# Department of Health

## Medicaid Program: Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders

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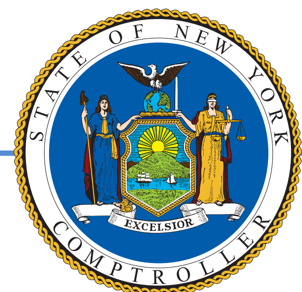
OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller
Division of State Government Accountability



# Audit Highlights

## Objective

To determine whether Medicaid recipients, including sex offenders, inappropriately received Medicaid-funded sexual dysfunction and erectile dysfunction drugs, procedures, and supplies, and whether controls are in place to prevent abuse and misuse of these products. The audit covered the period from April 1, 2012 to July 1, 2018.

## About the Program

Federal and State laws prohibit Medicaid payment of drugs for the treatment of sexual or erectile dysfunction (herein referred to as ED) for all Medicaid recipients, including registered sex offenders. In addition, Medicaid must not pay for ED drugs, unless that drug has another FDA-approved use and the recipient's treatment is for that other use. To protect public safety, State laws are more restrictive and also prohibit Medicaid payment of procedures and supplies to treat ED for registered sex offenders.

## Key Findings

- Medicaid made improper payments of $933,594 for drugs, procedures, and supplies to treat ED. Of that, Medicaid paid $63,301 for 47 sex offenders (30 of whom were classified as a level-2 or a level-3 sex offender).
- Medicaid made questionable payments for ED drugs that are approved to also treat other medical conditions (primarily benign prostatic hyperplasia [BPH] and pulmonary arterial hypertension [PAH]). We identified the following concerns:
  - Significant percentages of recipients prescribed ED drugs approved to also treat BPH or PAH may not have had diagnoses of BPH or PAH – elevating the risk of abuse and diversion associated with these drugs. We found that between $2.8 million and $5.2 million in payments for ED drugs approved to also treat BPH or PAH were made on behalf of recipients who did not have a corresponding BPH or PAH diagnosis on their Medicaid claims that were submitted within two to six months of the drug prescription. Further, among those payments, we found 411 recipients who had a diagnosis of ED (but no BPH or PAH diagnosis) on their claims submitted within six months of the drug prescription, totaling $207,256 in Medicaid payments.
  - Medicaid paid $285,641 for ED drugs approved to also treat BPH or PAH for 14 sex offenders (11 of whom were classified as a level-2 or a level-3 sex offender). We reviewed the medical records of 13 of the 14 sex offenders to determine if the records supported a diagnosis of BPH or PAH and found: 4 of 13 cases supported a diagnosis of ED (31 percent), 8 of 13 cases supported diagnoses of BPH or PAH, and 1 case was indeterminate.
- Managed care organizations (MCOs) made most of the payments we reported on. We found the Department did not monitor utilization of ED drugs, procedures, and supplies,

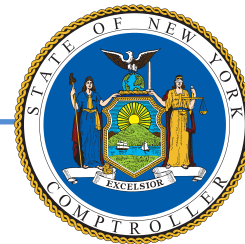
including payments by MCOs. We further found some MCO controls are not designed to prevent sex offenders from obtaining treatment for ED. Specifically, after a recipient obtains services to treat ED, if an MCO finds out the recipient is a registered sex offender, the MCO merely does not pay for the services. Certain steps could be taken to help prevent sex offenders from obtaining the services.

- We observed that certain Medicaid laws and policies are inconsistent:
  - State policy does not allow payment of ED drugs for the treatment of BPH under fee-for-service (because at the approved dosage to treat BPH, the drugs can be used to treat ED), but allows payment of these drugs under managed care.
  - State law prohibits payment of ED procedures and supplies for sex offenders, whereas federal laws do not address ED procedures and supplies for sex offenders.

## Key Recommendations

Throughout the audit, we made the Department aware of our findings, and the Department took steps to promptly address many of the problems we identified. We recommended that the Department:

- Review the payments we identified and ensure recoveries are made, as appropriate.
- Regularly provide MCOs with detailed lists of all ED drugs, procedures, and supplies that are excluded or have limited Medicaid coverage.
- Periodically monitor coverage, utilization, and payment of ED drugs, procedures, and supplies; and take corrective actions to ensure compliance with laws, policies, and procedures.
- Improve the Department's eMedNY computer system controls to (a) apply sex offender status in the processing of certain claims and (b) prevent the processing of incomplete Division of Criminal Justice Services sex offender registry files.




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

June 3, 2019

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 of the Medicaid Program entitled *Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders.* 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

| Abbreviation | Description | Identifier |
|---|---|---|
| BPH | Benign prostatic hyperplasia | *Key Term* |
| CMS | Centers for Medicare & Medicaid Services | *Agency* |
| DCJS | Division of Criminal Justice Services | *Agency* |
| Department | Department of Health | *Agency* |
| ED | Erectile or sexual dysfunction | *Key Term* |
| EDVS | Erectile Dysfunction Verification System | *System* |
| eMedNY | Department’s Medicaid claims processing system | *System* |
| FDA | Food and Drug Administration | *Agency* |
| FFS | Fee-for-service | *Key Term* |
| HIC3 | Hierarchical Specific Therapeutic Classes | *Key Term* |
| ICD | International Classification of Diseases | *Key Term* |
| MCO | Managed care organization | *Key Term* |
| NDC | National Drug Code | *Key Term* |
| OSC | Office of the New York State Comptroller | *Agency* |
| PA | Prior authorization | *Key Term* |
| PAH | Pulmonary arterial hypertension | *Key Term* |

# Background

The New York State Medicaid program is a federal, state, and local government-funded program that provides a wide range of medical services to those who are economically disadvantaged and/or have special health care needs. The Centers for Medicare & Medicaid Services (CMS) oversees the Medicaid program at the federal level, and the State Department of Health (Department) administers the Medicaid program in New York. For the State fiscal year ended March 31, 2018, New York's Medicaid program had approximately 7.3 million enrollees 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's eMedNY computer system processes Medicaid claims submitted by health care providers for services rendered to Medicaid recipients and generates payments to reimburse the providers for their claims. The Department pays health care providers either directly through fee-for-service (FFS) arrangements (for instance, the Department makes payments directly to pharmacies for drugs dispensed 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 MCOs' managed care plans. MCOs are responsible for ensuring recipients have access to a comprehensive range of medical services, including pharmacy benefits. MCOs are responsible for reimbursing providers for services provided to their recipients. MCOs are contractually required to submit encounter claims to the Department, which provide information about each prescription drug or medical service provided to their recipients.

Many of the State's Medicaid recipients are also enrolled in Medicare, the federal health insurance program for the elderly and disabled. Individuals enrolled in both programs are referred to as "dual-eligibles." Generally, Medicare is the primary payer for medical services provided to dual-eligibles. Medicaid then typically pays for any remaining balance not covered by Medicare. The Department's Medicare/Medicaid crossover system allows providers to submit medical claims for dual-eligibles to Medicare, which, after processing, automatically sends the claims to eMedNY. The eMedNY system processes these crossover claims for payment of remaining balances and cost-sharing liabilities for Medicare coinsurance, copayments, and deductibles.

In 2005, a review by the Office of the New York State Comptroller (OSC) determined that Medicaid paid for the erectile dysfunction drug Viagra on behalf of 198 recipients who were also registered sex offenders classified

as level-3 (most likely to reoffend). Given the risk to public safety, the review sparked an overhaul of legislation at the federal and State levels to ensure such drugs are not paid under Medicaid.

