HOUSE DOCKET, NO. 3067 FILED ON: 1/18/2019

HOUSE . . . . . No. 1154

The Commonwealth of Massachusetts

PRESENTED BY:

Carmine Lawrence Gentile

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 to reduce drug costs through transparency.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Carmine Lawrence Gentile	*13th Middlesex*	*1/17/2019*
Christine P. Barber	*34th Middlesex*	*1/25/2019*
Nika C. Elugardo	*15th Suffolk*	*1/30/2019*
Tricia Farley-Bouvier	*3rd Berkshire*	*1/23/2019*
Carole A. Fiola	*6th Bristol*	*1/31/2019*
Carlos González	*10th Hampden*	*2/1/2019*
Richard M. Haggerty	*30th Middlesex*	*2/1/2019*
James K. Hawkins	*2nd Bristol*	*1/29/2019*
Stephan Hay	*3rd Worcester*	*1/24/2019*
Louis L. Kafka	*8th Norfolk*	*1/28/2019*
David Henry Argosky LeBoeuf	*17th Worcester*	*1/23/2019*
Michael O. Moore	*Second Worcester*	*2/1/2019*
James M. Murphy	*4th Norfolk*	*2/1/2019*
Patrick M. O'Connor	*Plymouth and Norfolk*	*2/1/2019*
Rebecca L. Rausch	*Norfolk, Bristol and Middlesex*	*1/30/2019*
Maria Duaime Robinson	*6th Middlesex*	*1/21/2019*
John H. Rogers	*12th Norfolk*	*2/1/2019*
Theodore C. Speliotis	*13th Essex*	*1/31/2019*

Bruce E. Tarr	*First Essex and Middlesex*	*1/31/2019*
José F. Tosado	*9th Hampden*	*1/28/2019*

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HOUSE . . . . . No. 1154

By Mr. Gentile of Sudbury, a petition (accompanied by bill, House, No. 1154) of Carmine Lawrence Gentile and others relative to pharmacy benefit managers and pharmaceutical manufacturing companies. Health Care Financing.

The Commonwealth of Massachusetts

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

An Act to reduce drug costs through transparency.

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 "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 2. 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 3. 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 4. 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 5. 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 6. 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 drug manufacturing, 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; (xiii) the assistant secretary for MassHealth; and (xiv) any witness identified by the attorney general or the center.

SECTION 7. 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 8. 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:- ; (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 date 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; and (iv) in the case of the assistant secretary for MassHealth, testimony concerning the structure, benefits, caseload and financing related programs administered by the office or entered into in partnership with other state and federal agencies and the agency's activities to align or redesign those programs in order to encourage the development of more integrated and efficient health care delivery systems. 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 9. 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 10. 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 11. Section 11 of said chapter 6D, as so appearing, is hereby amended by inserting after the figure "$500,000", in line 152, the following words:- the first time that a determination is made, not more than $750,000 for a second determination and not more than

$1,000,000 for a third or subsequent determination; provided, however, that a civil penalty assessed pursuant to 1 of the above clauses shall be a first offense if a previously assessed penalty was assessed pursuant to a different clause. A civil penalty assessed pursuant to this subsection shall be deposited into the Community Hospital Reinvestment Trust Fund established in section 2TTTT of chapter 29.

SECTION 12. 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 13. 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).

(4) develop annual research and analysis priorities for the center; provided however, that the council shall not require approval of the center’s actions pursuant to section 16, section 38C and 38D of chapter 3 or section 17 of chapter 176A.

SECTION 14. 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 15. 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 16. 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 17. 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 18. 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 19. Said chapter 12C is hereby further amended by inserting after section 10 the following 2 sections: -

Section 10A. (a) On or before March 1, 2020, 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 manufacturer of 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 manufacturer submits to the center pursuant to this section shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in: (i) such pharmaceutical manufacturer'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 manufacturers 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 manufacturers.

(e) The center shall compile an annual report that includes all 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 manufacturer 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 20. 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 21. 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 22. 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 23. 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 24. 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 subsection (a) of section 226 of chapter 175.

“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 21D. (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.

(b) A contract between a pharmacy benefit manager and a participating pharmacy or pharmacist or contracting agent shall not include any provision that prohibits, restricts, or limits a pharmacist or contracting agent or pharmacy's right to provide an insured with information on the amount of the insured's cost share for such insured's prescription drug and the clinical efficacy of a more affordable alternative drug if one is available. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for disclosing such information to an insured or for selling to an insured a more affordable alternative if one is available.

(c) A pharmacy benefits manager shall not charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including, without limitation, a fee for: (i) the receipt and processing of a pharmacy claim; (ii) the development or management of claims processing services in a pharmacy benefits manager network; or (iii) participation in a pharmacy benefits manager network, unless such fee is set out in a contract between the pharmacy benefits manager and the pharmacist or contracting agent or pharmacy.

(d) A contract between a pharmacy benefit manager and a participating pharmacy or pharmacist or contracting agent shall not include any provision that prohibits, restricts, or limits disclosure of information to the division deemed necessary by the division to ensure a pharmacy

benefits manager's compliance with the requirements under this section or section 21C of chapter 94C.