



General Medicaid Drug Cap FAQs

A. Drug Cap Legislation

1. Where can the Medicaid Drug Cap Legislation be found?

New York State Public Health Law (PHL) section 280.

2. How will "actual cost to the state" interact with the language in §280(4), which requires the state to consider both federal and state rebates when determining if there should be an extra rebate? Will this be limited to the state share of Medicaid spending and rebates?

In determining drug costs and whether to seek additional rebate for a drug, the State's share was evaluated. This is consistent with §280(3)(d), which indicates that prior to seeking an additional rebate, a drug's actual cost to the state, net of current rebate amounts, will be considered, as well as whether the manufacturer of the drug is providing significant discounts relative to other drugs covered by the Medicaid program. If the State has determined that it will seek additional rebates, §280(4) enables the DUR Board to also consider the state's net cost of the drug, amongst other things, as indicated in §280(4)(a)(b)(c).

As presented in the August 31, 2017 Webinar PowerPoint presentation ([Slide 6](#)), the Medicaid Drug Cap model is calculated based on the "Total State Rx Spend." The presentation is available on the DOH web-site posted [here](#).

3. How will the state define and consider items (i) through (x) of PHL §280(5)(e)?

Consistent with the current process of conducting DUR Board reviews, the Department will work with its contracted experts to develop evidenced based reviews aligned with the statutory provisions in PHL §280(5)(e). The DUR Board 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 DUR Board meeting, and the confidential financial information that will be reviewed in the Executive Session portion of the meeting.

4. Would you be able to confirm if PHL §272 11(c) does or does not have bearing on the Department's ability to accept non-supplemental rebate arrangements that are offered with respect to the expenditure cap excess and intended to fulfill NY PHL §280 3(b)? If it does, can you inform of the specific impact on prescription drugs for which the Department attempts to reach agreement, but which are not listed on the PDL?

PHL §272 11(c) applies to the Medicaid FFS Preferred Drug Program and does not have bearing on the Department's ability to accept rebates that are offered under PHL §280.

5. Are there other items the state plans to consider in considering the actual cost of a drug? If so, what are those items?

Pursuant to PHL § 280(5)(e), in formulating a recommendation concerning a specific drug, the DUR Board 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.

6. 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.

7. If the first step in the review is to assess whether spending is projected to exceed \$5M, why would all FDA approved drugs need to be considered?

Pursuant to PHL §280(3), the Department and the Division of Budget must project the annual expenditures for all drugs in Medicaid Program. As such, all FDA approved drugs would be considered for the purposes of completeness and monitoring/projecting spending for new drugs without utilization within the data time frame.

8. 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).

- 9. 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 drugs 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).

- 10. 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.

- 11. Will there be exemptions for and specific definitions of therapies for orphan indications/rare disorders?**

There are no exemptions for and specific definitions of therapies for rare disorder exceptions within PHL §280.

- 12. How will the DUR Board (DUR Board) be evaluating products and do they apply different parameters to orphan drugs that only apply to small populations?**

There DUR Board will evaluate drugs (orphan and non-orphan) consistent with PHL § 280.

B. Supplemental Rebate Timeline

- 1. Is there a deadline date for agreement on a voluntary supplemental rebate?**

No. However, a timely voluntary supplemental rebate agreement between the Department of Health (DOH) and the manufacturer is critical for DOH to keep pharmacy spending within the Medicaid Drug Cap established for State Fiscal Year 17–18 by Public Health Law Section 280.

- 2. How long does a manufacturer have to negotiate once the DUR Board 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 DUR Board or exercise other authorities under the Drug Cap legislation.

3. 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.

4. What is the process and timing for the state to reach an agreement with a manufacturer prior to referring a drug to the drug utilization review board for review?

The process to reach an agreement prior to a drug being referred to the DUR Board can be found on [Slide 11](#) of the August 31, 2017 Webinar PowerPoint Presentation: [here](#).

