HOUSE DOCKET, NO. 3249 FILED ON: 1/18/2019

HOUSE . . . . . No. 1178

The Commonwealth of Massachusetts

PRESENTED BY:

Ronald Mariano

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 relative to promoting transparency in the pharmaceutical industry.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Ronald Mariano	*3rd Norfolk*

HOUSE DOCKET, NO. 3249 FILED ON: 1/18/2019

HOUSE . . . . . No. 1178

By Mr. Mariano of Quincy, a petition (accompanied by bill, House, No. 1178) of Ronald Mariano for legislation to promote transparency in the pharmaceutical industry and to establish a prescription drug academic detailing program to enhance the health of residents of the Commonwealth. Health Care Financing.

The Commonwealth of Massachusetts

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

An Act relative to promoting transparency in the pharmaceutical industry.

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

SECTION 1. Section 1 of chapter 6D, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Disproportionate share hospital" the following definition:-

"Early notice", advanced notification by a pharmaceutical manufacturing company of a new drug, device or other development coming to market.

SECTION 2. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of "Performance penalty" the following 3 definitions:-

"Pharmaceutical manufacturing company", any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity

engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided however, that "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered pursuant to section 38 of said chapter 112.

"Pharmacy benefit manager", any person, business or entity, however organized, that administers, either directly or through its subsidiaries, pharmacy benefit services for prescription drugs and devices on behalf of health benefit plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions.

"Pharmacy benefit services" shall include, but not be limited to: formulary administration; drug benefit design; pharmacy network contracting; pharmacy claims processing; mail and specialty drug pharmacy services; and cost containment, clinical, safety, adherence programs for pharmacy services. For the purposes of the chapter, a health benefit plan that does not contract with a pharmacy benefit manager shall be a pharmacy benefit manager.

SECTION 3. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of "Physician" the following definition:-

"Pipeline drugs", prescription drug products containing a new molecular entity for which the sponsor has submitted a new drug application or biologics license application and received an action date from the federal Food and Drug Administration.

SECTION 4. Section 4 of said chapter 6D, as so appearing, is hereby amended by striking out, in lines 6 and 7, the word "manufacturers" and inserting in place thereof the following words:- manufacturing companies, pharmacy benefit managers.

SECTION 5. Section 6 of said chapter 6D, as so appearing, is hereby amended by adding the following paragraph:-

If the analysis of spending trends with respect to the pharmaceutical or biopharmaceutical products increases the expenses of the commission, the estimated increases in the commission's expenses shall be assessed fully to pharmaceutical manufacturing companies and pharmacy benefit managers in the same manner as the assessment pursuant to section 68 of chapter 118E. A pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and administers its own prescription drug, prescription device or pharmacist services or prescription drug and device and pharmacist services portion shall not be subject to additional assessment under this paragraph.

SECTION 6. Section 8 of said chapter 6D, as so appearing, is hereby amended by inserting after the word "organization" , in lines 6 and 7, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 7. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word "organizations", in line 14, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 8. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in lines 32 and 33 , the words "and (xi) any witness identified by the attorney general or the center" and inserting in place thereof the following words:- (xi) 2 pharmacy benefit managers; (xii) 3 pharmaceutical manufacturing companies, 1 of which shall be representative of a publicly traded company that manufactures specialty drugs, 1 of which shall be representative of and doing business in generic drug manufacturing and 1 of which shall

have been in existence for fewer than 10 years; and (xiii) any witness identified by the attorney general or the center.

SECTION 9. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 48, the first time it appears, the word “and”.

SECTION 10. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “commission”, in line 59, the first time it appears, the following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical manufacturing companies, testimony that is suitable for public release and that is not likely to compromise the financial, competitive or proprietary nature of any information and data concerning factors underlying prescription drug costs and price increases; the impact of aggregate manufacturer rebates, discounts and other price concessions on net pricing; and any other matters as determined by the commission. No pharmaceutical manufacturing company identified as a witness under this section, or any testimony by any such company, shall be subject to the provisions of section 17 of chapter 12C.

