

# SENATE . . . . . No. 2520

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Senate, May 20, 2025 -- Text of amendment (541) (offered by Senator Friedman) to the Ways and Means amendment (Senate, No. 3) to the House Bill making appropriations for the fiscal year 2026 for the maintenance of the departments, boards, commissions, institutions, and certain activities of the Commonwealth, for interest, sinking fund, and serial bond requirements, and for certain permanent improvements.

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## The Commonwealth of Massachusetts

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In the One Hundred and Ninety-Fourth General Court  
(2025-2026)  
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1 by inserting after section 7 the following 6 sections:-

2 "SECTION 7A. Section 1 of chapter 6D of the General Laws, as most recently amended  
3 by sections 11 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the  
4 definition of "Disproportionate share hospital" the following definition:-

5 "Early notice", advanced notification by a pharmaceutical manufacturing company of a:  
6 (i) new drug, device or other product coming to market; or (ii) a price increase, as described in  
7 subsection (b) of section 15A.

8 SECTION 7B. Said section 1 of said chapter 6D, as so amended, is hereby further  
9 amended by inserting after the definition of "Physician" the following definition:-

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

13 SECTION 7C. Said section 1 of said chapter 6D, as so amended, is hereby further  
14 amended by adding the following definition:-

15 “Wholesale acquisition cost”, the cost of a prescription drug as defined in 42 U.S.C.  
16 1395w-3a(c)(6)(B).

17 SECTION 7D. Said chapter 6D is hereby further amended by striking out section 2A, as  
18 appearing in the 2022 Official Edition, and inserting in place thereof the following section:-

19 Section 2A. The commission shall keep confidential all nonpublic clinical, financial,  
20 strategic or operational documents or information provided or reported to the commission in  
21 connection with any care delivery, quality improvement process, performance improvement plan  
22 or early notice authorized under sections 7, 10, 14, 15, 15A, 24 or 25 of this chapter or under  
23 section 2GGGG of chapter 29 and shall not disclose the information or documents to any person  
24 without the consent of the entity providing or reporting the information or documents under said  
25 sections 7, 10, 14, 15, 15A, 24 or 25 of this chapter or under said section 2GGGG of said chapter  
26 29, except in summary form in evaluative reports of such activities or when the commission  
27 believes that such disclosure should be made in the public interest after taking into account any  
28 privacy, trade secret or anticompetitive considerations. The confidential information and  
29 documents shall not be public records and shall be exempt from disclosure under clause Twenty-  
30 sixth of section 7 of chapter 4 or under chapter 66.

31 SECTION 7E. Said chapter 6D is hereby further amended by inserting after section 15  
32 the following section:-

33 Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to  
34 the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or

35 (iii) biosimilar drug. The commission shall provide nonconfidential information received under  
36 this section to the office of Medicaid, the division of insurance and the group insurance  
37 commission.

38 Early notice under this subsection shall be submitted to the commission in writing not  
39 later than 30 days after receipt of the United States Food and Drug Administration approval date.

40 For each pipeline drug, early notice shall include a brief description of the: (i) primary  
41 disease, health condition or therapeutic area being studied and the indication; (ii) route of  
42 administration being studied; (iii) clinical trial comparators; (iv) estimated date of market entry;  
43 and (v) any other information the commission deems relevant. To the extent possible,  
44 information shall be collected using data fields consistent with those used by the National  
45 Institutes of Health for clinical trials.

46 For each pipeline drug, early notice shall include whether the drug has been designated  
47 by the United States Food and Drug Administration: (i) as an orphan drug; (ii) for fast track; (iii)  
48 as a breakthrough therapy; (iv) for accelerated approval; (v) for priority review for a new  
49 molecular entity; or (vi) for an expedited approval program not listed in this subsection;  
50 provided, however, that notwithstanding clause (v), submissions for drugs in development that  
51 are designated as new molecular entities by the United States Food and Drug Administration  
52 shall be provided as soon as practical upon receipt of the relevant designations. For each generic  
53 drug, early notice shall include a copy of the drug label approved by the United States Food and  
54 Drug Administration. If said drug label has not been approved by the time early notice would  
55 otherwise be required, the label shall be provided within a reasonable time as determined by the  
56 commission.