Federal[1] and State[2] laws agree that Medicaid will not pay for drugs to treat sexual or erectile dysfunction (herein referred to as ED) for Medicaid recipients (which would include registered sex offenders).[3] State law[4] is more restrictive than federal law, specifying that Medicaid will not pay for drugs, but will also not pay for procedures or supplies to treat ED for registered sex offenders. Federal laws are silent on a recipient's sex offender status and also do not address procedures or supplies to treat ED. Despite that, in response to OSC's 2005 audit, CMS addressed ED drugs and recipient sex offender status in a 2005 letter to State Medicaid Directors, which stated, "A state can find that the use of certain drugs and the treatment of impotence for such individuals could constitute fraud, abuse, or inappropriate use." CMS said states should use their drug use review program and procedures of the Social Security Act to prevent payment for inappropriate drugs to sex offenders.

Federal and State laws also agree to only pay for ED drugs to treat a condition other than ED, for which the drugs were approved by the federal Food and Drug Administration (FDA). Table 1 shows how federal and State laws address Medicaid payment for drugs, procedures, and supplies.

**Table 1 – Medicaid Payment Laws**

| | Drugs That Only Treat ED | Drugs That Treat ED and Another Condition | Procedures and Supplies That Treat ED |
|---|---|---|---|
| **Registered Sex Offender** | Federal* & State – Not allowed | Federal* & State – Allowed only for other indicated condition | State – Not allowed<br>Federal – Not addressed |
| **Not a Registered Sex Offender** | Federal* & State – Not allowed | Federal* & State – Allowed only for other indicated condition | State – Not addressed (Department allows with prior approval)<br>Federal – Not addressed |

* Federal laws are silent on sex offender status; rather, the laws refer to Medicaid recipients in general.

1 Public Law No.109-91, section 104.

2 N.Y. Soc. Serv. Law § 365-a(4)(f).

3 To the extent a state Medicaid program decides to cover drugs for the treatment of ED, there is no federal financial participation (i.e., no federal payment). See 42 U.S.C. § 1396r-8(d)(2)(H) and 42 U.S.C. § 1396b(i)(21).

4 N.Y. Soc. Serv. Law § 365-a(4)(e).

The FDA approves a drug at specified dosages (i.e., strengths) to treat a specific medical condition, referred to as the "indicated use." Every drug has a distinct National Drug Code (NDC is a unique 10-digit number that serves as a universal product identifier for each medication and is based on drug manufacturer, strength, dosage form and formulation, and package form and size). This helps to distinguish the drug's indicated use. The FDA also approves generic drugs. A generic drug contains the same active ingredient, works in the same way, and provides the same clinical benefit as a brand name drug.

Two common brand name drugs to treat ED, Viagra and Cialis, have Sildenafil citrate (Sildenafil) and Tadalafil, respectively, as their active ingredient. However, these two active ingredients were also FDA approved for other (non-ED) indicated uses: pulmonary arterial hypertension (PAH, which is a condition characterized by abnormally high blood pressure in the pulmonary artery, the blood vessel that carries blood from the heart to the lungs) and benign prostatic hyperplasia (BPH, which is a condition in men in which the prostate gland is enlarged). Confusion regarding indicated use may arise when drugs are identified by name instead of by NDC. Tables 2A and 2B show the other indicated uses of these drugs by active ingredient name and dosage.

## Tables 2A and 2B – FDA-Indicated Uses by Active Ingredient

| **Table 2A – FDA-Indicated Use for Sildenafil by Name and Dosage** | | | |
|---|---|---|---|
| Dosage | Generic | Viagra | Revatio |
| 20 mg | PAH | – | PAH |
| 25 mg | ED | ED | – |
| 50 mg | ED | ED | – |
| 100 mg | ED | ED | – |

| **Table 2B – FDA-Indicated Use for Tadalafil by Name and Dosage** | | | |
|---|---|---|---|
| Dosage | Generic | Cialis | Adcirca |
| 2.5 mg | ED | ED | – |
| 5 mg | ED/BPH | ED/BPH | – |
| 10 mg | ED | ED | – |
| 20 mg | ED*/PAH* | ED | PAH |

* Depends on the NDC.

The Department recognized that, while the FDA's only approved use for the drugs Revatio and Adcirca is the treatment of PAH, they contain the same active ingredient as Viagra (Sildenafil) and Cialis (Tadalafil). In other words, one should expect the same result from an identical dose of Revatio and Viagra or Adcirca and Cialis.

The Department also acknowledged the historical high risk of abuse of these drugs. As a result, Adcirca, Revatio, and Sildenafil became part of the Medicaid Clinical Drug Review Program (requires prior authorization). (Note: generic versions of Adcirca and Cialis [i.e., Tadalafil] were added near

the end of our audit period.) The Department concluded that use of these drugs should be monitored to prevent fraud and abuse. The Department also required determination of a recipient's sex offender status before approving a prior authorization request for Adcirca, Revatio, or Sildenafil, 20-mg dosage. In FFS, if the recipient is a sex offender, the Department's Medical Director must also review and approve the request before prior authorization is given.

The Department manages a range of controls to prevent inappropriate Medicaid payments for ED-related drugs. The Department employs a formulary (a list of prescription drugs, brand name and generic, covered by the Medicaid program) and a prior authorization (PA) contractor to control FFS claims for ED drugs. The Department also uses eMedNY to identify recipients who are registered sex offenders and to distinguish ED-related supplies and procedures.

In 2011, Medicaid pharmacy benefit management (i.e., processing and payment of prescription drug claims) for managed care recipients was transferred from the Department to MCOs (prior to 2011, pharmacy benefits were not covered by managed care; rather, Medicaid FFS paid drug claims for recipients in managed care). To prepare for the transition, the Department directed MCOs on how to handle ED drug exclusions and indicated uses. Under managed care, MCOs are responsible for drugs allowed for Medicaid recipients enrolled in their plans and, as such, are expected to determine the medical necessity of the ED drug.

In addition, the Department requires MCOs to determine the sex offender status of a recipient before allowing an ED drug to be prescribed and dispensed for other approved medical conditions. For this purpose, the Department created the Erectile Dysfunction Verification System (EDVS) for MCOs to request a recipient's sex offender status. Chapter 645 of the Laws of 2005 authorizes the State Division of Criminal Justice Services (DCJS) to make sex offender registry data available to the Department for purposes of identifying persons ineligible to receive drugs, procedures, or supplies to treat ED. DCJS administers the State's sex offender registry. According to DCJS, the court assigns one of the following three risk levels to a sex offender: level-1 (low risk of repeat offense), level-2 (moderate risk of repeat offense), or level-3 (high risk of repeat offense and a threat to public safety exists).

During the 6.25-year period April 1, 2012 through July 1, 2018, Medicaid paid approximately $14.4 million for ED drugs. MCOs account for most ($12.4 million) of this total, primarily for ED drugs that also treat BPH or PAH conditions ($11.6 million).

# Audit Findings and Recommendations

The Department's oversight has not kept pace with changes in the Medicaid program to ensure that sexual or erectile dysfunction (herein referred to as ED) drugs, procedures, and supplies are only provided within the framework established by the Social Services Law – to prevent recipients, including sex offenders, from receiving treatment for ED. As a result, since the transition of pharmacy benefit management to MCOs in 2011, Medicaid continued, primarily under managed care, to fund drugs, procedures, and supplies that enhance sexual and erectile function in recipients, including registered sex offenders. This, consequently, increased risks to public safety.

Our audit determined Medicaid improperly paid $933,594 for drugs, procedures, and supplies to treat ED. Of that amount, Medicaid paid $63,301 for 47 sex offenders (30 of whom were classified as a level-2 or a level-3 sex offender).

Additionally, Medicaid made payments of $13,527,649 for ED drugs that are approved to also treat other medical conditions (primarily BPH and PAH). Of that amount, Medicaid paid $285,641 on behalf of 14 sex offenders (11 of whom were classified as a level-2 or a level-3 sex offender). We found about $11.6 million of the $13.5 million in payments for ED drugs that also treat other conditions were made without verifying recipient sex offender status through the Department's sex offender verification system, as required. We also found that significant percentages of recipients prescribed ED drugs approved to also treat BPH or PAH did not have a corresponding diagnosis of BPH or PAH – elevating the risk of abuse and diversion associated with these drugs. We estimated between $2.8 million and $5.2 million in Medicaid payments for ED drugs approved to also treat BPH or PAH were at risk of drug abuse and diversion.

