

**SENATE . . . . . No. 695**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

***Jason M. Lewis***

*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 specialty medications and patient safety.**

PETITION OF:

NAME:

*Jason M. Lewis*

DISTRICT/ADDRESS:

*Fifth Middlesex*

**SENATE . . . . . No. 695**

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By Mr. Lewis, a petition (accompanied by bill, Senate, No. 695) of Jason M. Lewis for legislation relative to specialty medications and patient safety. Financial Services.

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**The Commonwealth of Massachusetts**

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

An Act relative to specialty medications and patient safety.

*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. Chapter 32A of the General Laws, as appearing in the 2018 Official  
2 Edition, is hereby amended by inserting after section 17O the following new section:-

3 Section 17OO. a) The following words as used in this section shall have the following  
4 meanings:

5 “Specialty pharmacy” means a pharmacy that is providing specialty pharmacy practice  
6 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
7 injury, illness, and disease are dispensed and compounded.

8 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
9 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
10 communication with other health care providers, extensive patient monitoring and case  
11 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed

12 by a specialty pharmacy may also require instruction and training on complex administration  
13 processes and/or handling and storage considerations.

14 b) Any coverage offered by the commission to an active or retired employee of the  
15 commonwealth insured under the group insurance commission shall not require a specialty  
16 pharmacy to dispense a medication directly to a patient with the intention that the patient will  
17 transport the medication to a healthcare provider for administration.

18 c) Any coverage offered by the commission to an active or retired employee of the  
19 commonwealth insured under the group insurance commission may offer but shall not require  
20 the use of a home infusion pharmacy to dispense sterile intravenous drugs ordered by physicians  
21 to patients in their homes or the use of an infusion site external to a patient's provider office or  
22 clinic.

23 d) Any coverage offered by the commission to an active or retired employee of the  
24 commonwealth insured under the group insurance commission shall, when requiring the  
25 distribution of patient-specific medication from a specialty pharmacy to a physician's office,  
26 hospital or clinic for administration, require: i) at least 60 days' notice to providers and patients  
27 from the insurer prior to the implementation of such a requirement; ii) a patient-specific  
28 expedited exception process for cases in which a provider certifies that it is unsafe for a patient  
29 to receive medication from a third party specialty pharmacy or to have the drug administered in  
30 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-  
31 call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure  
32 that a drug remains at the appropriate temperature through all stages of supply and storage; vi)  
33 the provision of a medication's pedigree to certify to the hospital pharmacy that the drug was

34 handled appropriately through the supply chain; vii) demonstration of expertise and reliability in  
35 risk evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
36 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
37 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
38 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
39 with hospitals responsible for receiving and administering medications dispensed by the  
40 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
41 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
42 pharmacy for the purposes of this paragraph.

43 e) Any coverage offered by the commission to an active or retired employee of the  
44 commonwealth insured under the group insurance commission shall not require a medication  
45 requiring sterile compounding by health system pharmacy staff or a medication with a patient-  
46 specific dosage requirement dependent upon lab or test results on the day of the clinic visit, or a  
47 federally controlled substance, to be distributed from a specialty pharmacy to a physician's  
48 office, hospital or clinic for administration.

49 f) Any coverage offered by the commission to an active or retired employee of the  
50 commonwealth insured under the group insurance commission shall, when requiring the  
51 distribution of patient-specific medication from a specialty pharmacy to a physician's office,  
52 hospital or clinic for administration, shall offer site neutral payment for such medication to the  
53 healthcare providers administering the medication. Such payment shall include the costs for the  
54 providers to intake, store and dispose of such medications.

55 SECTION 2. Chapter 118E of the General Laws, as appearing in the 2018 Official  
56 Edition, is hereby amended by inserting after section 10L the following new section:-

57 Section 10M. a) The following words as used in this section shall have the following  
58 meanings:

59 “Specialty pharmacy” means a pharmacy that is providing specialty pharmacy practice  
60 services and where Drugs, Devices, and other materials used in the diagnosis and treatment of  
61 injury, illness, and disease are Dispensed and Compounded.

62 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
63 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
64 communication with other health care providers, extensive patient monitoring and case  
65 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
66 by a specialty pharmacy may also require instruction and training on complex administration  
67 processes and/or handling and storage considerations.