57 (b) A pharmaceutical manufacturing company shall provide early notice to the  
58 commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by  
59 more than 15 per cent per wholesale acquisition cost unit during any 12-month period; or (ii) a  
60 brand-name drug, generic drug or biosimilar drug with a significant price increase as determined  
61 by the commission during any 12-month period; provided, however, that a significant price  
62 increase may include, but need not be limited to, a price increase below 15 per cent. The  
63 commission shall provide non-confidential information received under this section to the office  
64 of Medicaid, the division of insurance and the group insurance commission.

65 Early notice under this subsection shall be submitted to the commission in writing not  
66 less than 60 days before the planned effective date of the increase.

67 A pharmaceutical manufacturing company required to notify the commission of a price  
68 increase under this subsection shall, not less than 30 days before the planned effective date of the  
69 increase, report to the commission any information regarding the price increase that the  
70 commission deems relevant including, but not limited to: (i) drug identification information; (ii)  
71 drug sales volume information; (iii) wholesale price and related information for the drug; (iv) net  
72 price and related information for the drug; (v) drug acquisition information, if applicable; (vi)  
73 revenue from the sale of the drug; and (vii) manufacturer costs.

74 (c) If a pharmaceutical manufacturing company fails to timely comply with the  
75 requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the  
76 commission's ability to receive early notice under this section, including, but not limited to,  
77 providing false or misleading information, the commission may impose sanctions against the  
78 manufacturer, including monetary penalties not more than \$500,000, per violation. The

79 commission shall seek to promote compliance with this section and shall only impose a civil  
80 penalty on the manufacturer as a last resort. Amounts collected under this section shall be  
81 deposited into the Prescription Drug Cost Assistance Trust Fund established in section  
82 2KKKKKK of chapter 29.

83 (d) The commission may promulgate regulations to implement this section.

84 SECTION 7F. Said chapter 6D is hereby further amended by adding the following 2  
85 sections:-

86 Section 24. (a) As used in this section, the following words shall have the following  
87 meanings unless the context clearly requires otherwise:

88 “Eligible drug”, (i) a brand name drug or biologic, not including a biosimilar, that has a  
89 launch wholesale acquisition cost of \$25,000 or more for a 1-year supply or full course of  
90 treatment; (ii) a biosimilar drug that has a launch wholesale acquisition cost that is less than 15  
91 per cent lower than the referenced brand biologic at the time the biosimilar is launched; (iii) a  
92 generic drug that has a wholesale acquisition cost of \$100 or more for a 30-day supply or full  
93 course of treatment, for which the wholesale acquisition cost increased by 200 per cent or more  
94 during the preceding 12 months; (iv) a public health essential drug, as defined in subsection (f)  
95 of section 13 of chapter 17, with a significant price increase over a defined period of time as  
96 determined by the commission by regulation or with a wholesale acquisition cost of \$10,000 or  
97 more for a 1-year supply or full course of treatment; (v) all drugs selected pursuant to section  
98 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DDD  
99 of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G; (vi) a brand  
100 name, generic or biologic drug with a total aggregate annual spend by public and private payors

101 of \$25 million or more; or (vii) other prescription drug products which, due to their cost or an  
102 increase in their cost: (A) may have a significant negative impact on patient access, such as by  
103 significantly contributing to high patient out-of-pocket costs compared to other drugs, increased  
104 utilization management compared to other drugs, lack of coverage by payers or similar factors as  
105 determined by the commission; or (B) may create significant affordability challenges for the  
106 commonwealth's health care system and patients, such as by contributing significantly to  
107 increased premiums, costs to the commonwealth or patient out-of-pocket costs compared to other  
108 drugs, by having a substantial impact on state programs involved in the provision of health care,  
109 by affecting the ability of the state and other entities that contribute to the health care cost growth  
110 benchmark to meet said benchmark or similar factors, as determined by the commission;  
111 provided, however, that the commission shall promulgate regulations to establish the type of  
112 prescription drug products classified under clause (vii) prior to classification of any such  
113 prescription drug product under said clause (vii), and the commission may adjust the dollar  
114 amounts in this definition from time to time for good cause including, but not limited to,  
115 inflation.

116 "Manufacturer", a pharmaceutical manufacturer of an eligible drug.

117 "Public health essential drug", shall have the same meaning as defined in subsection (f)  
118 of section 13 of chapter 17.

