maryland
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Payment Model Workgroup

Proposed Revisions to Outpatient High-Cost Drug Funding Policy

October 24, 2024

Introduction

- HSCRC Staff are proposing to change the method of reimbursing high-cost drugs from the current approach to one that provides 100% cost reimbursement for the direct cost of the covered drugs.
  - High-cost drugs are already exempted from population-based methodologies under the TCOC contract.
  - Staff believe now is an opportune time to change from the current complex policy to a simpler approach.
- Topics
  - Recap of Current Policy and Reasons for Change
  - Proposed Changes
  - Next Steps

Recap of Current Policy

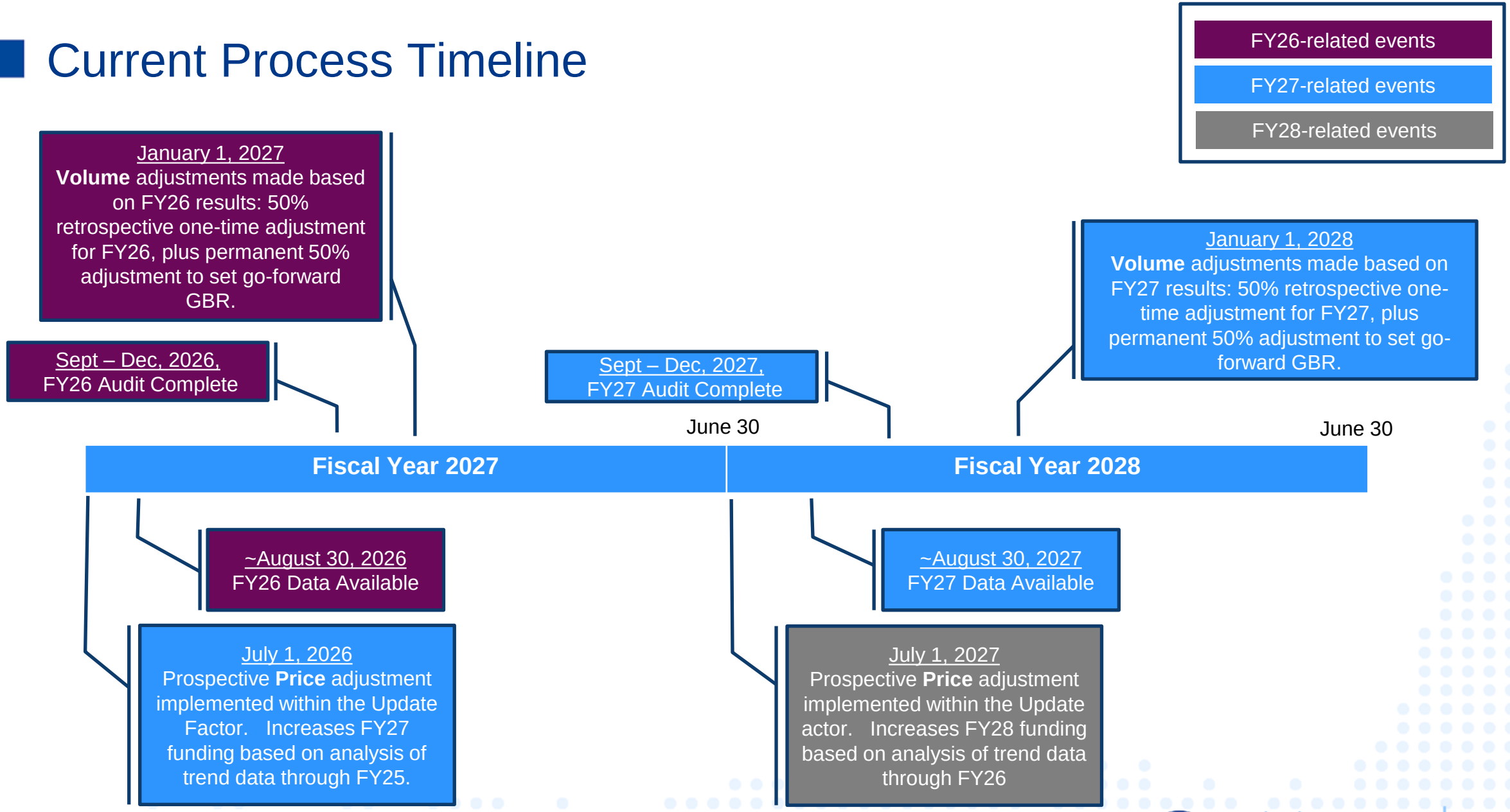
Review of Current Funding Approach

1. In HSCRC rate setting certain “High Cost” drugs that are drugs paid under the medical benefit (aka Part B drugs) are subject to a special funding provisions. Drugs under this policy are typically referred to as “CDS-A Drugs”[1] .
2. Hospitals receive/lose funding for changes in volume in these drugs at 50% of the change in cost.
   a. Cost is defined as ASP or 340B, whichever is applicable (note funding impacted relates only to direct cost, no changes are made in indirect loads).
   b. Volumes are reported in Casemix and validated through an annual audit process completed in the 6 months after each fiscal year.
      i. Once the audit is completed, adjustments are made on January 1 of the following fiscal year.
      ii. A one-time retroactive adjustment is made to settle the prior fiscal year.
      iii. A permanent adjustment is made to true up the go-forward GBR.
3. Hospitals are funded for the remaining 50% of cost changes through a prospective price inflation factor applied to CDS-A Drugs during the update factor.
   a. The inflation factor covers only price increases not volume, but it includes the impact of drug volume mix changes on price (which is also reflected in volume changes).
   b. The inflation factor is typically set industry-wide, although for FY25 a higher value was set for academic hospitals.
   c. Because it is prospective, the value must be estimated based on data from 2 years prior (FY25 prospective inflation was based on FY23 drug spending). As a result, prospective funding tends to lag actual trend.
4. Revenue adjustments resulting from this process are added to the total hospital GBR.
   a. Drugs are billed based on the ratio of revenue allocated to the drug cost center to the cost of the drug across all drugs (not just the CDS-A drugs).
   b. To avoid overburdening high-cost drugs with overhead loads hospitals are supposed to tier overhead based on the drug cost.

Because this approach is volume variable it is scored against the requirement that 95% of hospital revenues use a population-based methodology under the TCOC model. It contributes ~2% against the 5% limit.

1. CDS-A stands for Costs of Drugs Sold – Audit and refers to the statewide list of physician administered outpatient drugs meeting certain defined inclusions criteria, these criteria are listed in Appendix A. These drugs are subject to an annual audit to validate reported amounts and ensure appropriate funding.