Table 3 summarizes the Medicaid payments made during the 6.25-year period from April 1, 2012 through July 1, 2018.

## Table 3 – Medicaid Payments for Drugs, Procedures, and Supplies That Treat ED

| From 4/1/2012 Through 7/1/2018 | | Drugs That Only Treat ED | Drugs That Treat ED and Other Approved Conditions | Procedures and Supplies That Treat ED |
|---|---|---|---|---|
| MCOs | Sex Offender | $7,762 (15 recipients) | $260,652 (14 recipients) | $28,251* (18 recipients) |
| | Not a Sex Offender | $853,362 | $11,327,065 | $110,580 |
| **Total MCO Payments** | | **$861,124** | **$11,587,717** | **$138,831** |
| FFS | Sex Offender | – | $24,989 (2 recipients) | $27,288* (15 recipients) |
| | Not a Sex Offender | $16,931 | $1,914,943 | $16,232 |
| **Total FFS Payments** | | **$16,931** | **$1,939,932** | **$43,520** |
| **Total MCO and FFS Payments** | | **$878,055*** | **$13,527,649**** | **$182,351** |

* Improper Medicaid payments of $933,594 = $878,055 + $28,251 + $27,288.

** Questionable payments between $2.8 million and $5.2 million for ED drugs approved to also treat BPH or PAH were made for recipients who did not have a corresponding BPH or PAH diagnosis on their claims submitted within two to six months of the drug prescription.

We determined inadequate Department guidance and oversight and weak control systems allowed sex offenders to obtain drugs and services to treat ED. Furthermore, we determined that MCOs in general and, in one case, the Department's PA contractor (for FFS claims) did not comply with Department policies and procedures to verify a recipient's sex offender status using the Department's sex offender verification system prior to authorizing treatment. In response to our audit findings, the Department took prompt actions to improve compliance with State laws and Department policies and procedures. However, we recommend the Department further improve guidance to and oversight of MCOs, as well as update and improve eMedNY FFS controls to better protect the public.

# Improper Payments for Drugs That Only Treat ED

Drugs approved by the FDA to only treat ED were, by State law, excluded from the Medicaid program since 2006 (refer to Table 1). However, we determined MCOs improperly paid for excluded ED drugs totaling $861,124 to 1,603 Medicaid recipients, of whom 15 were registered sex offenders (at least 11 of 15 were classified as a level-2 or level-3 sex offender). We also

determined FFS improperly paid for 77 claims totaling $16,931 contrary to State law because Department personnel mistakenly removed only one of the two NDCs for an excluded drug from the Medicaid formulary (none of these recipients were sex offenders). The Department noticed the error nearly three years later and removed the other NDC of the excluded drug prior to the start of our audit. (See Table 3 for summary of payments.)

We concluded that, since MCOs became responsible for pharmacy benefit management in 2011, the Department did not adequately communicate excluded drug reminders to MCOs. Prior to our audit, the Department addressed ED drug exclusions in formal communications to MCOs twice – in 2013 and in 2017 – but neither communication addressed all excluded drugs to treat ED. For example, in 2013, the Department listed only excluded brand name drugs and in 2017 did not mention Revatio or Adcirca were excluded when used to treat ED.

No other Department communications to MCOs addressing ED drug exclusions were issued until after our audit was engaged. Specifically, during our audit, we informed Department officials that MCOs continued to improperly provide excluded ED drugs, such as Viagra, to recipients. As a result, in May 2018, the Department notified all MCOs of their improper ED drug coverage and launched discussions of improper MCO ED drug coverage at regularly scheduled MCO Pharmacy Directors meetings. However, MCOs indicated continued confusion and requested that the Department provide a complete list of the excluded drugs. In July 2018, the Department provided all MCOs with a list of the classes of excluded drugs by Hierarchical Specific Therapeutic Classes (HIC3). However, HIC3 is not a universally known identifier, and it excludes certain information needed by MCOs to differentiate indicated drug use. We determined the Department did not identify the drugs by their NDCs, which are universally known (assigned by the FDA) and uniquely identify each excluded drug.

## Questionable Payments for Drugs That Treat ED and Other Conditions

Federal and State laws stipulate that payment for ED drugs is allowed only if the drugs are used to treat a condition other than ED, for which the drugs have been approved by the FDA (refer to Table 1). However, the State's Medicaid policy is more restrictive: FFS also does not cover any ED drugs approved to treat BPH because, at the same approved dosage, the drugs can also be used for the treatment of ED (refer to Table 2B). However, this policy restriction does not apply to MCOs. As shown in Table 4, MCOs paid $1,240,714 for such drugs.

During the 6.25-year period from April 1, 2012 through July 1, 2018, Medicaid – primarily MCOs – paid for ED drugs that also treat another condition for 2,078 recipients, totaling $13.5 million. See Table 4 for the breakdown of these payments.

**Table 4 – Payments for Drugs That Treat ED in Addition to BPH or PAH**

| From 4/1/2012 Through 7/1/2018 | MCOs | FFS | Totals |
|---|---|---|---|
| **PAH** | $10,347,003 (654 recipients) | $1,939,932 (149 recipients) | $12,286,935 (803 recipients) |
| **BPH** | $1,240,714 (1,275 recipients) | – | $1,240,714 (1,275 recipients) |
| **Totals** | **$11,587,717 (1,929 recipients)** | **$1,939,932 (149 recipients)** | **$13,527,649 (2,078 recipients)** |

Department officials stated that MCOs and the Pharmacy PA contractor are required to verify that a recipient is not a sex offender prior to providing ED drugs. To verify the recipient's eligibility to obtain an ED drug (as determined solely by their sex offender status), MCOs are required to use the Department's EDVS sex offender verification system and the Pharmacy PA contractor is required to fax a sex offender verification request to DCJS. However, we determined that MCOs generally did not use the Department's EDVS, and the Pharmacy PA contractor did not always follow Department procedures to obtain a sex offender verification before processing a prior authorization request for the drugs. Further, we found that MCOs provided ED drugs that are approved to treat other conditions without adequately ensuring recipients had the required non-ED (i.e., BPH or PAH) diagnosed condition.

## MCOs Not Verifying Sex Offender Status Through the EDVS

MCOs paid for ED drugs approved to treat other conditions for 1,929 recipients totaling about $11.6 million. However, the MCOs paid for most of the ED drugs without verifying the recipient's sex offender status through the Department's EDVS, as required. To determine the extent of recipient sex offender verifications, we compared MCO verification requests made in the EDVS from April 2012 through July 2018 to MCO claims paid for these drugs. We found MCOs used the EDVS to verify the sex offender status for only 17 of the 1,929 recipients who received ED drugs approved to treat other conditions (totaling $27,841). The 17 verified recipients did not include any sex offenders. However, we determined 14 of the 1,912 recipients (1,929 – 17 = 1,912) whose sex offender status was not verified through the EDVS by the

MCOs were sex offenders (at least 11 of the 14 were classified as a level-2 or level-3 sex offender) for which the MCOs paid $260,652 for drugs that could be diverted to treat ED (for instance, multiple pills for the treatment of PAH could be used for ED). (Refer to Table 3 for summary of payments.)

We asked two MCOs if they verified the sex offender status of recipients prescribed ED drugs. One MCO had not used the EDVS to verify the sex offender status of recipients. The other MCO said it used a different system provided by the State Department of Financial Services to verify the sex offender status of recipients, but only for procedures and supplies, not for drugs. Both MCOs questioned whether they were required to verify the sex offender status of a recipient for drugs because the drugs are either excluded (i.e., for ED) or approved for other uses (i.e., for BPH or PAH).

