Drug Cap Projection Questions

Q1. 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.*

Q2. 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.*

Q3. 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.*

Q4. 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.*

Q5. What happens if supplemental agreements are reached with some or all of the targeted manufacturers, and the cap is still projected to be exceeded? Will DOH seek additional rebates from the same manufacturers, or will additional drugs from those manufacturers or others then be targeted?

*If supplemental agreements are reached with some or all of the manufacturers that were sent letters (as referenced in Slide 11 of the PowerPoint), and the Drug Cap is still projected to be exceeded, DOH will seek additional rebates for other drugs and/or utilize other actions authorized in PHL § 280(7)(a), to bring spending in line with the Drug Cap.*
Q6. If spend comes in under the cap, either because the projection was incorrect or because other manufacturers have entered into agreements, does that mean that targeted manufacturers who have not yet entered agreements no longer need to participate in negotiations?

*If drug spending is projected to be under the Drug Cap, as assessed on a quarterly basis by the Department and the Division of Budget, negotiations in progress may cease. However, if a subsequent quarterly assessment by the Department and the Division of Budget projects that expenditures will be over the cap, additional actions may be taken to bring spending in line with the Drug Cap. This may mean that the previous negotiations would resume.*

Q7. 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.”*

**Negotiation Process Questions**

Q8. What is the process and timeline following manufacturer and department negotiations for a drug to be referred to the DURB, if referral is required?

*See FAQ #1 Q1, Q5 and Q8
https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2017-09-22_faqs.pdf*

Q9. Once a drug is identified for possible recommendation to the DURB, the Department indicated that it would attempt to reach an agreement with a manufacturer prior to the DURB referral. Does the Department of Health determine its own targeted rebate amount? If so, how does the Department reach its conclusions or calculations regarding a desired rebate amount?

*Supplemental rebates will be negotiated by the Department and the manufacturers, and the Department may propose rebate amounts based on information available to it. The Department will also consider any additional information the manufacturer may supply during the negotiation. For drugs referred to the DURB for review, any negotiated rebate may not be greater than the target rebate amount recommended by the Board.*

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Q10. Will any supplemental rebate agreement that is entered into after the products have been identified for potential review to the DURB allow those products to be exempt from any future reviews for the duration of the rebate agreement?

Products could still be reviewed under the authority of other programs (drug utilization review, preferred drug program, etc.) and because of other market occurrences (patent expiration, competing products, price changes, etc.).

Q11. How long does a manufacturer have to negotiate once the DURB sets a suggested rebate amount? If an agreement is not reached, can a manufacturer renegotiate at a later time?

A specific time period for negotiations has not been established. 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 exercise other authorities under the Drug Cap legislation.

Q12. Once a rebate amount is agreed to, what is the length of the contract terms?

The length of the contract term will be determined by the Department and the manufacturer.

Q13. Will targeted manufacturers have the ability to provide information on the applicable factors to DOH during the current negotiation process?

Yes.

If so, will they be able to submit such information on an interactive basis, or will they be confined to a single submission?

The existing DURB processes for making public comments and submitting information prior to the meeting will continue, along with the 5-day comment period after the meeting summary is posted.

The negotiation process may occur before or after a DURB meeting. Submission of information as part of the negotiations, is not confined to a single submission. However, outstanding submissions may not prevent drugs from being referred to the DURB.

In light of the potentially serious impact of the DURB recommendation, will they have a similar opportunity to submit information on an interactive basis during the DURB process? (For example, will they be confined to one submission of information ahead of the meeting and providing comments at the meeting, or may they submit information and respond to questions or concerns ahead of the meeting?)

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As mentioned above, the current DURB submission process would remain in place. This includes the comment period prior to the meeting and a 5-day comment period after the meeting summary has been posted. See a previous DURB agenda (via hyperlink below) as an example of the current submission timelines and procedures. 
https://www.health.ny.gov/health_care/medicaid/program/dur/index.htm

Q14. Can you confirm if rebates would be payable on both MC as well as FFS utilization?

Yes, rebates would be payable on both MC and FFS utilization.

Can you confirm rebates would be payable on such utilization regardless of whether the conditions to earn rebates under the supplemental rebate agreement are met (e.g., the Medicaid MCO must have aligned its formulary and/or preferred drug list, as applicable, with the PDL)?

The State cannot confirm the conditions in which rebates would be payable for all manufacturers. Such conditions would be agreed upon between the State and the manufacturer, and documented in the applicable attachment(s) of the CMS approved contract template.

Drug Utilization Review Board (DURB) Questions

Q15. 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.

As stated in Q11, 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):


Q16. 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.

Q17. Is there an appeals process after the DURB recommends the target rebate amount?

Consistent with the current DURB process, there is a 5-day comment period after a DURB meeting summary is posted. These comments are evaluated by Department staff in determining additional actions.

Q18. How does the Department of Health determine a drug to be targeted for additional supplemental rebates?

The process used by the department to identify drugs for possible DURB review and recommended target supplemental rebates is illustrated in the PowerPoint at: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2017-8-29 medicaid drug cap.pdf. (See slide #8).

Q19. Is there a DURB meeting scheduled in December?

See FAQ #1 Q1: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2017-09-22_faqs.pdf

Presumably, if a targeted manufacturer attempts to negotiate a supplemental rebate, they will not be placed on the December agenda. If they do begin negotiations, at minimum can they assume that they will not appear on the December agenda?