68 b) The division, its Medicaid contracted health insurers, health plans, health maintenance  
69 organizations, behavioral health management firms and third party administrators under contract  
70 to a Medicaid managed care organization, the Medicaid primary care clinician plan, and  
71 accountable care organizations shall not require coverage for a specialty pharmacy that dispenses  
72 a medication directly to a patient with the intention that the patient will transport the medication  
73 to a healthcare provider for administration.

74 c) The division, its Medicaid contracted health insurers, health plans, health maintenance  
75 organizations, behavioral health management firms and third party administrators under contract  
76 to a Medicaid managed care organization, the Medicaid primary care clinician plan, and

77 accountable care organizations may offer coverage for but shall not require the use of a home  
78 infusion pharmacy to dispense sterile intravenous drugs ordered by physicians to patients in their  
79 homes or the use of an infusion site external to a patient’s provider office or clinic.

80 d) The division, its Medicaid contracted health insurers, health plans, health maintenance  
81 organizations, behavioral health management firms and third party administrators under contract  
82 to a Medicaid managed care organization, the Medicaid primary care clinician plan, and  
83 accountable care organizations shall when requiring the distribution of patient-specific  
84 medication from a specialty pharmacy to a physician’s office, hospital or clinic for  
85 administration, require: i) at least 60 days’ notice to providers and patients from the insurer prior  
86 to the implementation of such a requirement; ii) a patient-specific expedited exception process  
87 for cases in which a provider certifies that it is unsafe for a patient to receive medication from a  
88 third party specialty pharmacy or to have the drug administered in the home setting; iii) same day  
89 delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or  
90 nurse; v) provision of cold chain logistics or other ability to ensure that a drug remains at the  
91 appropriate temperature through all stages of supply and storage; vi) the provision of a  
92 medication’s pedigree to certify to the hospital pharmacy that the drug was handled appropriately  
93 through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and  
94 mitigation strategy to comply with USFDA reporting requirements; viii) demonstrated  
95 accreditation from a national accreditation organization; ix) demonstrated ability to deliver  
96 medications to a health system pharmacy in a ready-to-administer dosage form and clinically  
97 appropriate dosage; and x) third-party specialty pharmacies to establish agreements with  
98 hospitals responsible for receiving and administering medications dispensed by the specialty  
99 pharmacy to ensure proper receipt, transfer, handling, and storage of the medication prior to

100 administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
101 pharmacy for the purposes of this paragraph.

102 e) The division, its Medicaid contracted health insurers, health plans, health maintenance  
103 organizations, behavioral health management firms and third party administrators under contract  
104 to a Medicaid managed care organization, the Medicaid primary care clinician plan, and  
105 accountable care organizations shall not require a medication requiring sterile compounding by  
106 health system pharmacy staff or a medication with a patient-specific dosage requirement  
107 dependent upon lab or test results on the day of the clinic visit, or a federally controlled  
108 substance, to be distributed from a specialty pharmacy to a physician's office, hospital or clinic  
109 for administration.

110 f) The division, its Medicaid contracted health insurers, health plans, health maintenance  
111 organizations, behavioral health management firms and third party administrators under contract  
112 to a Medicaid managed care organization, the Medicaid primary care clinician plan, and  
113 accountable care organizations, shall, when requiring the distribution of patient-specific  
114 medication from a specialty pharmacy to a physician's office, hospital or clinic for  
115 administration, shall offer site neutral payment for such medication to the healthcare providers  
116 administering the medication. Such payment shall include the costs for the providers to intake,  
117 store and dispose of such medications.

118 SECTION 3. Chapter 175 of the General Laws, as appearing in the 2018 Official Edition,  
119 is hereby amended by inserting after section 47I the following new section:-

120 Section 47II. a) The following words as used in this section shall have the following  
121 meanings:

122 “Specialty pharmacy” means a pharmacy that is providing specialty pharmacy practice  
123 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
124 injury, illness, and disease are dispensed and compounded.

125 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
126 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
127 communication with other health care providers, extensive patient monitoring and case  
128 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
129 by a specialty pharmacy may also require instruction and training on complex administration  
130 processes and/or handling and storage considerations.

131 b) A policy, contract, agreement, plan or certificate of insurance issued, delivered or  
132 renewed within the commonwealth that provides medical expense coverage shall not require a  
133 specialty pharmacy to dispense a medication directly to a patient with the intention that the  
134 patient will transport the medication to a healthcare provider for administration.