We concluded the Department did not adequately inform MCOs of the policy to use the EDVS since the MCOs became responsible for pharmacy benefit management in October 2011. After we informed Department officials that MCOs were not using the EDVS to verify sex offender status, the Department took steps to educate MCOs on sex offender verification policies and procedures and required MCOs to update their authorized EDVS users.

## Questionable MCO Verification of Medical Necessity

As shown in Tables 2A and 2B, at different dosages, drugs to treat BPH and PAH can also be used for ED. MCOs are responsible for determining the medical necessity of a treatment, including drugs, prescribed for a recipient. Therefore, it is expected MCOs would determine, with a reasonable level of assurance, that an ED drug approved by the FDA to treat a different medical condition was prescribed to a recipient who was diagnosed with that non-ED medical condition (i.e., BPH or PAH). However, we found that MCOs provided these drugs without adequately ensuring the recipient had the required BPH or PAH diagnosed condition, resulting in significant risk that recipients abused or diverted these drugs to treat ED.

To assess the risk of potential abuse or diversion of drug use, we reviewed medical records of 13 of the 14 sex offenders who received ED drugs from MCOs to determine if their medical records supported a diagnosis of the other indicated use of the drug (i.e., a BPH or PAH condition). We determined medical records in 4 of the 13 cases (31 percent) supported a diagnosis of ED; 8 of 13 cases supported diagnoses of BPH or PAH; and 1 case was indeterminate. We concluded a significant risk of abuse or drug diversion existed. Therefore, we conducted a diagnosis analysis to review all 2,078 recipients who received ED drugs approved to treat BPH or PAH, for which Medicaid payments totaled $13.5 million (refer to Table 4).

To assess the risk of abuse or diversion in the recipient population, we analyzed diagnosis codes on recipients' paid claims within two to six months of the order date on the prescription (i.e., the date the original prescription was written) for the drugs. Table 5 presents the results.

Using the two parameters, we found the risk of abuse/diversion of these drugs ranged between $2.8 million (six months) and $5.2 million (two months), primarily in MCOs. The number of recipients ranged between 1,436 (six months) and 1,624 (two months). Accordingly, between 69 and 78 percent of the Medicaid recipients prescribed these drugs lacked a diagnosis in their recent claims to support either a BPH or a PAH condition. Of the 1,436 recipients without a BPH or PAH diagnosis in their claims over the past six months before the prescription was ordered, we found 411 recipients had an ED diagnosis. As a result, we question the adequacy of the determinations of medical necessity of these drugs.

### Table 5 – Risk of Recipients Abusing or Diverting ED Drugs That Treat BPH and PAH

| | Claim Diagnosis Lookback: Within Six Months of Drug Prescription Order Date | Claim Diagnosis Lookback: Within Two Months of Drug Prescription Order Date |
|---|---|---|
| **No corresponding claim diagnosis of BPH or PAH** | $2,819,469<br>1,436 recipients | $5,172,869<br>1,624 recipients |
| **No corresponding claim diagnosis of BPH or PAH, but had an ED diagnosis** | $207,256<br>411 recipients | $180,349<br>371 recipients |

A separate Department analysis of ED drugs approved to treat BPH or PAH for all Medicaid recipients reached similar conclusions. Furthermore, the Department's analysis showed, since 2012, an average of only 38 percent of MCO recipients prescribed ED drugs for BPH had a BPH diagnosis in their claims history and an average of 78 percent of MCO recipients prescribed ED drugs for PAH had a PAH diagnosis in their claims history. Therefore, significant percentages of MCO recipients prescribed ED drugs approved to also treat BPH or PAH may not have had a diagnosis of BPH or PAH.

We concluded the Department did not adequately communicate its concern to MCOs to mitigate the elevated risks of abuse and diversion associated with these drugs. For example, of the two Department communications to MCOs prior to our audit, only the 2013 communication addressed the inappropriate usage of the drugs Revatio and Adcirca. Furthermore, the Department did no

monitoring or oversight of ED drugs to detect potential recipient drug abuse or diversion.

## Pharmacy PA Contractor's Non-Compliance Verifying Sex Offender Status

We found the Pharmacy PA contractor erroneously approved one sex offender (classified as a level-2 sex offender) to obtain ED drugs that also treat PAH, for which Medicaid FFS paid $18,214, due to a documentation error while requesting the sex offender verification.

Sex offender status must be verified to allow for proper determination of medical necessity. We reviewed FFS prior authorizations for the two sex offenders who received ED drugs to treat PAH (refer to Table 3). We found the Department's Pharmacy PA contractor twice inappropriately authorized one of the sex offenders to obtain the ED drug. In the first instance, the Pharmacy PA contractor input inaccurate data in its sex offender verification request to DCJS, which caused DCJS to not find the recipient on the sex offender registry, even though the recipient has been a registered sex offender since 2003. As a result, Medicaid authorized and paid $18,214 for six prescriptions of an ED drug to treat PAH for a level-2 sex offender.

In the second instance, the Pharmacy PA contractor inappropriately authorized the same drug for the same sex offender five months later because it did not follow Department procedures and approved the PA request before receipt of the DCJS sex offender verification response. The DCJS response showed the recipient was a level-2 sex offender.

We concluded the verification process the Pharmacy PA contractor was required to use was inefficient and unnecessarily raised the risk of errors. For example, the PA contractor was required to complete seven data fields on the sex offender verification request form. If the PA contractor made a mistake documenting the first or last name or the date of birth of the recipient on the form, it could result in an inaccurate DCJS search result – that is, showing a recipient is not a sex offender when the recipient is actually a sex offender. The eMedNY Offender Search is more efficient because it requires one field of input (recipient ID), reduces the likelihood of human error, and provides immediate results. As a result of our audit, the Department made the eMedNY Offender Search available to certain employees (managers and supervisors) of the Pharmacy PA contractor.

## Improper Payments for Procedures and Supplies That Treat ED

State law excludes procedures and supplies for the treatment of ED provided to a registered sex offender (refer to Table 1). However, we determined MCOs paid $28,251 for a total of 24 excluded ED procedures and supplies provided to 18 sex offenders (14 of the 18 were classified as a level-2 or level-3 sex offender). We also determined FFS inappropriately paid $27,288 for 21 excluded ED procedures and supplies provided to 15 sex offenders (at least 6 of the 15 were classified as a level-2 or level-3 sex offender). (See Table 3 for summary of payments.)

Department policy requires MCOs to verify a recipient is not a sex offender prior to providing ED procedures or supplies. We concluded that MCOs did not always comply with Department policies and procedures to verify the sex offender status for recipients of ED procedures and supplies, nor did MCOs always comply with State law excluding coverage for sex offenders. FFS uses eMedNY prior approval controls over procedures and supplies to prevent ED services for sex offenders. We also concluded the Department incompletely incorporated controls in eMedNY to prevent ED procedures and supplies to sex offenders.

### MCO Non-Compliance

According to Department officials, MCOs are required to use the EDVS to verify a recipient's sex offender status prior to providing ED procedures or supplies. However, we found MCOs requested the recipient's sex offender status in only 3 of the 18 cases where sex offenders obtained procedures or supplies to treat ED. Furthermore, we determined that, in all three of the EDVS verifications, the EDVS correctly responded to the MCO that the recipient was not eligible to receive these services (i.e., the services were not allowed because the recipient was a sex offender), yet MCOs allowed the services and paid the claims. In the three EDVS verifications, the sex offenders represented each classification of registered sex offenders: one was a level-1, one was a level-2, and one was a level-3 sex offender.

Additionally, we found MCOs reported they "administration denied" six ED medical procedures or supplies provided to three sex offenders (all three were classified as a level-2 or level-3 sex offender). According to one MCO, "administration denied" means the MCO did not pay the billing providers who performed ED medical procedures or permitted ED supplies. The MCO further explained that an administration-denied claim indicated that the sex offender received the procedure or supply, but because of their sex offender status,

the MCO subsequently denied payment to the medical provider. MCO officials believe this administration-deny process complies with State law because the MCO did not pay for the services. We concluded that MCOs' controls are not designed to prevent sex offenders from obtaining treatment for ED.

