NEW YORK STATE | Department of Health | Office of Health Insurance Programs

SFY 2017 - 2018 Medicaid Drug Cap Webinar FAQs

1. **Referring to Slide 9 of the PowerPoint presentation dated August 31, 2017, explain what criteria was used to narrow the number of drugs from seventy–three (73) to thirty (30)?**

   The criteria used to narrow the number of drugs is illustrated in Slide 8 of the PowerPoint presentation and summarized below. Generics were evaluated separately from brands because generic rebates are set in statute and do not vary by drug.

   - Generic drugs were evaluated for root cause impact on the Medicaid Drug Cap (e.g. unit cost net of rebates vs. high utilization), and whether existing controls, such as State and Federal Consumer Price Index (CPI) penalties, already achieve cost reductions and address this impact.
   - Brand drugs were evaluated based on (1) the actual cost to the State for each drug, minus rebate amounts and a comparison of such cost to other drugs within the class and, (2) whether the manufacturer provides significant discounts relative to other drugs covered by the Medicaid program.

2. **On Slide 9 of the PowerPoint presentation dated August 31, 2017, there are seventy–three (73) drugs identified as having >$5 million in spend, net of all rebates. How many of these drugs are generics?**

   Thirty (30) of the seventy–three (73) drugs are generics.

   [Note: For drugs with multiple strengths, each strength is counted as 1 drug].

3. **On Slide 9 of the PowerPoint presentation dated August 31, 2017, there are thirty (30) drugs identified as possibly being referred to the Drug Utilization Review Board (DURB). To which classes do these drugs belong? Are any of them psychotropics?**

   The classes to which drugs belong will be apparent if and when these drugs are actually referred to the DUR Board. This will be done via a posting to the following link 30 days prior to the meeting: https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/

4. **Will the Medicaid Drug Cap webinar presentation be made available?**

   The slide presentation is available on the DOH web–site posted at the following link: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/2017–8–29_medicaid_drug_cap.htm

   The classes to which drugs belong will be apparent if and when these drugs are actually referred to the DUR Board. This will be done via a posting to the following link 30 days prior to the meeting: https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/

5. **Was epidemiological data considered during the initial identification process and, if so, how was it considered when deciding which drugs to include on the list for possible DURB review?**

   No. Epidemiological data was not included in the drug identification flowchart methodology on slide 8. Factors considered to determine drugs for possible DURB referral are:

   - Generic drugs were evaluated for root cause impact on the Medicaid Drug Cap (e.g. unit cost net of rebates vs. high utilization), and whether existing controls, such as State and Federal Consumer Price Index (CPI) penalties, already achieve cost reductions and address this impact.
   - Brand drugs were evaluated based on (1) the actual cost to the State for each drug, minus rebate amounts and a comparison of such cost to other drugs within the class and, (2) whether the manufacturer provides significant discounts relative to other drugs covered by the Medicaid program.

6. **Referring to Medicaid Drug Cap Webinar flowchart, drugs were not considered for potential DURB review if the annual Medicaid spend on the drug, net of all rebates, was less than $5 million. If the Medicaid spend on these drugs exceeds $5 million in the future, will these drugs undergo further review?**

   Yes. All drugs will be monitored by DOH on a quarterly basis.

7. **Do the 30 drugs on the list include ´new´ recently launched drugs?**

   Recently released drugs were considered, and this will be apparent if and when these drugs are referred to the DUR Board, via a DOH web–site posting of the DURB agenda thirty (30) days prior to a DUR Board meeting.

8. **If the Medicaid Drug Cap letter from DOH, mailed August 25th, was not received by a company does this mean the company will not be asked to provide supplemental rebates?**

   No. DOH will continue to monitor drug expenditures related to the Medicaid Drug Cap and identify additional drugs and notify manufacturers as necessary.

9. **The June Global Cap Report seems to indicate that a significant amount of the growth in Medicaid spending was due to increases in enrollment. How does DOH account for enrollment growth in the Medicaid Drug Cap?**

   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.

10. **How did the state come up with the $55M State Share Savings number?**

    $55M is a Medicaid pharmacy savings target for SFY 17–18 established by the Legislature in Public Health Law (PHL) § 280.

11. **The Department has indicated it expects to exceed the spending growth cap by $119 million in FY17–18. Will the Department continue to re–evaluate this on a quarterly**

basis? Will the Department be identifying additional drugs for possible referral to the DURB for the remainder of this fiscal year?