119 (b)(1) The commission shall review: (i) the negative impact of eligible drug costs on  
120 patient access, such as by significantly contributing to high patient out-of-pocket costs compared  
121 to other drugs, increased utilization management compared to other drugs, lack of coverage by  
122 payers or similar factors as determined by the commission; and (ii) the extent to which eligible

123 drug costs have created or likely will create affordability challenges for the state’s health care  
124 system and patients, such as by contributing significantly to increased premiums, costs to the  
125 state, or patient out-of-pocket costs compared to other drugs, by having a substantial impact on  
126 state programs involved in the provision of health care, by affecting the ability of the state and  
127 other entities that contribute to the health care cost growth benchmark to meet said benchmark or  
128 similar factors, as determined by the commission; provided, however, that the commission shall  
129 review the eligible drugs that the commission determines may have the most significant impact  
130 to patients under clause (i) or may create the most significant affordability challenges under  
131 clause (ii).

132 (2) In conducting a review of eligible drugs, the commission shall consider:

133 (i) available information about the relevant factors contributing to the price paid and  
134 amount spent in the state for the drug, including the wholesale acquisition cost, change in price  
135 as compared to the launch price, annual price increases over time, discounts, rebates or other  
136 price concessions, utilization and utilization trends, aggregate annual spending in the state on the  
137 drug and the impact of the drug’s cost on the state budget;

138 (ii) the average patient co-pay or other cost-sharing for the drug in the commonwealth;

139 (iii) whether the cost of the drug contributes to inequities in health care access or  
140 outcomes;

141 (iv) the price and availability of therapeutic alternatives in the commonwealth;

142 (v) input from patients affected by the condition or disease treated by the drug and  
143 individuals with medical or scientific expertise related to the condition or disease treated by the  
144 drug;

145 (vi) input from other stakeholders, which may include, but shall not be limited to, patient  
146 advocacy organizations, consumer advocacy organizations, providers, provider organizations and  
147 payers; and

148 (vii) any other factors the commission deems relevant.

149 (3) In conducting a review of eligible drugs, the commission shall notify the  
150 manufacturer that the commission is reviewing the manufacturer's drug, and shall provide the  
151 manufacturer with the opportunity to provide relevant information about the drug's pricing. The  
152 commission may request relevant information from the manufacturer of said eligible drug and  
153 from pharmacy benefit managers, payers, wholesalers, pharmacies, clinical experts, providers  
154 and other persons or entities. The commission, to the extent feasible, shall collaborate with the  
155 center to avoid collecting duplicative information and reduce the administrative burden on all  
156 parties.

157 (c)(1) Using the records and information provided under subsection (b), available  
158 information from the center, from an outside third party, from another agency or department  
159 within the commonwealth or that is otherwise available to the commission or any of its  
160 subdivisions, the commission shall identify a proposed value for eligible drugs the commission  
161 has reviewed pursuant to subsection (b) and which the commission has determined have or likely  
162 will have a significant impact on patient access or which have created or likely will create  
163 significant affordability challenges for the state's health care system or patients, as described in

164 clauses (i) and (ii) of paragraph (1) of subsection (b). In identifying proposed values for eligible  
165 drugs, the commission may prioritize drugs based on the commission's determination of the  
166 significance of the drug cost's negative impact on patient access or the extent to which the drug's  
167 cost has created or likely will create affordability challenges for the state's health care system or  
168 patients, as described in clauses (i) and (ii) of paragraph (1) of subsection (b) of this section.

169 (2) The commission shall base the proposed value on:

170 (i) the cost of delivering and administering the drug and other administrative costs related  
171 to the production and delivery of the drug that the commission deems relevant;

172 (ii) the status of the drug on the drug shortage list published by the United States Food  
173 and Drug Administration;

174 (iii) the drug's status as an orphan drug;

175 (iv) information the commission collected pursuant to paragraph (2) of subsection (b) that  
176 the commission deems relevant, including, but not limited to input from patients and  
177 stakeholders; and

178 (v) other factors the commission deems relevant in determining a drug's value.

