SFY 2018 - 2019 Medicaid Drug Cap Webinar FAQs

1. **Can you confirm that the State's target adjustment from manufacturers is $30M across 42 drugs?**

   No, the $30M is not the State's target adjustment associated with the 42 drugs referenced in slide 7 of the Medicaid Drug Cap Webinar. The $30M in slide 5 of this webinar refers to the **incremental** SFY 2018-19 statutory pharmacy savings target above the achieved level in the prior year. The Department reduced the $85M SFY 2018-19 savings target in PHL § 280, by the $55M savings achieved by the Drug Cap in SFY 2017-18, as the $55M in savings was already included in the SFY 2017-18 base pharmacy spend.

   Was the driver, utilization or price increases? Or was the determination based on cost per script?

   The driver of the projected excess above the Medicaid Drug Cap target (shown on slide 5 of the webinar) is a combination of the statutory savings target (reference in the question above), Managed Care pharmacy premium increases related to specialty drugs (e.g. rheumatoid arthritis, new HIV therapies, and antipsychotic agents), as well as unanticipated drug mix changes from SFY 17-18, which reduced overall rebate collections (i.e. new drugs with spend but low rebate levels).

2. **How have the number of Medicaid (FFS and MMC) lives changed during the time period in question?**

   The Department accounted for enrollment growth in both Fee for Service and Medicaid managed care populations using historical data to develop a utilization trend and accounting for any relevant program related changes which may have impacted enrollment for the rate period.

   MMC drug costs are increasing, while FFS costs are decreasing due to the additional populations that have been transitioned from fee for service to managed care. Managed Care enrollment increased by 105,248 people between March 2017 and March 2018, while Fee for Service enrollment decreased by 76,251 over that same period.

   For more information on MMC and FFS enrollment, please see the Medicaid Global Cap Spending Reports, which are available on the Global Cap website.

3. **Is the "Projected Excess (Shortfall)" of $74,723,793 based on WAC (gross) sales?**

   The projected excess of $74,723,793 is based on the amount that Medicaid Drug expenditures (net of all rebates) is projected to exceed the statutory Medicaid Drug Cap. This is shown on Slide 5 of the PowerPoint Presentation, which can be found here.

4. **What is the timeline and format of discussion for a drug referral to the DURB?**

Pursuant to PHL § 280, if the Department intends to refer a drug to the DURB, it will notify the manufacturer of such drug. The initial notifications were sent to affected drug manufacturers on 09/17/2018.

The Department will continue its negotiations with manufacturers in an attempt to come to an agreement and will communicate to the manufacturer if it intends to refer a drug to the DURB, or take other authorized action under PHL § 280.

If a drug is referred to the DURB for review, it will be apparent via a DOH website posting of the DURB agenda thirty (30) days prior to a DUR Board meeting: https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/

5. **In the flowchart of slide 6 in the SFY 18-19 Medicaid Drug Cap Webinar, one of the criteria to be considered for DURB referral is if the net spend is >$2.2M OR if the net cost/claim is >$13,000 the drug. The chart states these are the top 3% for all drugs. How did the department determine a threshold of 3%? Is this literally the drugs that fall within the top 3% of the overall drug spend or was there some sort of formula to decide top 3%?**

   The Department determined a threshold of the top 3 percent based upon statistical methods that analyzed both drug spend net of all rebates and net cost per claim. No formula was applied to drugs thereafter except for a credit to Manufacturers who provided discounts for other drugs in the Medicaid program.

6. **Can we have the list of the other drugs and manufacturers targeted this year?**

   The Department will not disclose the list of drugs or manufacturers. Drugs will be identified if/when they are referred to the DUR Board. This will be done via a DOH web–site posting of the DURB agenda (hyperlink below) thirty (30) days prior to a DUR Board meeting: https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/.

7. **Why are the criteria for the determination of which drugs made the list different from last year? For example: Net spend of >$2.2M this year, versus >$5M last year, new criteria this year of "net cost/claim >$13,000?**

   The process for determining drugs for potential DURB referral for SFY 2018-19 was consistent with SFY 2017-18, though SFY 2018-19 data was refreshed to account for actual experience in SFY 17-18. For both years, statistical methods (e.g. scatterplots and marginal histograms) were used that identify outlier drugs across multiple variables. In SFY 17-18 the statistical methods were applied only to one variable (net spend). The SFY 18-19 methodology broadened the initial criteria to consider low utilization/high cost drugs and only outlier drugs were identified for potential DURB referral.

8. **Why is the number of drugs and manufacturers targeted this year (42 drugs and 25 manufacturers) so much bigger than last year (30 drugs and 12 manufacturers)?**

   The number of drugs and manufacturers is higher than last year for a couple of reason. One reason is the incorporation of net cost per claim when identifying outliers and the second one is the lowering of the net spend threshold, both of which are a result of successfully negotiating rebate agreements under PHL § 280 during SFY 17-18. Pursuant to PHL § 280,

the Department cannot refer a drug with an existing supplemental rebate contract under the Medicaid Drug Cap to the DURB for the duration of the rebate agreement &8211; meaning that drugs identified in SFY 17-18 for which the Department successfully negotiated new rebate agreements are barred from DURB referral for the duration of the agreement.

9. **Are products and manufacturers from last year also included in this year's list of targeted drugs and manufacturers?**

   No.

