HOUSE DOCKET, NO. 2969 FILED ON: 1/18/2019

HOUSE . . . . . No. 1193

The Commonwealth of Massachusetts

PRESENTED BY:

Lindsay N. Sabadosa

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act providing for the establishment of a drug cost review commission.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Lindsay N. Sabadosa	*1st Hampshire*	*1/15/2019*
Nika C. Elugardo	*15th Suffolk*	*1/18/2019*
Tami L. Gouveia	*14th Middlesex*	*2/1/2019*
David Henry Argosky LeBoeuf	*17th Worcester*	*1/31/2019*
Maria Duaime Robinson	*6th Middlesex*	*1/21/2019*

HOUSE DOCKET, NO. 2969 FILED ON: 1/18/2019

HOUSE . . . . . No. 1193

By Ms. Sabadosa of Northampton, a petition (accompanied by bill, House, No. 1193) of Lindsay N. Sabadosa and others relative to providing for the establishment of a drug cost review commission. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

An Act providing for the establishment of a drug cost review commission.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

The General Laws are hereby amended by adding the following chapter:

Chapter 6E. Drug Cost Review Commission

SECTION 1: Definitions

(a) "Advisory Board", the drug cost review advisory board.

(b) "Commission", the health policy commission established in chapter 6D and the drug cost review commission established in chapter 6E.

(c) "Excess Cost:", cost of appropriate utilization of a prescription drug product that are not sustainable to public and private health care systems over a 10-year time frame.

SECTION 2: Drug cost review commission; governing board; members

(a) There shall be established within the executive office for administration and finance, but not under its control, a state agency known as the drug cost review commission. The commission shall be an independent public entity not subject to the supervision and control of any other executive office, department, commission, board, bureau, agency or political subdivision. The commission shall protect state residents, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from excessive cost of prescription drugs.

(b) The commission shall meet in open session at least every six weeks to review prescription drug product information submissions, provided, however, that the Chair may cancel or postpone a meeting if there are no prescription drug product submissions to review.

(c) The commission may meet in closed session but decisions of the commission shall be made in open session.

(d) The commission shall provide public notice at least two weeks in advance of every meeting. The commission shall make written materials for each commission meeting available to the public at least one week in advance of the meeting.

(e) The commission shall provide an opportunity for public comment at each open meeting of the commission, and the commission shall provide the public with the opportunity to provide written comments on pending decisions of the commission.

(f) The commission may allow expert testimony at Commission meetings, including when the Commission meets in closed session.

(g) the following actions by the Commission shall be made in open session:

(1) deliberations on whether to subject a prescription drug to a full cost review;

(2) any review of a prescription drug cost analysis; and

(3) any vote on whether to impose a cost or payment limits on payors for a prescription drug product.

(h) There shall be a board, with duties and powers established by this chapter, which shall govern the commission. The board shall consist of 7 members who have expertise in health care economics or clinical medicines: 1 of whom shall be appointed by the governor; 2 of whom shall be appointed by the State Treasurer; 1 of whom shall be appointed by the President of the Senate; 1 of whom shall be appointed by the Speaker of the House; and 2 of whom shall be appointed by the Attorney General. All appointments after the initial term of appointment shall serve a term of 5 years, but a person appointed to fill a vacancy shall serve only for the unexpired term. An appointed member of the board shall be eligible for reappointment; however, no appointed member shall hold full or part-time employment in the executive branch of state government. The board shall annually elect 1 of its members to serve as vice-chairperson. Each member of the board shall be a resident of the commonwealth.

The person appointed by the Attorney General to serve as chairperson shall have expertise in health care economics, clinical medicine, and health care finance and administration, including payment methodologies. The initial appointment of the chairperson shall be for a term of 3 years.

(1) Four members of the board shall constitute a quorum, and the affirmative vote of 4 members of the board shall be necessary and sufficient for any action taken by the board. No vacancy in the membership of the board shall impair the right of a quorum to exercise all the

rights and duties of the commission. Members shall serve without pay, but shall be reimbursed for actual expenses necessarily incurred in the performance of their duties. A member of the board shall not be employed by, a consultant to, a member of the board of directors of, affiliated with, have a financial stake in or otherwise be a representative of a pharmaceutical entity while serving on the board.

