NEW YORK STATE | Department of Health

State Fiscal Year (SFY) 2020-21 High Cost Drug Initiative

Briefing

August 2020

Agenda

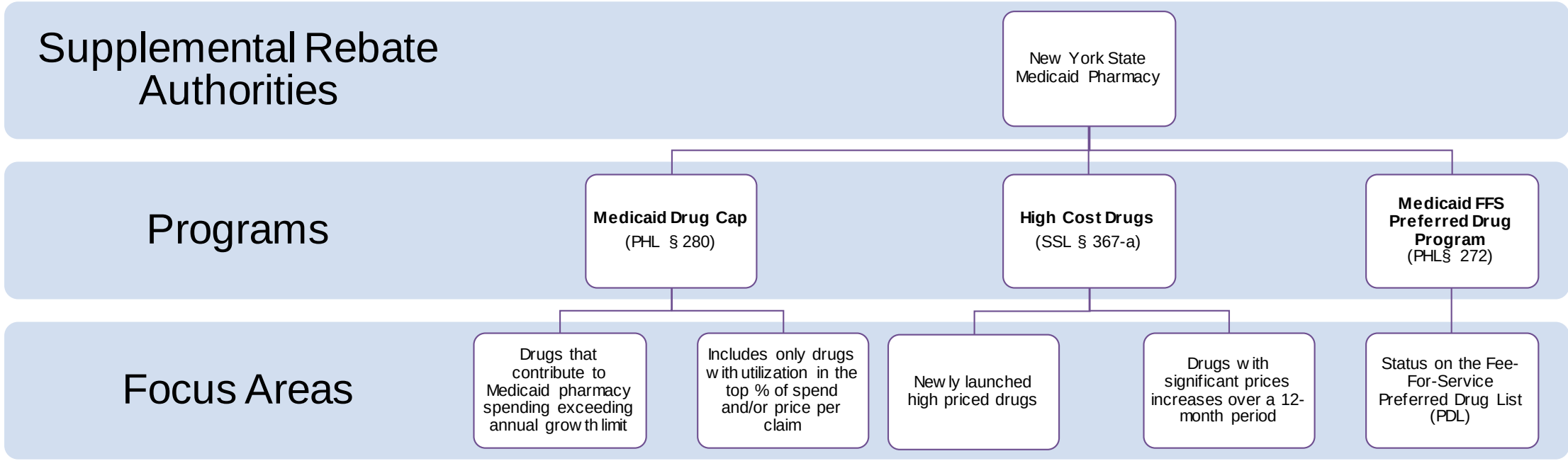
1. Overview of Enacted Statutory Provisions
2. Overview of Supplemental Rebate Authorities
3. Criteria for Identifying High Cost Drugs
4. Summary: Drugs Identified for Potential Drug Utilization Review (DUR) Board Referral
5. Overview of Process
6. Drug Utilization Review (DUR) Board
7. Next Steps

Overview of Statutory Provisions – SSL §367a

High Cost Drug Initiative

- Authorizes the Department of Health (DOH) to:
  - identify and negotiate enhanced rebates for newly launched high cost drugs, including gene therapies;
  - negotiate rebates based on evidence-based research that considers the effectiveness of the drug and whether it improves health, quality of life, or overall health outcomes, and whether the drug will reduce the need for other medical care, including hospitalization;
  - request drug development costs as well as other pricing information to inform target rebate amounts; and,
  - refer a certain high cost drugs and gene therapies to the Drug Utilization Review (DUR) Board for a recommended target supplemental rebate.