SECTION 11. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:- The report shall be based on the commission's analysis of information provided at the hearings by witnesses, providers, provider organizations, insurers, pharmaceutical manufacturing companies and pharmacy benefit managers, registration data collected pursuant to section 11, data collected or analyzed by the center pursuant to sections 8, 9, 10,10A and 10B of chapter 12C and any other available information that the commission considers necessary to fulfill its duties in this section, as defined in regulations promulgated by the commission.

SECTION 12. Section 9 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization”, in line 72, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 13. Said chapter 6D is hereby further amended by adding the following 2 sections:-

Section 20. (a) For the purposes of this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

“Academic detailing”, the provision of information regarding prescription drugs based on scientific and medical research, including information on therapeutic and cost-effective use of prescription drugs.

“Dispenser” means any person or entity licensed to dispense prescription drugs pursuant to the General Laws.

“PCORI”, patient-centered outcomes research institute

“Prescriber”, a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

“Program”, an academic detailing program designed and implemented pursuant to this section.

(b) On or before July 1, 2020, the commission shall establish a prescription drug academic detailing program to enhance the health of residents of the commonwealth, improve the quality of decisions regarding drug prescribing, encourage better communication between the commission and health care providers participating in publicly funded health programs and

reduce the health complications and unnecessary costs associated with inappropriate drug prescribing.

(c) The commission shall design the program after consultation with prescribers and dispensers of drugs, private insurers offering prescription drug coverage, hospitals, pharmacy benefit managers, consumers and the MassHealth drug utilization review board. The program, as well as any affiliated organizations, shall be required to use transparent procedures for development of assessments, summaries and decision-support tools that describe the methods used. Such methods shall be consistent with best practices for academic detailing and systematic evidence reviews. Any organization referenced or research conducted shall align with the patient-centered outcomes research institute's standards for patient-centeredness in health outcomes research. There shall be opportunity for input from clinical experts and patients in research process and development of materials. In view of the widely recognized limitations of cost-effectiveness research, the academic detailing program shall not conduct research or communicate information in ways that discriminate against or otherwise disadvantage vulnerable populations, including populations with health disparities, or individuals with special health needs. In planning for the design of the prescription drug academic detailing program, the commission shall review and evaluate use of the educational and assessment materials developed by (i) the University of Massachusetts medical school, (ii) PCORI, (iii) Pennsylvania PACE/Harvard University Independent Drug Information Service, and (iv) the North Carolina evidence-based peer-to-peer education program outreach program.

(d) The program components shall include outreach and education regarding the therapeutic and cost-effective use of prescription drugs as issued in peer-reviewed scientific, medical and academic research publications and made available to prescribers and dispensers of

drugs in the commonwealth, including through written information and through personal visits from program staff. To the extent possible, program components shall also include information regarding clinical trials, pharmaceutical efficacy, adverse effects of drugs, evidence-based treatment options and drug marketing approaches that are intended to circumvent competition from generic and therapeutically equivalent drugs. Academic detailers shall observe standards of conduct in their educational materials and written and oral presentations as established by rules adopted by the commission that are consistent with the following federal regulations regarding labeling and false and misleading advertising: (i) the Food and Drug Administration labeling requirements of 21 CFR, Part 201, prescription drug advertising provisions of 21 CFR, Part 202 and related guidance; and (ii) the Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended. The commission's rules shall require academic detailers to disclose evidence-based information about the range and cost of appropriate drug treatment options and the health benefits and risks of all appropriate drugs.

(e) The program shall provide outreach and education to prescribers and dispensers who participate in, contract with or are reimbursed health care programs funded by the commonwealth, including but not limited to, those programs for which the group insurance commission purchases health insurance pursuant to section 4 of chapter 32A. The program may provide outreach and education to private insurers offering prescription drug coverage, hospitals, employers and other persons interested in the program on a subscription or fee-paying basis pursuant to rules adopted by the commission.

(f) On or before April 1st each year, the commission shall provide the governor with an annual report on the operation of the program. The report shall include information regarding: (i) the outreach and education components of the program; (ii) revenues, expenditures and balances;

and (iii) savings attributable to the program in health care programs funded by the commonwealth. During the first 2 annual reports to the governor, the commission shall also include discussion regarding its review and evaluation of the use of the educational and assessment materials developed by educational institutions pursuant to subsection (c).