179 (3) The commission shall not base its determination on the proposed value of the eligible  
180 drug solely on the analysis or research of an outside third party and shall not employ a measure  
181 or metric that assigns a reduced value to the life extension provided by a treatment based on a  
182 pre-existing disability or chronic health condition of the individuals whom the treatment would  
183 benefit. If the commission relies upon a third party to provide cost-effectiveness analysis or  
184 research related to the proposed value of the eligible drug, such analysis or research shall also

185 include, but not be limited to: (i) a description of the methodologies and models used in the  
186 analysis; (ii) any assumptions and potential limitations of research findings in the context of the  
187 results; and (iii) outcomes for affected subpopulations that utilize the drug, including, but not  
188 limited to, potential impacts on individuals of marginalized racial or ethnic groups and on  
189 individuals with specific disabilities or health conditions who regularly utilize the eligible drug.

190 (d) If, after review of an eligible drug the commission determines that the cost of the  
191 eligible drug, as determined by the commission, does not substantially exceed the proposed value  
192 of the drug, the commission shall notify the manufacturer, in writing, of its determination and  
193 shall evaluate other ways to mitigate the eligible drug’s cost in order to improve patient access to  
194 the eligible drug and help address affordability challenges. For the purposes of this subsection, to  
195 “substantially exceed” shall mean to exceed by not less than 15 per cent; provided, however, that  
196 for good cause, the commission may determine that a drug’s cost does not substantially exceed  
197 the proposed value even if the cost exceeds the value by more than 15 per cent; provided further,  
198 that the commission shall adopt regulations defining good cause prior to making such a  
199 determination. The commission may engage with stakeholders, including, but not limited to,  
200 patients, patient advocacy organizations, consumer advocacy organizations, providers, provider  
201 organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the  
202 conclusion of a stakeholder engagement process under this subsection, the commission shall  
203 issue recommendations on ways to reduce the cost of the eligible drug for the purpose of  
204 improving patient access to the eligible drug and helping to address affordability challenges.  
205 Recommendations may include but shall not be limited to: (i) an alternative payment plan or  
206 methodology; (ii) a bulk purchasing program; (iii) co-payment, deductible, co-insurance or other  
207 cost-sharing restrictions; (iv) risk-based solutions; and (v) public reporting of the drugs. The

208 recommendations shall be publicly posted on the commission’s website and provided to the  
209 clerks of the house of representatives and senate, the joint committee on health care financing  
210 and the house and senate committees on ways and means; provided, however, that the report  
211 shall be published on the website of the commission.

212 (e) If, after review of an eligible drug, the commission determines that the cost of the  
213 eligible drug, as determined by the commission, substantially exceeds the proposed value of the  
214 drug, the commission shall notify and provide the manufacturer with an opportunity provide  
215 further information related to the pricing of the eligible drug, the manufacturer’s reasons for the  
216 pricing, and any actions the manufacturer has taken or will imminently take that have a high  
217 likelihood of lowering the cost of the drug for units of the drugs that are dispensed or  
218 administered to an individual in the state in person, by mail, or by other means. For the purposes  
219 of this subsection, to “substantially exceed” shall mean to exceed by at least 15 per cent.  
220 However, the commission may determine that a drug’s cost substantially exceeds the proposed  
221 value even if the cost exceeds the value by less than 15 per cent, if the commission has good  
222 cause for making such a determination; provided however, that the commission shall adopt  
223 regulations defining good cause prior to making such a determination.

224 (f) The commission may revise the proposed value for an eligible drug based on the  
225 information provided, if any, pursuant to subsection (e). Not later than 60 days after receiving  
226 information from the manufacturer under subsection (b) or subsection (e), if any, the commission  
227 shall publicly issue a determination on whether the cost of an eligible drug, as determined by the  
228 commission, substantially exceeds the commission’s proposed value of the drug. If the  
229 commission determines that the cost of an eligible drug substantially exceeds the commission’s  
230 proposed value of the drug, the commission shall confidentially notify the manufacturer, in

231 writing, of its determination and shall set an upper payment limit for the drug pursuant to section  
232 25. For the purposes of this subsection, to “substantially exceed” shall mean to exceed by not  
233 less than 15 per cent; provided, however, that, for good cause, the commission may determine  
234 that a drug’s cost substantially exceeds the proposed value if the cost exceeds the value by less  
235 than 15 per cent; and provided further, that the commission shall adopt regulations defining good  
236 cause prior to making such a determination.