## Incomplete eMedNY Payment Controls

Medicaid policy[5] implementing the State law specified that prior approval was required for ED drugs, procedures, or supplies to prevent Medicaid coverage for convicted sex offenders. It stated, "When a procedure is to be performed in a facility, the facility must verify with the practitioner that prior approval has been obtained by the practitioner. When billing for their portion of payment, facilities must place the prior approval number obtained by the practitioner on the claim." In addition, inpatient providers "must report the applicable CPT/HCPCS, ICD diagnosis and/or ICD procedure code(s) when requesting or billing erectile dysfunction services for Medicaid recipients." The policy also stated, "Prior approval is not required when billing for Medicare coinsurance."

However, we determined eMedNY incompletely incorporated controls to prevent ED procedures and supplies for convicted sex offenders. Consequently, Medicaid inappropriately paid $27,288 for 21 excluded ED procedures and supplies provided to 15 sex offenders (at least 6 of the 15 were classified as level-2 or level-3 sex offenders). Claims for 11 of the 15 sex offenders involved Medicare, for which – in contrast to State law – Medicaid paid the Medicare patient responsibility, totaling $469. This is because the federal Medicare program allows payment for these procedures and supplies (with the exception of one supply as of July 2015) for Medicare enrollees, which would include registered sex offenders. Medicaid claims for 3 of the 15 sex offenders were inpatient claims and the remaining were practitioner claims.

Prior approval controls in eMedNY prevent sex offenders from obtaining authorization for ED procedures and supplies, but only for those procedures coded to require a PA. We determined that none of the 21 claims for sex offenders had a PA. During the audit, we informed the Department one procedure code was missing from eMedNY's control list, which Department officials immediately corrected. However, we also found missing ICD-10 codes and ED-related procedure codes that did not indicate a PA was required.

Department officials said that, even if all the codes were corrected, Medicaid still would have paid the claims because eMedNY prior approval controls are

5 Office of Medicaid Management, DOH Medicaid Update, dated January 2006, Vol. 21, No. 1.

not applied to claims that involve Medicare, inpatient claims, and most clinic claims. According to the Department, claims with Medicare involvement do not require prior approval by Medicaid. This, however, does not account for State law excluding Medicaid coverage for ED treatment to sex offenders. For example, in one case, the Department paid the patient responsibility for a dual-eligible recipient who was a sex offender to receive a male vacuum erection system billed to Medicaid on a pharmacy claim.

### Gaps in eMedNY Sex Offender Identification

The eMedNY system is programmed to identify sex offenders using a weekly file provided by DCJS. We found multiple occasions where the DCJS file was incomplete. For example, on two separate occasions, the DCJS file contained a single record. However, we determined eMedNY lacked controls to prevent processing an incomplete file and, as a result, eMedNY processing removed all known recipients identified as sex offenders, except for the single recipient record on the DCJS file. Recipients were subsequently re-identified as sex offenders after eMedNY next processed a complete DCJS sex offender file.

Processing incomplete DCJS files created date segment gaps in eMedNY controls that may allow inappropriate Medicaid eligibility and services to sex offenders for these time periods. Unless the Department implements controls to prevent processing an incomplete DCJS sex offender file, it risks allowing sex offenders to receive treatment for ED when an incomplete file is processed.

## Inconsistent Laws and Policies

Despite efforts to protect public safety by eliminating Medicaid coverage of ED drugs, procedures, and supplies for sex offenders, our audit demonstrates that existing controls are insufficient to ensure compliance. Additionally, our audit signals there is increased risk that sex offenders may obtain ED drugs to divert the drug’s use from treating the other FDA-approved use conditions of BPH or PAH to improve sexual function.

We also observed that certain Medicaid laws and policies are inconsistent. For example, New York State law governing Medicaid prohibits ED procedures and supplies for sex offenders, but federal Medicaid laws do not address sex offenders or ED procedures and supplies or explicitly prohibit payment for these services.

In addition, State Medicaid policy does not cover ED drugs for treatment of BPH under FFS, but this policy restriction does not apply to MCOs. As such, MCOs may cover these drugs. During the 6.25-year period ended

July 1, 2018, MCOs paid about $11.6 million for ED drugs approved to treat other conditions for 1,929 recipients, and of that, $1.2 million for ED drugs approved to treat BPH (see Table 4). Our audit and the Department's analysis both indicate a large portion of MCO claims for ED drugs approved to treat other medical conditions lack assurance of medical necessity. Our analysis presented in Table 5 found between $2.8 million and $5.2 million in ED drugs approved to also treat BPH or PAH was paid on behalf of recipients who did not have a corresponding BPH or PAH diagnosis on their Medicaid claims submitted within two to six months of the drug prescription. Further, our review of medical records found only 62 percent (8 of 13) of the sex offenders receiving these drugs from MCOs were diagnosed with the indicated BPH or PAH condition. The Department's analysis also showed recipients diagnosed with the indicated condition averaged only 38 percent for BPH and 78 percent for PAH. Table 6 shows the breakdown by the approved other condition.

### Table 6 – MCO Payments for ED Drugs FDA Approved for Other Use

| Other Condition | MCO Payments | MCO Recipients | Recipient Sex Offenders | Recipients Diagnosed With Other Condition (Department Analysis) |
|---|---|---|---|---|
| **BPH** | $1,240,714 | 1,275 | 9 | 38% |
| **PAH** | $10,347,003 | 654 | 5 | 78% |
| **Totals** | **$11,587,717** | **1,929** | **14** | **–** |

ED drugs for treatment of BPH appear to be at higher risk of drug diversion, due to the higher number of recipients and the lower percentage of diagnosis of the BPH condition. Therefore, attention should be given to mitigate drug diversion by assessing restrictions of MCO coverage of ED drugs to treat BPH (similar to FFS coverage). One element could be to prohibit ED drugs to treat BPH when other non-ED drugs with similar effectiveness exist to treat BPH. For example, insurers (including Medicaid) have long relied on step therapy, a restriction on insurance coverage that requires providers to prove that less-expensive drugs are ineffective before getting coverage for a more expensive drug. Applying similar step therapy restrictions could require recipients (especially sex offenders) to try certain other drugs that treat BPH – and be proven ineffective – before allowing an ED drug to treat BPH.

## Recommendations

1. Review the $933,594 in improper payments we identified and ensure recoveries are made, as appropriate. Using a risk-based approach, assess the questionable payments we identified for ED drugs approved to also treat BPH or PAH (identified in Table 5) and ensure recoveries are made, as appropriate.
2. Regularly (at least annually) provide MCOs with complete lists that contain sufficient detail (e.g., NDC and procedure code) of all ED drugs, procedures, and supplies that are excluded or have limited Medicaid coverages.
3. Regularly communicate to MCOs, with sufficient detail, the policies and procedures that MCOs must adhere to, including verification of recipient sex offender status before providing coverage of an ED drug, procedure, or supply. Assess policy changes regarding MCO coverage of ED drugs that are also indicated for the treatment of BPH – to be consistent with FFS coverage. When updates occur, provide MCOs with updated policies and procedures.
4. Periodically monitor compliance of:
   - MCO and FFS coverage, utilization, and payment of ED drugs, procedures, and supplies;
   - MCO use of EDVS to verify sex offender status;
   - MCO determination of medical necessity of ED drugs, procedures, and supplies (i.e., recipient has the diagnosis for the other non-ED indicated use); and
   - Pharmacy PA contractor adherence to procedures for ED drug authorizations.
5. Educate and take corrective action, as necessary, to enforce MCO and Pharmacy PA contractor compliance with laws and Department policies and procedures. Assess the appropriateness of MCO administration-deny processes and their compliance with laws and Department policies and procedures.
6. Improve eMedNY controls and update corresponding Department policy, if applicable, to:
   - Address sex offender status in Medicare-involved claims;
   - Address sex offender status in inpatient and clinic claims;

- Ensure all ED-related procedures and supplies require a prior approval;
- Improve Pharmacy PA contractor sex offender verification efficiency; and
- Prevent processing incomplete DCJS sex offender registry files, and assess the feasibility of correcting gaps that resulted from previously processed incomplete files.

# Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether Medicaid recipients, including sex offenders, inappropriately received Medicaid-funded sexual dysfunction and erectile dysfunction drugs, procedures, and supplies, and whether controls are in place to prevent abuse and misuse of these products. The audit covered the period from April 1, 2012 to July 1, 2018.

To accomplish our objective and assess related internal controls, we interviewed officials from the Department, two MCOs, the State Office of Information Technology Services, DCJS, and the Department's contracted fiscal agent. We also reviewed applicable sections of State and federal laws and regulations and examined relevant Medicaid policies and procedures. We also examined the Medicaid Managed Care Model Contract and eMedNY system documentation.

To identify inappropriate drug payments, we identified the NDCs of drugs classified to treat impotency and drugs that contain their same generic active ingredient. To identify inappropriate supply and procedure payments, we used ED procedure codes identified by the Department and their corresponding updated ICD-10 codes. We obtained all MCO encounters and FFS claims (grouped together as "claims" for this report) for the identified NDCs and procedure codes that were paid between April 1, 2012 through July 1, 2018. We eliminated claims for ED drugs approved to treat PAH for female recipients because women receive no other clinical benefit beyond the treatment of PAH.

To identify recipients who are sex offenders, we used eMedNY's Sex Offender table. To verify the medical necessity in the cases of the 14 sex offenders who obtained ED drugs for the BPH or PAH condition, we reviewed medical records of 13 sex offenders to find evidence of the diagnosis (medical records for the remaining sex offender were not obtained in time for us to consider in this audit). We also reviewed medical records of five sex offenders who received drugs that only treat ED.

# 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. 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.

## 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 concurred with many of the audit recommendations and indicated that certain actions have been and will be taken to address them. Our rejoinders to certain misleading Department comments are included in the report's State Comptroller's Comments, which are embedded in the Department's response.

Within 90 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 where recommendations were not implemented, the reasons why.

# Agency Comments and State Comptroller's Comments

ANDREW M. CUOMO
Governor

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

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner


April 11, 2019

Ms. Andrea Inman, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, New York 12236-0001

Dear Ms. Inman:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2018-S-16 entitled, "Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders."

Thank you for the opportunity to comment.

Sincerely,

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

Enclosure

cc: Marybeth Hefner
Donna Frescatore
Dennis Rosen
Erin Ives
Brian Kiernan
Timothy Brown
Amber Rohan
Elizabeth Misa
Geza Hrazdina
Daniel Duffy
Jeffrey Hammond
Jill Montag
Ryan Cox
James Dematteo
James Cataldo
Jessica Lynch
DOH Audit SM

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 2018-S-16 entitled, "Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2018-S-16 entitled, "Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders."

**Recommendation #1:**

Review the $933,594 in improper payments we identified and ensure recoveries are made, as appropriate. Using a risk-based approach, assess the questionable payments we identified for ED drugs approved to also treat BPH or PAH (identified in Table 5) and ensure recoveries are made, as appropriate.

**Response #1:**

The Department summarily rejects OSC's contention that $933,594 in claims over the six-year audit period were improper. Per policy, the Medicaid program is prohibited from covering drugs used for the treatment of sexual or erectile dysfunction. However, drugs that are used to treat sexual or erectile dysfunction can also be used for other indications approved by the U.S. Food and Drug Administration (FDA). For example, phosphodiesterase type 5 (PDE5) inhibitor drugs are covered by the Medicaid program when used to treat pulmonary arterial hypertension (PAH) and benign prostatic hyperplasia (BPH). It is important to note that this is a commonly used drug class by practitioners given the high prevalence of BPH. OSC either ignored the law or the facts, which undermines any value that can be associated with its findings.

**State Comptroller's Comment 1 -** The Department's response appears to be an attempt to confuse readers through misdirection. The Department rejects the improper payments identified by the audit by making a general comment that drugs used to treat sexual and erectile dysfunction (ED) can also be used for other indications approved by the FDA, including BPH or PAH. However, the improper drug payments identified by the audit (specifically, $878,055 of the $933,594 in improper drug, procedure, and supply payments) were for drugs approved by the FDA to treat ED – not BPH or PAH as the Department asserts – and are unequivocally barred from the Medicaid program. In fact, if these same drug claims were processed today by the Department's eMedNY system under the FFS reimbursement methodology and not by the MCOs' claim processing systems, the Department would deny these claims.

Additionally, it is the Department that appears to be ignoring the facts. During the audit, the Department agreed the ED claims were not in compliance with the law or Medicaid policy. From the onset of this audit, we established a collaborative effort with the Department to allow for immediate improvements to protect the public on such a serious matter. Shortly after we engaged the audit and notified Department officials of the problematic payments, the Department analyzed claims and similarly determined that MCOs were not in compliance with Medicaid policy or laws regarding ED

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drugs. The Department immediately notified MCOs that they were paying ED claims “inconsistent with Medicaid policy & the legislation” and provided the MCOs with text of State laws (N.Y. Soc. Serv. Law §365-a(4)(e), (f) and Public Health Law §2510 paragraph 7). The Department then instructed all MCOs to take corrective action to “make any necessary changes/controls immediately to align with the policy.”

The Department allowed ED drugs, procedures, and supplies and, in some cases, allowed them for sex offenders. The audit’s findings should compel Department officials to take immediate corrective actions.

The Department also dismisses the assumptions used by OSC to identify questionable payments for drugs indicated to treat sexual or erectile dysfunction which can also be used to treat other indications (e.g., BPH, PAH, smooth muscle spasm, hypertensive episode). There was absolutely no consideration for diagnoses contained in the medical or prior authorization record, and the look-back period for diagnosis in claim records should have been for one year from the prescription fill date, rather than 6 months or less. OSC's incorrect use of a one-year look-back period accounts for the limitations in claims data related to timeliness and completeness.

**State Comptroller’s Comment 2 -** The Department dismisses the lookback period we used to identify questionable payments (ranging between $2.8 million and $5.2 million) for ED drugs approved to also treat BPH or PAH that were made on behalf of recipients who did not have a corresponding BPH or PAH diagnosis on their Medicaid claims submitted up to two and six months before the drugs were prescribed (i.e., ordered). However, the Department did a comparable analysis using a one-year lookback period from the date a prescription was filled (i.e., when the drugs were received) and arrived at similar conclusions, as follows.

State regulations allow refills up to six months after they are prescribed. Therefore, according to the Department’s analysis, if a patient filled a drug prescription six months after they received the original prescription, per the Department’s one-year lookback period from the date a prescription was filled, their methodology would expect the patient to have seen their doctor (and received a BPH or PAH diagnosis) up to six months before the drugs were originally prescribed – which matches our six-month lookback period from the date a drug was originally prescribed. We concluded it is probable that a recipient would be prescribed drugs for a BPH or PAH condition that was diagnosed during a medical visit that occurred six months or less before the date the prescription was ordered. Moreover, our test and the Department’s test both determined that a significant portion of these claims did not have diagnoses supporting the condition of BPH or PAH. For instance, the Department’s analysis showed that, since 2012, an average of 62 percent of MCO recipients prescribed ED drugs that are also approved to treat BPH did *not* have a BPH diagnosis in their claims history (see page 15 of the report). Again, it appears the Department’s comments are an attempt to confuse readers.