Yes, the Department and the Division of Budget shall assess on a quarterly basis the projected total amount of drug expenditures, and whether additional drugs will be identified for possible referral to the DURB, in SFY 17–18.

12. **When will the Department first execute its review for FY18–19 in terms of calculating whether the projected drug spend will exceed the spending growth cap?**

    The Department and the Division of Budget will monitor the Drug Cap on a quarterly basis.

13. **The webinar identified a goal of 1.8% in additional rebates. Are the targeted manufacturers jointly liable for reaching that goal? That is, if some of the targeted manufacturers refuse to negotiate, are the remaining manufacturers expected to make up the difference?**

    Manufacturers that received letters are not jointly liable for achieving the 1.8% referenced as the "Estimated Target for Additional Rebates" on Slide 6 of the PowerPoint presentation. If a particular manufacturer refuses to negotiate, it would not be expected that the other manufacturers that received letters would "make up the difference."

14. **How will a manufacturer be notified that a drug has been referred to the DURB and in what timeframe will such notifications occur? Will each instance always be brought up at the next scheduled DURB meeting?**

    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 08/25/2017.

    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 web–site posting of the DURB agenda thirty (30) days prior to a DUR Board meeting (hyperlink below): https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/.

15. **Regarding slide 15 of the PowerPoint Presentation, entitled "Step 4: After DURB Recommendation" – who would review the information given by the manufacturer and ultimately make the decision?**

    Department staff will review the information and consider such information in relation to the DURB recommended target rebate amount. All information given by a manufacturer will be considered confidential and will not be disclosed by the Department in a form that identifies a specific manufacturer or prices charged for drugs by such manufacturer.

16. **The webinar indicated that proprietary information will only be required where targeted manufacturers are not able to enter into ANY agreement after the DURB recommendation; the statute suggests that such information may be required even where an agreement has been entered if the agreement is not "satisfactory to the**

department". Can you say unequivocally that such information will not be required unless NO agreement has been reached?

The Department does not intend to enter into an agreement under PHL § 280 that it does not consider to be satisfactory. Pursuant to § 280, only after the DURB recommends a target rebate amount and the Department is unsuccessful in negotiating a satisfactory rebate agreement with the manufacturer, the manufacturer be required to provide DOH with information such as drug development, marketing, research and distribution costs.

17. **The statute provides that DURB–recommended rebates must be retroactive to April 1, 2017, and must apply to managed care as well as fee for service; is that going to be required for pre–DURB rebates, as well, or can Fee–for–Service (FFS) or Managed Medicaid (MC) rebates alone be sufficient?**

    Only rebates agreed upon pursuant to PHL § 280 will be retroactive to April 1, 2017.

18. **Have there been drugs introduced this year that have contributed to piercing the cap?**

    Recently released drugs were considered, and this will be apparent if and when these drugs are referred to the DUR Board, via a DOH web–site posting of the DURB agenda thirty (30) days prior to a DUR Board meeting.

19. **There was a 15 percent year to year increase this year. What was the increase between the prior two FYs?**

    Prior to the implementation of the Drug Cap, the average growth rate in Medicaid drug expenditures exceeded 13 percent between SFY 14–17. Please note, the calculation of the SFY17–18 Medicaid Drug Cap does not consider drug expenditures prior to SFY 16–17.

20. **Was it expected that as many as 30 drugs would be targeted in one year?**

    The Department did not have a predetermined expectation of the number of drugs prior to utilizing the process for initial identification of drugs for possible DURB referral, as provided during the August 31, 2017 webinar (on slide 8).

    Is DOH planning to remove any/all of those drugs from Medicaid Managed Care (MMC) formularies? Can you describe what that process would entail?

    The Department has not yet determined whether it will direct the MMC Plans to remove any drugs from their formularies. If DOH does move forward with directing MMC plans to remove drugs from their formularies, it will do so in accordance with statutory provisions. This would include considering all rebates received, whether total drug expenditures are still projected to exceed the cap, and whether the drug is the only treatment for a particular disease or condition. The Department will also adhere to the notice requirements, consistent with PHL § 280(7)(a)(b).

