

**SENATE . . . . . No. 732**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

***John J. Cronin***

*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 comprehensive transparency in the pharmaceutical industry.

PETITION OF:

NAME:

*John J. Cronin*

DISTRICT/ADDRESS:

*Worcester and Middlesex*

**SENATE . . . . . No. 732**

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By Mr. Cronin, a petition (accompanied by bill, Senate, No. 732) of John J. Cronin for legislation to promote comprehensive transparency in the pharmaceutical industry. Health Care Financing.

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**The Commonwealth of Massachusetts**

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**In the One Hundred and Ninety-Third General Court  
(2023-2024)**  
\_\_\_\_\_

An Act relative to promoting comprehensive 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:*

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

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

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

8 “Pharmaceutical manufacturing company”, any entity engaged in the production,  
9 preparation, propagation, compounding, conversion or processing of prescription drugs, either  
10 directly or indirectly, by extraction from substances of natural origin, or independently by means  
11 of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity  
12 engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs;

13 provided however, that “pharmaceutical manufacturing company” shall not include a wholesale  
14 drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered  
15 pursuant to section 38 of said chapter 112.

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

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

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

27 “Pipeline drugs”, which are defined as those drugs that contain a new molecular entity  
28 (“NME”) for which the sponsor has submitted a new drug application or biologics license  
29 application (“BLA”).

30 SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further  
31 amended by inserting after the definition of “State Institution” the following definition:-

32 “Sponsor”, any person who submits an NDA (including a 505(b)(2) application), ANDA,  
33 BLA or an amendment or supplement to an NDA, ANDA, or BLA to obtain FDA approval of a

34 new drug or FDA licensure of a biological product application and any person who owns an  
35 approved NDA (including a 505(b)(2) application), ANDA, or BLA.

36 SECTION 5. Section 4 of said chapter 6D, as so appearing, is hereby amended by  
37 striking out, in lines 6 and 7, the word “manufacturers” and inserting in place thereof the  
38 following words:- manufacturing companies, pharmacy benefit managers.

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

41 To the extent that the analysis of spending trends with respect to pharmaceutical or  
42 biopharmaceutical products increases the expenses of the commission, such expenses shall be  
43 fully assessed to pharmaceutical manufacturing companies and pharmacy benefit managers. Any  
44 fees assessed by the commission under this section, when paid by every pharmaceutical  
45 manufacturing company and pharmacy benefit manager, shall not exceed the commission’s  
46 reasonable regulatory costs to analyze such spending trends, and in no event shall exceed \$2000  
47 annually as assessed against each such pharmaceutical manufacturing company and pharmacy  
48 benefit manager. A pharmacy benefit manager that is a surcharge payor subject to the preceding  
49 paragraph and administers its own prescription drug, prescription device or pharmacist services  
50 or prescription drug and device and pharmacist services portion shall not be subject to additional  
51 assessment under this paragraph.

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

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

58 SECTION 9. Said section 8 of said chapter 6D, as so appearing, is hereby further  
59 amended by striking out, in lines 32 and 33 , the words “and (xi) any witness identified by the  
60 attorney general or the center” and inserting in place thereof the following words:- (xi) 2  
61 pharmacy benefit managers; (xii) 3 pharmaceutical manufacturing companies, 1 of which shall  
62 be representative of a publicly traded company that manufactures specialty drugs, 1 of which  
63 shall be representative of and doing business in generic drug manufacturing and 1 of which shall  
64 have been in existence for fewer than 10 years; and (xiii) any witness identified by the attorney  
65 general or the center.

66 SECTION 10. Said section 8 of said chapter 6D, as so appearing, is hereby further  
67 amended by striking out, in line 48, the first time it appears, the word “and”.