(j) Any action taken by the commission may take effect immediately and need not be published or posted unless otherwise provided by law. Meetings of the commission shall be subject to sections 18 to 25, inclusive, of chapter 30A. The commission shall be subject to all other provisions of said chapter 30A, and records pertaining to the administration of the commission shall be subject to section 42 of chapter 30 and section 10 of chapter 66. All moneys of the commission shall be considered to be public funds for purposes of chapter 12A. Except as otherwise provided in this section, the operations of the commission shall be subject to chapter 268A and chapter 268B.

The commission shall not be required to obtain the approval of any other officer or employee of any executive agency in connection with the collection or analysis of any information; nor shall the commission be required, prior to publication, to obtain the approval of any other officer or employee of any executive agency with respect to the substance of any reports which the commission has prepared under this chapter.

(k) The board shall appoint an executive director by a majority vote. The executive director shall supervise the administrative affairs and general management and operations of the commission and also serve as secretary of the commission, ex officio. The executive director shall receive a salary commensurate with the duties of the office. The executive director may

appoint other officers and employees of the commission necessary to the functioning of the commission.

The executive director shall not be required to obtain the approval of any other executive agency in connection with appointment of employees. Sections 9A, 45, 46 and 46C of chapter 30, chapter 31 and chapter 150E shall not apply to the executive director of the commission. Sections 45, 46 and 46C of chapter 30 shall not apply to any employee of the commission. The executive director may establish personnel regulations for the officers and employees of the commission.

The executive director shall file an annual personnel report not later than the first Wednesday in February with the senate and house committees on ways and means containing the job classifications, duties and salary of each officer and employee within the center together with personnel regulations applicable to said officers and employees. The executive director shall file amendments to such report with the senate and house committees on ways and means whenever any changes become effective.

The executive director shall, with the approval of the board:

(1) plan, direct, coordinate and execute administrative functions in conformity with the policies and directives of the board;

(2) employ professional and clerical staff as necessary;

(3) report to the board on all operations under their control and supervision;

(4) prepare an annual budget and manage the administrative expenses of the commission; and

(5) undertake any other activities necessary to implement the powers and duties under this chapter.

The board may approve the use of funds from the Healthcare Payment Reform Fund to support the annual budget of the commission, in addition to funds from any other source and any funds appropriated therefor by the general court. The commission shall not be required to obtain the approval of any other executive agency in connection with the development and administration of its annual budget.

(l) Chapter 268A shall apply to all board members, except that the commission may purchase from, sell to, borrow from, contract with or otherwise deal with any organization in which any board member is in anyway interested or involved; provided, however, that such interest or involvement shall be disclosed in advance to the board and recorded in the minutes of the proceedings of the board; and provided further, that no member shall be deemed to have violated section 4 of said chapter 268A because of such member's receipt of such member's usual and regular compensation from such member's employer during the time in which the member participates in the activities of the board.

(m) The executive director shall appoint and may remove such agents and subordinate officers as the executive director may consider necessary and may establish such subdivisions within the commission as the executive director considers appropriate to fulfill the purposes under this chapter,.

The commission shall adopt and amend rules and regulations, under chapter 30A, for the administration of its duties and powers and to effectuate this chapter.

SECTION 3: Board's power and duties

For the purposes of this chapter, the board shall be authorized and empowered as follows:

(a) to develop a plan of operation for the commission. The plan of operation shall include, but not be limited to:

(1) implementation of procedures for operations of the commission; and

(2) implementation of procedures for communications with the executive director;

(b) to make, amend and repeal rules and regulations for the management of its affairs;

(c) to make contracts and execute all instruments necessary or convenient for the carrying on of its business;

(d) to acquire, own, hold, dispose of and encumber personal property and to lease real property in the exercise of its powers and the performance of its duties;

(e) to seek and receive any grant funding from the federal government, departments or agencies of the commonwealth, and private foundations;

(f) to enter into and execute instruments in connection with agreements or transactions with any federal, state or municipal agency or other public institution or with any private individual, partnership, firm, corporation, association or other entity, including contracts with professional service firms as may be necessary in its judgment, and to fix their compensation;

(g) to maintain a prudent level of reserve funds to protect the solvency of any trust funds under the operation and control of the commission;

(h) to enter into interdepartmental agreements with any other state agencies the board considers necessary to implement this chapter.

(i) to adopt an official seal and alter the same;

(j) to sue and be sued in its own name, plead and be impleaded;

(k) to establish lines of credit, and establish 1 or more cash and investment accounts to receive payments for services rendered, appropriations from the commonwealth and for all other business activity granted by this chapter except to the extent otherwise limited by any applicable provision of the Employee Retirement Income Security Act of 1974; and

(l) to approve the use of its trademarks, brand names, seals, logos and similar instruments by participating carriers, employers or organizations.