An attempt to negotiate or a negotiation in process will not prohibit a drug from being referred to the DURB. If an agreement that is satisfactory to the Department is reached, then the affected drug(s) will not be included on a DURB agenda. The Department will negotiate in good faith and will communicate its thinking regarding the possibility of a DURB referral.

Statutory Provision Questions (Section 280 PHL)

Q20. Is there a State Plan Amendment (SPA) available for viewing associated with the Drug Cap legislation?

A SPA was not required. Information regarding the Drug Cap was provided in a Federal Public Notice titled Miscellaneous Notices/Hearings NYS Register dated March 29, 2017 on page 95.

October 6, 2017
Q21. Does existing statute in the Social Service and/or Public Health law prohibit the DOH from applying prior authorization to products, including those used in opioid detoxification or maintenance treatment of opioid addiction under the authority of the Drug Cap provision?

Social Services Law § 364-j(26-b) and PHL § 273(10) both provide that prior authorization shall not be required for an initial or renewal prescription for buprenorphine or injectable naltrexone for detoxification or maintenance treatment of opioid addiction unless the prescription is for a non-preferred or non-formulary form of the drug. Therefore, the Department is not authorized to require prior authorization for such a prescription pursuant to PHL § 280(7)(a).

If prior authorization under the Drug Cap provision cannot be used for products used in opioid detoxification or maintenance treatment of opioid addiction, can the DOH still direct managed care plan to remove drugs from their formularies where no supplemental rebate agreement has been entered into, promoting the use of other clinically effective drugs, and such other actions as authorized by law?

Yes. The provisions of Social Services Law § 364-j(26-b) and PHL § 273(10) would not prevent the Department from taking any of the other actions authorized by PHL § 280(7)(a).

Can the DOH remove the prescriber prevails provision for products used in opioid detoxification or maintenance treatment of opioid addiction in the fee for service program?

Yes. If the conditions set forth in PHL § 280(5)(c) are met, the Department may waive the prescriber prevails provisions with respect to both Medicaid managed care and fee for service, subject to the limitations imposed by that paragraph.

Q22. If manufacturers do not provide rebates and the drug is referred to the DURB, based on the legislative language, the DURB will consider the drug’s cost, value, affordability, “significant and unjustified” price increases, and whether the drug is priced “disproportionately to its therapeutic benefits.” How does the DURB intend to develop its recommendation related to the targeted rebate amount? More specifically, how does the DURB reach its conclusions or calculations regarding a desired rebate?

Consistent with the current process of conducting DURB reviews, the Department will work with its contracted experts to develop evidenced based reviews aligned with the statutory provisions in PHL § 280(5)(e), which are outlined below. The DURB will make recommendations for target supplemental rebates based on these reviews, which will include publicly available information, information provided in the public comment portion.
of the DURB meeting, and the confidential financial information that will be reviewed in the Executive Session portion of the meeting.

Pursuant to PHL § 280(5)(e), in formulating a recommendation concerning a target rebate amount for a drug, the DURB may consider:

(i) publicly available information relevant to the pricing of the drug;

(ii) information supplied by the department relevant to the pricing of the drug;

(iii) information relating to value-based pricing;

(iv) the seriousness and prevalence of the disease or condition that is treated by the drug;

(v) the extent of utilization of the drug;

(vi) the effectiveness of the drug in treating the conditions for which it is prescribed, or in improving a patient’s health, quality of life, or overall health outcomes;

(vii) the likelihood that use of the drug will reduce the need for other medical care, including hospitalization;

(viii) the average wholesale price, wholesale acquisition cost, retail price of the drug, and the cost of the drug to the Medicaid program minus rebates received by the state;

(ix) in the case of generic drugs, the number of pharmaceutical manufacturers that produce the drug;

(x) whether there are pharmaceutical equivalents to the drug; and

(xi) information supplied by the manufacturer, if any, explaining the relationship between the pricing of the drug and the cost of development of the drug and/or the therapeutic benefit of the drug, or that is otherwise pertinent to the manufacturer’s pricing decision; any such information provided shall be considered confidential and shall not be disclosed by the drug utilization review board in a form that identifies a specific manufacturer or prices charged for drugs by such manufacturer.

Q23. For current and future drugs that might be considered, the legislative language includes a caveat that the waiver cannot be implemented in situations where “it would prevent access by a Medicaid recipient to a drug which is the only treatment for a particular disease or condition.” This reads as if it would exclude drugs without direct competitors. What is the New York Department of Health or Medicaid’s interpretation of this provision?

As referenced in PHL § 280, the waiving of “prescriber prevails” shall not be implemented in situations where it would prevent access by a Medicaid recipient to a drug which is the only treatment for a disease or condition. The determination regarding
whether this criterion is applicable to a drug would be based on a thorough, evidenced based review of treatment options.

Q24. If the Department of Health intends to place access restrictions on a drug, can managed care organizations (MCOs) override these determinations in certain circumstances, e.g., when access to a drug is medically necessary and/or the patient has tried and failed on other therapies on the formulary?

See answer to FAQ #1 Q11

Q25. In recommending a target rebate amount, the DURB is required to consider a variety of factors; will the DURB identify the impact of each of those factors on the recommendation for each drug?

See PHL § 280 (5)(e) for the list of items the DURB may consider in recommending a target rebate amount. There is no requirement for the DURB to identify the impact of each of those factors when recommending a target supplemental rebate amount. See Q22 in this document for more information regarding the DURB review process.

Q26. 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.

Q27. 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.