21. **How does the State´s projection of 15.4 percent gross pharmacy spending growth in managed and fee for service from SFY17 to SFY18 compare to CMS´s national Medicaid prescription drug spending trend of between 6.1 percent and 6.4 percent during this same time period?**

The State is not sure what the source is for the 6.1–6.4 percent trend referenced in the question. However, the underlying CMS national trend for Medicaid prescription drug spending, if available, would utilize information from all states in this projection, and it is likely that the average spending trend would be reduced by smaller states; therefore, it would not provide a suitable basis for comparison. Furthermore, it is unclear where the NYS–specific information derives from, as CMS 64 data shows only FFS pharmacy costs and managed care premiums paid by the State. The growth in the managed care premium specifically for pharmaceutical costs is not detailed on the CMS 64.

The CMS National Health Expenditure projections (2016–2025) predicts on average 6.3 percent growth for prescription drugs per year. However, it is important to note that this projection uses a "real aggregate per capita drug spending" model. In other words, CMS is projecting out–of–pocket drug costs, which would not correlate to a program like Medicaid where there is little to no out–of–pocket expense to the patient.

The Medicaid Drug Cap accounts for actual premium growth within the Medicaid managed care rates certified by an actuary. The projected pharmacy spending growth for SFY 17–18 is based upon the difference between actual Medicaid drug expenditures in both Managed Care and Fee for Service populations in SFY 16–17 and projected Medicaid drug expenditures in both Managed Care and Fee for Service populations in SFY 17–18. Managed Care expenditures drive a majority of the increase (18 percent).

22. 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.

23. Can the state provide the aggregate amount of drug rebates, including supplemental rebates, in 2016 for both fee–for–service and managed care?

The State is using cash collections to calculate drug rebate amounts for the Medicaid Drug Cap. As reflected on Slide 6 of the August 31st Webinar PowerPoint, this includes all 2016 rebates, including those received via the Federal Rebate Program for Managed Care and Fee for Service (FFS) and FFS supplemental rebates.

24. Why are expenses related to the HARP program projected to increase by over 55 percent from SFY17 to SFY18?

The over 55 percent projected increase in the HARP program is directly related to enrollment growth in the program. HARP enrollment has been effective since 10/1/15 in NYC, and 7/1/16 in Rest of State.

25. In the second footnote, the Per Member Per Month (PMPM) premium is referenced as part of the SFY18 drug spending calculation number. Is that the projected premium growth related to prescription drugs, or is it for overall premium growth?

The PMPM premium referenced as part of the SFY 17–18 Drug Cap calculation is the projected premium growth for only the pharmacy component of the premium.

26. 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.

27. **Will physician–administered drugs, both inpatient and outpatient drugs, that are included in the medical benefit be excluded from the prescription drug spending cap?**

    Expenditures for physician administered drugs were not included in the FY 2017 Base calculation as presented during the August 31, 2017 Webinar PowerPoint (Slide 6). However, physician administered drugs are not excluded from the Medicaid Drug Cap provisions and expenditures for physician administered drugs could be included in the Medicaid Drug Cap Base calculation in the future. The slide presentation is available on the DOH website posted here.

28. **What data sources and methods will be used on a quarterly basis to determine the "projected total amount to be expended in the year...on a cash basis" for drugs in SFYs 2018 and 2019, as well as the 10–year rolling average medical component of the consumer price index?**

    Data and methods used to determine the Medicaid Drug Cap were presented during the August 31, 2017 Webinar PowerPoint (see Slide 6). The slide presentation is available on the DOH web–site posted here.

29. **How will the state determine "significant discounts relative to other drugs covered by the Medicaid program"?**

    As referenced in the August 31, 2017 Webinar PowerPoint Presentation (Slide 9), there were 12 manufacturers and 30 drugs identified for possible DURB referral. The state evaluated rebate levels for other drugs made by these 12 manufacturers by comparing their 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.

30. **Referring to August 31, 2017 webinar slide #8, does this indicate that all drugs utilized in Medicaid formularies and all FDA approved drugs on the market (not included in the formularies) are considered in evaluation of the Medicaid programs drug spending?**

    Yes, all FDA approved drugs for which there is New York Medicaid utilization and any new drugs without utilization, were considered in the evaluation of drug spending.

31. **Referring to the August 31, 2017 webinar slide #9, does 7,662 indicate the number of drugs utilized by Medicaid recipients and other drugs not included in the formulary that were evaluated?**

    Yes; this includes drugs without utilization in SFY 2016–2017.