



AN ACT TO ESTABLISH RATE SETTING OF PRESCRIPTION DRUGS IN [STATE]

Whereas prescription medications are as important to the health and safety of State residents as traditional public services or utilities such as transportation, gas, electric, telecommunications, and water;

Whereas [State] has traditionally regulated the consumer price of utilities because of the monopoly structure of the market;

Whereas the cost of many prescription drugs have become increasingly unaffordable for [State] residents, [State] employers, and [State] and local governments because parts of the prescription drug market are monopolies or oligopolies, and the costs to consumers in these parts of the market are not managed;

Whereas Canada has a national drug price review board that seldom has to exert its express authority in order for the industry to offer drugs to market at prices that are, on average, 30 percent less than U.S. list prices;

Whereas the difference between the affordability of traditional utilities and the costs/affordability of prescription drugs is due in part to the active role of our State government in directing how much consumers pay for utilities and the corresponding inactive role of our State government in directing how much consumers pay for drugs;

Whereas state and federal agencies have a long history of health care rate setting including for brand pharmaceuticals and biologics, and generic drugs to control health care costs;

Therefore, be it resolved that [State] will create a Drug Cost Review Commission with authority to protect State residents, state and local governments (including their contractors and vendors), commercial health plans, providers, state-licensed pharmacies, and other health care system stakeholders from excessive costs of certain prescription drugs.

Overview

This Act creates a new [State] Drug Cost Review Commission with five members and a full time staff to receive and review statutorily-required information submissions from the makers of brand name and generic prescription drug products, the price for which triggers reporting. The Commission will be supported by an 11 stakeholder Advisory Board.

Manufacturer submissions, based on requirements established by the Commission, will be used to determine the reasonableness of the costs created by a prescription drug product. The Commission will have a public process for each drug under review. The Commission will accept analysis and data from manufacturers, payors, consumers, as well as staff or Commission contractors to determine if the cost to

the system of appropriate utilization of a drug is commensurate with its benefit to the system and whether the drug is affordable to State residents.

The Commission will review submissions that concern drug cost to make a determination as to whether the cost of a drug under review is affordable. If the Commission finds that the cost in the State is not affordable to State health care systems and State residents, the Commission is authorized to establish a cost or payment rate for the drug to which all State programs, local governments, State-licensed commercial health plans (including State marketplace plans), State-licensed pharmacies, wholesalers and distributors must abide. These 'covered entities' are prohibited from paying more for the drugs than the Commission-established rate and would be enforced by the Attorney General.

The Commission can contract-out the cost/affordability analysis or have in-house expertise.

The Commission will have an Advisory Board of experts and stakeholders.

The Commission's operations can be funded by a variety and combination of entity-appropriate fees (see Section 8).

Section 1. Operation of the Commission

1) MEETINGS:

- a) The Commission shall meet in public session at least every six weeks to review prescription drug (biologic and pharmaceutical) product information submissions. Meetings can be cancelled or postponed upon the decision of the Chair if there are no pending submissions.
- b) Each public meeting will be announced two weeks in advance.
- c) Materials for the meeting will be made public at least one week in advance.
- d) Each public meeting will provide opportunity for comments from the public.
- e) The Commission will provide the opportunity for written comments on pending decisions.
- f) The Commission may allow expert testimony at the meetings and in Executive Session.
- g) The Commission shall publicly deliberate on whether to subject a prescription drug product to a full cost review.
- h) The Commission shall publicly review a prescription drug product cost analysis and take a public vote on whether to impose a cost or payment limit on payors for a prescription drug product.
- i) The Commission may meet in Executive Session, so long as decisions are made in public.

- 2) PUBLIC ACCESS TO DATA: All submissions to the Commission pertaining to a drug price notices and drug cost review are to be made publicly available with the exception of information determined to be proprietary for different industries that may be submitting information. After public notice and comment, the Commission will establish parameters for what is considered proprietary, and will give particular attention to any pre-market submissions.

- 3) QUORUM: The Commission may make binding decisions in the presence of a simple majority of Commissioners.