(g) The commission shall undertake a public education initiative to inform residents of the commonwealth about clinical trials and drug safety information.

(h) The commission may seek funding from nongovernmental health access foundations and undesignated drug litigation settlement funds associated with pharmaceutical marketing and pricing practices and any unused funds collected under the annual disclosure report fee promulgated by the executive office pursuant to chapter 111N. The commission may also develop a subscription fee through which any interested party in the commonwealth may voluntarily purchase a subscription to the program.

Section 21. (a) In the course of its duties the commission may contract with a third-party entity, such as an accounting firm, to conduct an annual study of pharmaceutical or biopharmaceutical companies with pipeline drugs, generic drugs or biosimilar drugs that may have a significant impact on state health care expenditures.

(b) For purposes of this section, early notice shall be provided for the following:

(1) Pipeline drugs; and

(2) All biosimilar biologics license applications (BLA), upon the receipt of an action date from the FDA. (c) In connection with the annual study, the applicant for a pipeline brand or biosimilar shall provide the commission or the contracted third-party entity with a brief

description of the following for each drug, using data fields consistent with those employed by the United States National Institutes of Health in clinicaltrials.gov, if applicable:

(1) The primary disease, health condition or therapeutic area being studied and the indication;

(2) The routes of administration being studied;

(3) Clinical trial comparators, if applicable; and

(4) Estimated year of market entry.

(d) As part of such submission, manufacturers shall also report the receipt of any of the following designations from the FDA for each pipeline drug:

(1) Orphan Drug;

(2) Fast Track;

(3) Breakthrough Therapy;

(4) Accelerated Approval; or

(5) Priority Review for New Molecular Entities NMEs.

(e) The data submissions required by this section shall be submitted to the commission or the contracted third-party entity no later than 60 days after receipt of the FDA action date, provided, however, that for drugs in development that receive any of the FDA designations listed in subsection (d) for NMEs, such submissions shall be provided as soon as practical upon receipt of the relevant designation.

(f) Any study conducted pursuant to this section shall be funded by annual registration fees and any other assessments that accompany the annual marketing disclosure reports required pursuant to chapter 111N.

(g) Notwithstanding any general or special law to the contrary, information provided pursuant to this section shall be protected as confidential and shall not be a public record pursuant to clause Twenty-sixth of section 7 of chapter 4 or chapter 66.

SECTION 14. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby amended by striking out subsection (a) and inserting in place thereof the following subsection:-

(a) The attorney general shall monitor trends in the health care market including, but not limited to, trends in provider organization size and composition, consolidation in the provider market, payer contracting trends, patient access and quality issues in the health care market and prescription drug cost and price trends. The attorney general may obtain the following information from a private health care payer, public health care payer, pharmacy benefit manager, provider or provider organization, as any of those terms may be defined in section 1 of chapter 6D: (i) any information that is required to be submitted pursuant to sections 8, 9, 10 and 10B of chapter 12C; (ii) filings, applications and supporting documentation related to any cost and market impact review pursuant to section 13 of said chapter 6D; (iii) filings, applications and supporting documentation related to a determination of need application filed pursuant to section 25C of chapter 111; and (iv) filings, applications and supporting documentation submitted to the federal Centers for Medicare and Medicaid Services or the Office of the Inspector General for any demonstration project. Pursuant to section 8 of said chapter 6D and section 17 of said chapter 12C, and subject to the limitations in said sections, the attorney general may require that

any provider, provider organization, pharmacy benefit manager, private health care payer or public health care payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, the factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates.

SECTION 15. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby amended by inserting after the definition of “Patient-centered medical home” the following 4 definitions:-

“Pharmaceutical manufacturing company”, any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided however, that “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered pursuant to section 38 of said chapter 112.