5. How long does a manufacturer have to negotiate once the DUR Board 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 DUR Board, or exercise other authorities under the Drug Cap legislation.

C. Supplemental Rebate Process

1. Drugs have been identified and letters have been sent to manufacturers. Is there a list of these drugs?

Drugs will be identified if these drugs are referred to the DUR Board. This will be done via a DOH web-site posting of the DUR Board agenda (hyperlink below) thirty (30) days prior to a DUR Board meeting:

https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/

2. Once a drug is identified for possible recommendation to the DUR Board, the Department indicated that it would attempt to reach an agreement with a manufacturer prior to the DUR Board 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 DUR Board for review, any negotiated rebate may not be greater than the target rebate amount recommended by the Board.

3. Will any supplemental rebate agreement that is entered into after the products have been identified for potential review to the DUR Board 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.).

4. If manufacturers do not provide rebates and the drug is referred to the DUR Board, based on the legislative language, the DUR Board 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 DUR Board intend to develop its recommendation related to the targeted rebate amount? More specifically, how does the DUR Board reach its conclusions or calculations regarding a desired rebate?

Consistent with the current process of conducting DUR Board 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 DUR Board 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 DUR Board 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 DUR Board 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.

5. In recommending a target rebate amount, the DUR Board is required to consider a variety of factors; will the DUR Board 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 DUR Board may consider in recommending a target rebate amount. There is no requirement for the DUR Board to identify the impact of each of those factors when recommending a target supplemental rebate amount.

6. If the selected drug is currently "Non-Preferred" on the NYS Medicaid Fee for Service (FFS) Preferred Drug List (PDL), will the drug be moved to "Preferred" status after NY and manufacture agreed on the supplemental rebate agreement?

Conditions, such as a drug's preferred or non-preferred status on the Medicaid FFS Preferred Drug list, would be discussed between the State and the manufacturer, and documented in the applicable attachment(s) of the CMS approved contract template.

7. If Medicaid spending does not exceed the spending cap as projected, will the state refund supplemental rebates negotiated under this law to drug manufacturers?

Supplemental rebates will be pursued and assessed quarterly as long as total Medicaid drug expenditures are projected to exceed annual growth limitation of the Medicaid Drug Cap. The State will not provide refunds to drug manufacturers for previously collected supplemental rebates.

8. How does the new law interact with the state's existing Magellan National Medicaid Pooling Initiative (NMPI) pool? And existing supplemental rebate contracts?

The Department considered rebates realized through the NMPI and other supplemental contracts when identifying drugs for possible Drug Utilization Review Board (DUR Board) referral. The Department will evaluate existing NMPI or new rebate offers as part of the negotiation process with manufacturers.

9. If Medicaid spending does not exceed the spending cap as projected, will the state refund supplemental rebates negotiated under this law to drug manufacturers?

Supplemental rebates will be pursued and assessed quarterly as long as total Medicaid drug expenditures are projected to exceed annual growth limitation of the Medicaid Drug Cap. The State will not provide refunds to drug manufacturers for previously collected supplemental rebates.

10. As the state is monitoring prescription drug spending in its entirety to determine when the spending cap is pierced, how will the state determine which drugs to send to the drug utilization review board to determine a target supplemental Medicaid rebate?

As presented in the August 31, 2017 Webinar PowerPoint presentation, the criteria used to narrow the number of drugs is illustrated on [Slide 8](#). The slide presentation is available on the DOH web-site posted [here](#).

11. Will any supplemental rebate agreement that is entered into after the products have been identified for potential review to the DUR Board 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.).

12. 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.

13. Will the state consider offsets in other areas of Medicaid spending (e.g., prevented hospitalizations) in determining the actual cost of a drug to the state?

The evaluation of whether a drug will reduce the need for other medical care, including hospitalization, will be done via the DUR Board review process, if and when a drug is referred to the DUR Board, pursuant to PHL §280(5)(e). Further, reductions in medical spending, reflected as savings within the Global Medicaid cap, will be considered in the financial calculations to implement more aggressive tools to address pharmaceutical spending to achieve financial targets.