Section 2. Required Manufacturer Notice of Introductory Price and Price Increases

1) FOR PATENTED PRODUCTS

- a) A manufacturer shall notify the Commission if it is increasing the Wholesale Acquisition Cost (WAC) of a patent-protected brand-name drug by more than 10 percent or by more than \$10,000 during any 12-month period, or if it intends to introduce to market a brand-name drug that has a WAC of \$30,000 per year or per course of treatment. The notice shall be provided in writing at least 30 days prior to the planned effective date of the increase or launch and include a justification as detailed in Paragraph 3 of this Section.
- b) After consultation with stakeholders and experts, the Commission will establish a third threshold that, when breached, triggers manufacturer reporting for brand prescription drugs, including biologics and biosimilars. The third, distinct threshold will achieve reporting by branded products that have launch prices or price increases below thresholds in (1)(a), but impose costs on the State health care system that create significant challenges to affordability.

2) FOR GENERIC PRODUCTS AND OFF-PATENT SOLE SOURCE BRANDED PRODUCTS:

- a) a manufacturer shall notify the Commission if it is increasing the WAC of a generic or off-patent sole source branded drug with a WAC unit price of \$10 or more by more than 20 percent during any 12-month period¹, or if it intends to introduce to market a generic drug that has a WAC of \$3,000 or more annually. The notice shall be provided in writing at least 30 days prior to the planned effective date of the increase or launch and include a justification as detailed in Paragraph 3 of this Section.
 - b) After consultation with stakeholders and experts, the Commission will establish a third threshold that when breached, triggers manufacturer reporting for generic and off-patent, sole source branded prescription drugs. The third, distinct threshold will achieve reporting by products that have price increases below thresholds in (2)(a), but impose costs on the State health care system that create significant challenges to affordability.
- 3) JUSTIFICATION: Justification for the proposed launch price or price increases specified in (1) and (2) of this section shall include all documents and research related to the manufacturer's selection of the launch price or price increase, including but not limited to life cycle management, net average

¹ The threshold for generics was established to require notification to the Commission for generic drugs with significant price increases only. Based on an analysis of price trends in recent years, this threshold should result in reporting on fewer than 30 generic drugs to the Commission for their consideration. NASHP's analysis of the threshold in Maryland's 2019 law establishing a Prescription Drug Affordability Board (HB 768), which is set at an increase of 200% or more, indicated the 200% threshold would effectively exempt generics from reporting. States may wish to consider which generic thresholds to establish based on their goals for Drug Affordability Review Board review of generic drugs.

price in the State (net of all price concessions but excluding in-kind concessions), market competition and context, projected revenue, and if available, estimated value/cost-effectiveness of the product

Section 3. Criteria for Selection of Drugs for Review of Cost

- 1) PUBLIC COMMENT: The Commission will keep the public informed about manufacturer price decision reporting under Section 2. The Commission will provide the public an opportunity to request Commission review of the cost of any prescription drug that triggered reporting under Section 2.
- 2) ROLE OF THE CHAIR: The Commission Chair will review the public comments and decide whether to undertake a review of a particular drug that triggered reporting under Section 2. The Chair can decide that the Commission will undertake a review in the absence of public comments.
- 3) ROLE OF COMMISSIONERS: The Commission members can request a vote on whether or not to undertake a review if there is not consensus with the decision of the Chair.

Section 4. Determining Excess Costs to Payors and Consumers

- 1) IN GENERAL: Once a decision has been made to undertake a cost review pursuant to Section 3, the Commission review will determine if appropriate utilization (utilization fully consistent with the FDA label) of a prescription drug product has led or will lead to excess costs for health care systems in the State.
- 2) DEFINITION OF EXCESS COSTS: "Excess Costs" is defined as
 - a) Costs of appropriate utilization of a prescription drug product that exceed the therapeutic benefit relative to other therapeutic options/alternative treatments or
 - b) Costs of appropriate utilization of a prescription drug product that are not sustainable to public and private health care systems over a ten-year timeframe.
- 3) PHASE ONE DETERMINATIONS: Factors the Commission may consider in determining cost and excess cost include the following:
 - a) The price at which the prescription drug has been/will be sold in the State
 - b) The average monetary price concession/discount/rebate the manufacturer provides to payors in the State/or is expected to provide to payors in the State as reported by manufacturers and health plans
 - c) The price at which therapeutic alternates have been/will be sold in the State
 - d) The average monetary price concession/discount/rebate the manufacturer provides to health plan payors in the State or is expected to provide to payors in the State for therapeutic alternates
 - e) The relative clinical merits of the product under review compared to therapeutic alternates
 - f) The cost to payors based on patient access consistent with FDA labeled indication(s)
 - g) The impact on patient access resulting from the cost of the product relative to insurance benefit design
 - h) The current or expected value of manufacturer-supported, drug-specific, patient access