68 SECTION 11. Said section 8 of said chapter 6D, as so appearing, is hereby further  
69 amended by inserting after the word “commission”, in line 59, the first time it appears, the  
70 following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical  
71 manufacturing companies, testimony that is suitable for public release and that is not likely to  
72 compromise the financial, competitive or proprietary nature of any information and data  
73 concerning factors underlying prescription drug costs and price increases; the impact of  
74 aggregate manufacturer rebates, discounts and other price concessions on net pricing; and any  
75 other matters as determined by the commission. No pharmaceutical manufacturing company

76 identified as a witness under this section, or any testimony by any such company, shall be subject  
77 to the provisions of section 17 of chapter 12C.

78 SECTION 12. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is  
79 hereby amended by striking out the second sentence and inserting in place thereof the following  
80 sentence:-

81 The report shall be based on the commission's analysis of information provided at the  
82 hearings by witnesses, providers, provider organizations, insurers, pharmaceutical manufacturing  
83 companies and pharmacy benefit managers, registration data collected pursuant to section 11,  
84 data collected or analyzed by the center pursuant to sections 8, 9, 10, 10A and 10B of chapter  
85 12C and any other available information that the commission considers necessary to fulfill its  
86 duties in this section, as defined in regulations promulgated by the commission.

87 SECTION 13. Section 8A of chapter 6D is hereby deleted and replaced in its entirety  
88 with the following new section:-

89 Section 8A. (a) As used in this section, the following word shall, unless the context  
90 clearly requires otherwise, have the following meaning:

91 "Manufacturer", an entity that manufactures a pharmaceutical drug covered by  
92 MassHealth.

93 "Rare disease", any disease that affects fewer than 200,000 people in the United States,  
94 which has status as an "orphan" disease for research purposes, or is known to be substantially  
95 under diagnosed and unrecognized as a result of lack of adequate diagnostic and research  
96 information.

97 “Wholesale acquisition cost”, the cost of a prescription drug as defined in 42 U.S.C.  
98 §1395w-3a(c)(6)(B).

99 (b) The commission may require a manufacturer specified in subsection (c) to disclose to  
100 the commission within a reasonable time the following information relating to the  
101 manufacturer’s pricing of that drug, as applicable, on a standard reporting form developed by the  
102 commission with the input of the manufacturers:

103 (1) A schedule of the drug’s wholesale acquisition cost increases over the previous five  
104 calendar years if the drug was manufactured by the company;

105 (2) A written description suitable for public release of the specific financial and  
106 nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the  
107 drug over the previous five calendar years including, but not limited to, an explanation of how  
108 these factors explain the increase in the wholesale acquisition cost;

109 (3) The manufacturer’s aggregate, company-level research and development and other  
110 relevant capital expenditures, including facility construction, for the most recent year for which  
111 final audited data are available;

112 (4) If the drug was acquired by the manufacturer within the previous 5 years, all of the  
113 following information:

114 (A) The wholesale acquisition cost at the time of acquisition and in the calendar year  
115 prior to acquisition.

116 (B) The name of the company from which the drug was acquired, the date acquired,  
117 and the purchase price.

118 (C) The year the drug was introduced to market and the wholesale acquisition cost at  
119 the time of introduction.

120 (5) The patent expiration date of the drug if it is under patent.

121 (6) If the drug is a multiple source drug, an innovator multiple source drug, a  
122 noninnovator multiple source drug, or a single source drug, as defined in subparagraph (A) of  
123 paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code.

124 (7) A description of the change or improvement in the drug, if any, that necessitates  
125 the price increase.

126 (8) Volume of sales of the drug in the US for the previous year.

127 (9) If the drug was approved during the preceding 5 calendar years, and the wholesale  
128 acquisition cost of the drug exceeded a current average annual gross cost per utilizer for public  
129 and private health care payers in Massachusetts of greater than \$50,000 during the immediately  
130 preceding calendar year, all of the following information:

131 (A) A description of the marketing and pricing plans used in the launch of the drug in  
132 the US and internationally.

133 (B) The estimated volume of patients that are prescribed the drug.

