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March 6, 2014

Nirav R. Shah, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Re: Rebates and Discounts on Physician-
Administered Drugs
Report 2013-F-23

Dear Dr. Shah:

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 (Department) to implement the recommendations contained in our audit report, *Rebates and Discounts on Physician-Administered Drugs* (Report 2010-S-72).

Background, Scope and Objective

Physician-administered drugs, such as chemotherapy, are administered to patients by a medical professional in an office setting. To reduce Medicaid costs for prescription drugs, the federal government established the Medicaid Drug Rebate Program. Under the rebate program, state Medicaid programs recover a portion of their prescription drug costs by obtaining rebates from drug manufacturers. In addition to the rebate program, Medicaid obtains savings on the costs of designated drugs through the 340B Drug Pricing Program, which requires drug manufacturers to discount, at the time of sale, the price of drugs sold to certain qualified providers. Providers are required to pass on the savings to Medicaid when they submit claims for 340B drugs.

We issued our initial audit report on July 24, 2012. Our objective was to determine if the Department maximized Medicaid rebate collections on physician-administered drugs and ensured that 340B physician-administered drugs were billed to Medicaid properly. Our initial audit found that during the audit period of January 2008 through April 2011, the Department had neither

maximized rebate collections on physician-administered drugs nor ensured the proper billing for 340B drugs. These problems cost the Medicaid program an estimated \$24.3 million. The objective of our follow-up was to assess the extent of the implementation, as of January 31, 2014, of the five recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

Department officials made progress in addressing the problems we identified in the initial audit. However, significant Department actions are still needed as millions of dollars in rebates remain uncollected. From April 2011 through January 2014, the Department had not collected about \$26.2 million in available rebates, due considerably to delays in fully implementing some of our initial report's recommendations. Of the five prior recommendations, two have been implemented and three have been partially implemented.

Follow-Up Observations

Recommendation 1

Formally assess the option of obtaining rebates on the physician-administered drug claims we identified. This would include requesting providers who failed to include NDCs to resubmit such claims with the pertinent NDC data.

Status - Implemented

Agency Action - The Department assessed the option of obtaining rebates on the physician-administered drug claims we identified. As a result, in December 2013, the Department sent letters to 20 providers who the Department determined had the highest amount of obtainable rebates. In the letter, the Department requested that the providers review their previously submitted physician-administered drug claims that lacked NDCs and resubmit the claims with the appropriate NDC information.

Recommendation 2

Obtain rebates on all physician-administered drug claims, regardless of claim type.

Status - Implemented

Agency Action - Effective January 29, 2014, the Department expanded the number of claim types that rebates will be collected on. Our initial audit determined the Department only collected rebates on physician-administered drug claims that were processed as two claim types (practitioner and referred ambulatory). However, eMedNY also processes rebate-eligible physician-administered drug claims as other claim types. Because of Department delays in expanding the rebate process to other claim types, we determined that nearly \$26.2 million in rebates went uncollected from April 2011 (the end of our prior audit's scope period) through January 2014. Department officials state they are taking steps to obtain

rebates back to January 1, 2008 on the physician-administered drug claims processed under the additional claim types. The Department is also evaluating the feasibility of adding another claim type to their rebate collection efforts.

Recommendation 3

Take steps to improve the eMedNY system edit controls in place for physician-administered drug claims. This would include:

- *setting the edit to deny all types of physician-administered drug claims submitted without an NDC, and*
- *ensuring adjustment claims do not bypass the edit.*

Status - Partially Implemented

Agency Action - The Department has taken steps to improve the eMedNY system edits for physician-administered drug claims. On September 20, 2013, the Department implemented an eMedNY project to deny certain physician-administered drug claims lacking an NDC that we identified in our initial audit. However, the new edit controls do not deny all physician-administered drug claims submitted without NDC information. For example, eMedNY will not deny claims for “Durable Medical Equipment/Supply” physician-administered drug claims that lack an NDC. As a result, Department officials are taking steps to establish a new eMedNY project to remedy the shortcomings of the edit. In addition, the Department is taking steps to ensure adjustment claims submitted without an NDC do not bypass the edit.

Recommendation 4

Recover the \$1.4 million in overpayments made to the hospitals identified by our audit and review payments for high risk 340B claims (when charges exceed the Medicaid maximum fee) made to other providers.

Status - Partially Implemented

Agency Action - The Office of the Medicaid Inspector General (OMIG) investigates and recovers improper Medicaid payments on behalf of the Department. Although the OMIG recently began a review of the overpayments identified in our initial audit, none of the \$1.4 million in overpayments has been recovered and no timeline for recoveries has been established. In addition, the Department has taken steps to review high risk 340B claim payments by introducing a prepayment review process for providers that meet certain “high risk” criteria.

Recommendation 5

Take steps to ensure that payments for 340B drug claims are proper. At a minimum, these steps should include:

- *formally reminding all 340B participating providers to charge drug acquisition costs with the appropriate discounts on 340B drug claims;*
- *monitoring high risk providers to ensure future claims for physician-administered drugs contain accurate drug acquisition costs; and*
- *implementing an eMedNY system edit to capture and pend claims with unreasonably high charges for 340B drugs.*

Status - Partially Implemented

Agency Action - The Department has taken steps to ensure that payments for 340B drug claims are proper. The steps taken include the following:

- In August 2013, the Department published a *Medicaid Update* article that reminded 340B providers to bill Medicaid for the actual drug acquisition cost on 340B drug claims.
- The Department placed 36 providers on a prepayment review list. These providers will be required to submit invoices supporting their drug acquisition costs, which will help ensure accurate Medicaid reimbursements.
- At the time of our follow-up, the Department had not implemented an eMedNY system edit to capture and pend claims with unreasonably high charges for 340B drugs. However, officials had initiated a project to create an edit to deny payment of such claims.

Major contributors to this report were Paul Alois, Daniel Towle and Kate Merrill.

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 Manager

cc: Ms. Diane Christensen, Department of Health
Mr. James Cox, Medicaid Inspector General