- programs
- i) The relative financial impacts to health, medical and other social services costs, as can be quantified and compared to baseline effects of existing therapeutic alternatives
 - j) Other such factors as may be specified in regulation by the Commission.
- 4) PHASE TWO DETERMINATIONS: If, after considering the factors in (3), the Commission is unable to determine if a prescription drug product will produce or has produced excess costs, then the Commission may consider the following:
- a) Manufacturer research and development costs, as shown on the company's federal tax filing for the most recent tax year multiplied by the proportion of manufacturer in-State sales to U.S. sales;
 - b) That portion of direct to consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year, which are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in-State sales to total manufacturer U.S. sales for the product under review;
 - c) Gross and net manufacturer revenues for the most recent tax year; and
 - d) Any additional factors which can be specified in regulations or that the Commission considers relevant to the circumstances, as may be proposed by the manufacturer.

Section 5. Commission Determinations, Compliance and Remedies

- 1) RATE SETTING: In the event the Commission finds that the spending on the prescription drug product under review creates excess costs for payors and consumers, the Commission shall establish the level of reimbursement that shall be billed and paid among payors and pharmacies/administering providers, wholesalers/distributors and pharmacies/administering providers, and pharmacies/administering providers and uninsured consumers or consumers in a deductible period.
- 2) COMPLIANCE WITH RATE SETTING: Instances of failure to bill and pay at Commission-established levels under Section 4 shall be referred to the Attorney General
 - a) Upon a finding of non-compliance with the Commission requirements, the Attorney General may pursue remedies consistent with the State Fair Market Practice statutes, or in the case of intentional profiteering, other appropriate criminal statutes.
 - b) It shall not be considered non-compliance if a health care stakeholder obtains price concessions from a manufacturer that result in an insurer's net cost lower than the rate established by the Commission.
 - c) The Attorney General shall provide guidance to stakeholders concerning activities that could be considered non-compliant, in addition to payment transactions where drug costs exceed the Commission established limit.
- 3) COMPLIANCE WITH REPORTING: Instances of manufacturer failure to report under Sections 2 or 4 shall be referred to the Attorney General for review. The Attorney General may pursue remedies available based on State Fair Market Practice or Consumer Protection laws.

Section 6. Appeals

- 1) APPEALS: Individuals and entities affected by a decision of the Commission can request an appeal within 30 days of the Commission decision. The full Commission will hear the appeal and make a decision within 60 days.
- 2) JUDICIAL REVIEW: Decisions on appeal can be subject to judicial review.

Section 7. Financing

- 1) ESTABLISHING AN OPERATING BUDGET: The Commission Chair shall recommend to the legislature financing options within six months of establishment of the Commission.
- 2) INTERIM FUNDING Commission will be funded for the first two years with such sums as are necessary but not to exceed \$___per year until the financing option selected from the recommendations in Subsection 1 are enacted.

Section 8. Annual Reports

- 1) The Commission shall report annually to the public on general drug price trends, the number of companies required to report because of drug pricing decisions, and the number of products that were subject to Commission review and analysis – including the results of that analysis, as well as the number and disposition of appeals and judicial reviews.

