New York State Office of the State Comptroller
Thomas P. DiNapoli

Division of State Government Accountability

Rebates and Discounts on Physician-Administered Drugs

Medicaid Program
Department of Health

Report 2010-S-72 July 2012

Executive Summary

Purpose

To determine if the Department of Health maximized Medicaid rebate collections on physician-administered drugs and ensured that 340B physician-administered drugs were billed to Medicaid properly. The audit covers the period January 2008 - April 2011.

Background

Physician-administered drugs, such as chemotherapy, are administered to patients by a medical professional in an office setting. During our audit scope, Medicaid spent $309 million on physician-administered drugs. 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.

Key Findings

- 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.
- Delays in the Department's implementation of certain Medicaid computer system edits precluded nearly $8.5 million in rebate collections for physician-administered drugs. Also, flaws in the Department's collection process and the edits' design precluded additional rebates of over $13.5 million.
- The Department missed an estimated $2.3 million in savings on 33,006 claims for 340B physician-administered drugs because medical providers billed Medicaid more than the discounted (actual) acquisition costs of the drugs.

Key Recommendations

- We made five recommendations to the Department to recover the Medicaid overpayments and improve eMedNY system controls to allow for additional Medicaid rebate collections and ensure providers bill physician-administered drugs at the discounted drug acquisition cost.

Other Related Audits/Reports of Interest

Department of Health: Administration of the Medicaid Drug Rebate Program (2000-S-33)

State of New York
Office of the State Comptroller

Division of State Government Accountability

July 24, 2012

Nirav Shah, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower Building
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Dear Dr. Shah:

The Office of the State Comptroller is committed to helping State agencies, public authorities and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Medicaid Program entitled *Rebates and Discounts on Physician-Administered Drugs*. This audit was performed pursuant to the State Comptroller's authority under Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

Office of the State Comptroller
Division of State Government Accountability

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This report is also available on our website at: www.osc.state.ny.us

Background

The New York State Department of Health (Department) is responsible for administering the State's Medicaid program. Medicaid is a federal, state and locally funded program which provides a wide range of medical services to those who are economically disadvantaged and/or have special health care needs. For the fiscal year ended March 31, 2011, New York's Medicaid program had more than five million enrollees and costs totaled approximately $53 billion. The federal government funds about 49 percent of Medicaid costs; the State funds about 34.4 percent; and the localities (the City of New York and counties) fund the remaining 16.6 percent.

The Department's Office of Health Insurance Programs administers the Medicaid program. The Department's eMedNY computer system processes Medicaid claims submitted by providers for services rendered to Medicaid eligible recipients and generates payments to reimburse the providers for their claims. The eMedNY system has various automated edits to determine whether the claims are eligible for reimbursement and the amounts claimed for reimbursement are appropriate. Annually, eMedNY processes about 330 million claim payments.

To reduce Medicaid costs for prescription drugs, the federal government established the Medicaid Drug Rebate Program (Rebate Program) which became effective in 1991. Under the Rebate Program, Medicaid recovers a portion of prescription drug costs by obtaining rebates from drug manufacturers. To determine which drug manufacturer to seek a rebate from, most drug claims (usually submitted by pharmacies) are billed to Medicaid using a National Drug Code (NDC). The NDC identifies the manufacturer responsible for paying the rebate.

However, not all drug claims had an NDC. For instance, certain drugs (such as chemotherapy) are "physician-administered" in an office, clinic or hospital, and these drugs are generally billed to Medicaid through procedure codes - not NDCs. Because procedure codes do not identify the drug manufacturer responsible for a rebate, states were unable to claim and collect rebates on physician-administered drugs. To correct this problem, effective January 1, 2008, Title 42-Public Health of the Code of Federal Regulations provided for states to collect the NDCs for certain physician-administered drug claims to allow for the collection of rebates.

In addition to the Rebate Program, state Medicaid programs reduce the costs of certain drugs through the 340B Drug Pricing Program (340B Program). In this regard, Section 340B of the Public Health Service Act requires drug manufacturers to discount, upfront, the cost of drugs supplied to certain qualified health care providers. In turn, these providers pass on the savings by billing Medicaid at the discounted prices.