134 (C) If the drug was granted breakthrough therapy designation or priority review by  
135 the Federal Food and Drug Administration prior to final approval.

136 (D) The date and price of acquisition if the drug was not developed by the  
137 manufacturer.



138 (10) Any other information that the manufacturer wishes to provide to the commission.

139 The manufacturer may limit the information reported pursuant to this section to that  
140 which is otherwise in the public domain or publicly available. Based on the records furnished, as  
141 well as any records relied upon by the executive office of health and human services in  
142 connection with the procedures under section 12A of chapter 118E and any other publicly  
143 available records, the commission may identify a proposed supplemental rebate, in consultation  
144 with the executive office, for a prescribed drug specified in subsection (c); provided that the  
145 proposed supplemental rebate may be based on a proposed value of the drug; and provided  
146 further, that the commission shall consider any proposed supplemental rebate framework or other  
147 information provided to the commission under subsection (g) of section 12A of chapter 118E.

148 (c) A manufacturer of the following prescribed drugs shall comply with the requirements  
149 set forth in this section: a drug for which the executive office was unable to successfully  
150 conclude supplemental rebate negotiations with the manufacturer under subsections (b) and (c)  
151 of section 12A of chapter 118E, and for which the commission has received notice from the  
152 executive office under subsection (g) of said section 12A of said chapter 118E.

153 (d) Records disclosed by a manufacturer under this section shall: (i) be accompanied by  
154 an attestation that all information provided is true and correct; (ii) not be public records under  
155 section 7 of chapter 4 or chapter 66; and (iii) remain confidential; provided, however, that the  
156 commission may produce reports summarizing any findings; provided that any such report shall  
157 not be in a form that identifies specific prices charged for or rebate amounts associated with  
158 drugs by a manufacturer, or in a manner that is likely to compromise the financial, competitive or  
159 proprietary nature of any information.

160 (e) If, after review of any records furnished to the commission under subsection (b), the  
161 commission determines that the manufacturer's pricing of the drug is potentially unreasonable or  
162 excessive in relation to the commission's proposed value under subsection (b), the commission  
163 shall, with 30 days' advance notice to the manufacturer, request that the manufacturer provide, at  
164 the manufacturer's discretion, further information related to the pricing of the prescribed drug  
165 and the manufacturer's justification for the pricing. In addition to the manufacturer, the  
166 commission may identify other relevant parties including but not limited to patients, providers,  
167 provider organizations, external experts and payers who may provide information to the  
168 commission.

169 (f) Any information, analyses or reports regarding a particular drug reviewed or used in  
170 identifying the supplemental rebate or assessing the proposed value of the drug shall be provided  
171 to the manufacturer for review and input. The commission shall consider any clarifications or  
172 data provided by the manufacturer with respect to its drug. The commission may not base its  
173 determination on the supplemental rebate, the proposed value or the reasonableness of the drug  
174 pricing, solely on the analysis or research of an outside third party.

175 (g) If the commission relies upon a third party to provide cost-effectiveness analysis or  
176 research related to the proposed value, such analysis or research shall also provide, but not be  
177 limited in scope to, (i) a description of the methodologies and models used in its analysis; (ii) any  
178 assumptions and potential limitations of research findings in the context of the results; and (iii)  
179 outcomes for affected subpopulations that utilize the drug.

180 (h) (1) In connection with the identification of a proposed supplemental rebate or a  
181 proposed value for a drug that is approved for the treatment of a rare disease or that is otherwise

182 identified as first-in-class, including without limitation any consultation with a third party to  
183 provide cost effectiveness analysis or research related to the proposed value for such a drug, the  
184 commission shall ensure that opportunities exist, at a time the commission determines  
185 appropriate, for consultations with stakeholders on the following topics:

186 (A) the disease treated by such drug;

187 (B) the severity of disease treated by such drug;

188 (C) the unmet medical need associated with the disease treated by such drug;