Section 9. The Drug Cost Review Commission Membership and Staff Membership

- 1) COMMISSION COMPOSITION AND APPOINTMENTS:
 - a) The DCRC will have 5 members appointed as follows: 3 members appointed by the Governor, 1 member appointed by the Senate, and 1 member appointed by the Assembly.
 - b) Initial Appointees serve staggered terms of 3, 4 and 5 years, and subsequent appointees shall serve 5 year terms. The Governor shall name the Chair, and the Chair shall designate the Co-Chair. The Governor will appoint two alternate Commissioners to participate in deliberations in the event a regular Commissioner must be recused.
 - c) Commissioners should have expertise in health care economics or clinical medicine.
- 2) ADVISORY BOARD COMPOSITION AND APPOINTMENTS:
 - a) The Governor will appoint an 11 member Board to advise the Commission on drug cost issues and represent stakeholder views.
 - b) Initial Appointees serve staggered terms of 3, 4 and 5 years, and subsequent appointees shall serve 2 year terms. The Governor shall name the Chair, and the Chair shall designate the Co-Chair.
 - c) The Advisory Board members will be selected based on their knowledge of one or more of the following: the pharmaceutical business model, practice of medicine/clinical knowledge and training, patients' perspectives, health care cost trends and drivers, clinical and health services research, and the state health care marketplace generally.

- d) The Board must include at least 2 members representing patients and health care consumers, 2 members representing physicians and providers, 2 members each representing commercial payors, government employee benefits, and large employer plans, 1 member representing pharmaceutical manufacturers, 1 health services researchers, 1 clinical researcher, 1 pharmacologist, and 1 state budget office representative.
- 3) CONFLICT OF INTEREST:
- a) In appointing the Commission or the Board, any conflicts of interest shall be considered and disclosed. Members of the Commission and the Board shall be recused from relevant Commission activities in the case where the member (or an immediate family member of such member) has a real conflict of interest directly related to the drug product under review.
 - b) With regard to Commissioners, Board members, staff and contractors, the term 'conflict of interest' means an association, including a financial or personal association, which has the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Commission or the conduct of the Commission's activities.
 - c) A Commission member, staff or contractor with a real conflict of interest with regard to any prescription drug under review will recuse themselves from the review. The term 'real conflict of interest' means any instance where a member of the Commission (or a close relative), has received or could receive either of the following:
 - (I) A direct financial benefit of any amount deriving from the result or findings of a study or determination by or for the Commission or
 - (II) A financial benefit from individuals or companies that own or manufacture prescription drugs, services, or items to be studied by the Commission that in the aggregate exceeds \$5,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member's (or close relative's) already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.
- 4) DISCLOSURE TIMING: In general, a conflict of interest shall be disclosed in the following manner:
- a) By the Commission in the employment of Commission senior staff;
 - b) By the Governor, Senate or House/Assembly in appointing members to the Commission and Advisory Board;
 - c) By the Commission, describing any recusals as part of any final decision resulting from a review of a prescription drug product; and
 - d) By the fifth day after a conflict is identified or if sooner, in advance of any public meeting.
- 5) MANNER OF DISCLOSURE: Conflicts of interest will be publicly posted on the website of the Commission. The information disclosed under the preceding sentence shall include the type, nature and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of any activity with respect to the study for which the potential conflict exists.
- 6) GENERAL PROHIBITIONS: The Commission, the Advisory Board, staff and third party contractors shall be prohibited from accepting gifts, bequests or donations of services or property that raise the specter of conflict of interest or have the appearance of injecting bias into the work of the Commission.
- 7) APPOINTMENTS AND HIRING: The Commission shall be organized as follows:

- a) The Governor shall appoint the Chair;
 - b) The Chair shall appoint the co-Chair;
 - c) The Chair shall hire an Executive Director and General Counsel;
 - d) The Executive Director, with the approval of the Commission, shall hire staff; and
 - e) Staff positions and salary shall, to the extent feasible, comport with state personnel rules and requirements. Exceptions can be made for necessary positions that have no equivalent to state government schedules in terms of expertise or function.
- 8) COMPENSATION:
- a) Commissioners and Board Members will be paid a per diem and travel reimbursement consistent with the State Administrative Procedures Act
 - b) Staff will be paid based on State Office of Personnel policies except as described in (6).

Contact Us

States interested in this model legislation will have access to a legislator's guide and additional background materials as they become available. If you have questions about the model act or are interested in technical assistance please contact Jennifer Reck (jreck@nashp.org).

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