Current Process Timeline

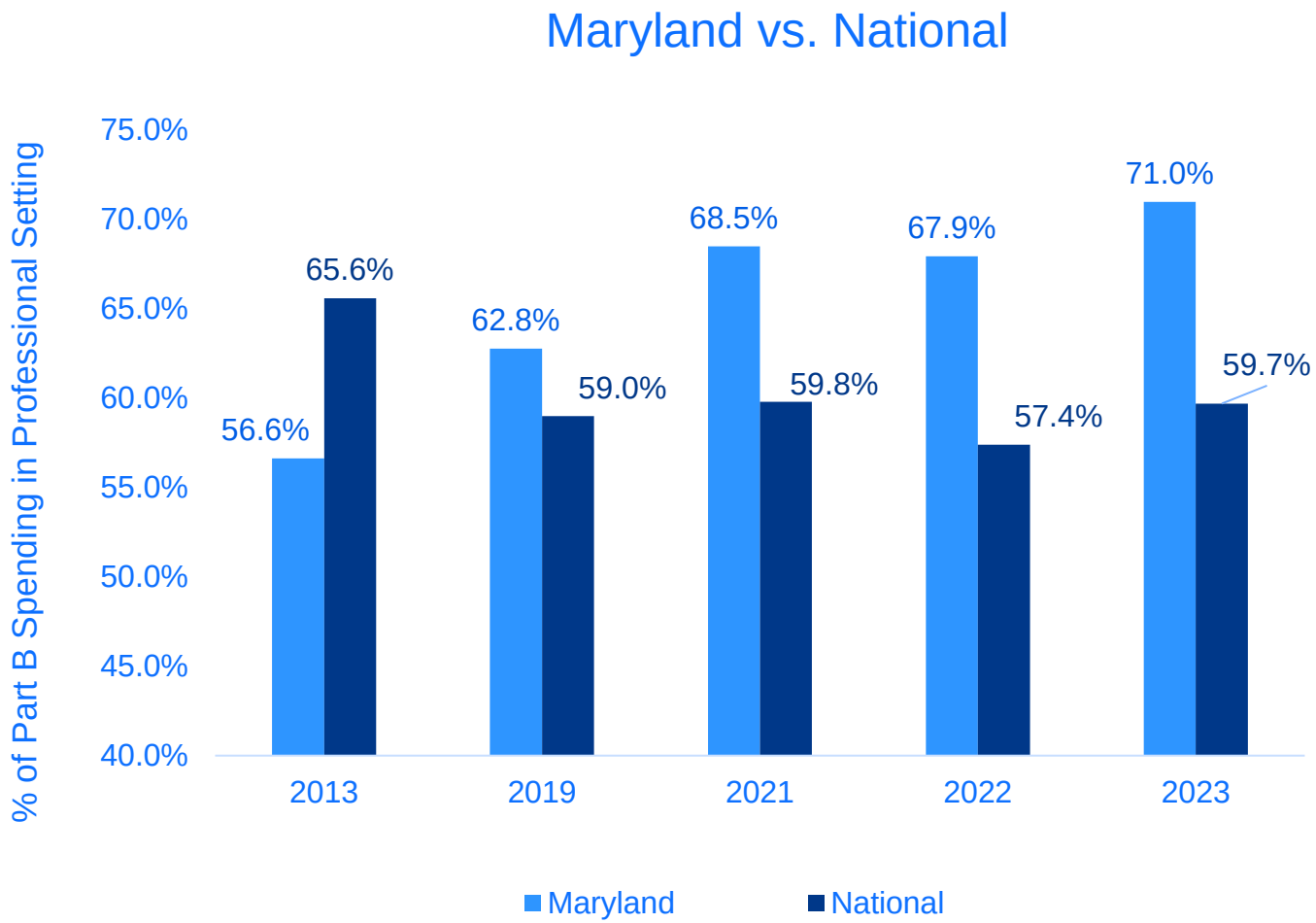


CDS-A Drug Trend, Actual Statewide Experience

- In 2023 CDS-A Drugs cost ~$380 M, which was about 40% of total statewide hospital drug costs
- CDS-A Approach was implemented in 2016 in response to high Part B drug trends.
- Trends mitigated later in the decade but have begun to accelerate again, particularly at the top end of the market.
- Staff expects trend acceleration seen in FY23 to continue into FY24.

	FY18	FY19	FY20	FY21	FY22	FY23
Volume	-12.5%	8.0%	7.2%	3.7%	3.9%	6.6%
Pure Price	-0.5%	-0.7%	1.1%	1.7%	1.5%	2.9%
Mix-Driven Price	18.3%	-3.7%	-5.3%	-1.3%	-2.0%	0.8%
Total	3.0%	3.3%	2.5%	4.1%	3.3%	10.5%

Outcomes - Model Has Achieved Significant Medicare Savings in Part B Drugs[1]



- During the past decade, Maryland's use of the professional setting has increased by almost 15% while the nation's decreased by about 6%. After a brief slow down during the pandemic the nation has gone back to the secular trend.
- On a PMPY basis Maryland has gone down from 19% greater than the nation to 2%.
- Estimate is that Part B place of service drove savings of ~$180 million dollars.
- Outside Maryland higher reimbursement in facility site of service discourages site of service shifts.

1. CDS-A Drugs are billed under Medicare Part B and therefore are part of the model savings test. See July 2025 TCOC workgroup materials for further information on model savings. (https://hscrc.maryland.gov/Pages/hscrc-tcoc.aspx)

Discussion of Current Approach

- The blend of 50% specific volume-based funding and across the board inflation funding was intended to maintain the incentive for hospitals to manage cost:
  - Hospitals that move to lower cost drugs or shift site of service out of the hospital benefit by retaining 50% of the drug cost in their GBR.
  - Hospitals can also benefit by “beating” the average prospective inflation by negotiating prices with suppliers. However, 340B prices generally start lower and these hospitals may have less opportunity.
  - Hospitals absorb 50% of volume increases, therefore a hospital that fails under the prior bullets will lose money under the policy.
- Approach assumes every hospital will have an equal opportunity to succeed under this policy and that the impact of new high-cost drugs is also evenly distributed.
  - Volume levers – opportunity for a hospital to earn upside by shifting drug mix and/or site of service is likely variable. HSCRC does not have the ability to assess this opportunity.
  - Price levers - HSCRC analysis historically has shown all hospitals experience similar price trends although that was less true in the most recent year (which result in a separate inflation factor for academics).
- In addition to their clinical benefits, high-cost drugs should reduce the need for acute hospitalization and other expensive services and therefore their adoption is strongly aligned with the goals of the model.
- Net for FY23, HSCRC estimates the average hospital was overfunded by 0.4% of total GBR based on the two-prong drug funding approach (median = 0.24%).