189 (D) the impact of particular coverage, cost-sharing, tiering, utilization management, prior  
190 authorization, medication therapy management, or other Medicaid policies on access to such  
191 drug;

192 (E) an assessment of the benefits and risks of such drug for patients;

193 (F) the impact of particular coverage, cost-sharing, tiering, utilization management, prior  
194 authorization, medication therapy management, or other policies on patients' adherence to the  
195 treatment regimen prescribed or otherwise recommended by their physicians;

196 (G) Whether beneficiaries who need treatment from or a consultation with a rare disease  
197 specialist or a specialist in the disease being treated by the first-in-class drug have adequate  
198 access and, if not, what factors are causing the limited access; and

199 (H) the demographics and the clinical description of patient populations.

200 (2) The commission shall develop and maintain a list of external experts who, because of  
201 their special expertise, are qualified to provide advice on rare disease issues and topics described

202 in subsection (h)(1) of this section. The commission may, when appropriate to address a specific  
203 question, consult such external experts when making a determination on a proposed  
204 supplemental rebate or proposed value of a drug approved for the treatment of a rare disease or  
205 that is designated first-in-class, when consultation is necessary because the commission lacks the  
206 specific scientific, medical, or technical expertise necessary for the performance of its  
207 responsibilities and the necessary expertise can be provided by the external experts.

208 (3) For purposes of this section, external experts are individuals who possess scientific or  
209 medical training that the commission lacks with respect to one or more rare diseases or the  
210 disease treated by the first-in-class therapy under review.

211 (i) Not later than 60 days after receiving information from the manufacturer, as required  
212 under subsection (b) or (e), the commission shall issue a determination on whether the  
213 manufacturer's pricing of a drug subject to the supplemental rebate negotiation that resulted in  
214 the provision of notice under section 12A of chapter 118E is unreasonable or excessive in  
215 relation to the commission's proposed value of the drug.

216 (j) If the manufacturer fails to timely comply with the commission's request for records  
217 under subsections (b) or otherwise knowingly obstructs the commission's ability to issue its  
218 determination under subsection (i), including, but not limited to, providing incomplete, false or  
219 misleading information, the commission may impose appropriate sanctions against the  
220 manufacturer, including reasonable monetary penalties not to exceed \$500,000, in each instance.  
221 The commission shall seek to promote compliance with this section and shall only impose a civil  
222 penalty on the manufacturer as a last resort.

223 (k) The commission shall adopt any written policies, procedures or regulations the  
224 commission determines necessary to implement this section.

225 SECTION 14. Section 9 of said chapter 6D, as so appearing, is hereby amended by  
226 inserting after the word “organization”, in line 72, the following words:- , pharmacy benefit  
227 manager, pharmaceutical manufacturing company.

228 SECTION 15. Said chapter 6D is hereby further amended by adding the following  
229 section:-

230 Section 20. (a) In the course of its duties the commission may contract with a third-party  
231 entity, such as an accounting firm, to conduct an annual study of pharmaceutical or  
232 biopharmaceutical companies with pipeline drugs, generic drugs or biosimilar drugs that may  
233 have a significant impact on state health care expenditures.

234 (b) For purposes of this section, early notice as described in subsections (c) and (d) shall  
235 be provided in the timeframes set forth in subsection (e) for the following:

236 (1) Pipeline drugs, which are defined as those drugs that contain a new molecular entity  
237 (“NME”) for which the sponsor has submitted a new drug application or biologics license  
238 application (“BLA”);

239 (2) All abbreviated new drug applications for generic drugs; and

240 (3) All biosimilar biologics license applications,

241 (c) In connection with the annual study, if requested, the applicant for a pipeline brand,  
242 biosimilar or generic drug shall provide notice to the contracted third-party entity with a brief

243 description of the following for each drug, using data fields consistent with those employed by  
244 the United States National Institutes of Health in [clinicaltrials.gov](http://clinicaltrials.gov), if applicable:

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

247 (2) The routes of administration being studied;

248 (3) Clinical trial comparators, if applicable; and

249 (4) Estimated year of market entry or applicable FDA user fee action date, per the  
250 discretion of the manufacturer.