237 (g) Records disclosed by a manufacturer or other person or entity pursuant to this section,  
238 if any, shall: (i) be accompanied by an attestation that all information provided is true and  
239 correct; (ii) not be public records as defined under clause Twenty-sixth of section 7 of chapter 4  
240 or chapter 66; and (iii) remain confidential; provided, however, that the commission may  
241 produce reports summarizing any findings; provided further, that any such report shall not be in a  
242 form that identifies specific prices charged for or rebate amounts associated with drugs by a  
243 manufacturer or in a manner that is likely to compromise the financial, competitive or  
244 proprietary nature of the information.

245 A request for further information made by the commission under subsection (e) or a  
246 determination issued or written notification made by the commission under subsection (f) shall  
247 not be public records as defined under said clause Twenty-sixth of said section 7 of said chapter  
248 4 or said chapter 66.

249 In issuing public determinations under subsection (f), the commission shall not identify  
250 specific prices charged for, or rebate amounts associated with, drugs by a manufacturer or in a  
251 manner that is likely to compromise the financial, competitive or proprietary nature of the

252 information. Such prices or rebates shall not be public records as defined under said clause  
253 Twenty-sixth of said section 7 of said chapter 4 or said chapter 66.

254 (h) The commission's proposed value of an eligible drug and the commission's  
255 underlying analysis of the eligible drug shall not be used to determine whether any individual  
256 patient meets prior authorization or utilization management criteria for the eligible drug. The  
257 proposed value and underlying analysis shall not be the sole factor in determining whether a drug  
258 is included in a formulary or whether the drug is subject to step therapy.

259 (i) The commission may request relevant information to implement this section from the  
260 manufacturer of eligible drug and from pharmacy benefit managers, payers, wholesalers,  
261 pharmacies, clinical experts, providers and other persons or entities; provided, however, that if a  
262 manufacturer, pharmacy benefit manager, wholesaler or payer fails to timely comply with the  
263 commission's request for records pursuant to subsections (b) or (e), or otherwise knowingly  
264 obstructs the commission's ability to issue its determination under subsection (f), by taking  
265 actions including, but not limited to, providing false or misleading information, the commission  
266 may impose sanctions against the entity, including monetary penalties not to exceed \$500,000,  
267 per violation. The commission shall promote compliance with this section and shall only impose  
268 a civil penalty on the manufacturer as a last resort. Penalties collected under this subsection shall  
269 be deposited into the Prescription Drug Cost Assistance Trust Fund established under section  
270 2KKKKKK of chapter 29. The commission, to the extent feasible, shall collaborate with the  
271 center to avoid collecting duplicative information and reduce the administrative burden on all  
272 parties.

273           The failure of an entity to provide requested information to the commission or the center  
274 pursuant to paragraph (3) of subsection (b), paragraph (3) of subsection (c), subsection (e) or any  
275 other provision in this section or sections 23 or 25 shall not impair the commission’s ability to  
276 determine which drugs are eligible drugs, to review eligible drugs, to determine proposed values,  
277 to set upper payment limits or otherwise exercise the commission’s authority under this section  
278 or sections 23 or 25.

279           (j) The commission shall adopt any written policies, procedures or regulations that it  
280 determines necessary to implement this section.

281           Section 25. (a) Upon providing written notice provided under subsection (f) of section 24,  
282 the commission shall set an upper payment limit for an eligible drug. The upper payment limit  
283 shall be the maximum amount that may be paid or billed for a prescription drug purchased or  
284 reimbursed in any financial transaction under subsection (c).

285           (b) The upper payment limit shall be the proposed value for the eligible drug; provided,  
286 however, that if the commission revised the proposed value pursuant to subsection (f) of section  
287 24, the upper payment limit shall be the drug’s revised proposed value. The commission may set  
288 an upper payment limit that is different than the proposed value for good cause; provided,  
289 however, that the commission shall adopt regulations defining good cause prior to setting any  
290 upper payment limit. The commission may annually raise a drug’s upper payment limit to  
291 account for inflation. An upper payment limit shall not include a pharmacy dispensing fee and  
292 nothing in this section shall be interpreted to prevent a retail pharmacy from receiving a payment  
293 that includes a dispensing fee above the upper payment limit.

