



Department of Health

ANDREW M. CUOMO
Governor

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

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

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Andrea Inman
Audit Director
Division of State Government Accountability
NYS Office of the State Comptroller
110 State Street, 11th Floor
Albany, New York 12236

Dear Ms. Inman:

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

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 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) Final 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 \$933,594 (\$878,055 for drugs; \$55,539 for procedures and supplies) are actual overpayments. 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 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 – identified in Table 5) 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 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 – The audit identified \$933,594 in actual overpayments (the \$7,762 is included in these overpayments), and between \$2.8 million and \$5.2 million in questionable payments. 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 because 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 its 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 (once in 2013 and once 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, it fails to specify or commit to how often it 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 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 guidance. 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-denial 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.

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). Additionally, 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 the issue 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.