From January 1, 2008 through April 21, 2011, Medicaid spent about $309 million on nearly 1.1 million physician-administered drug claims. Of the $309 million paid, about $24.7 million (for 72,387 claims) pertained to the 340B Program.

Audit Findings and Recommendations

Rebates on Physician-Administered Drugs

Effective January 1, 2008, the federal government required state Medicaid programs to include the NDCs on claims for physician-administered drugs so that the manufacturers responsible for paying rebates on such drugs could be identified. However, delays in the Department's implementation of the federal requirements precluded the collection of approximately $8.5 million in rebates. Further, flaws in the Department's rebate collection process prevented Medicaid from obtaining over $13.5 million in additional rebates.

Delays in Implementing the Federal Requirements

Federal regulations require NDCs for all single source physician-administered drugs and the top 20 highest paid multiple source physician-administered drugs. A single source drug is produced by only one manufacturer, and a multiple source drug is produced by more than one manufacturer. Since January 1, 2008, the Department collected rebates on 283 physician-administered drugs. To enforce the NDC requirement, the Department created an eMedNY system edit to deny payment of physician-administered drug claims submitted without the required NDC. The Department, however, did not have the necessary eMedNY edit in place in time to meet the January 1, 2008 start date for NDCs and, instead, phased in the edit through October 1, 2010.

The Department collects rebates on physician-administered drug claims submitted as both Referred Ambulatory claims (submitted by institutions such as hospital outpatient centers) and Practitioner claims (submitted by physicians). We determined the edit for Referred Ambulatory claims was not set to deny until February 20, 2009, and the edit for Practitioner paper claims was not set to deny until October 1, 2010.

The delays in setting the edit cost the State rebates on multiple source physician-administered drug claims. (Because there is only one manufacturer of a single source drug, the Department could, through other means, identify which manufacturer to obtain the rebate from on these claims). Since January 1, 2008, the edit did not deny 99,540 multiple source physician-administered drug claims that lacked an NDC. The payments on the 99,540 claims totaled about $24.2 million.

From 2007 through 2009, experience shows that the Department recouped about 35 percent of Medicaid's costs for rebate-eligible drugs. Thus, the Department could have obtained rebates totaling about $8.5 million ($24.2 million times 35 percent) if the required edits were put into operation timely. As part of the rebate process, states retain 50 percent of rebate collections and the remaining 50 percent is submitted to the federal government. As such, the Department's delays in setting the edit cost the State about $4.25 million ($8.5 million times 50 percent) in rebates.

Department officials told us they delayed implementation of the eMedNY edit because certain providers resisted the prescribed changes. According to officials, some providers were unable

to update their billing systems timely to collect NDC information. Nevertheless, Department officials were aware of the NDC requirements more than two years prior to their effective date (January 1, 2008). Thus, providers had sufficient time to update their billing systems, and the Department should have made the eMedNY system edit operational on January 1, 2008.

Moreover, given the magnitude of the rebates (about $8.5 million) that were not collected, the Department should formally assess the option of requesting providers to resubmit the 99,450 claims in question (along with the corresponding NDCs) to obtain rebates otherwise owed to the State.

Flaws in the Rebate Process

The Department failed to collect over $13.5 million in rebates (from about 103,000 claim payments) because of flaws in the rebate collection process, including problems with certain eMedNY processing controls. Most of the uncollected rebates pertained to claims involving third party coverage (most often Medicare).

In general, Medicaid claims fall under one of fifteen categories, including Referred Ambulatory, Practitioner, and 13 others. The Department, however, collects rebates on physician-administered drugs only for Referred Ambulatory and Practitioner claims (and for none of the remaining 13 categories). We asked Department pharmacy officials why rebates on physician-administered drugs were limited to Referred Ambulatory and Practitioner claims. In response, officials told us that, for Medicaid purposes, claims for physician-administered drugs can be classified as either Referred Ambulatory or Practitioner only. However, this is not the case.