The DUR Board may consider "offsets" in other areas of Medicaid spending when recommending a target rebate amount. These offsets will also be reflected in the overall fiscal management within the Medicaid Global cap.

14. What is the “target amount of rebate” (if any) that the New York State Division of Budget is recommending to the State’s Drug Utilization Review Board (DUR Board)?

The New York State Division of Budget does not recommend a ‘target amount of rebate’ to the DUR Board. The DUR Board will recommend a target supplemental rebate, if and when a drug is referred to the DUR Board for review. Pursuant to PHL § 280(5)(e) in formulating a recommendation concerning a target rebate amount for a drug, the DUR Board 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.

15. Does the request for “voluntary supplemental rebate” fall under the current Medicaid supplemental rebate contract, or is it a completely different contract with the State of NY?

The State Direct Supplemental Rebate Contract Template has been used to effectuate rebates negotiated under the Drug Cap statute. This template can be found [here](#), see SPA 14–38.

16. Will these rebates apply going forward only from the signing of the agreement, or will they also apply retrospectively? If retrospective, then to what date?

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

17. Did the state consider the WAC price trends on these products, as well as net sales trends on these products?

In determining drug costs and whether to seek additional rebate for a drug, the State's share was evaluated. This is consistent with §280(3)(d), which indicates that prior to seeking an additional rebate, a drug's actual cost to the state, net of current rebate amounts, will be considered, as well as whether the manufacturer of the drug is providing significant discounts relative to other drugs covered by the Medicaid program. If the State has determined that it will seek additional rebates, §280(4) enables the DUR Board to also consider the state's net cost of the drug, amongst other things, as indicated in §280(4)(a)(b)(c).

As presented in the September 17, 2018 Webinar PowerPoint presentation ([Slide 5](#)), the Medicaid Drug Cap model is calculated based on the "Total State Rx Spend." The presentation is available on the DOH web-site posted [here](#).

18. How did the state quantify the avoided medical costs and clinical effectiveness, and subtract those prevented costs from the target rebates?

The evaluation of whether a drug will reduce the need for other medical care, including hospitalization, will be done via the DUR Board review process, if and when a drug is referred to the DUR Board, pursuant to PHL §280(5)(e). The DUR Board may consider "offsets" in other areas of Medicaid spending when recommending a target rebate amount. Further, reductions in medical spending, reflected as savings within the Global Medicaid cap, will be considered in the financial calculations to implement more aggressive tools to address pharmaceutical spending to achieve financial targets.

19. Would the program consider rebates on other drugs, in place of the targeted drugs?

The focus of the Drug Cap is to obtain rebates for drugs that have been identified as contributing to the piercing of the Drug Cap. However, rebates on other drugs could be considered.

20. Would the state consider using the current supplemental rebate framework already in place for the requested rebates under the New York Medicaid Drug Cap program?

Yes, depending on the circumstance the Department would consider using the current supplemental rebate framework already in place with a specific manufacturer.

- 21. Can a manufacturer submit for the Department’s consideration an alternative agreement (e.g., value-based arrangement, alternative financing model, etc.) in place of a supplemental rebate amount? Is the Department able to accept such agreements, and if so, would it be considered by the Department as having satisfied their attempt to obtain a voluntary agreement, pursuant to PHL §280?**

While the Department is interested in value-based payment and alternative financing models, only supplemental rebate agreements under a [CMS approved contract template](#) are applicable to and considered under PHL §280. Additional discussion and evaluation of specific alternative arrangements would be required in order for the Department to consider and accept such an agreement, but the Department is willing to consider such alternatives if they meet the savings goals identified.

- 22. 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, 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.

