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October 23, 2018

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

Re: Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program
Report 2018-F-14

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, *Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program* (Report 2016-S-6).

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. Congress created the Medicaid Drug Rebate Program in 1990. The program requires drug manufacturers to pay rebates to state Medicaid programs for prescription drugs dispensed to Medicaid recipients. To collect rebates, states determine the amount of rebates owed to them and send quarterly invoices to the manufacturers. Congress also created the 340B Drug Pricing Program in 1992. The 340B program requires drug manufacturers to discount the price of drugs sold to eligible health care providers.

Federal law prohibits duplicate discounts, which occur if manufacturers pay Medicaid rebates on drugs sold at the already-discounted 340B price. Consequently, to collect allowable rebates and avoid duplicate discounts, states must accurately exclude 340B drugs from the Medicaid Drug Rebate Program.

The Department developed its own 340B provider list for use in the drug rebate program,

which contained about 200 Medicaid provider ID numbers. During the initial audit, the accuracy of the Department's 340B provider list was crucial to ensuring proper rebates were sought because the Department excluded drugs from the rebate process based on this list. Effective April 1, 2017, the Department began solely relying on 340B drug identifiers on Medicaid claims to exclude 340B drugs from the rebate process. Accordingly, the Department has instructed providers to accurately identify 340B drugs with the required claim identifiers.

The federal Health Resources and Services Administration (HRSA) administers the 340B program. To participate in the 340B program, eligible providers must register and be enrolled with the 340B program and comply with all program requirements. Providers must also recertify their eligibility every year and notify HRSA whenever there is a change in their eligibility. HRSA also maintains a list of providers who use 340B drugs for Medicaid patients known as the Medicaid Exclusion File (MEF).

We issued our initial audit report on June 30, 2017. The audit objective was to determine whether the Department accurately excluded 340B drugs from the Medicaid Drug Rebate Program and sought appropriate rebates. The audit covered the period from April 1, 2010 through June 30, 2015. We found that the Department incorrectly identified 13 Medicaid providers as 340B providers. As a result, the providers' drug claims were excluded from the Medicaid Drug Rebate Program. These errors, if left undetected, could have resulted in $10.7 million in uncollected rebates. About $4.7 million of the $10.7 million in rebates was invoiced by the Department prior to the end of the audit's fieldwork. Additionally, we identified 26 providers whom the Department identified as 340B providers, but who were not on the MEF. As a result, we estimated that $531,650 in potential rebates may have gone uncollected.

The objective of our follow-up was to assess the extent of implementation, as of September 13, 2018, of the four recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

Department officials made progress addressing the problems identified in the initial audit report. The Department also invoiced about $15.6 million in drug rebates as a result of the audit. The Department has also contracted with a vendor to perform its rebate invoicing and to monitor and make recommendations for improvements in the rebate process. Of the initial audit report's four recommendations, two were implemented and two were partially implemented.

Follow-Up Observations

Recommendation 1

Review the remaining $6 million in drug rebates identified for the 13 providers and seek retroactive rebates where appropriate.

Status – Partially Implemented

Agency Action – The Department invoiced about $1.9 million of the $6 million in drug rebates. Department officials stated they will work with their new rebate vendor to review the remaining claims and seek rebates where appropriate.

Recommendation 2

Determine whether the $531,650 in drug rebates can be collected for the 26 providers who were not on the MEF and seek retroactive rebates where appropriate.

Status – Partially Implemented

Agency Action – The Department invoiced $146,613 of the $531,650 in drug rebates. Department officials stated they will work with their new rebate vendor to review the remaining claims and seek rebates where appropriate.

Recommendation 3

Ensure that rebates from July 1, 2015 and thereafter are appropriately claimed and collected for the providers we identified, including the two providers with service locations that did not administer 340B drugs to Medicaid recipients.

Status – Implemented

Agency Action – As a result of the initial audit, the Department improved the process used to develop its 340B provider list. Additionally, beginning on April 1, 2017, the Department began solely relying on 340B drug claim identifiers to identify which claims to exclude from rebates. Subsequently, for the period from July 1, 2015 to December 31, 2017, the Department invoiced a total of $13.6 million in drug rebates for 34 providers identified in the initial audit. According to Department officials, rebates were not invoiced for the remaining providers because 340B drug claim identifiers were present or there was no drug claim activity.

Recommendation 4

Monitor providers' use of 340B claim level identifiers to ensure they properly identify 340B drugs. If errors are detected (i.e., providers inaccurately identified 340B drugs on claims and encounters), ensure providers correct their submissions of such information and retroactively invoice manufacturers for the corresponding rebates.

Status – Implemented

Agency Action – The Department contracted with a vendor to perform rebate invoicing, monitor discrepancies in the data used in the rebate process, identify outliers (providers using 340B claim identifiers who are not on HRSA's list of eligible 340B providers), and report to the Department with recommendations on how to correct errors. Department officials

stated they will refer any outliers to the Office of the Medicaid Inspector General (OMIG) for further review. At the time of our review, the Department had not made any referrals to OMIG because the Department recently moved into the contract's implementation phase, and the first invoices were released on August 29, 2018.

Department officials have instructed providers on Medicaid's requirements for identifying 340B drugs with claim identifiers. The Department has also informed providers that if a rebate is received by the Department for a drug obtained via the 340B program due to incorrect claim-level identifiers, then the provider will be responsible for reimbursing the manufacturer for the 340B discount.

Major contributors to this report were Mark Breunig, Joe Paduano, and Alyssa Mumford.

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,

Warren Fitzgerald
Audit Manager

cc: Ms. Diane Christensen, Department of Health
Mr. Dennis Rosen, Medicaid Inspector General