In fact, we identified 97,406 rebate-eligible physician-administered drug payments that eMedNY processed as other than Referred Ambulatory and Practitioner claims. All of these claims involved third parties. For example, they included payments of Medicare coinsurance for recipients with both Medicaid and Medicare coverage. Nevertheless, because these 97,406 claims were not classified as Referred Ambulatory or Practitioner claims, the Department did not collect rebates on them. We further noted that 34,001 (34.9 percent) of the 97,406 claims lacked the NDCs required to obtain rebates. However, the Department set the related eMedNY edit to pay the claims although they lacked NDCs. Moreover, without the NDCs, the Department could not request rebates for these payments.

The payments on the 97,406 claims totaled $36.6 million. If the Department enforced the requirement for NDCs and sought rebates on these claims, the Department could have obtained rebates totaling $12.8 million ($36.6 million times 35 percent). The State's portion of the uncollected rebates would have been about $6.4 million ($12.8 million times 50 percent).

In addition, we identified eMedNY processing problems with adjustments to previously paid claims for physician-administered drugs. When an adjustment for this claim type is submitted without an NDC, it bypasses the eMedNY edit which prevents payment unless the NDC is provided. Department officials could not explain why these adjustment claims bypassed the edit. We identified 2,480 adjustment claims that totaled $1.2 million in payments. If these

adjustments did not bypass the edit and the NDCs were provided, the Department could have obtained rebates totaling $413,000 ($1.2 million times 35 percent). This error cost the State about $206,500 ($413,000 times 50 percent).

Also, other physician-administered drug claims had incorrect Service Area codes that caused the Department to miss additional rebates totaling about $190,000. The Service Area code in the eMedNY system specifies a procedure's service category. A 'J' Service Area code, for example, denotes a drug claim, and an 'M' code represents medicine claims. Further, J code claims are rebate-eligible while M code claims are not. Nonetheless, we identified 3,320 claim payments (totaling about $1.1 million) for five rebate-eligible physician-administered drugs that had an 'M' code instead of a 'J' code. Because of the coding error, the Department could not collect rebates totaling about $380,000 ($1.1 million times 35 percent). At the time of our audit fieldwork, Department Pharmacy officials were unaware of this problem, and as a result of the audit, the Department took immediate actions to correct it in July of 2011.

Recommendations

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

Drugs That Were not Properly Discounted

Medicaid providers who qualify for the 340B Drug Pricing Program receive discounts from drug manufacturers at the time they purchase program-eligible drugs. The discounts are then passed on to Medicaid - thus reducing Medicaid payments. Medicaid requires all providers to bill physician-administered drugs at their actual acquisition costs (per invoice). For 340B providers, this includes the 340B discount and any other promotional discounts given to providers by drug manufacturers. During our audit period, 67 providers received over $24.7 million from Medicaid for 72,387 physician-administered drugs that were purchased at discounts through the 340B Program.

When billing for a physician-administered drug, providers are required to charge the drug's actual acquisition cost. The eMedNY system relies on providers to input drug acquisition costs accurately to ensure claims process correctly. In addition, eMedNY assigns a maximum allowable fee that a provider can be paid for a physician-administered drug. The Department periodically adjusts the maximum fees to reflect current acquisition costs. Typically, a provider's 340B drug acquisition cost is at least 20 percent less than the maximum allowable Medicaid fee. Further, when eMedNY

processes a claim for a physician-administered drug, it pays the lesser of the amount charged or the maximum Medicaid fee.

When providers charged an amount equal to or greater than the maximum Medicaid fee, we questioned if they correctly reported the acquisition cost (accounting for the 340B discount). For the period January 1, 2008 through April 21, 2011, we identified $11.8 million in high risk Medicaid payments for 33,006 claims for physician-administered drugs eligible for 340B discounts. Specifically, for these claims, providers reported drug acquisition costs that equaled or exceeded the maximum Medicaid fees. If these claims were billed with a discount of 20 percent, Medicaid would have saved about $2.3 million ($11.8 million times 20 percent). Furthermore, there were 4,284 other 340B drug claims (totaling $2.1 million) that were discounted less than 20 percent. There is considerable risk that Medicaid should have paid less for these claims as well.