- 23. How will the state notify manufacturers that any targeted supplemental rebates and provisions under §280(3)(e) or §280(7)(e) will be rescinded if future quarter spending is projected to be under the cap?**

Supplemental rebates will be sought so long as total Medicaid drug expenditures are projected to exceed the annual growth limitation of the Drug Cap. Projected drug expenditures will be assessed quarterly by the Division of Budget and the Department. The State will notify manufacturers and other stakeholders of this quarterly review, via the MRT listserv and a web posting.

- 24. 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.

D. Drug Utilization Review (DUR) Board Referral

- 1. Relative to the drugs in the Medicaid Drug Cap letter, what is the date of the applicable DUR Board meeting scheduled?**

Specific dates have not been determined. DUR Board meeting dates and accompanying agendas are posted thirty (30) days prior to the scheduled meeting. Please use the following link to periodically check for updates:

https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/ and/or sign up for the DUR Listserv at:

https://www.health.ny.gov/health_care/medicaid/program/dur/DUR_Board-I_listserv.htm so that you are updated when the DUR Board agendas are posted.

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

Specific dates have not been determined. DUR Board meeting dates and accompanying agendas are posted thirty (30) days prior to the scheduled meeting. Please use the following link to periodically check for updates:

https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2017/ and/or sign up for the Drug Utilization Review Listserv at:

https://www.health.ny.gov/health_care/medicaid/program/dur/DUR_Board-I_listserv.htm so that you are updated when the DUR Board agendas are posted.

Drugs, and drug classes, will be identified if these drugs are referred to the DUR Board. This will be done via a DOH website posting of the DUR Board agenda (hyperlink below) thirty (30) days prior to a DUR Board meeting.

3. 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 DUR Board 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 DUR Board 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 DUR Board.

In light of the potentially serious impact of the DUR Board recommendation, will they have a similar opportunity to submit information on an interactive basis during the DUR Board 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?)

As mentioned above, the current DUR Board 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 DUR Board 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

4. Is there an appeals process after the DUR Board recommends the target rebate amount?

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

5. 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 DUR Board. If an agreement that is satisfactory to the Department is reached, then the affected drug(s) will not be included on a DUR Board agenda. The Department will negotiate in good faith and will communicate its thinking regarding the possibility of a DUR Board referral.

6. According to another FAQ, drugs are evaluated based solely on cost information and the state is not evaluating offsets in other areas of medical spending from patient adherence to a treatment plan that may include prescription drugs. How is the state ensuring that any changes made under the Medicaid Drug Cap do not result in higher spending in other areas of Medicaid?

The evaluation of whether a drug will reduce the need for other medical care, including hospitalization, will be done via the DUR Board review process, if and when a drug is referred to the DUR Board, pursuant to PHL §280(5)(e). Further, reductions in medical spending, reflected as savings within the Global Medicaid cap, will be considered in the financial calculations to implement more aggressive tools to address pharmaceutical spending to achieve financial targets.

7. Will there be an appeals process for both biopharmaceutical manufacturers and the public to appeal determinations made by the state on the target rebate amount for a drug?

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

8. What will the Department do with the information disclosed under this section? How would this information be used to further the goals of the Medicaid program?

The Department may use this information to further evaluate the target rebate amount determined by the DUR Board. All information provided 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.

9. Does the State keep drug development, cost/pricing and other data provided by the manufacturer confidential?

Yes. Pursuant to PHL § 280(6), all information given by a manufacturer will be considered confidential and will not be disclosed by the Department.

Does the DUR Board have a format or checklist for how it wants this data provided?

Pursuant to PHL § 280(6) this information would be provided on a standard reporting form developed by the Department.

10. When (what is the date) is the DUR meeting corresponding to the drugs targeted for SFY 18-19? Will the portion of the meeting dealing with Medicaid Drug Cap targeted drugs be public or private? Will other manufacturers be present during the discussion of another manufacturer's drugs?

Specific dates have not been determined. Drug Utilization Review (DUR) Board meeting dates and accompanying agendas are posted thirty (30) days prior to the scheduled meeting.