10. **Did NY include in the analysis of target rebates, the rebates that a manufacturer provides in other therapeutic classes, for example, Behavioral Health? How was this quantified, if so, and what specific effect did it have on the target rebate amount?**

    Initially, the Department identified 87 drugs and 45 manufacturers for possible DURB referral, as indicated in Slide 8 of the SFY 18-19 Medicaid Drug Cap Webinar. The Department then evaluated rebate levels for other drugs made by these 45 manufacturers, by comparing rebates as a percentage of spend in their respective classes. Manufacturers were given credit where rebate levels for other drugs were more than 10 percent greater than the average rebate levels provided in the class.

    As shown on Slide 7 of the SFY 18-19 Medicaid Drug Cap Webinar, manufacturers were credited $63M (state share) for providing rebates in other drugs in the Medicaid program. 20 manufacturers of 35 drugs were not identified for potential DURB referral because of this credit (shown on slide 8).

11. **Is the rebate agreement each company enters into with the Department tied to 2018-19 utilization and therefore retroactive since we are halfway through the fiscal year?**

    The effective date and terms of the rebate agreements pursuant to PHL § 280 will be determined by the Department and the manufacturer.

12. **Of the products currently identified on the newest drug cap legislation, could you provide the percentage of drugs that are Part B vs Part D? Or what the state would consider physician administered drugs vs. oral medications?**

    The Department considers physician administered drugs to be claims/encounters that were not billed by pharmacies. All 42 drugs that were identified for potential DURB referral were billed by pharmacies.

13. **On slide 4 of NY State's 9/17/2018 presentation, are the managed care expenditures referred to basically Managed Medicaid (MMC) premiums or something else? Since 9.7% of the 11.5% overspend was from rises in MMC premiums, Manufacturer would like to better understand how MMC plans justified their increases. Were the increases based on increases in drug spend or medical spend? If based on drug spend, were there particular drugs driving that increase?**

    The State's actuary develops an all-inclusive pharmacy rate by region and rate cell which is not specifically delineated by drug. Aggregate assumptions are used to capture the projected experience of drug mix and utilization. Medicaid Managed Care plans submit claim

encounter data to the State which is utilized as the historical base data in developing the pharmacy rate which is further adjusted for supplemental rebates, program policy changes, data completion factors, and trend. Although trends are rolled up by region and rate cell, they are specifically analyzed for the impact of high cost specialty drugs, new emerging therapies, and drugs exiting the market. Plan reported encounter data during the rate period allows for continued monitoring of actuarial assumptions within the capitated rate. The driver of the projected excess above the Medicaid Drug Cap target (shown on slide 5 of the September 17, 2018 Webinar) is a combination of the statutory savings target, Managed Care pharmacy premium increases related to specialty drugs (e.g. rheumatoid arthritis, new HIV therapies, and antipsychotic agents), as well as unanticipated drug mix changes from SFY 17-18, which reduced overall rebate collections (i.e. new drugs with spend but low rebate levels).

14. What counts as a "claim", in the ">$13K per claim" criterion used to filter out the targeted drugs for SFY 18-19?

If the net cost per claim for a drug exceeded $13,000, which is the top 3 percent of net cost per claim for all drugs, it was counted. The claim criterion used to filter out targeted drugs first removed any drug whose net spend was less than or equal to $0. Of those drugs with a net spend greater than $0, those in the top 3 percent of net cost per claim for all drugs and a minimum spend of $1 million (net of rebates) were identified for potential DURB referral.

15. Were generics included in the targeted drugs (slide 7 of 9/17/2018 deck)?

Generic drugs were included in the analysis for initial identification of new drugs, however it was determined that generic drugs did not contribute to the piercing of the Cap (see slide 6 of the September 17, 2018 Webinar).

16. What is the basis for managed care expenses to increase by 18% from SFY17 to SFY18?

Increases from SFY 2016-17 to SFY 2017-18 in the projected managed care pharmacy PMPMs were driven by an influx of new specialty drugs to the market.

17. If a manufacturer received a letter of notification, does that mean that the "manufacturer credit" was NOT applied?

No, manufacturers who received a notification may have had a credit applied. However, the amount of the credit was not substantial enough to remove a drug from potential DURB referral.

For example, as shown on Slide 7 of the *SFY 18-19 Medicaid Drug Cap Webinar*, manufacturers were credited $63M (state share) for providing rebates in other drugs in the Medicaid program. 20 manufacturers of 35 drugs were not identified for potential DURB referral because of this credit (shown on slide 8).

**Please note: this FAQ regarding "manufacturer credit" is no longer applicable as a result of a change in legislation.*

18. What data sources and methods will be used to determine the Medicaid drug spending amount that serves as the base (i.e., the amount to which the 10–year rolling average

of medical component of consumer price index plus 5 percent is applied) for calculating the "year to year...state funds Medicaid drug spending growth target" for SFY2018?

Data used to determine the Medicaid Drug Cap can be found in the August 31, 2017 Webinar PowerPoint presentation on Slide 6. The slide presentation is available on the DOH web–site posted here.

19. **Of the products currently identified on the newest drug cap legislation, could you provide the percentage of drugs that are Part B vs Part D? Or what the state would consider physician administered drugs vs. oral medications?**

    The Department considers physician administered drugs to be claims/encounters that were not billed by pharmacies. All 42 drugs that were identified for potential DURB referral were billed by pharmacies.