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

253 (1) Orphan Drug;

254 (2) Fast Track;

255 (3) Breakthrough Therapy;

256 (4) Accelerated Approval; or

257 (5) Priority Review for New Molecular Entities (“NMEs”).

258 (e) The data submissions required by this section shall be submitted to the contracted  
259 third-party entity no later than 60 days after receipt of the FDA user fee action date

260 (1) Notwithstanding the foregoing, for drugs in development that receive any of the FDA  
261 designations listed in subsection (d) for NMEs, such submissions shall be provided as soon as  
262 practical upon receipt of the relevant designation.

263 (f) Notwithstanding any provision of law to the contrary, information provided to the  
264 contacted third-party entity or to the Secretary pursuant to this section, any analysis of such  
265 information, and any resulting study or studies shall be considered to be a trade secret and  
266 confidential commercial information, and shall not be a public record pursuant to clause Twenty-  
267 sixth of section 7 of chapter 4 or chapter 66, and shall not be subject to public inspection, and  
268 shall not be released in a manner that would allow for the identification of an individual drug,  
269 therapeutic class of drugs, or manufacturer, or in a manner that is likely to compromise the  
270 financial, competitive, or proprietary nature of the information. Information disclosed pursuant  
271 to this section and any analyses of such information shall be used only by the contracted third-  
272 party entity or by the Secretary, and shall be used only for development of the study described in  
273 (a).

274 SECTION 16. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby  
275 amended by striking out subsection (a) and inserting in place thereof the following subsection:-

276 (a) The attorney general shall monitor trends in the health care market including, but not  
277 limited to, trends in provider organization size and composition, consolidation in the provider  
278 market, payer contracting trends, patient access and quality issues in the health care market and  
279 prescription drug cost and price trends. The attorney general may obtain the following  
280 information from a private health care payer, public health care payer, pharmacy benefit  
281 manager, provider or provider organization, as any of those terms may be defined in section 1 of

282 chapter 6D: (i) any information that is required to be submitted pursuant to sections 8, 9, 10 and  
283 10B of chapter 12C; (ii) filings, applications and supporting documentation related to any cost  
284 and market impact review pursuant to section 13 of said chapter 6D; (iii) filings, applications and  
285 supporting documentation related to a determination of need application filed pursuant to section  
286 25C of chapter 111; and (iv) filings, applications and supporting documentation submitted to the  
287 federal Centers for Medicare and Medicaid Services or the Office of the Inspector General for  
288 any demonstration project. Pursuant to section 8 of said chapter 6D and section 17 of said  
289 chapter 12C, and subject to the limitations in said sections, the attorney general may require that  
290 any provider, provider organization, pharmacy benefit manager, private health care payer or  
291 public health care payer produce documents, answer interrogatories and provide testimony under  
292 oath related to health care costs and cost trends, the factors that contribute to cost growth within  
293 the commonwealth's health care system and the relationship between provider costs and payer  
294 premium rates.

295 SECTION 17. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby  
296 amended by inserting after the definition of "Patient-centered medical home" the following 3  
297 definitions:-

298 "Pharmaceutical manufacturing company", any entity engaged in the production,  
299 preparation, propagation, compounding, conversion or processing of prescription drugs, either  
300 directly or indirectly, by extraction from substances of natural origin, or independently by means  
301 of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity  
302 engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs;  
303 provided however, that "pharmaceutical manufacturing company" shall not include a wholesale



304 drug distributor licensed pursuant to section 36A of chapter 112 or a retail pharmacist registered  
305 pursuant to section 38 of said chapter 112.

