

HOUSE No. 1254

The Commonwealth of Massachusetts

PRESENTED BY:

Edward F. Coppinger

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:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Edward F. Coppinger</i>	<i>10th Suffolk</i>	<i>2/16/2021</i>

HOUSE No. 1254

By Mr. Coppinger of Boston, a petition (accompanied by bill, House, No. 1254) of Edward F. Coppinger relative to comprehensive transparency in the pharmaceutical industry. Health Care Financing.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Second General Court
(2021-2022)**

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 words 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, 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, 2024, 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; and (5) additional information deemed
392 reasonable and necessary by the center as set forth in the center's regulations.

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

395 The center shall ensure the timely reporting of information required pursuant to sections
396 8, 9, 10, 10A, and 10B.

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

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

403 SECTION 28. Section 12 of said chapter 12C, as so appearing, is hereby amended by
404 striking out, in line 2, the words "9, and 10" and inserting in place thereof the following words:-
405 9, 10, 10A and 10B.

406 SECTION 29. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby
407 amended by striking out the first sentence and inserting in place thereof the following sentence:-
408 The center shall publish an annual report based on the information submitted pursuant to sections
409 8, 9, 10, 10A and 10B concerning health care provider, provider organization, pharmaceutical

- 410 manufacturing company, pharmacy benefit manager and private and public health care payer
- 411 costs and cost and price trends, pursuant to section 13 of chapter 6D relative to market impact
- 412 reviews and pursuant to section 15 relative to quality data.