294           (c)(1) The upper payment limit shall apply:

295 (i) when an individual purchases a prescription drug from a provider located in the  
296 commonwealth or a pharmacy licensed by the commonwealth and the drug is dispensed or  
297 administered to an individual in the commonwealth in person, by mail or by other means;  
298 provided, however, that if the person is insured, the amount the person pays, plus the amount the  
299 person's carrier, the commonwealth or entity acting on behalf of the commonwealth, including,  
300 but not limited to the medical assistance program established under chapter 118E, or the  
301 participating self-insured plan pays, shall not exceed the upper payment limit plus applicable  
302 dispensing fees; and provided further, that a person shall be considered to have purchased a drug  
303 if they are not required to pay any cost-sharing amount;

304 (ii) when a provider located in the commonwealth or a pharmacy licensed by the  
305 commonwealth purchases from a wholesaler or other entity a prescription drug that is dispensed  
306 or administered to a person in the commonwealth in person, by mail or by other means;

307 (iii) when a carrier, a pharmacy benefits manager, the commonwealth or entity acting on  
308 behalf of the commonwealth, including, but not limited to, the medical assistance program  
309 established under chapter 118E, or a participating self-insured plan pays or reimburses a  
310 pharmacy, provider or other entity for a prescription drug that is dispensed or administered to a  
311 person in the commonwealth in person, by mail or by other means; provided, however, that the  
312 amount the person pays for the drug, plus the amount the carrier, the commonwealth or entity  
313 acting on behalf of the commonwealth, or the participating self-insured plan pays shall not  
314 exceed the upper payment limit plus applicable dispensing fees; and

315 (iv) to any other transaction within the commonwealth's jurisdiction to which the  
316 commission determines is necessary to apply the upper payment limit to effectuate the purposes  
317 of this section.

318 (2) For the purposes of this subsection, "carrier" shall have the same meaning as in  
319 section 1 of chapter 176O.

320 (d) Upper payment limits shall become effective 6 months after the commission has  
321 issued a public determination pursuant to subsection (f) of section 24.

322 (e) A self-insured plan governed by the Employee Retirement Income Security Act of  
323 1974 may elect to be subject to the upper payment limits.

324 (f) The commission may suspend an upper payment limit if the commission determines  
325 that there is a shortage of the drug in the commonwealth, unless the commission determines that  
326 the shortage was caused by a manufacturer or the manufacturer's agent due to the commission  
327 establishing an upper payment limit for the drug.

328 (g) Any manufacturer or wholesaler that intends to withdraw from sale or distribution  
329 within the commonwealth a drug for which the commission has established an upper payment  
330 limit shall provide a notice of withdrawal in writing not less than 6 months before the withdrawal  
331 to the commission, the commissioner of the division of insurance, the attorney general and any  
332 entity in the commonwealth with which the manufacturer or wholesaler has a contract for the  
333 sale or distribution of the drug. The commission shall assess a penalty not more than 1 year's  
334 worth of the manufacturer's revenue attributable to use of the drug in the commonwealth, as  
335 determined by the commission, if the commission determines that a manufacturer or wholesaler  
336 failed to provide said notice. This subsection shall not apply in instances where the drug is being

337 withdrawn due to a recall or revocation of the drug’s approval by the United States Food and  
338 Drug Administration or similar reasons as determined by the commission.

339 (h) Any savings that a carrier, a participating self-insured plan or the group insurance  
340 commission generates due to the implementation of an upper payment limit shall be used to  
341 reduce costs to consumers, prioritizing the reduction of premiums or out-of-pocket costs for  
342 prescription drugs. Annually, each carrier, participating self-insured plan, the group insurance  
343 commission and the division of medical assistance shall submit to the commission a report  
344 describing the savings achieved as a result of implementing upper payment limits and how those  
345 savings were used to reduce costs to consumers.

346 (i) The attorney general may enforce this section.

347 (j) The commission shall promulgate regulations, including, but not limited to, civil  
348 penalties, as necessary to implement this section.”; and

349 By inserting after section 9 the following section:-

350 “SECTION 9A. Section 13 of said chapter 17 , as so appearing, is hereby amended by  
351 adding the following subsection:-

352 (f) As used in this subsection, “Public health essential drug” shall mean a prescription  
353 drug, biologic or biosimilar approved by the United States Food and Drug Administration that:

354 (i) appears on the Model List of Essential Medicines most recently adopted by the World Health  
355 Organization; (ii) is selected pursuant to section 17Z of chapter 32A, section 10Z of chapter  
356 118E, section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter  
357 176B and section 4VV of chapter 176G; or (iii) is deemed an essential medicine by the

358 commission due to its efficacy in treating a life-threatening health condition or a chronic health  
359 condition that substantially impairs an individual’s ability to engage in activities of daily living  
360 or because limited access to a certain population would pose a public health challenge.

