 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 help 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.

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. As OSC acknowledges, Treatment Programs cannot disclose the identity of any patient who is in a program to the Department's Prescription Monitoring Program (PMP) because it is protected by confidentiality rules as described by OSC in its report. Although the PMP has no way to independently identify who is in a Treatment Program at any given time, the Department will explore whether it may, and how to, use Medicaid data to determine whether recipients who are being treated for Opioid Use Disorder (OUD) are also receiving potentially dangerous controlled substance prescriptions.

b. As part of the guidance to Treatment Programs and the practitioners who treat patients with OUD about best practices, the Centers for Disease Control and Prevention (CDC) guidelines, and the obligations to continue to check the PMP prior to dispensing, the Department and OASAS will include a reminder that up to 30 patients at a time may be queried through batch uploads to the PMP. The Department is currently developing guidance language to review with OASAS.

c. The Department shared the fee-for-service (FFS) controls/criteria with the Managed Care Organizations (MCOs) on October 2, 2018 and January 8, 2019 with instructions to implement such criteria/controls. The Department will monitor the MCOs to ensure that MCOs have processes in place to identify and review opioid claims for medical appropriateness, including claims for members in which OUD can be identified, consistent with Medicaid FFS controls.

d. The Office of the Medicaid Inspector General'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 make 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:

OASAS is in the process of drafting guidance to our field addressing the need to check the Internet System for Tracking Over-Prescribing (I-STOP) when dispensing medications and at other times as clinically appropriate. We disagree with OSC in that OTP's should check I-STOP every time they dispense. That was not the intent of the law and would cause an enormous

burden on OTPs and I-STOP staff given the literal interpretation which would require every OTP to check for every patient on days they are closed, e.g. one day a week (typically Sunday and major holidays). Rather, OASAS will issue guidance consistent with federal guidelines applicable to OTPs which suggest checking a PMP prior to initial dosing, before ordering take-home and periodically through treatment.

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 is in the process of drafting guidance to our field on the need to coordinate care with prescribers and other practitioners involved in treating OTP patients.

Office of the State Comptroller's Comments:

OSC Comment #1:

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 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.

Response to Comment #1:

OASAS disagrees with OSC's comment. We affirm that the characterization of the audit is misleading. The sample was non-randomized and too small for a system that serves 40,000 people annually. OASAS also conducted additional fact-finding while this audit was pending including surveying providers and conversations with groups representing OTPs to determine practices regarding checking I-STOP which affirmed that the vast majority of OTPs already check I-STOP consistent with federal guidelines.

OSC Comment #2:

We recognized, throughout our report, that federal law prevents information about a recipient's participation in a Treatment Program from being disclosed to ISTOP (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.

Response to Comment #2:

The Department may be able to run data analysis in the Medicaid system to identify individuals enrolled in an OTP that have also been prescribed an Opioid. However, to comply with the confidentiality provisions of 42 CFR Part 2, this information may only be disclosed back to the treating OTP, not used for any other purpose by the State, and will likely be out of date due to claiming lags in Medicaid.

OSC Comment #3:

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.

Response to Comment #3:

As stated in the response to Recommendation #1, as part of the guidance to Treatment Programs and the practitioners who treat patients with OUD about best practices, CDC guidelines, and the obligations to continue to check the PMP prior to dispensing, the Department and OASAS will include a reminder that up to 30 patients at a time may be queried through batch uploads to the PMP.

OSC Comment #4:

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.

Response to Comment #4:

OASAS is in the process of drafting guidance to our field addressing the need to check I-STOP when dispensing medications and at other times as clinically appropriate. We disagree with OSC in that OTP's should check I-STOP every time they dispense. That was not the intent of the law and would cause an enormous burden on OTPs and I-STOP staff given the literal

interpretation which would require every OTP to check for every patient on days they are closed, e.g. one day a week (typically Sunday and major holidays). Rather, OASAS will issue guidance consistent with federal guidelines applicable to OTPs which suggest checking a PMP prior to initial dosing, before ordering take-home and periodically through treatment.