“Pharmacy benefit manager”, any person, business, or entity, however organized, that administers, either directly or through its subsidiaries, pharmacy benefit services for prescription drugs and devices on behalf of health benefit plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions;

“Pharmacy benefit services” shall include, but not be limited to, formulary administration; drug benefit design; pharmacy network contracting; pharmacy claims processing;

mail and specialty drug pharmacy services; and cost containment, clinical, safety, and adherence programs for pharmacy services. For the purposes of this section, a health benefit plan that does not contract with a pharmacy benefit manager shall be a pharmacy benefit manager, unless specifically exempted.

"Pipeline drug", a prescription drug product containing a new molecular entity for which the sponsor has submitted a new drug application or biologics license application and received an action date from the federal Food and Drug Administration.

SECTION 16. Said section 1 of said chapter said 12C, as so appearing, is hereby further amended by adding the following definition:-

"Wholesale acquisition cost", the cost of a prescription drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B).

SECTION 17. Section 3 of said chapter 12C, as so appearing, is hereby amended by inserting after the word "organizations", in lines 13 and 14, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 18. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 24, the words "and payer" and inserting in place thereof the following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit manager.

SECTION 19. Section 5 of said chapter 12C, as so appearing, is hereby amended by inserting after the word "organizations", in line 11, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 20. Said section 5 of said chapter 12C, as so appearing, is hereby further amended by inserting after the word “providers”, in line 15, the following words:- , affected pharmaceutical manufacturing companies, affected pharmacy benefit managers.

SECTION 21. Section 7 of said chapter 12C, as so appearing, is hereby further amended by adding the following paragraph:-

To the extent that the analysis and reporting activities pursuant to sections 10A or 10B increases the expenses of the center, the estimated increase in the center’s expenses shall be fully assessed to pharmaceutical manufacturing companies and pharmacy benefit managers in the same manner as the assessment pursuant to section 68 of chapter 118E.

SECTION 22. Said chapter 12C is hereby further amended by inserting after section 10 the following 2 sections:-

Section 10A. (a) On or before March 1, 2022, and annually thereafter, the center shall prepare a list of not more than ten outpatient prescription drugs that the center determines account for a significant share of state health care spending, considering the net cost of such drugs in the immediately preceding calendar year. The list shall include outpatient prescription drugs from different therapeutic classes and no more than three generic outpatient prescription drugs. The center shall not list any outpatient prescription drug pursuant to this subsection unless the wholesale acquisition cost of the prescription drug, less all rebates paid to the commonwealth for such drug during the immediately preceding calendar year, increased by not less than 25 per cent during the immediately preceding calendar year.

(b) The pharmaceutical manufacturing company that manufacturers a prescription drug included on a list prepared by the center pursuant to subsection (a) shall provide to the center the

following: (i) a written, narrative description, suitable for public release, of factors that caused the increase in the wholesale acquisition cost of the listed prescription drug; and (ii) aggregate, company-level research and development costs and such other capital expenditures that the center deems relevant for the most recent year for which final audited data is available.

(c) The quality and types of information and data that a pharmaceutical manufacturing company submits to the center pursuant to this section shall be consistent with the quality and types of information and data that the pharmaceutical manufacturing company includes in: (i) such pharmaceutical manufacturing company's annual consolidated report on Securities and Exchange Commission Form 10-K or (ii) any other public disclosure.

(d) The center shall consult with pharmaceutical manufacturing companies to establish a single, standardized form for reporting information and data pursuant to this section. The form shall minimize the administrative burden and cost imposed on the center and pharmaceutical manufacturing companies.

(e) The center shall compile an annual report based on the information that the center receives pursuant to subsection (b). The center shall post such report and the information described in this subsection on the center's website on or before October 1 of each year.

(f) Except as otherwise provided in this section, information and data submitted to the center pursuant to this section shall not be a public record and shall be exempt from disclosure pursuant to clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66. No such information and data shall be disclosed in a manner that may compromise the financial, competitive or proprietary nature of such information and data, or that would have enable a third party to identify an individual drug, therapeutic class of drugs or pharmaceutical manufacturing

company the prices charged for any particular drug or therapeutic class of drugs, or the value of any rebate or discount provided for any particular drug or class of drugs.

