MASSACHUSETTS
HEALTH POLICY COMMISSION

Health Policy Commission Board Meeting

Drug Pricing Review Regulation

February 5, 2020

Drug Pricing Review

Overview

Chapter 41 of the Acts of 2019 (the "Budget") was signed by Governor Baker on July 31, 2019.

Statutory Authority

(1) Section 46 gives the Executive Office of Health and Human Services (EOHHS) authority to negotiate a supplemental rebate agreement (SRA) directly with pharmaceutical drug manufacturers for MassHealth. If EOHHS is unable to successfully negotiate an SRA, they may refer the manufacturer to the Health Policy Commission (HPC).

(2) Upon referral from EOHHS, Section 6 gives the HPC the authority to propose a *supplemental rebate… based on a proposed value of the drug.* The commission may request records from the manufacturer, with sanctions for non-compliance. Finally, the Commission will issue a determination on whether the manufacturer's pricing of a drug is *unreasonable or excessive in relation to the commission's proposed value of the drug.*

The MassHealth Process

Direct Negotiations

MassHealth negotiates directly with a drug manufacturer for a supplemental rebate.

Proposed Value & Public Input

If negotiations fail for high cost drugs, MassHealth may propose a value for the drug and solicit public input on the proposed value for the drug.

Further Negotiations

MassHealth updates its proposed value for the drug as necessary and solicits further negotiations with the manufacturer.

Referral to the HPC

HPC

If negotiations with the manufacturer fail, MassHealth may refer the manufacturer to the HPC for review.

The HPC Process

HPC

The HPC Process

Notice & Requests for Information

HPC notifies the manufacturer that it has been referred by MassHealth for review and requests information, including completion of the Standard Reporting Form.

- HPC determines that a manufacturer's pricing is *potentially unreasonable or excessive*
- Notifies the manufacturer, and requests additional information.

Review

HPC reviews information submitted by the manufacturer.

- HPC solicits information from stakeholders.

Determination

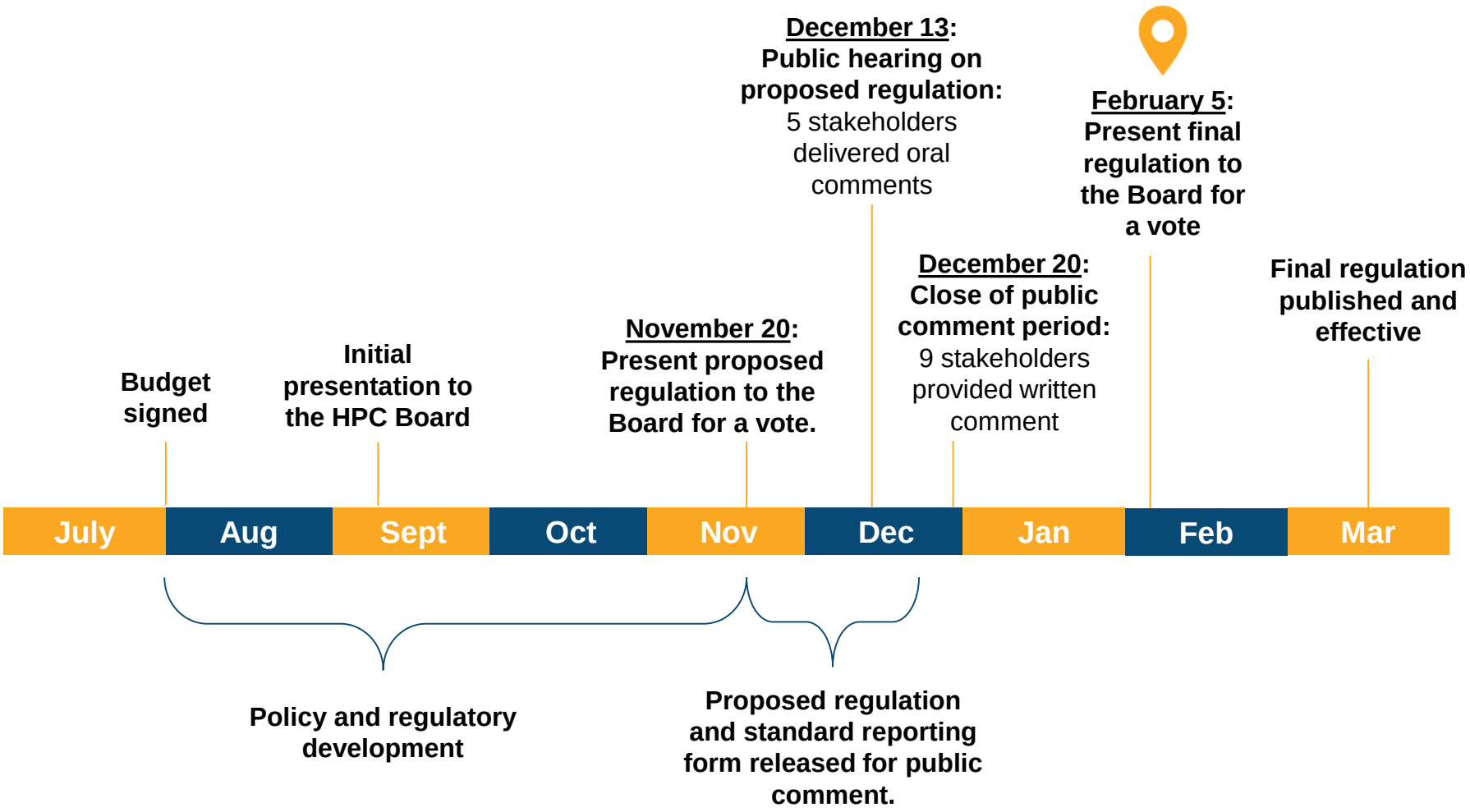
HPC may:

- Identify a proposed value for the drug;
- In consultation with MassHealth, propose a supplemental rebate for the drug;
- Determine that the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug; or
- Close its review of the drug.

- Within 60 days of receiving completed information from the manufacturer, HPC issues a determination on whether the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug.

HPC

Regulatory Development Timeline



The HPC plans to **finalize the Standard Reporting Form** over the coming weeks and look forward to continue working with stakeholders throughout this process.

Purpose of Regulation, Standard Reporting Form, and Framework

Regulation	Standard Reporting Form	Framework
Details the **process** for conducting our reviews	Details standardized **information we expect to collect** from all manufacturers	Describes **how we expect to evaluate** different data sources for assessing value and pricing
Broad descriptions of factors we consider and information we plan to collect reflect feedback from Commissioners and other experts as well as stakeholders	Content and format of form will be developed and refined based on ongoing feedback from manufacturers and other stakeholders	Data sources and methods will be developed in concert with experts, including Commissioners, and reflect feedback from stakeholders
Requires a **Commission vote** to promulgate or change.	Form is expected to change and be refined over time. Released as **sub-regulatory guidance** on our website with advance notice of changes to manufacturers	Will be **discussed publicly** at Board and Committee meetings and expected to change over time as new issues arise and new data sources become available.

HPC

Public Comment

The HPC held a public hearing and a one-month public comment period on the regulation and standard reporting form.

Comments and testimony submitted by 11 organizations:
1. Biotechnology Innovation Organization (BIO)
2. Blue Cross Blue Shield of Massachusetts
3. Disability Policy Consortium Representing 8 additional disability advocacy organizations^
4. Greater Boston Interfaith Organization^
5. Health Care for All and the Prescription Drug Affordability Coalition Representing 13 additional organizations^
6. Jewish Alliance for Law and Social Action*
7. Massachusetts Association of Health Plans
8. Massachusetts Biotechnology Council (MassBIO)
9. Mental Health Legal Advisors Committee*
10. Partnership to Improve Patient Care and 6 disease-specific advocacy groups
11. Pharmaceutical Research and Manufacturers of America (PhRMA)

*These groups presented oral testimony at the public hearing, but did not submit written testimony
^ these groups presented oral testimony at the public hearing and submitted written testimony

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Information submitted by the manufacturer	Industry groups voiced concern that certain data requested are confidential and proprietary, and asked that certain processes and safeguards be specified in the regulation.	**Add to 12.12** to specify that the HPC "shall develop protocols to protect the confidentiality of records received from EOHHS or disclosed by the Referred Manufacturer."
	Industry groups expressed concern that some of the information requested from Referred Manufacturers is vague and that it would be difficult to determine what constitutes a complete response, including the requirement that manufacturers submit an assessment of the value of the drug.	**Clarify in 12.04 (1)** that the Referred Manufacturer must provide its own estimation of value of the Drug with supporting information, such as existing analyses.
	Industry groups wanted to ensure that they have the opportunity to provide input on the Standard Reporting Form (SRF).	**Updated language in 12.04 (2)** that the Standard Reporting Form will be developed and updated with advanced notice to and input from Manufacturers and other interested stakeholders.

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Information submitted by the manufacturer	Industry groups generally objected to the requirement that the SRF include pricing information (both national and international) and financial information on an aggregate and per-drug basis. In addition, they had concerns that the information may not be available in the format specified in the draft SRF.	**Update language in 12.04 (3)(c)-(f)** to allow for more flexibility in development of the standard reporting form and to allow the Referred Manufacturer to submit drug-specific financial information using the best information available. The HPC will continue to work with stakeholders and experts on the information requested and the format in which it is submitted on the Standard Reporting Form.
	Industry groups were concerned that 30 days would not be enough time for Referred Manufacturers to respond to information requests.	**Add to 12.04 (1) and 12.09 (2)** that another timeframe may be agreed upon, in writing, between the Referred Manufacturer and the HPC, through the Executive Director.