11. Consistent with the current process of conducting DUR Board reviews, the Department will work with its contracted experts to develop evidenced based reviews aligned with the statutory provisions in PHL § 280(5)(e). The DUR Board 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 DUR Board meeting, and the confidential financial information that will be reviewed in the (private) Executive Session portion of the meeting.

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https://www.health.ny.gov/health_care/medicaid/program/dur/DUR_Board-I_listserv.htm so that you are updated when the DUR Board agendas are posted.

12. Would the state's determination of a drug's price point relative to its therapeutic benefits under §280(4)(c) amount to price fixing?

The Department does not view the DUR Board's consideration of a drug's price in comparison to its therapeutic benefits, for purposes of recommending a target supplemental rebate amount, to constitute the fixing of a drug's price.

13. Once a drug is identified for possible recommendation to the DUR Board, the Department indicated that it would attempt to reach an agreement with a manufacturer prior to the DUR Board 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 DUR Board for review, any negotiated rebate may not be greater than the target rebate amount recommended by the Board.

E. Fee for Service (FFS) and Managed Care Plan (MCP) Interface

- 1. Will the rebate offer be applicable to both FFS and Managed Medicaid utilization?**

Yes.

- 2. If you achieve savings, will you adjust Managed Care (MC) premiums mid-year?**

Managed Care premiums may be adjusted associated with the Medicaid Drug Cap.

- 3. 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.

- 4. 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.

- 5. How is it that the Medicaid Managed Care (MMC) drug costs are increasing so much and Fee for Service (FFS) is going down? Is there increased utilization in MMC?**

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.

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

*Please note: This FAQs is accurate back to the original time of publication (Oct 2017).

- 6. Will the Managed Medicaid plans (MMP) need to follow NY FFS PDL formulary for the specific drugs that reach agreement with NY on this initiative?**

Conditions, such as a drug's status on MMP formularies would be discussed between the State and the manufacturer, and documented in the applicable attachment(s) of the CMS approved contract template.

- 7. Has NY significantly increased prescription drug capitation rates to managed care organizations (MCOs)?**

Yes; over the past three years the pharmacy component of the Managed Care capitation premiums has increased by 24 percent.

*Please note: This FAQs is accurate back to the original time of publication (Oct 2017).

8. Are covered member months projected to increase?

The Department projects enrollment increases/decreases 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 impact enrollment for a given fiscal year.

9. How will the state determine MCO prescription drug spending as MCO claims data do not represent actual spending?

As presented in the August 31, 2017 Webinar PowerPoint presentation, the Managed Care premium is used to calculate the Medicaid Drug Cap as follows by multiplying projected Members Months by projected Per Member Per Month (PMPM) premium.

The slide presentation is available on the DOH web-site posted [here](#).

10. If a target rebate amount has been established, is the manufacturer prohibited from paying any other rebate to an MCO or PBM for purposes of Medicaid claims?

As indicated in PHL §280(5)(d), where the department and a manufacturer enter into a rebate agreement pursuant to PHL §280, which may be in addition to existing rebate agreements entered into by the manufacturer with respect to the same drug, no additional rebates shall be required to be paid by the manufacturer to a managed care provider or any of a managed care provider's agents, including but not limited to any pharmacy benefit manager, while the department is collecting the rebate pursuant to PHL §280.

11. How does the state determine what portion each targeted drug makes up of the overall drug premium cost paid to Managed Medicaid plans?

The State's actuary develops an all-inclusive pharmacy rate by region and rate cell which is not specifically delineated 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.

12. Would the state consider contracts that are inclusive only of state administered Medicaid (i.e. do not include Managed Medicaid plan utilization)?

The Drug Cap was established to ensure patient access to medically necessary drugs while providing financial stability to the state and participating providers. Given that the majority of drug spend is in Medicaid Managed Care, the state is to obtain rebates on both MC and FFS utilization.