Challenges Under the Current Policy

1. The prospective inflation factor is unlikely to be accurate given the data lag and the rapidly changing drug market. This volatility results in funding at a Statewide level that lags actual experience (over funding in times of slow growth, under funding in times of high growth).
2. While the policy is considered volume variable, the combination of the prospective inflation and 50% volume funding do not reliably match actual experience. Even if statewide funding is accurate individual hospitals are likely to experience over or underfunding. Hospitals facing the highest cost pressure are most likely to be underfunded.
3. Changes in drug mix receive overlapping funding as they are considered both in the volume and price adjustment (steps 2 and 3 in the approach slide).
4. The policy is complex and may lead to sub-optimal decision making due to misunderstanding of the funding approach.

Proposed New Policy

Case for Change

Staff believe we are at a tipping point for changing the policy:

- Hospitals are appropriately funded for the CDS-A Drugs through FY2023, this provides a window to change the funding approach.
- The current approach is complex, and it is hard to project how the two funding streams will interact to fund any given situation.
- There are indications that cost growth is moving to a small volume of very high-cost drugs, this is a situation which is poorly matched with the current approach.
- Given the CDS-A approach is already counted as a volume-variable component of the global budgets it would be simpler to make it directly volume variable.
- However, the current policy has been effective in driving Medicare savings, any policy change should look to maintain that advantage.

Proposed Change

To simplify the CDS-A policy, Staff propose to make it more directly volume variable:

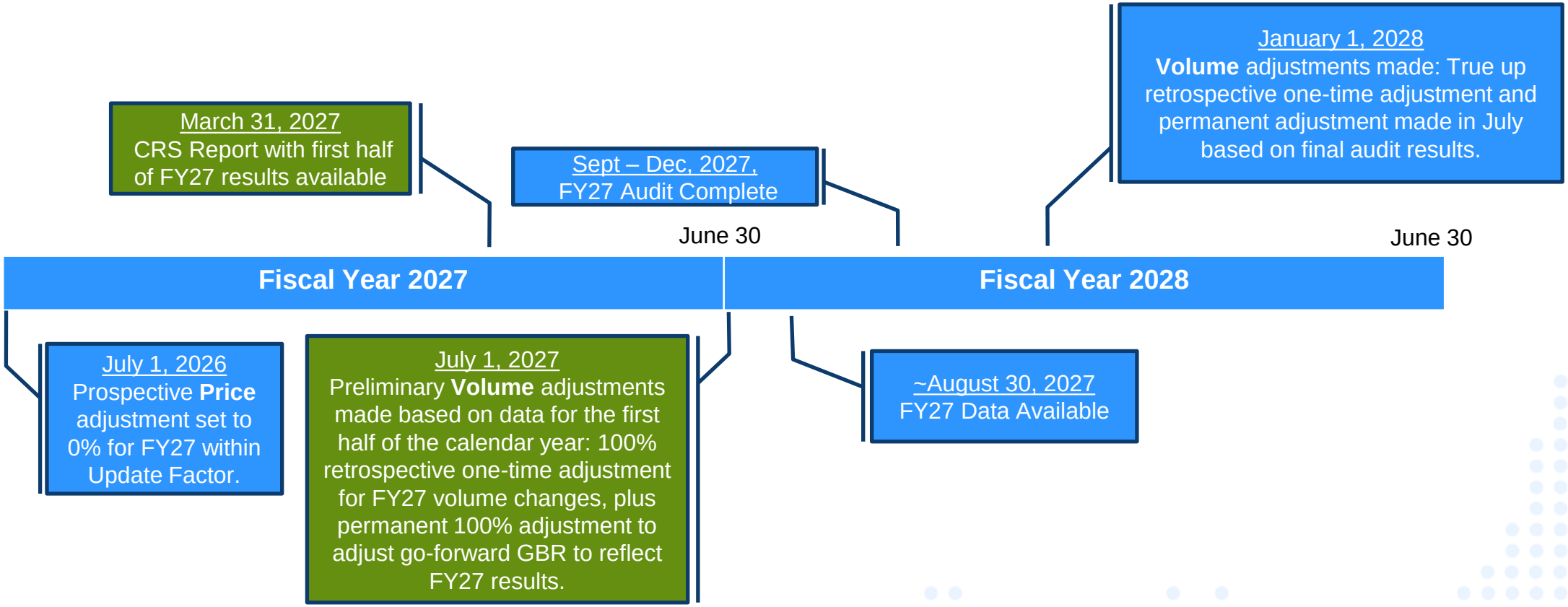
1. Change volume funding to 100% of measured cost change, per the audit, effective 1/1 of each year.
2. As this will increase the size of the adjustment, to smooth the impact, implement a provisional adjustment for each year at the end of the year based on the first 6 months of data for that year.
    a. Provisional adjustment will be calculated by staff directly from Casemix data, excluding drugs with outlier dosage counts. No manual adjustments will be made. HSCRC has worked with CRISP to create a report to support this approach.
    b. Provisional adjustment will be temporary only, final adjustment derived from the audit will supersede the provisional adjustment and all amounts will be trued up to the final audit.
3. Set the drug component of inflation in the update factor to 0% permanently, as inflation on drugs will be provided through the volume adjustment.
4. Implement the change retrospectively for FY2024, effective 1/1/2025, including reversing price inflation granted under the FY25 Update Factor recommendation (FY2024 was already set at 0). As the volume adjustments under this policy were always implemented retrospectively Staff feel it is appropriate to implement in FY2025 for FY2024 (see next slide for policy timelines).
5. Implement new reporting and penalties, as outlined later in this presentation.