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

310 “Pharmacy benefit services” shall include, but not be limited to, formulary  
311 administration; drug benefit design; pharmacy network contracting; pharmacy claims processing;  
312 mail and specialty drug pharmacy services; and cost containment, clinical, safety, and adherence  
313 programs for pharmacy services. For the purposes of this section, a health benefit plan that does  
314 not contract with a pharmacy benefit manager shall be a pharmacy benefit manager, unless  
315 specifically exempted.

316 SECTION 18. Said section 1 of said chapter said 12C, as so appearing, is hereby further  
317 amended by adding the following definition:-

318 “Wholesale acquisition cost”, the cost of a prescription drug as defined in 42 U.S.C.  
319 §1395w-3a(c)(6)(B).

320 SECTION 19. Section 3 of said chapter 12C, as so appearing, is hereby amended by  
321 inserting after the word “organizations”, in lines 13 and 14, the following words:- ,  
322 pharmaceutical manufacturing companies, pharmacy benefit managers.

323 SECTION 20. Said section 3 of said chapter 12C, as so appearing, is hereby further  
324 amended by striking out, in line 24, the words “and payer” and inserting in place thereof the

325 following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit  
326 manager.

327 SECTION 21. Section 5 of said chapter 12C, as so appearing, is hereby amended by  
328 inserting after the word “organizations”, in line 11, the following words:- , pharmaceutical  
329 manufacturing companies, pharmacy benefit managers.

330 SECTION 22. Said section 5 of said chapter 12C, as so appearing, is hereby further  
331 amended by inserting after the word “providers”, in line 15, the following words:- , affected  
332 pharmaceutical manufacturing companies, affected pharmacy benefit managers.

333 SECTION 23. Section 7 of said chapter 12C, as so appearing, is hereby further amended  
334 by adding the following paragraph:-

335 To the extent that the analysis and reporting activities pursuant to sections 10A or 10B  
336 increases the expenses of the center, the estimated increase in the center’s expenses shall be fully  
337 assessed to pharmaceutical manufacturing companies and pharmacy benefit managers. Any fees  
338 assessed by the center under this section, when paid by every pharmaceutical manufacturing  
339 company and pharmacy benefit manager, shall not exceed the center’s actual and reasonably  
340 regulatory costs to implement and enforce sections 10A or 10B, and in no event shall exceed  
341 \$2000 annually as assessed against each such pharmaceutical manufacturing company and  
342 pharmacy benefit manager.

343 SECTION 24. Said chapter 12C is hereby further amended by inserting after section 10  
344 the following 2 sections:-

345 Section 10A. (a) On or before March 1, 2026, and annually thereafter, the center shall  
346 prepare a list of not more than ten outpatient prescription drugs that the center determines  
347 account for a significant share of state health care spending, considering the net cost of such  
348 drugs in the immediately preceding calendar year. The list shall include outpatient prescription  
349 drugs from different therapeutic classes and no more than three generic outpatient prescription  
350 drugs. The center shall not list any outpatient prescription drug pursuant to this subsection unless  
351 the wholesale acquisition cost of the prescription drug, less all rebates paid to the commonwealth  
352 for such drug during the immediately preceding calendar year, increased by not less than 25 per  
353 cent during the immediately preceding calendar year.

354 (b) The pharmaceutical manufacturing company that manufactures a prescription drug  
355 included on a list prepared by the center pursuant to subsection (a) shall provide to the center the  
356 following:

357 (i) a written, narrative description, suitable for public release, of factors that caused the  
358 increase in the wholesale acquisition cost of the listed prescription drug; and

359 (ii) aggregate, company-level research and development costs and such other capital  
360 expenditures that the center deems relevant for the most recent year for which final audited data  
361 is available.

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

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

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

374 (f) Except as otherwise provided in this section, information and data submitted to the  
375 center pursuant to this section shall not be a public record and shall be exempt from disclosure  
376 pursuant to clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66. No such  
377 information and data shall be disclosed in a manner that may compromise the financial,  
378 competitive or proprietary nature of such information and data, or that would have enable a third  
379 party to identify an individual drug, therapeutic class of drugs or pharmaceutical manufacturing  
380 company the prices charged for any particular drug or therapeutic class of drugs, or the value of  
381 any rebate or discount provided for any particular drug or class of drugs.