361 The commission shall identify and publish a list of public health essential drugs. The list  
362 shall be updated not less than annually and be made publicly available on the department’s  
363 website; provided, however, that the commission may provide an interim listing of a public  
364 health essential drug prior to an annual update. The commission shall notify and forward a copy  
365 of the list to the health policy commission established under chapter 6D.”; and

366 By inserting after section 16 the following section:-

367 “SECTION 16A. Said chapter 29 is hereby further amended by inserting after section  
368 2JJJJJ the following section:-

369 2KKKKKK. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The  
370 secretary of health and human services shall administer the fund and shall make expenditures  
371 from the fund, without further appropriation, to provide financial assistance to residents of the  
372 commonwealth for the cost of prescription drugs through the prescription drug costs assistance  
373 program established under section 249 of chapter 111. For the purposes of this section,  
374 “prescription drug” shall mean a prescription drug and any drug delivery device needed to  
375 administer the drug that is not included as part of the underlying drug prescription.

376 The fund shall be credited with: (i) revenue from appropriations or other money  
377 authorized by the general court and specifically designated to be credited to the fund; and (ii)  
378 funds from public or private sources, including, but not limited to, gifts, grants, donations,  
379 rebates and settlements received by the commonwealth that are specifically designated to be

380 credited to the fund. Money remaining in the fund at the close of a fiscal year shall not revert to  
381 the General Fund and shall be available for expenditure in the following fiscal year.

382 (b) Annually, not later than March 1, the secretary shall report on the fund's activities  
383 detailing expenditures from the previous calendar year. The report shall include: (i) the number  
384 of individuals who received financial assistance from the fund; (ii) the breakdown of fund  
385 recipients by race, gender, age range, geographic region and income level; (iii) a list of all  
386 prescription drugs that were covered by money from the fund; and (iv) the total cost savings  
387 received by all fund recipients and the cost savings broken down by race, gender, age range and  
388 income level. The report shall be submitted to the clerks of the senate and house of  
389 representatives, senate and house committees on ways and means and the joint committee on  
390 health care financing; provided, however, that annually, not later than March 1, the report shall  
391 be published on the website of the executive office of health and human services.

392 (c) The secretary shall promulgate regulations for the expenditure of the funds under this  
393 section.”; and

394 By inserting after section 30 the following section:-

395 SECTION 30A. Said chapter 111 is hereby further amended by adding the following  
396 section:-

397 Section 249. (a) The department shall establish and administer a prescription drug cost  
398 assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund  
399 established in section 2KKKKKK of chapter 29. The program shall provide financial assistance  
400 for prescription drugs used to treat: (i) chronic respiratory conditions, including, but not limited  
401 to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions, including,

402 but not limited to, those heart conditions that disproportionately impact a particular demographic  
403 group; (iii) diabetes; and (iv) any other chronic condition identified by the department that  
404 disproportionately impacts a particular demographic group; provided, however, that  
405 “prescription drug” shall include the prescription drug and any drug delivery device needed to  
406 administer the drug that is not included as part of the underlying drug prescription. Financial  
407 assistance shall cover the cost of any copayment, coinsurance and deductible for the prescription  
408 drug for an individual who is eligible for the program.

409 (b) An individual shall be eligible for the program if the individual: (i) is a resident of the  
410 commonwealth; (ii) has a current prescription from a health care provider for a drug that is used  
411 to treat a chronic condition listed in subsection (a); (iii) has a family income of not more than  
412 500 per cent of the federal poverty level; and (iv) is not enrolled in MassHealth.

413 (c) The department shall create an application process, which shall be available  
414 electronically and in hard copy form, to determine whether an individual meets the program  
415 eligibility requirements under subsection (b). The department shall determine an applicant’s  
416 eligibility and notify the applicant of the department’s determination within 10 business days of  
417 receiving the application. If necessary for its determination, the department may request  
418 additional information from the applicant; provided, however, that the department shall notify  
419 the applicant within 5 business days of receipt of the original application as to what specific  
420 additional information is being requested. If additional information is requested, the department  
421 shall, within 3 business days of receipt of the additional information, determine the applicant’s  
422 eligibility and notify said applicant of the department’s determination.