F. Formulary Considerations

- 1. Current law states that in implementing the Drug Cap the DOH may not put in place restrictions that "prevent access by a Medicaid recipient to a drug which is the only treatment for a particular disease or condition". Therefore, what steps will the DOH take during the implementation of the drug cap to ensure patients are protected from access barriers to their treatment?**

If the statutory authority that allows for formulary removal is exercised (which would not occur until after the DUR Board has reviewed and made a target supplemental rebate recommendation), the DOH will consider the whether a drug is the only treatment option for a particular disease or condition [see PHL 280, paragraph 5(c)]. Current prior authorization policies and appeal processes will remain in place to ensure members have access to medically appropriate medication.

- 2. How will Medicaid apply the existing patient protection provision of the law that prohibits access restrictions when there is only one drug available in a class?**

If the statutory authority that allows for formulary removal is exercised (which would not occur until after the DUR Board has reviewed and made a target supplemental rebate recommendation), the DOH will consider the whether a drug is the only treatment option for a particular disease or condition [see PHL 280, paragraph 5(c)]. Current prior authorization policies and appeal processes will remain in place to ensure members have access to medically appropriate medication.

- 3. 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.

- 4. 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?**

If the statutory authority that allows for formulary removal is exercised (which would not occur until after the DUR Board has reviewed and made a target supplemental rebate recommendation), the DOH will consider the whether a drug is the only treatment option for a particular disease or condition [see PHL 280, paragraph 5(c)]. Current prior authorization policies and appeal processes will remain in place to ensure members have access to medically appropriate medication.

- 5. PhRMA interprets the requirements under §280(5) to mean that a drug may be removed from a preferred drug list, but patients would still be able to access**

drugs not on the preferred drug list per the requirements of Section 1927(a) of the Social Security Act. Is this interpretation correct?

§280(5)(c) authorizes the commissioner to waive "prescriber prevails" provisions for no more than two drugs in a given time. If such authority was utilized, current prior authorization processes would be used to ensure members have access to medically appropriate medication.

6. How will the state make a determination that a drug is the "only treatment for a particular disease or condition"?

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.

7. 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.

8. How will the state determine the two drugs for which they will waive the prescriber prevails provisions? Is this for two drugs total? Two drugs per disease? Per class? Per manufacturer?

The state will only waive prescriber prevails provisions for two drugs in a given time, and only if the DUR Board recommends a target rebate amount, and if after taking into account all rebates and supplemental rebates received, including rebates under PHL §280, total Medicaid drug expenditures are still projected to exceed the Drug Cap.

9. PhRMA interprets the requirements under §280(7)(a) to mean that a drug may be removed from an MCO preferred drug list, but patients would still be able to access drugs not on the preferred drug list per the requirements of Section 1927(a) of the Social Security Act. Is this interpretation correct?

If the statutory authority that allows for formulary removal is exercised (which would not occur until after the DUR Board has reviewed and made a target supplemental rebate recommendation), the DOH will consider the whether a drug is the only treatment option for a particular disease or condition [see PHL 280, paragraph 5(c)]. Current prior authorization policies and appeal processes will remain in place to ensure members have access to medically appropriate medication.

- 10. The law states that, "Under no circumstances shall the commissioner be authorized to waive such provisions with respect to more than two drugs in a given time." Does this refer to two drugs total or two drugs within a therapeutic class?**

§280(5)(c) authorizes the commissioner to waive "prescriber prevails" provisions for no more than two drugs in a given time, irrespective of therapeutic class.

- 11. How long can the commissioner waive these provisions for?**

Pursuant to PHL §280(7)(a)(b), the Commissioner shall be authorized to take the actions so long as total Medicaid drug expenditures are projected to exceed the annual growth limitation.

G. Drug Expenditure Growth Target

- 1. Will gross spending for drugs reflect amounts reported through the Drug Data Reporting for Medicaid (DDR) system for national rebate agreement purposes?**

No, gross spending for drugs will not reflect amounts reported through the DDR system for Managed Care because Managed Care spending is based on the pharmacy portion of Managed Care capitation premiums paid. Gross spending for Managed Care reflected in the DDR system is based on the amount paid, as reported by plans for encounters that tie Medicaid Drug Rebate Program invoices.

