Q1 Relative to the drugs in the Medicaid Drug Cap letter, what is the date of the applicable DURB meeting scheduled?

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. 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/durb-l_listserv.htm so that you are updated when the DURB agendas are posted.

Q2 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.

Q3 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.

Q4 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].

Q5 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/

Q6 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:

Q7 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 explained in the answer to Question 3.

Q8 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 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/

Q9 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.

Q10 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.
Q11 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.

Q12 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?

See answer to Q11.

Q13 Will the rebate offer be applicable to both FFS and Managed Medicaid utilization?

Yes.

Q14 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.

Q15 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.

Q16 Where can the Medicaid Drug Cap Legislation be found?

New York State Public Health Law (PHL) section 280

Q17 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

Q18 What if I had submitted a question but it does appear on this list?

A second set of FAQs is in process and will be posted soon.