423 If the department determines that an applicant is not eligible for the program, the  
424 department shall notify the applicant and shall include in said notification the specific reasons  
425 why the applicant is not eligible. The applicant may appeal this determination to the department  
426 within 30 days of receiving such notification.

427 If the department determines that an applicant is eligible for the program, the department  
428 shall provide the applicant with a prescription drug cost assistance program identification card,  
429 which shall indicate the applicant's eligibility; provided, however, that the program identification  
430 card shall include, but not be limited to, the applicant's full name and the full name of the  
431 prescription drug that the applicant is eligible to receive under the program without having to pay  
432 a co-payment, co-insurance or deductible. An applicant's program identification card shall be  
433 valid for 12 months and shall be renewable upon a redetermination of program eligibility.

434 (d) An individual with a valid program identification card may present such card at any  
435 pharmacy in the commonwealth and, upon presentation of such card, the pharmacy shall fill the  
436 individual's prescription and provide the prescribed drug to the individual without requiring the  
437 individual to pay a co-payment, co-insurance or deductible; provided, however, that the  
438 pharmacy shall be reimbursed by the Prescription Drug Cost Assistance Trust Fund established  
439 in section 2KKKKKK of chapter 29 in a manner determined by the department, in an amount  
440 equal to what the pharmacy would have received had the individual been required to pay a co-  
441 payment, co-insurance or deductible.

442 (e) The department, in collaboration with the division of insurance, board of registration  
443 in pharmacy and stakeholders representing consumers, pharmacists, providers, hospitals and  
444 carriers, shall develop and implement a plan to educate consumers, pharmacists, providers,

445 hospitals and carriers regarding eligibility for and enrollment in the program under this section.  
446 The plan shall include, but not be limited to, appropriate staff training, notices provided to  
447 consumers at pharmacies and a designated website with information for consumers, pharmacists  
448 and other health care professionals.

449 (f) The department shall compile a report detailing information about the program from  
450 the previous calendar year. The report shall include: (i) the number of applications received,  
451 approved, denied and appealed; (ii) the total number of applicants approved and the number of  
452 applicants approved delineated by race, gender, age range and income level; (iii) a list of all  
453 prescription drugs that qualify for the program under subsection (b) and a list of prescription  
454 drugs for which applicants actually received financial assistance; and (iv) the total cost savings  
455 received by all approved applicants and the cost savings delineated by race, gender, age range  
456 and income level. The report shall be submitted annually, not later than March 1, to the clerks of  
457 the senate and house of representatives, the house and senate committees on ways and means and  
458 the joint committee on health care financing; provided, however, that annually, not later than  
459 March 1, the report shall be published on the website of the department.

460 (g) The department shall promulgate regulations for the implementation and enforcement  
461 of this section.”; and

462 By inserting after section 85 the following 3 sections:-

463 “SECTION 85A. The health policy commission shall consult with relevant stakeholders,  
464 including, but not limited to, consumers, consumer advocacy organizations, organizations  
465 representing people with disabilities and chronic health conditions, providers, provider  
466 organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care

467 economists and other academics, to assist in the development and periodic review of regulations  
468 to implement section 24 of chapter 6D of the General Laws, including, but not limited to: (i)  
469 establishing the criteria and processes for identifying the proposed value of an eligible drug as  
470 defined in said section 24 of said chapter 6D; and (ii) determining the appropriate price increase  
471 for a public health essential drug as described within the definition of eligible drug in said  
472 section 24 of said chapter 6D.

473           The commission shall hold its first public outreach pursuant to this section not more than  
474 45 days after the effective date of this act and shall, to the extent possible, ensure fair  
475 representation and input from a diverse array of stakeholders.

476           SECTION 85B. Notwithstanding subsection (b) of section 15A of chapter 6D of the  
477 General Laws, for the purposes of providing an initial early notice under said section 15A of said  
478 chapter 6D, the health policy commission shall determine a significant price increase for a  
479 generic drug to be defined as a generic drug priced at \$100 or more per wholesale acquisition  
480 cost unit that increases in cost by 100 per cent or more during any 12-month period.

481           SECTION 85C. Section 85B is hereby repealed.”; and

482           By inserting after section 89 the following section:-

483           “SECTION 89A. Section 85C shall take effect on January 1, 2027.”.