In addition, we did consider diagnoses contained in medical records supporting claims for ED drugs also approved to treat BPH or PAH. We used medical professionals to review medical records of the sex offenders who received these ED drugs to determine the supporting diagnoses to prescribe the drugs, and our review concluded that a significant portion of the cases did not support a diagnosis to treat BPH or PAH – they only supported a diagnosis to treat ED (see pages 14–15 of the report).

Over the course of a six-year period, the OSC identified $7,762 of potential overpayments that

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were paid through the State's Medicaid Managed Care Organizations (MCOs) for drugs used to treat sexual or erectile dysfunction for level 2 or level 3 registered sex offenders. Although, additional review of supporting documentation, including the review of the Medicaid member's medical record by a medical professional, is necessary in order to make a final determination, the Department will perform a thorough review of these payments. If the review results in findings of inappropriate payments, the Department will work with MCOs to implement any necessary procedures and protocols to ensure all policies by are being adhered to.

**State Comptroller's Comment 3 -** Table 3 on page 11 of our report summarizes all the Medicaid payments made for drugs, procedures, and supplies used to treat ED for sex offenders, including the $7,762 referenced by the Department. The Department's response refers to the $7,762 as "potential" overpayments. However, the $7,762 are actual overpayments because the Medicaid program does not cover these drugs since they are approved by the FDA to only treat ED. Also, as stated in State Comptroller's Comment 1, claims for these same drugs would have been denied by Medicaid under the FFS reimbursement methodology. Lastly, we did review medical records for a portion of the payments and found the records supported a diagnosis of ED. We are glad the Department will review these MCO payments and work with MCOs to ensure all policies are being adhered to.

Of note, for Medicaid Managed Care payments, recoveries are not applicable for drugs because capitated rates assume that drugs used to treat sexual or erectile dysfunction (ED) are not covered under New York State Law. However, the Department will continue to collaborate with the OMIG to review the identified payments and pursue recovery of any payment determined to be inappropriate. Findings will be distributed to the MCOs with instructions to review, recover and properly report any recoveries.

**State Comptroller's Comment 4 -** Department officials acknowledge that the improper MCO payments identified by the audit should be excluded from managed care premium rates – we agree. Despite policies and laws prohibiting them, MCOs paid for these claims. Accordingly, we are glad the Department is taking steps to implement our recommendation and ensure improper payments are recovered.

**Recommendation #2:**

Regularly (at least annually) provide MCOs with complete lists that contain sufficient detail (e.g., NDC and procedure code) of all ED drugs, procedures, and supplies that are excluded or have limited Medicaid coverages.

**Response #2:**

The Department already provides clear guidance to its MCOs and is in frequent contact with MCOs regarding compliance with laws, rules and regulations. The Department maintains that it has clearly communicated to MCOs Medicaid coverage of drugs, procedures, and supplies indicated for the treatment of sexual or erectile dysfunction, which includes PDE5 inhibitors and does so annually. The Department will continue to regularly update MCOs and monitor claim encounter activity to ensure plan compliance with coverage parameters of drugs, procedures, and supplies that are indicated for the treatment of sexual or erectile dysfunction.

**State Comptroller's Comment 5 -** The Department's actions during the audit period contradict its response. While the Department sent MCOs two ED drug coverage policy reminders after October

2011 when MCOs became responsible for pharmacy benefits, these do not align with the clear and frequent contact noted in the Department's response: twice in six years (one in 2013 and one in 2017 as noted on page 12) was not annual or regular. Our audit further showed these communications were not always complete or effective. It was only after our audit began that the Department reached out to MCOs more to discuss excluded drugs, procedures, and supplies. We are glad the Department is taking steps to implement our recommendation; however, they fail to specify or commit to how often they will "regularly update MCOs" and "monitor claim encounter activity" to ensure plan compliance with coverage parameters of drugs, procedures, and supplies for the treatment of ED.

**Recommendation #3:**

Regularly communicate to MCOs, with sufficient detail, the policies and procedures that MCOs must adhere to, including verification of recipient sex offender status before providing coverage of an ED drug, procedure, or supply. Assess policy changes regarding MCO coverage of ED drugs that are also indicated for the treatment of BPH–to be consistent with FFS coverage. When updates occur, provide MCOs with updated policies and procedures.

**Response #3:**

The Department already provides detailed information to the MCOs on Medicaid coverage of drugs indicated for the treatment of sexual or ED, which includes PDE5 inhibitors, since the pharmacy benefit was carved-in to MCOs in October of 2011, starting with a reference guide document that was provided to the Plans prior to the transition. Furthermore, the Medicaid Managed Care Model Contract, Appendix K.2, §10 (c)(vi)(5) states that drugs used for the treatment of sexual or ED are not covered, unless they are used to treat a condition, other than sexual or ED, for which the drug has been approved by the Food and Drug Administration.

In order to ensure compliance with the State's coverage policies, the Department has sent numerous updates to MCOs, as referenced below:

- On December 29, 2005, the Department sent MCOs information on the policy for drugs, procedures, and supplies indicated for the treatment of erectile dysfunction, as well as notifying MCOs of the policy published in the January 2006 Medicaid Update.
- On January 9, 2006, the Department sent clarification to the MCOs on the policy for drugs, procedures, and supplies indicated for the treatment of erectile dysfunction.
- On August 30, 2013, the Department sent a list of drugs indicated for erectile dysfunction to MCOs and provided guidance that Revatio and Adcirca are not covered when used for erectile dysfunction;
- On April 17, 2017, the Department sent an updated list of the drugs indicated for erectile dysfunction to MCOs;
- On May 17, 2018,the Department shared CMS State Release #179, which provided a policy overview regarding drugs used to treat sexual or erectile dysfunction;
- On July 30, 2018, the Department provided MCOs with an updated list in a standardized classification method [hierarchical specific therapeutic class code], which enables a Pharmacy Director to easily identify new drugs used to treat sexual or erectile

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dysfunction;

The Department also discussed this topic at several Pharmacy Directors meetings. Meeting dates and topic discussed are referenced below:

- On January 17, 2012, the Department discussed sex offender registry compliance;
- On September 3, 2013, the Department reviewed the excludable drug information that was sent out to Plans;
- On April 17, 2017, the Department reviewed the CMS State Release #179; which provided a policy overview regarding drugs used to treat sexual or erectile dysfunction;
- On April 3, 2018, the Department reviewed applicable state and federal legislation and· the excludable drug list, which includes drugs indicated for the treatment of sexual or erectile dysfunction;
- On July 5, 2018, the Department provided Plans with data on drugs indicated for the treatment of sexual or erectile dysfunction, including member data for sex offenders that had claim encounters for such drugs;
- On July 10, 2018, the Department conducted a review of drugs indicated for the treatment of sexual or erectile dysfunction; and
- On October 2, 2018, the Department reviewed the policies regarding drugs indicated for the treatment of sexual or erectile dysfunction.

**State Comptroller's Comment 6 -** Since MCOs were given the responsibility of administering pharmacy benefits in 2011, the Department had only two policy communications (in 2013 and 2017). However, after we engaged our audit and brought the problem to the attention of the Department, the Department sent two policy updates and had four meetings to clarify issues with MCOs – all during our audit fieldwork in 2018.

As demonstrated above, the Department has provided consistent and clear communication with MCOs regarding Medicaid coverage of drugs indicated for sexual or erectile dysfunction, as well as procedures and supplies. The Department will continue to regularly update MCOs and regularly monitor claim encounter activity to ensure Plan compliance with drug coverage parameters for drugs, procedures, and supplies indicated for sexual or erectile dysfunction.

**State Comptroller's Comment 7 -** Communications themselves are not effective without follow-up to ensure MCOs understand and are complying with the information. After the audit began, in 2018 the Department began reaching out to MCOs to discuss coverage and procedures. Yet, as noted on page 12 of our report, after three months of discussions and communications in 2018, MCOs indicated continued confusion.