Overview of Medicaid Supplemental Rebate Authorities



Differences Between the Medicaid Drug Cap and the High Cost Drug Rebate Initiatives

	Medicaid Drug Cap	High Cost Drugs
Authorizing Statute	PHL § 280	SSL § 367-a
Applicable	Only if Medicaid Drug Spending is projected to exceed the annual Drug Cap limitation	For newly launched high cost drugs starting April 1st, 2020
Criteria for Identification of Drugs	Meets one of the following conditions: Top % in terms of net spend and/or cost per claim for all drugs with utilization In SFY 19 and SFY 20 the percentage threshold for net spending and cost per claim was the top 3% for all drugs, respectively	Meets one of the following conditions: (i) High launch price; or (ii) Excessive price increase within any twelve-month period (iii) Biosimilar drug with a launch price that is not at least 15% lower than the referenced brand biologic at the time the biosimilar is launched, or (iv) a generic drug that has a WAC of $100 or more for a thirty-day supply; or (v) A Gene Therapy as defined on the following slide
Overview of Process	Step 1: Voluntary Supplemental Rebate Step 2: DUR Board Referral Step 3: Request for Confidential Information Step 4: Additional Actions (e.g., removal from managed care formularies, requiring prior authorization, etc.)	Step 1: Voluntary Supplemental Rebate Step 2: Request for Confidential Information Step 3: DUR Board Referral Step 4: Additional Actions (e.g., removal from managed care formularies, requiring prior authorization, etc.)

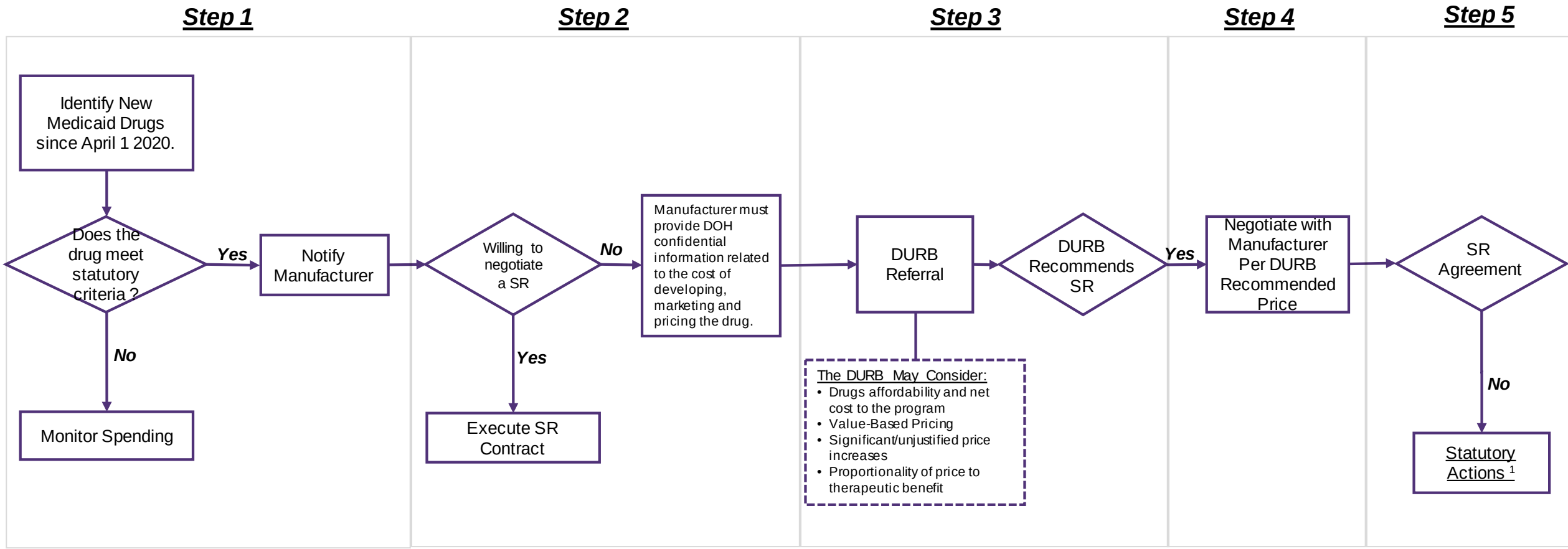
Criteria under which High Cost Drugs were Identified for Possible DUR Board Referral (4/1/2020-6/30/2020)

