

FY19 H.2 MassHealth Value-Based Pharmacy Purchasing Proposal

January 24, 2018

MassHealth pharmacy spend has doubled from \$1.1B to \$2.2B over the past five years, twice the growth vs. other MassHealth spending.

- Rapid pharmacy growth is expected to continue, with high cost drugs as a major driver.
- Just 19 high cost drugs pending FDA approval or recently approved are expected to cost over \$80 million annually, after expected rebates.
- The top 30 drugs, or one percent, account for ~30% of MassHealth pharmacy costs, or over \$600 million per year.
- Increasingly, new high cost drugs are the only drugs in their classes. With no competition, manufacturers are less likely to offer supplemental rebates and/or value-based payment arrangements.

MassHealth has maximized rebates and management of pharmacy to the extent possible under current statutory and federal authorities.

- MassHealth lacks the levers needed to manage high-cost drugs consistent with commercial/ Medicare insurers:
 - State procurement rules limit MassHealth's ability to directly negotiate with drug manufacturers
 - Under current rules, if manufacturers choose not to negotiate, MassHealth has no recourse.
- As a result, new high-cost drugs (at times ~\$1 million per course of treatment) threaten MassHealth's ability to maintain robust eligibility and benefits for members and reasonable reimbursement rates for providers.

Overview of Value-Based Pharmacy Purchasing Proposal

- MassHealth is committed to ensure members maintain access to clinically effective & medically necessary treatments.
- MassHealth submitted a new federal waiver amendment request in September 2017; the proposal has been updated with input from federal and local stakeholders.
- The proposal will:
 - **Add new direct negotiating (Step 1a) and transparency approaches (Step 1b) that provide MassHealth leverage to establish fair and reasonable cost-effective prices with manufacturers** and require disclosures when manufacturers fail to reach an agreement (*similar process used by New York Medicaid*).
 - **Allow MassHealth to exclude certain drugs from its formulary (Step 2) if there is no agreement on direct negotiating and transparency approaches (step 1a and 1b), or the drug has no proven clinical efficacy. No drug will be excluded unless it is also excluded on either the Commonwealth's GIC plan or at least one national pharmacy benefits manager (with >10m lives).**
 - **Put in place strict guardrails, member protections and a public process to limit when formulary exclusions could apply.** This is expected to apply to no more than ~1% of drugs that are high cost and/or have no proven clinical efficacy, for which MassHealth's currently available levers are not adequate.
- The specific **member protections** include:
 - a. Member representative/advocate and health economist will be added to Drug Utilization Review (DUR) Board.
 - b. No formulary changes for behavioral health drugs (anti-psychotics and others) without DMH approval.
 - c. Drug exclusions cannot be discriminatory based on the member population benefitting from the drug (e.g., race, gender, sexual orientation, etc.).
 - d. The decision to exclude a drug would be subject to the restrictions described above and in Step 2, would be made in consultation with the DUR Board and would include a public comment process.
 - e. Exceptions process for unique circumstances (e.g., allergies to preferred drugs).
 - f. Members maintain the right to appeal a coverage decision through the MassHealth Board of Hearings.
- Excluding certain drugs (Step 2) requires federal approval of the 1115 waiver request. MassHealth will incorporate these updates, including member protections, into ongoing discussions with federal authorities and the Commonwealth's 1115 waiver amendment request.
- Background: federal rules require a DUR Board composed of at least 1/3 but no more than 51% practicing physicians, and at least 1/3 practicing pharmacists. The DUR Board currently includes 7 physicians, 6 pharmacists, and 1 nurse practitioner. **We will be adding a member representative/advocate & a health economist to the DUR Board.**

Value-based pharmacy purchasing proposal

“MassHealth Drug Pricing I” Outside Section

1a

Step 1a:
Direct negotiating ability for value-based pricing

- MassHealth to negotiate directly with manufacturers, even with one drug in a class
- MassHealth defines and offers a cost-effective target price
- Target price determined objectively, including:
 - 3rd party independent analysis
 - Cost of existing therapies
- Includes value-based payment arrangements (e.g., payments required only if proven clinically effect)

1b

Step 1b:
Transparency and public hearings on manufacturer pricing

- If no agreement under 1a, require manufacturer disclosures to justify drug pricing through disclosures (e.g., cost of R&D, cost of marketing)
- Make information available publicly to the extent permissible by the state and federal law
- Manufacturer may be required to testify at a public hearing
- HHS Secretary may impose appropriate sanctions/ reasonable penalties for non-compliance or unreasonable/ excessive price

“MassHealth Drug Pricing II” Outside Section

2

Step 2:
Potential Formulary exclusions

- May exclude certain drugs from the formulary only if one or both of the following are true:
 - No agreement under 1a & 1b between the manufacturer and MassHealth, or
 - The drug has no proven clinical efficacy
- And, the Commonwealth’s GIC plan or at least one national pharmacy benefits manager (covering >10 million lives) are not covering the drug
- Robust protections/guardrails, such as:
 - DUR Board consultation (add consumer/ member advocate)
 - Public comment process
 - Cannot be discriminatory
 - No BH formulary changes without DMH approval
 - Exceptions/ appeals