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Public notice, public summary, and stakeholder input	Patient and disability advocates and industry groups requested that the HPC have a clear process for considering input from stakeholders, including patients, caregivers, and clinical experts, in identifying a proposed value for the Drug.	**Add a section, 12.05**, which specifies: • Following notice to a Referred Manufacturer, the HPC shall post a notice on its website. • Interested stakeholders may provide data or information they consider pertinent to the HPC's review of a Referred Manufacturer's pricing and factors for identifying a proposed value for the Drug. **Clarification throughout the regulation** that the HPC will consider information submitted by interested stakeholders.
	Patient and disability advocates requested transparency on the rationale for determining that a Referred Manufacturer's pricing is potentially unreasonable or excessive and the sources of information used in making its determination.	**Add to 12.08** that the HPC "shall publicly post a summary of the rationale for determining that the Referred Manufacturer's pricing of the Drug is potentially unreasonable or excessive in relation to the value of the Drug and a list of any third-party cost-effectiveness analysis relied upon in identifying the proposed value."

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Public notice, public summary, and stakeholder input	Patient groups supported the proposed regulation's requirement that following a determination the pricing of a Drug is unreasonable or excessive, the HPC post its proposed value of the drug; however, industry groups opposed publication of a proposed value in the proposed regulation.	**We recommend no change** to the regulation given differing comments received from stakeholders.
Factors in identifying a proposed value	Disability advocates requested that the HPC consider both clinical efficacy (performance under research conditions) *and effectiveness* (performance under "real world" conditions) in its process.	**Update and align language in 12.04 (3)(a) and 12.06 (2)(a)** to include "clinical efficacy, effectiveness, and outcomes" in the information requested in the Standard Reporting Form and in the factors for identifying a proposed value.
	Industry groups and payers recommended the HPC consider therapeutic equivalents, rather than pharmaceutical equivalents, of a Drug in identifying a proposed value for the Drug.	**In 12.06 (2)(f), replace** "pharmaceutical" with "therapeutic."

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Factors in identifying a proposed value	Disability advocates and industry groups requested clarification on how the HPC will consider the clinical importance of the Drug to patients and recommended including outcomes important to patients and families, such as the ability of patients to work and the impact on caregivers; the impact of treatment on future medical care; if the treatment addresses an unmet medical need; the effectiveness in comparison with standard care; disease severity and prevalence; benefits and risks of treatment; and the impact on subpopulations.	**Update 12.06 (2)(c)** to consider: "the extent to which the Drug addresses an unmet medical need or impacts patient subpopulations" **Update 12.06 (2)(e)** to consider: "the likelihood that the use of the Drug will reduce the need for other care or reduce caregiver burden, or enhance quality of life." **Add 12.06 (2)(g):** "characteristics of the Drug, including means and setting of administration, dosing frequency, duration of therapy, side effects, interactions and contraindications, and potential for misuse or abuse."
	Disability advocates and industry groups voiced concerns and recommended a prohibition on use of any cost-effectiveness analyses that use Quality-Adjusted Life Years (QALY) in identifying the proposed value of a Drug.	**Add to 12.06 (2)(h)**: "provided that the Commission shall consider the methodologies and models underlying such analyses, any assumptions or limitations of research findings in the context of the results, and any outcomes for affected subpopulations that utilize the Drug, if applicable."

Comments and Proposed Updates to Regulation

Topic	Comment	Recommendation
Impact on access for individual patients	Disability advocates expressed concern that identifying the proposed value of a Drug could negatively impact patient access.	**Add a section, 12.14,** clarifying that: “A determination of the value of a Drug pursuant to 958 CMR 12.00 et seq. is not intended to be a determination of the value of a Drug for any individual patient”

The HPC also recommends some minor technical edits and updates to streamline language and to align with EOHHS’s regulation, 101 CMR 801.

Proposed Vote and Next Steps

- The Board is asked to approve the issuance of the final regulation 958 CMR 12.00, *Drug Pricing Review*.

- If approved by the Board, the final regulation will be filed with the Secretary of State and is anticipated to become effective upon publication in the Massachusetts Register on March 6, 2020.

MASSACHUSETTS
HEALTH POLICY COMMISSION

VOTE: Drug Pricing Review Regulation

MOTION: That the Commission hereby authorizes the issuance of the final regulation for 958 CMR 12.00, Drug Pricing Review, pursuant to M.G.L. c. 6D, § 8A and M.G.L. c. 118E, § 12A.