Identified High Cost Drugs SFY 2020-21 (Quarter 1)		
Qualifying Criteria *(Meets at least one of the following)*	**Number of Drugs**	**Number of Manufacturers**
A brand name drug or biologic with launch Wholesale Acquisition Cost (WAC) > $30,000/year OR per course of treatment	10	9
Biosimilar with a launch WAC > 85% of the referenced brand biologic at the time of launch	-	-
Launch of a generic with $100 or more per 30-day supply or recommended dosage approved for labeling by the Food and Drug Administration (FDA)	-	-
Brand name drug or biologic with WAC increase $3,000 or more per 12-month period or course of treatment	-	-
Gene Therapy *	-	-

** Gene Therapy is defined by the following criteria: (i) Approved under section 505 of Food, Drug and Cosmetics Act (FD&C); (ii) Licensed under subsection (a) or (k) of section 351 of Public Health Services Act; (iii) Treats a rare disease or condition that is life threatening; (iv) Considered gene therapy by the FDA for which biologics license is held; (v) Results in a cure OR reduction of symptoms of such disease approved by labeling after 3 administrations or less.*

Overview of Process

High Cost Drug Initiative – Process Overview



SR = Supplemental Rebate; DURB = Drug Utilization Review Board

1: Statutory actions includes enforcing additional utilization management controls and directing managed care plans to reduce reimbursement to providers (if applicable)

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After the DURB Recommendation

- If agreement cannot be reached, Public Health Law § 280 authorizes, to the extent applicable under the law:
  - Directing managed care plans to remove from their Medicaid formularies those drugs for which a manufacturer has failed to enter into a rebate agreement;
  - Subjecting drugs to prior approval;
  - Promoting the use of cost effective and clinically appropriate drugs other than those of a manufacturer who has failed to enter into a rebate agreement; and
  - Directing a managed care plan to limit or reduce reimbursement for a drug provided by a medical practitioner

Drug Utilization Review Board (DURB)

DUR Board Overview

- The DURB provides clinical guidance to the Commissioner regarding the utilization of pharmaceuticals and the evaluation of drug expenditures within the Medicaid program.*
- DURB activities include but are not limited to the following:
    - Establishment and implementation of medical standards and criteria for the prospective and retrospective DUR program;
    - Development, selection, application, and assessment of educational interventions for physicians, pharmacists and recipients that improve care;
    - Administration of pharmacy programs including the Preferred Drug Program and the Clinical Drug Review Program; and
    - Evaluation of drugs which that contribute to exceeding the Drug Cap and making recommendations for target supplemental rebates
    - Evaluation of new high cost drugs that meet the conditions summarized in slide 5 (new)

**The purpose and responsibilities of the DURB are established in Social Services Law section 369-bb and Public Health Law Title 1 sections 270, 272, 274 and 280.*

DUR Board Process

High Cost Drug Reviews will be integrated into the current DUR Board processes:

- Publicly Held Meeting
- Agenda Posted 30 days prior to Meeting
- Public Comment Period
- Financial Information Reviewed in Executive Session
- DURB Recommendations Made During the Meeting
- DURB Recommendations Posted after Meeting
- 5 Day comment Period
- Commissioner Final Determinations Posted

Next Steps

Next Steps	Timeline/Target Dates
Notification Letters/Bid Packages to Manufacturers	• Week of August 17th 2020
Stakeholder Webinar	• Week of August 24th 2020
Negotiations with Manufacturers	• Immediately, following distribution of letters/bid packages
Drug Utilization Review Board (DURB) Meetings *[30 days prior to the DURB meeting, DOH will post an agenda on its website, which will (if applicable) include the names of drugs that will be reviewed for recommended target supplemental rebate amounts]*	• November / December 2020

Resources

- Questions should be sent to MASuppRebate@health.ny.gov

- This webinar presentation will be available online at: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/