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OFFICE OF THE STATE COMPTROLLER

February 8, 2021

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

Re: Improper Payments for Sexual and
Erectile Dysfunction Drugs,
Procedures, and Supplies Provided
to Medicaid Recipients, Including Sex
Offenders
Report 2020-F-15

Dear Dr. Zucker:

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 have followed up on the actions taken by officials of the Department of Health to implement the recommendations contained in our audit report, *Improper Payments for Sexual and Erectile Dysfunction Drugs, Procedures, and Supplies Provided to Medicaid Recipients, Including Sex Offenders* (Report [2018-S-16](#)).

Background, Scope, and Objective

The Department of Health (Department) administers the State's Medicaid program, which provides a wide range of health care services to individuals who are economically disadvantaged and/or have special health care needs. 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 or indirectly through monthly premium payments to managed care organizations (MCOs), who, in turn, pay providers.

At the time of the initial audit, the Department administered the Medicaid pharmacy benefit for recipients enrolled in FFS and MCOs administered the pharmacy benefit for recipients enrolled in managed care. According to the Medicaid Redesign Team (MRT-II) State Fiscal Year 2020-21 budget initiative, the Department will assume responsibility for administering Medicaid pharmacy benefits (both FFS and most managed care) starting April 1, 2021.

Federal and State laws agree that Medicaid will not pay for drugs to treat sexual or erectile dysfunction (herein collectively referred to as ED) for Medicaid recipients, which would include registered sex offenders. In addition to drugs, State law further specifies that Medicaid

will not pay for procedures or supplies to treat ED for registered sex offenders. Additionally, federal and State laws agree that Medicaid will 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), herein referred to as “limited coverage” drugs. For example, Medicaid will pay for certain ED drugs approved by the FDA to treat pulmonary arterial hypertension (PAH) and benign prostatic hyperplasia (BPH). A notable distinction is that Medicaid FFS will not pay for ED drugs with certain active ingredients and dosages approved to treat BPH, because the drugs can be abused or diverted to manage ED. However, the Department applies this policy inconsistently by not requiring MCOs to adhere to it. The Department acknowledged the historical high risk of abuse of these drugs and required controls be in place, including determining a recipient’s sex offender status and the medical necessity, before prior authorization is given to ensure payments are appropriate.

The Department employs a formulary (a list of prescription drugs covered by the Medicaid program) and a prior authorization (PA) contractor to control FFS claims for ED drugs. MCOs are responsible for drugs allowed for Medicaid recipients enrolled in their plans. As such, the MCOs must determine the medical necessity of the ED drug as well as the sex offender status of the recipient before authorizing payment. The Department created the Erectile Dysfunction Verification System (EDVS) and required that MCOs use it to request a recipient’s sex offender status. The EDVS uses data from the State Division of Criminal Justice Service (DCJS) sex offender registry. According to DCJS, the court assigns one of 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).

We issued our initial audit report on June 3, 2019. The audit objective was to determine whether Medicaid recipients, including sex offenders, inappropriately received Medicaid-funded ED drugs, procedures, and supplies, and whether controls were in place to prevent abuse and misuse of these products. The audit covered the period April 1, 2012 through July 1, 2018. The audit identified \$933,594 in improper payments 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). Medicaid also made payments of \$13.5 million for ED drugs that are approved to also treat other medical conditions (primarily BPH and PAH). We found about \$11.6 million of the \$13.5 million in payments were made without verifying recipient sex offender status through the EDVS system, as required – consequently, auditors found Medicaid paid \$285,641 on behalf of 14 sex offenders. Additionally, the audit found between \$2.8 million and \$5.2 million in questionable payments for ED drugs that treat BPH and PAH that were made without the recipient having a diagnosis of BPH or PAH on their Medicaid claims within the two prior months (\$5.2 million) or within the six prior months (\$2.8 million) of the drug prescription.

MCOs made most of the payments we reported on. Overall, we determined inadequate Department guidance and oversight, and incomplete control systems allowed payments for recipients, including sex offenders, to obtain drugs and services to treat ED.

The objective of our follow-up was to assess the extent of implementation, as of October 22, 2020, of the six recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

Department officials made some progress in addressing the problems identified in the initial audit report. We found the Department took some corrective steps, such as improving certain payment controls to prevent improper FFS payments and providing quarterly utilization

reports to MCOs of the ED drugs they paid for. However, more improvements are needed to prevent payments for excluded ED drugs, procedures, and supplies for Medicaid recipients, including sex offenders. Further, the Department had not recovered a significant amount of the identified improper payments for ED drugs, procedures, or supplies. Of the initial report's six audit recommendations, one was implemented and five were partially implemented.

Follow-Up Observations

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.

Status – Partially Implemented

Agency Action – The Office of the Medicaid Inspector General (OMIG) investigates and recovers improper Medicaid payments on behalf of the Department. During our initial audit, we provided OMIG staff with claim details of 4,934 improper payments totaling \$933,594 for drugs, procedures, and supplies to treat ED. Of these, 83 improper payments totaling \$63,301 were made for 47 sex offenders.

The Department passively pursued improper payment recoveries by allowing MCOs to decide which of their claims for procedures, supplies, or ED drugs only approved by the FDA to treat ED (which are unequivocally barred) to void. As of July 20, 2020, OMIG reported that MCOs voided 80 pharmacy claims totaling \$20,435, which included a void of one claim payment of \$133 for a sex offender. No recovery efforts addressed improper FFS claims.