- 2. If other data sources are used for gross spending, what additional Medicaid drug spending amounts will they reflect? For example, will they include 340B drugs for Medicaid enrollees?**

As indicated in the answer to the question above, the data source used to determine Managed Care spending is the pharmacy portion of the Managed Care capitation premiums paid. The FFS data source is paid claims, and therefore, includes 340B reported claims.

- 3. Will rebates reflect the amounts reported by the state to CMS on CMS-64 submissions?**

In general, yes. The CMS-64 is sourced out of the drug rebate accounting system, while the rebates used for modeling in this initiative have come from cash collected by the Financial Management Group (FMG). The accounting group makes every effort to process all batches received by FMG; missing or incomplete supporting documentation could delay their work, causing a difference in totals between these sources.

- 4. If other data sources are used for rebates, will they reflect supplemental amounts separately negotiated between manufacturers and Managed Care Organizations (MCOs)?**

Supplemental rebate amounts negotiated between manufacturers and MCOs are reflected in the Per Member Per Month (PMPM) premiums paid to managed care plans. The Department of Health surveys MCOs regarding supplemental rebate amounts to validate premium assumptions.

5. **Will the medical component of consumer price index reflect calendar year values published by the Bureau of Labor Statistics, or will state fiscal years be calculated from the monthly values that are published?**

The State fiscal years are calculated from the monthly data values that are published.

6. **Since there is a lag in the availability of consumer price index data, at what point in time will the 10-year rolling average be determined? For example, will the growth target for SFY 2018 reflect the medical component of consumer price index average for 2007 - 2016, the most recent 10-year period with complete data prior to the start of the state fiscal year?**

Yes, the 10-year period is calculated on a year lag to reflect actual data and is updated each year.

7. **Has NY taken into account whether the net prices of the targeted drugs have increased more or less than the net prices of other drugs?**

Yes.

8. **The new law limits year-to-year spending growth to the 10-year rolling average of medical component of the consumer price index plus 5 percent in SFY2017-2018 and 4 percent in SFY 2018-2019. Does the Department interpret "percent" to mean percentage or percentage points?**

Percent means percentage points (e.g. 10 year rolling average of CPI-M plus 5 percentage points).

In quarterly assessments of drug spending, the projected annual amount of drug expenditures will be "on a cash basis." How will prior period adjustments be treated in such a calculation? For example, if rebates received on a cash basis in the current year are unusually high due to an update or correction of utilization data for a prior year (leading to net drug expenditures that are unusually low), would this be taken into account when determining whether the following year's expenditures are in excess of the growth target?

Prior period adjustments will be reflected on a "cash basis" when they materialize in payments. The Department and the Division of the Budget will consider adjustments to future calculations to appropriately reflect significant one-time occurrences.

How soon after the end of a quarter will an updated assessment of the projected annual amount of drug expenditures be calculated?

The Department will aim to complete updated quarterly assessment calculations before the end of each subsequent quarter. However, there may be instances in which updated assessment calculations extend beyond the subsequent quarter to ensure sufficient time for all spending data to be included in the calculation. (e.g. Given all spending data is available, Q2 projections will be updated by the start of Q3).

H. Resources

1. **How can I obtain more information about the Medicaid Drug Cap?**

Updates will be made available on the Monthly and Regional Global Cap web–page at https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/

For more information, send your questions to MADrugcap@health.ny.gov

2. **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 DUR Board review and recommended target supplemental rebates is illustrated in the PowerPoint at: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/2017-8-29_medicaid_drug_cap.htm.

3. **Is there a sample contract available for manufacturer to review and if the contract has been approved by CMS?**

The National Medicaid Pooling Initiative (NMPI) Contract Template can be obtained by contacting Magellan Medicaid Administration at NYPDPnotices@magellanhealth.com. The State Specific Supplemental Rebate Contract Template can be found [here](#), See SPA 14–38.