382 Section 10B. The center shall promulgate regulations necessary to ensure the uniform  
383 analysis of information regarding pharmacy benefit managers that enables the center to analyze:  
384 (1) year-over-year wholesale acquisition cost changes; (2) year-over-year trends in formulary,  
385 maximum allowable costs list and cost-sharing design, including the establishment and  
386 management of specialty product lists; (3) aggregate information regarding discounts,  
387 utilizations limits, rebates, manufacturer administrative fees and other financial incentives or  
388 concessions related to pharmaceutical products or formulary programs; (4) information regarding

389 the aggregate amount of payments made to pharmacies owned or controlled by the pharmacy  
390 benefit managers and the aggregate amount of payments made to pharmacies that are not owned  
391 or controlled by the pharmacy benefit managers; (5) pharmacy benefit manager practices related  
392 to spread pricing, administrative fees, clawbacks and formulary placement; and (6) additional  
393 information deemed reasonable and necessary by the center as set forth in the center's  
394 regulations.

395 (b) Not later than March 1 of each year, each pharmacy benefit manager shall file a report  
396 with the center. The report must state for the immediately preceding calendar year:

397 (1) the aggregated rebates, fees, price protection payments, and any other payments  
398 collected from pharmaceutical drug manufacturers; and

399 (2) the aggregated dollar amount of rebates, fees, price protection payments, and any  
400 other payments collected from pharmaceutical drug manufacturers that were:

401 (A) passed to:

402 (i) health plan issuers; or

403 (ii) enrollees at the point of sale of a prescription drug; or

404 (B) retained as revenue by the pharmacy benefit manager.

405 (b) A report submitted by a pharmacy benefit manager may not disclose the identity of a  
406 specific health plan or enrollee, the price charged for a specific prescription drug or class of  
407 prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or  
408 class of prescription drugs.

409 (c) Not later than June 1 of each year, the center shall publish the aggregated data from  
410 all reports for that year required by this section in an appropriate location on the center’s website.  
411 The combined aggregated data from the reports must be published in a manner that does not  
412 disclose or tend to disclose proprietary or confidential information of any pharmacy benefit  
413 manager, and any such information shall not be a public record and shall be exempt from  
414 disclosure pursuant to clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66.

415 SECTION 25. Section 11 of said chapter 12C, as so appearing, is hereby amended by  
416 striking out the first sentence and inserting in place thereof the following sentence:-

417 The center shall ensure the timely reporting of information required pursuant to sections  
418 8, 9, 10, 10A, and 10B.

419 SECTION 26. Said section 11 of said chapter 12C, as so appearing, is hereby further  
420 amended by striking out, in line 11, the figure “\$1,000” and inserting in place thereof the  
421 following figure:- \$5,000.

422 SECTION 27. Said section 11 of said chapter 12C, as so appearing, is hereby further  
423 amended by striking out, in line 16, the figure “\$50,000” and inserting in place thereof the  
424 following figure:- \$200,000.

425 SECTION 28. Section 12 of said chapter 12C, as so appearing, is hereby amended by  
426 striking out, in line 2, the words “9, and 10” and inserting in place thereof the following words:-  
427 9, 10, 10A and 10B.

428 SECTION 29. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby  
429 amended by striking out the first sentence and inserting in place thereof the following sentence:-

430 The center shall publish an annual report based on the information submitted pursuant to sections  
431 8, 9, 10, 10A and 10B concerning health care provider, provider organization, pharmaceutical  
432 manufacturing company, pharmacy benefit manager and private and public health care payer  
433 costs and cost and price trends, pursuant to section 13 of chapter 6D relative to market impact  
434 reviews and pursuant to section 15 relative to quality data.