MCOs made the majority of the \$2.8 million to \$5.2 million (identified in Table 5 in the initial audit) in questionable payments for ED drugs approved to also treat BPH or PAH on behalf of recipients who did not have a corresponding BPH or PAH diagnosis on their claims submitted within two to six months of the drug prescription. It is the Department's position that, because the Department excludes ED drugs from the computation of an MCO's capitation rate, the questionable MCO payments are not recoverable. Instead of further assessing these past questionable payments, the Department is monitoring current questionable MCO payments to help MCOs make improvements (see Agency Action for Recommendations 4 and 5).

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.

Status – Partially Implemented

Agency Action – The Department provided the dates they sent MCOs detailed lists of excluded and limited coverage ED drugs. We obtained two samples and confirmed the lists were reasonably complete and had sufficient detail. However, the Department has not provided MCOs with any lists addressing limited coverage ED procedures and supplies.

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.

Status – Partially Implemented

Agency Action – The Department communicated policies and procedures to MCOs on various occasions during our initial audit. However, since our initial audit report was issued on June 3, 2019, the Department sent MCOs clarification once: guidance on how to use the EDVS was sent on July 16, 2019. Department officials explained that they did not pursue more MCO policy and procedure communications due to COVID-19 activities and work on MRT-II pharmacy benefit administration.

Additionally, the Department provided no evidence it assessed policy changes regarding MCO coverage of ED drugs that are also indicated for the treatment of BPH to be consistent with FFS coverage.

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.*

Status – Partially Implemented

Agency Action – The Department runs quarterly reports to ensure excluded ED drugs are not included on the FFS formulary and provides quarterly utilization reports to MCOs of the ED drugs they paid for. However, the Department has not monitored coverage, utilization, or payment for ED procedures and supplies. Additionally, the Department has not monitored MCOs' use of the EDVS to verify sex offender status. However, Department officials provided their work plan to implement monitoring of EDVS use, beginning in December 2020.

Regarding MCO determinations of medical necessity, on March 29, 2019, the Department requested each MCO's criteria for authorization and utilization of limited coverage ED drugs for review. The Department reviews MCO determinations as part of operational surveys performed periodically for each MCO. However, Department officials stated that only a "limited number" of surveys involved a review of ED drugs and none involved ED procedures or supplies. Lastly, Department officials did not provide evidence that they periodically monitor Pharmacy PA contractor adherence to ED drug PA procedures; however, officials stated they hold monthly meetings with Pharmacy PA

contractor staff and plan to create monthly reports and formalize a monitoring process going forward.

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.

Status – Partially Implemented

Agency Action – The Department educated MCOs on compliance with laws and Department policies and procedures for ED drugs using quarterly MCO ED drug utilization reports that show MCOs inappropriately paid for excluded and limited coverage ED drugs. The Department has the right to issue a statement of deficiency to MCOs for non-compliance. However, despite continued non-compliance by certain MCOs (as indicated in the reports), Department officials have not issued any statements of deficiency for non-compliance which, in effect, allows MCOs to continue to pay for ED drugs. It is crucial that the Department take corrective actions with non-compliant MCOs to enforce laws and Department policies to ensure public safety.

Furthermore, since our initial audit, the Department has not provided any evidence of educating MCOs or taking corrective action regarding ED procedures and supplies.

Additionally, during our initial audit, the Department worked with the FFS Pharmacy PA contractor to improve their procedures. Department officials also hold monthly meetings with Pharmacy PA contractor staff and educate them, when necessary. However, the Department does not have a formal monitoring process to ensure the PA contractor is in compliance, which could prevent its ability to take timely corrective action. Department officials stated they intend to create monthly reports and formalize monitoring of PA contractor activity.

Finally, Department officials stated that the MCO administration-deny process (e.g., when MCOs subsequently deny payment to providers who provided ED services) complies with laws and Department policies and procedures because it ensures MCOs do not pay for ED drugs, procedures, or supplies. Department officials also assert each MCO's administration-deny process is assessed during operational surveys (see Agency Action in Recommendation 4).

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.

Status – Implemented

Agency Action – The Department implemented a new system control to deny ED claims based on sex-offender status for Medicare-involved (i.e., crossover) and inpatient claims. However, during our review, we found the system control did not address one ED procedure code. We informed the Department and they immediately corrected it. The Department is currently working to implement another system control to address sex offender status on clinic claims.

For the ED-related procedures we found during the initial audit that did not require prior approval, Department officials stated they are denied by the new system control.

During the initial audit, the Department provided key Pharmacy PA contractor staff direct access to the eMedNY sex offender search, improving the efficiency of the FFS PA sex offender verification process. The Department also updated the PA contractor's process to verify recipient sex offender status before approving prior authorization for ED drugs, procedures, and supplies.

The Department improved the process of integrating the sex offender file from DCJS into eMedNY to prevent incomplete files from being processed and corrected the gaps in sex offender data from previously incomplete files.

Major contributors to this report were Warren Fitzgerald, Gail Gorski, Jonathan Brzozowski, Amanda Basle, and Reid Vogel.

We would appreciate your response to this report within 30 days, indicating any actions planned to address the unresolved issues discussed in this report. We thank the management and staff of the Department for the courtesies and cooperation extended to our auditors during this review.

Very truly yours,

Andrea Inman
Audit Director

cc: Mr. Robert Schmidt, Department of Health
Ms. Erin Ives, Acting Medicaid Inspector General