Section 10B. The center shall promulgate regulations necessary to ensure the uniform analysis of information regarding pharmacy benefit managers that enables the center to analyze: (1) year-over-year wholesale acquisition cost changes; (2) year-over-year trends in formulary, maximum allowable costs list and cost-sharing design, including the establishment and management of specialty product lists; (3) aggregate information regarding discounts, utilizations limits, rebates, manufacturer administrative fees and other financial incentives or concessions related to pharmaceutical products or formulary programs; (4) information regarding the aggregate amount of payments made to pharmacies owned or controlled by the pharmacy benefit managers and the aggregate amount of payments made to pharmacies that are not owned or controlled by the pharmacy benefit managers; and (5) additional information deemed reasonable and necessary by the center as set forth in the center's regulations.

SECTION 23. Section 11 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:-

The center shall ensure the timely reporting of information required pursuant to sections 8, 9, 10, 10A, and 10B.

SECTION 24. Said section 11 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 11, the figure "$1,000" and inserting in place thereof the following figure:- $5,000.

SECTION 25. Said section 11 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 16, the figure “$50,000” and inserting in place thereof the following figure:- $200,000.

SECTION 26. Section 12 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 2, the words “9, and 10” and inserting in place thereof the following words:- 9, 10, 10A and 10B.

SECTION 27. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- The center shall publish an annual report based on the information submitted pursuant to sections 8, 9, 10, 10A and 10B concerning health care provider, provider organization, pharmaceutical manufacturing company, pharmacy benefit manager and private and public health care payer costs and cost and price trends, pursuant to section 13 of chapter 6D relative to market impact reviews and pursuant to section 15 relative to quality data.

SECTION 28. Chapter 94C of the General Laws is hereby amended by inserting after section 21B the following section:-

Section 21C. (a) For the purposes of this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

“Cost sharing”, amounts owed by a consumer under the terms of the consumer’s health benefit plan as defined in section 1 of chapter 176O or as required by a pharmacy benefit manager as defined in section 1 of chapter 6D.

"Pharmacy retail price", the amount an individual would pay for a prescription medication at a pharmacy if the individual purchased that prescription medication at that pharmacy without using a health benefit plan as defined in section 1 of chapter 176O or any other prescription medication benefit or discount.

"Registered pharmacist", a pharmacist who holds a valid certificate of registration issued by the board of registration in pharmacy pursuant to section 24 of chapter 112.

(b) A pharmacy shall post a notice informing consumers that a consumer may request, at the point of sale, the current pharmacy retail price for each prescription medication the consumer intends to purchase. If the consumer's cost-sharing amount for a prescription medication exceeds the current pharmacy retail price, the pharmacist, or an authorized individual at the direction of a pharmacist, shall notify the consumer that the pharmacy retail price is less than the patient's cost-sharing amount. The pharmacist shall charge the consumer the applicable cost-sharing amount or the current pharmacy retail price for that prescription medication, as directed by the consumer.

A pharmacist shall not be subject to a penalty by the board of registration in pharmacy or a third party for failure to comply with this section.

(c) A contractual obligation shall not prohibit a pharmacist from complying with this section; provided however, that a pharmacist shall submit a claim to the consumer's health benefit plan or its pharmacy benefit manager if the pharmacist has knowledge that the prescription medication is covered under the consumer's health benefit plan.

(d) Failure to post notice pursuant to subsection (b) shall be an unfair or deceptive act of practice under chapter 93A.

SECTION 29. Section 4N of said chapter 111 is hereby repealed.

SECTION 30. Chapter 176O of the General Laws is hereby amended by adding the following new section:-

Section 28. (a) As used in this section, the term “pharmacy benefit manager” shall mean any person, business, or entity, however organized, that administers, either directly or through subsidiaries, pharmacy benefit services for prescription drugs and devices on behalf of health benefit plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions; provided however, that “pharmacy benefit services” shall include, but not be limited to, formulary administration; drug benefit design; pharmacy network contracting; pharmacy claims processing; mail and specialty drug pharmacy services; and cost containment, clinical, safety and adherence programs for pharmacy services. A health benefit plan that does not contract with a pharmacy benefit manager shall be considered a pharmacy benefit manager for the purposes of this section.