We examined 3,500 of the 33,006 claims in detail and determined that certain hospitals frequently overcharged Medicaid for physician-administered 340B drugs. For example, a hospital submitted five claims for Pemetrexid (a chemotherapy drug) from November 2010 through January 2011. The maximum Medicaid fee for this drug was $4,652. However, the hospital reported acquisition costs ranging from $17,946 to $18,212 on each of its claims. Because the reported acquisition costs exceeded the maximum Medicaid fees, eMedNY processed and paid each claim $4,652 (the lesser of the amount reported or the maximum Medicaid fee).

However, the hospital's actual acquisition costs for Pemetrexid were only $2,955 (per claim). Thus, Medicaid overpaid the hospital by $1,697 ($4,652 - $2,955) on each claim, and the overpayments for the five claims totaled $8,485 ($1,697 times 5). We advised hospital officials of these errant claims, and they agreed to repay the resulting overpayments. Moreover, as a result of our inquiry, officials initiated a system-wide review to identify other improper 340B claims, and they will develop controls to ensure future 340B claims include the correct acquisition costs.

We also selected five additional hospitals that were among the highest paid 340B drug providers for detailed claims payment reviews. The five hospitals received $7.6 million of the $11.8 million Medicaid paid for 340B physician-administered drugs when the providers' purported acquisition costs equaled or exceeded the maximum Medicaid fees. For each of the five hospitals, we identified the ten highest Medicaid-paying 340B drugs for the period April 1, 2010 through March 31, 2011. Thus, we identified 3,495 claim payments (totaling $4.8 million) for further review.

To calculate the overpayments, we compared the drug acquisition costs charged by the hospitals on their claims against the actual acquisition costs reported on the hospitals' invoices. When the acquisition (invoice) cost of the drug was less than the amount Medicaid paid, the difference was an overpayment. In total, we identified overpayments in excess of $1.4 million for the five hospitals, as summarized in the following table.

Provider	Number of Claims in Sample	Number of Claims That Were Overpaid	Total Medicaid Payments on Claims with Overpayments	Total Acquisition Costs (Per Invoices) on Claims with Overpayments	Amount of Overpayments
Hospital 1	483	340	$811,685	$589,450	$222,235
Hospital 2	473	447	1,139,006	842,341	296,665
Hospital 3	546	534	1,053,020	691,707	361,313
Hospital 4	1,511	1,296	986,503	654,956	331,547
Hospital 5	482	472	713,018	510,652	202,366
Totals	**3,495**	**3,089**	**$4,703,232**	**$3,289,106**	**$1,414,126**

As the table indicates, Medicaid overpaid 3,089 (88.4 percent) of the 3,495 high risk claims. For Hospital 1, Medicaid overpaid 340 claims by $222,235 (38 percent above the proper amounts). Officials from Hospital 1 agreed with our conclusions and will reimburse Medicaid for the overpayments. In addition, officials told us they will review their billing system and correct the problems that caused the overpayments.

Hospitals 2-5 are part of the New York City Health and Hospitals Corporation (HHC). Based on our tests, we determined that Medicaid overpaid the four HHC hospitals on 2,749 (91 percent) of the 3,012 high risk 340B claims we reviewed. Medicaid paid the four hospitals almost $3.9 million on the 2,749 errant claims. Because the correct charges for these claims totaled only $2.7 million, Medicaid overpaid HHC by $1.2 million (44 percent). When we advised HHC officials of this matter, they explained that HHC purchases its drugs centrally and then distributes them among all HHC hospitals. However, HHC's billing system lacked the functionality needed to include precise 340B drug acquisition data (i.e., the date a drug was purchased and its cost) on Medicaid claims from the individual hospitals. Consequently, HHC staff entered incorrect cost data on the claims in question.

According to HHC officials, they have been aware of this problem since June 2008. However, officials have been unable to rectify problems with pertinent computer program logic within HHC's claims processing system - and, consequently, the errant 340B claims (and related Medicaid overpayments) we identified have persisted for several years. Further, in response to our audit, HHC has begun testing certain manual processes to help ensure that future claims for physician-administered 340B drugs are correct.