We are glad the Department indicates it will take steps to implement our recommendation. However, we note that the Department fails to specify or commit to a time frame that defines "regularly" when it states the Department will "regularly update MCOs and regularly monitor claim encounter activity to ensure Plan compliance with drug coverage parameters." See also State Comptroller's Comment 5.

Additionally, the Department will continue to disseminate policies via email, recurring plan meetings or other methods, as needed. The Department is reassessing current policies regarding MCO coverage of drugs used to treat sexual or erectile dysfunction that are also indicated for the treatment of BPH to be consistent with fee-for-service (FFS) coverage. The Department also disseminated clarifying guidance to the MCOs that sets forth overall Department policies regarding Medicaid coverage of drugs indicated for the treatment of sexual or erectile dysfunction and will disseminate clarifying guidance for procedures and supplies for sexual or erectile dysfunction, as well as the procedures for verifying a member's sex offender status.

**State Comptroller's Comment 8 -** We are glad the Department is taking steps to implement our recommendation.

**Recommendation #4:**

Periodically monitor compliance of:

- MCO and FFS coverage, utilization, and payment of ED drugs, procedures, and supplies;
- MCO use of EDVS to verify sex offender status;
- MCO determination of medical necessity of ED drugs, procedures, and supplies (i.e., recipient has the diagnosis for the other non-ED indicated use); and
- Pharmacy PA contractor adherence to procedures for ED drug authorizations.

**Response #4:**

The Department already implemented mechanisms years ago to routinely review medical necessity reviews/prior authorizations processes for drugs indicated for the treatment of sexual or erectile dysfunction to ensure compliance with applicable policies, the plan contract and statutes.

**State Comptroller's Comment 9 -** The Department's response is misleading. The statements appear to pertain to fee-for-service claims; however, the majority of the audit's findings pertain to managed care claims and processes and, as discussed on page 16 of our report, we found the Department did not monitor ED drugs provided by MCOs.

The Department will continue to educate MCOs regarding coverage of drugs indicated for the treatment of sexual or erectile dysfunction, which includes PDE5 inhibitors, consistent with how such education has been handled since the pharmacy benefit was moved into managed care.

**See State Comptroller's Comments 5, 6, and 7.**

As referenced in the response to Recommendation #2, the Department will also continue to regularly monitor claim encounter activity to ensure plan compliance with coverage parameters for drugs, procedures, and supplies indicated for the treatment of sexual or erectile dysfunction and will also incorporate monitoring methods into established processes and surveys conducted.

**State Comptroller's Comment 10 -** We are glad the Department is taking steps to implement our

recommendation. However, we note that the Department fails to specify or commit to a time frame that defines "regularly" when it states the Department will "regularly monitor claim encounter activity."

Furthermore, the Department will continue to routinely monitor MCO claim encounter activity and report results to the Plans. The Department will cross-check MCO claim encounter activity with the sex offender registry to determine if any such drugs, procedures, or supplies were prescribed to a sex offender. If so, the Plan would be cited and a corrective action plan required. The Department will review the MCOs' policies and procedures specific to this matter during regularly scheduled on-site operational surveys.

**State Comptroller's Comment 11 -** We are pleased the Department is taking steps to implement our recommendation. However, we note that the Department fails to specify or commit to a time frame that defines "routinely" when it states the Department will "routinely monitor MCO claim encounter activity."

**Recommendation #5:**

Educate and take corrective action, as necessary, to enforce MCO and Pharmacy PA contractor compliance with laws and Department policies and procedures. Assess the appropriateness of MCO administration-deny processes and their compliance with laws and Department policies and procedures.

**Response #5:**

The Department implemented this recommendation beginning last year. The Department has reviewed the laws with the Pharmacy prior authorization (PA) contractor and has reviewed the policy and procedures.

**State Comptroller's Comment 12 -** We are pleased the Department implemented this recommendation in 2018 as a result of this audit.

The Department will work to ensure that MCOs found not to be in compliance with laws or the Medicaid Managed Care Model Contract regarding the coverage of drugs, procedures, and supplies to treat sexual or erectile dysfunction continue to be educated to be in compliance. A statement of deficiencies will be issued, and a corrective action plan will be required to ensure compliance.

**State Comptroller's Comment 13 -** We are pleased the Department is taking steps to implement our recommendation.

**Recommendation #6:**

Improve eMedNY controls and update corresponding Department policy, if applicable, to:

- Address sex offender status in Medicare-involved claims;
- Address sex offender status in inpatient and clinic claims;
- Ensure all ED-related procedures and supplies require a prior approval;
- Improve Pharmacy PA contractor sex offender verification efficiency; and
- Prevent processing incomplete DCJS sex offender registry files, and assess the feasibility of correcting gaps that resulted from previously processed incomplete files.

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**Response #6:**

The Department maintains that it has clearly communicated Medicaid coverage of drugs, procedures, and supplies indicated for the treatment of sexual or erectile dysfunction and will continue to improve eMedNY systems controls by implementing the following:

**State Comptroller's Comment 14 -** As our audit has shown, the Department did not clearly communicate Medicaid coverage of these drugs (see State Comptroller's Comments 5, 6, and 7). As well, there were ineffective control activities and insufficient monitoring to detect and prevent sexual and erectile dysfunction treatments, including those provided to sex offenders.

- The Department is working to design and implement an eMedNY system change that will prevent payments for ED-related procedures provided to sex offenders that Medicare has reimbursed and Medicaid is the secondary payer.
- The eMedNY system change will prevent payments for ED-related procedures given to sex offenders in institutional and clinic settings.

**State Comptroller's Comment 15 -** We are pleased the Department is taking action to implement our recommendations to improve eMedNY controls.

- All ED-related procedures and supplies presently require prior approval. The list of procedures/supplies will be reviewed on a regular basis and updates will be made to eMedNY, as appropriate, and communicated to MCOs.

**State Comptroller's Comment 16 -** We are pleased the Department is taking action to implement our recommendation. However, we note that the Department fails to specify or commit to a time frame that defines "regular basis" when it says "will be reviewed on a regular basis."

- The Department has already improved sex offender verification with the Pharmacy PA contractor. Effective June 29, 2018 the PA contractor received access to the eMedNY Offender Search page.

**State Comptroller's Comment 17 -** We are pleased the Department took immediate action to implement our recommendation after we brought it to their attention.

- The Department is working on system upgrades to address any deficiencies in transfer of the Division of Criminal Justice Services (DCJS) sex offender registry files. The Department will engage its Fiscal Agent via the system change request process to explore cost-minimizing opportunities to establish controls to mitigate the processing of incomplete file transmissions from DCJS and will correct table gaps related to files previously transmitted on the dates noted in the recommendation.

**State Comptroller's Comment 18 -** We are pleased the Department is taking action to implement our recommendation.

# Contributors to Report

## Executive Team

**Andrew A. SanFilippo -** *Executive Deputy Comptroller*

**Tina Kim -** *Deputy Comptroller*

**Ken Shulman -** *Assistant Comptroller*

## Audit Team

**Andrea Inman -** *Audit Director*

**Warren Fitzgerald -** *Audit Manager*

**Gail Gorski -** *Audit Supervisor*

**Daniel Rossi -** *Examiner-in-Charge*

**Yanfei Chen -** *Examiner-in-Charge*

**Jonathan Julca -** *Examiner-in-Charge*

**Suzanne Loudis -** *Supervising Medical Care Representative*

**Gary Czosnykowski -** *Senior Examiner*

**Misty Daiyan -** *Senior Examiner*

**Francesca Greaney -** *Senior Examiner*

**Xiaohu Nian -** *Senior Examiner*

**Edward Reynoso -** *Senior Examiner*

**Zachary Schulman -** *Senior Examiner*

**Daniel Zimmerman -** *Project Assistant*


**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

Like us on Facebook at facebook.com/nyscomptroller
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