SECTION 4: Drug cost review advisory council

There shall be a drug cost review advisory council to the commission. The council shall serve to provide stakeholder input to assist the Commission in performing its duties.

(a) The council shall consist of the following members:

(1) two members who represent patients and health care consumers;

(2) two members who represent physicians and providers;

(3) three members who represent commercial payors, government employee benefit plans, or large employer plans;

(4) one member who represents pharmaceutical manufacturers;

(5) one health services researcher;

(6) one clinical researcher;

(7) one pharmacologist; and

(8) one representative from the Massachusetts Budget and Policy Office.

(b) The members of the advisory council shall have knowledge of one or more of the following:

(1) the pharmaceutical business model;

(2) the practice of medicine or clinical training;

(3) patient perspectives;

(4) health care cost trends and drivers;

(5) clinical and health services research; or

(6) the state's health care marketplace.

(c) The advisory council shall consist of 4 members who have expertise in health care economics or clinical medicines: 1 of whom shall be appointed by the governor; 1 of whom shall be appointed by the Attorney General; 1 of whom shall be appointed by the President of the Senate; and 1 of whom shall be appointed by the Speaker of the House. All appointments after the initial term of appointment shall serve a term of 2 years, but a person appointed to fill a vacancy shall serve only for the unexpired term. An appointed member of the board shall be eligible for reappointment; however, no appointed member shall hold full or part-time employment in the executive branch of state government. The chair and co-chair shall be elected by the members of the advisory board, and each member of the board shall be a resident of the commonwealth.

(d) Members shall serve without pay, but shall be reimbursed for actual expenses necessarily incurred in the performance of their duties. A member of the board shall not be employed by, a consultant to, a member of the board of directors of, affiliated with, have a financial stake in or otherwise be a representative of a pharmaceutical entity while serving on the board.

(e) Any potential conflict of interest, including whether the individual has an association, including a financial or personal association that has the potential to bias or has the appearance of biasing an individual's decisions in matters related to the commission or the conduct of the commission's activities shall be considered and disclosed when making appointments to the advisory council.

SECTION 5: Reporting requirements for patent-protected brand-name drug or biological manufacturers

The drug cost review commission shall be notified by a manufacturer of a patent-protected, brand-name drug or biological:

(1) if the wholesale acquisition cost of the drug is increasing by more than 10% or by more than $10,000 during any 12-month period; or

(2) if the manufacturer intends to introduce to market a brand-name drug that has a wholesale acquisition cost of $30,000 per calendar year or per course of treatment.

(a) The notice provided by the manufacturer under letter (a) of Section 5 shall:

(1) be provided in writing at least 30 days before the planned effective date of the increase or the introduction of the drug to market; and

(2) include a justification for the proposed pricing that includes any documents and research related to the manufacturer's selection of the introductory price or price increase, including life-cycle management, net average price to the state, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the product, if available.

(b) The commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of brand prescription drugs, including biologics and biosimilars. The reporting threshold established by the commission under point 1 under letter a of Section 5 shall apply to brand name prescription drugs that are not reported under letter (a) of this section but that impose costs on the State Health Care system that create significant challenges to affordability.

(c) A manufacturer of a generic or off-patent sole source brand product drug shall notify the commission if the manufacturer is increasing the wholesale acquisition cost of the drug by more than 25% or more than $300 during any 12-month period. The notice provided by the manufacturer shall be provided in writing at least 30 days before the planned effective date of the increase or the introduction of the drug to market and must include a justification for the proposed pricing that includes any documents and research related to the manufacturer's selection of the price increase, including life-cycle management, net average price to the state, market competition, and context, projected revenue, and the estimated value or cost effectiveness of the product if available.

(d) The commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of generic and off-patent sole source branded prescription drugs. The reporting threshold established by the commission shall apply to generic and off-

patent sole source branded prescription drugs that are not reported in this section but that impose costs on the State Health Care System that create significant challenges to affordability.

(e) To the extent feasible and practicable, the commission shall access manufacturer justification information made public by other states. If the manufacturer justification information is not available from other state sources, the commission shall require a manufacturer to submit to the commission any documents and research related to the manufacturer's selection of the introductory price or price increase, including life-cycle management, net average price in the state, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the product, if available.