Proposed Process Timeline

FY27-related events

New FY27-related events

Focus on FY27-related Events



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Additional Reporting and Penalties

- NDC code will be added to the case mix Data Submission Requirements (DSR) as a required field effective, 7/1/25
  - Enhances the analytic capabilities on drug spending
  - Will be included in DSR release in Spring of 2025.
- As a 100% cost reimbursement policy does not maintain the same incentives to manage costs effectively the HSCRC is proposing to contract for an annual report to monitor the State's use of Part B drugs (see next slide).
  - If the report finds an erosion in the efficiency of Maryland spending from 2023 levels, GBR reductions equal to 20% of CDS-A spending will be assessed on a statewide, regional or hospital basis, depending on the extent of the erosion.
  - The report would become the basis for future policy changes.
- HSCRC intends to evaluate hospital tiering of drug prices over the coming year to ensure high-cost drugs are not being loaded with overhead on a $ for $ basis resulting in unfair costs to consumers.

Annual Evaluation Report Outline and Impact

- Report would be compiled by a consultant with expertise in Pharmacoeconomics and other relevant topics. HSCRC has enlisted the assistance of the Prescription Drug Affordability Board (PDAB) in managing the report.
- Report would assess the following regarding high-cost drugs:
  - Place of service use rates.
  - Generic and biosimilar use rates.
  - Adoption of new drugs.
  - Acquisition pricing
- Report will allow the HSCRC to evaluate whether:
  - The policy change has impacted the efficiency of high-cost drug utilization in Maryland.
  - There are additional opportunities for improved utilization efficiency.
  - Efficacious new drugs are being adopted in at a rate at or better than the nation.
- First report would be released in late CY25 based on FY25 data to assess the baseline and observe any initial impacts from this change. Report would then be release annually thereafter.

Revised Approach Would Not Impact

- Audit timing and process
- Criteria for identifying drugs under the policy
- Treatment of high-cost drugs under the TCOC revenue exception with CMS
- Treatment of oncology drugs in the ICC, market shift or other HSCRC policies

Appendix

Criteria for Drugs to be Treated under CDS-A Policy

The state-wide list is composed of Billed High-Cost Physician-Administered Outpatient Infusion, Chemotherapy, & Biological Oncology Drugs meeting all the following criteria:

- 3M's EAPG Class Code of VII or higher in either of the past two fiscal years (to reference relatively high cost per patient visit), and
- State-wide case-mix charges in either of the past two fiscal years of $2 million or greater (to reference relatively high-cost utilization), and
- Market share by point of service of less than 90% at physicians' offices (to minimize inclusion of drugs best served outside of a hospital setting), and
- An Ambulatory Payment Classification - OPPS Payment Status Indicator of G or K, Paid under OPPS/Separate APC payment (to preclude drugs packaged under other charge codes), and
- Inclusion of alternate codes for same listed drug (so to capture brand, generic, biologic, biosimilar, replacement, discontinued and temporary codes)