NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

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

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Executive Deputy Commissioner

August 30, 2017

Ms. 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 2016-S-6 entitled, "Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program."

Please feel free to contact Amy Nickson, Assistant Commissioner, Office of Governmental and External Affairs, at (518) 473-1124 with any questions.

Sincerely,

Howard Zucker, M.D.

Howard A. Zucker, M.D., J.D.
Commissioner of Health

Enclosure

cc: Ms. Nickson

Department of Health
Comments on the
Office of the State Comptroller's
Final Audit Report 2016-S-6 entitled,
Errors in Identification of 340B Providers in the
Medicaid Drug Rebate Program

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Final Audit Report 2016-S-6 entitled, "Errors in Identification of 340B Providers in the Medicaid Drug Rebate Program."

Background

New York State (NYS) is a national leader in its oversight of the Medicaid Program. The Office of the Medicaid Inspector General (OMIG) conducts on-going audits of the Medicaid program and managed care plans. The Department and OMIG will continue to focus on achieving improvements to the Medicaid program and aggressively fighting fraud, waste and abuse.

Under Governor Cuomo's leadership, the Medicaid Redesign Team (MRT) was created in 2011 to lower health care costs and improve quality of care for its Medicaid members. Since 2011, Medicaid spending has remained under the Global Spending Cap, while at the same time providing health care coverage to an additional 1,475,319 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient decreased to $8,305 in 2015, consistent with levels from a decade ago.

Recommendation #1:

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

Response #1:

The Department agrees with the Office of the State Comptroller's (OSC) recommendation and has researched the claims against the Medicaid Exclusion File (MEF) to validate if invoicing was needed. The Department is conducting a more comprehensive analysis of potential missed rebate invoicing for the entire audit period of April 1, 2010 through June 30, 2016 to validate all claims for 340B status. The federal MEF has been utilized for periods July 1, 2016 and forward. Invoicing for this will be issued by September 2017. The Department will seek and collect all retroactive 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.

Response #2:

Of the 26 providers OSC identified as incorrectly treated as 340B providers in the invoice process, 9 providers are found on the MEF file for each of the quarters identified as problematic. Another 3 providers were not on each Health Resources and Services Administration file for the quarters identified but when they start appearing on a MEF file, they are listed with an effective date prior to the quarters identified by OSC.

The department will invoice the remaining 14 providers in the upcoming "Wave 4" retroactive invoice, planned to be sent in September 2017.

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.

Response #3:

The Department agrees with OSC and is conducting a more comprehensive analysis of potential missed rebate invoicing for the entire audit period of April 1, 2010 through June 30, 2016 to validate all claims for 340B status. The federal MEF has been utilized for periods July 1, 2016 and forward. Invoicing for this will be issued by September 2017.

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.

Response #4:

The Department agrees with OSC, and effective April 1, 2017, Medicaid providers will be mandated to identify claims for 340B drugs by including claim submission level identifiers; only claims with the claim submission level identifiers will be removed from the rebate system. If a rebate is received by the Department for a drug obtained via the 340B program due to incorrect claim level identifiers, the 340B covered entity will be responsible to reimburse the manufacturer the 340B discount.