(f) The commission shall inform the public about the reports provided under this section. The commission shall allow the public to request commission review of the cost of any prescription drug reported under this section.

(g) The chair of the commission shall review any public request made under letter g of this section to determine whether to review the cost of the prescription drug. The chair may initiate a review of the cost of a prescription drug reported under this section in the absence of a public request. If there is no consensus among the members of the commission on a decision by the chair whether to review a prescription drug, the members of the commission may request a vote on whether to review the prescription drug.

(h) If the commission conducts a review of the cost a prescription drug, the review shall determine if a utilization of the drug that is fully consistent with the Federal Food and Drug Administration label has led or will lead to excess cost for health care systems in the state. The commission may consider the following factors in determining cost and excess cost:

(1) the price at which the prescription drug has been or will be sold in the state;

(2) the average monetary price concession, discount, or 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, expressed as a percentage of the wholesale acquisition cost for the prescription drug under review;

(3) the total amount of the concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager operating in the state for the prescription drug under review, expressed as a percentage of the wholesale acquisition cost;

(4) the price at which therapeutic alternatives have been or will be sold in the state;

(5) the average monetary price concession, discount, or rebate the manufacturer provides to health plan payors in the state or is expected to provide to payors in the state for therapeutic alternatives;

(6) the cost to payors based on patient access consistent with the Federal Food and Drug Administration labeled indications;

(7) the impact of patient access resulting from the cost of the product relative to insurance benefit design;

(8) the current or expected dollar value of drug-specific patient access programs that are supported by manufacturers;

(9) the relative financial impacts to health, medical, or other social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives; and

(10) any other factors as determined by the commission in regulations adopted by the commission.

(i) If the commission is unable to determine whether a prescription drug product will produce or has produced excess costs using the factors listed in letter (i) of this section, the commission may consider the following factors:

(1) manufacturer research and development costs, as indicated on the manufacturer's federal tax filing for the most recent tax year in proportion to the manufacturer's sales in the state;

(2) the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year, that are specific to the prescription drug product under review and are multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the product under review;

(3) gross and net manufacturer revenues for the most recent tax year;

(4) any additional factors proposed by the manufacturer that the commission considers relevant; and

(5) any additional factors as established by the commission in regulations.

(j) If the Commission finds that the spending on a prescription drug product reviewed under this section creates excess costs for payors and consumers, the commission shall establish the level of reimbursement that shall be billed and paid among:

(1) payors and pharmacies or administering providers;

(2) wholesalers and distributors and pharmacies or administering providers; and

(3) pharmacies or administering providers and uninsured consumers or consumers in a deductible period.

(k) The commission shall determine how each participant in the supply chain of the prescription drug shall be remunerated.

(l) Any submission made to the commission related to a drug cost review shall be made available to the public with the exception of information determined by the commission to be proprietary.

(m) The commission, after public notice and comment, shall establish the standards for the information to be considered proprietary under this section including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the Federal Food and Drug Administration.

SECTION 6: Cases of non-compliance

The non-compliance of an entity to bill or pay the reimbursement rates established by the commission under this chapter shall be referred to the Office of the Attorney General.

(a) It may be considered non-compliance if an entity obtains price concessions from a manufacturer that result in the insurer's net cost being lower than the rate established by the commission.

(b) If the Office of the Attorney General finds that an entity was non-compliant with the commission reimbursement requirements, the Office of the Attorney General may pursue

remedies consistent with state law or other appropriate criminal laws if there is evidence of intentional profiteering.

(c) The Office of the Attorney General shall provide guidance to stakeholders concerning activities that could be considered non-compliant that are in addition to billing and payment where drug costs exceed the rates established by the commission.

(d) Failure by the manufacturer to notify the commission as required under this chapter shall be referred to the Office of the Attorney General.

(e) The Office of the Attorney General may pursue any available remedy under state law when enforcing this subtitle.

SECTION 7: Appeals

A person aggrieved by a decision of the commission may request an appeal of the decision within 30 days after the finding of the commission.

(a) The commission shall hear the appeal and make a final decision within 60 days of the hearing.

(b) Any person aggrieved by a final decision of the commission may take a direct judicial appeal.

SECTION 8: Annual reports

The commission shall make available an annual report to the public on:

(a) prescription drug price trends;

(b) the number of manufacturers required to notify the commission about drug pricing as required under this chapter; and

(c) the number of products that were subject to commission review, including the results of the review and the number and disposition of appeals and judicial reviews of commission decisions.