Based on our review, we concluded that eMedNY lacks adequate system edits to flag or pend 340B drug claims which do not include accurate drug discount (cost) data. Consequently, as previously detailed, certain providers reaped significant profits on their 340B drug claims. Moreover, we conclude that Department officials should take prompt and meaningful actions to ensure that eMedNY prevents excessive payments for 340B drugs in the future.

Recommendations

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.
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.

Audit Scope and Methodology

We audited selected Medicaid claims to determine whether the Department collected rebates on all physician-administered drugs it was entitled to and whether 340B qualified providers billed the Medicaid program at their discounted drug acquisition costs. The scope of our audit was from January 1, 2008 through April 21, 2011.

To accomplish our audit objectives, we performed various analyses of claims from Medicaid payment files and verified the accuracy of certain payments. We interviewed officials from the Department and several Medicaid providers. We reviewed applicable sections of federal and State laws and regulations and examined the Department's Medicaid payment policies and procedures.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members (some of whom have minority voting rights) to certain boards, commissions and public authorities. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these management functions do not affect our ability to conduct independent audits of program performance.

Authority

The audit was performed 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.

Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered the Department's comments in preparing this report and have included them in their entirety at the end of it. In their response, Department officials generally agreed with our recommendations and indicated that certain actions are planned or have been taken to address them.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons why.

Contributors to This Report

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Vision

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To improve government operations by conducting independent audits, reviews and evaluations of New York State and New York City taxpayer financed programs.

Agency Comments

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

June 8, 2012

Mr. Brian E. Mason
Audit Director
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Division of State Government Accountability
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Dear Mr. Mason:

Enclosed are the New York State Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2010-S-72 on "Rebates and Discounts on Physician-Administered Drugs."

Thank you for the opportunity to comment.

Sincerely,

Sue E. Kelly
Executive Deputy Commissioner

Enclosure

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Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2010-S-72 on Rebates and Discounts
on Physician-Administered Drugs

The following are the Department of Health's (Department) comments in response to Office of the State Comptroller (OSC) Draft Audit Report 2010-S-72 on "Rebates and Discounts on Physician-Administered Drugs," including general comments followed by responses to the specific recommendations contained in the report.

General Comments:

Regarding the responses by former Department officials that are highlighted under the Flaws in the Rebate Process section of the report, the Department shares OSC's concern and recognizes the importance of resolving these issues. The Department is committed to fully investigating the issues raised in the report and to implementing the changes needed to ensure it obtains all rebates to which it is entitled. However, the OSC findings should be framed in context to the $2.7 billion in total drug rebates collected by the Department over the past year. Additionally, regarding the final sentence of the above-noted section of the report, the Department would like to clarify that once it was notified of the auditors' finding, it took immediate action to correct the coding error.

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.

Response #1:

The Department will assess the feasibility of obtaining rebates on the physician-administered drug claims identified by OSC, and invoice for rebates where feasible.

Recommendation #2:

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

Response #2:

The Department will perform an assessment of its rebate policies and operations, following which it will implement any changes necessary to ensure that rebates are obtained consistent with program requirements.

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.

Response #3:

The Department implemented system edits in October 2010 requiring hospital-ordered ambulatory claims and physician practitioner claims to include the NDC code when a J code for a physician-administered drug is submitted. The Department will perform a review to determine whether all types of physician-administered drug claims, including adjustment claims, are subjected to these edits. Should this review determine system changes are needed, the Department will develop an action plan accordingly.

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.

Response #4:

The Office of the Medicaid Inspector General will review the data and recover overpayments as appropriate.

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.

Response #5:

The Department agrees and is committed to ensuring its reimbursements comply with program requirements, notwithstanding the Federal government's lack of legislative authority to share 340B

ceiling prices with states. The Department will publish an article in an upcoming edition of its Medicaid Update monthly provider publication reminding providers of the requirement to bill 340B drugs at acquisition cost, and will consider sending individual reminder letters to all 340B participating providers. The Department is additionally researching different drug pricing options that may provide more precise Medicaid maximum fees for certain 340B drug acquisition costs, for utilizing as a basis for capturing and pending/denying claims with unreasonably high charges.