135 c) A policy, contract, agreement, plan or certificate of insurance issued, delivered or  
136 renewed within the commonwealth that provides medical expense coverage may offer coverage  
137 for but shall not require the use of a home infusion pharmacy to dispense sterile intravenous  
138 drugs ordered by physicians to patient in their homes or the use of an infusion site external to a  
139 patient’s provider office or clinic.

140 d) A policy, contract, agreement, plan or certificate of insurance issued, delivered or  
141 renewed within the commonwealth that provides medical expense coverage shall, when requiring  
142 the distribution of patient-specific medication from a specialty pharmacy to a physician’s office,  
143 hospital or clinic for administration, require: i) at least 60 days’ notice to providers and patients



144 from the insurer prior to the implementation of such a requirement; ii) a patient-specific  
145 expedited exception process for cases in which a provider certifies that it is unsafe for a patient  
146 to receive medication from a third party specialty pharmacy or to have the drug administered in  
147 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-  
148 call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure  
149 that a drug remains at the appropriate temperature through all stages of supply and storage; vi)  
150 the provision of a medication's pedigree to certify to the hospital pharmacy that the drug was  
151 handled appropriately through the supply chain; vii) demonstration of expertise and reliability in  
152 risk evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
153 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
154 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
155 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
156 with hospitals responsible for receiving and administering medications dispensed by the  
157 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
158 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
159 pharmacy for the purposes of this paragraph.

160 e) A policy, contract, agreement, plan or certificate of insurance issued, delivered or  
161 renewed within the commonwealth that provides medical expense coverage shall not require a  
162 medication requiring sterile compounding by health system pharmacy staff or a medication with  
163 a patient-specific dosage requirement dependent upon lab or test results on the day of the clinic  
164 visit, or a federally controlled substance, to be distributed from a specialty pharmacy to a  
165 physician's office, hospital or clinic for administration.

166 f) A policy, contract, agreement, plan or certificate of insurance issued, delivered or  
167 renewed within the commonwealth that provides medical expense coverage shall, when requiring  
168 the distribution of patient-specific medication from a specialty pharmacy to a physician's office,  
169 hospital or clinic for administration, offer site neutral payment for such medication to the  
170 healthcare providers administering the medication. Such payment shall include the costs for the  
171 providers to intake, store and dispose of such medications.

172 SECTION 4. Chapter 176A of the General Laws, as appearing in the 2018 Official  
173 Edition, is hereby amended by inserting after section 8LL the following new section:-

174 Section 8LLL. a) The following words as used in this section shall have the following  
175 meanings:

176 "Specialty pharmacy" means a pharmacy that is providing specialty pharmacy practice  
177 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
178 injury, illness, and disease are dispensed and compounded.

179 "Specialty pharmacy practice" means the provision of pharmacist care services, which  
180 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
181 communication with other health care providers, extensive patient monitoring and case  
182 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
183 by a specialty pharmacy may also require instruction and training on complex administration  
184 processes and/or handling and storage considerations.

185 b) Any contracts, except contracts providing supplemental coverage to Medicare or other  
186 governmental programs, between a subscriber and the corporation under an individual or group  
187 hospital service plan which is delivered, issued or renewed in the commonwealth shall not

188 require a specialty pharmacy to dispense a medication directly to a patient with the intention that  
189 the patient will transport the medication to a healthcare provider for administration.

190 c) Any contracts, except contracts providing supplemental coverage to Medicare or other  
191 governmental programs, between a subscriber and the corporation under an individual or group  
192 hospital service plan which is delivered, issued or renewed in the commonwealth may offer  
193 coverage for but shall not require the use of a home infusion pharmacy to dispense sterile  
194 intravenous drugs ordered by physicians to patient in their homes or the use of an infusion site  
195 external to a patient's provider office or clinic..

196 d) Any contracts, except contracts providing supplemental coverage to Medicare or other  
197 governmental programs, between a subscriber and the corporation under an individual or group  
198 hospital service plan which is delivered, issued or renewed in the commonwealth shall when  
199 requiring the distribution of patient-specific medication from a specialty pharmacy to a  
200 physician's office, hospital or clinic for administration, require: i) at least 60 days' notice to  
201 providers and patients from the insurer prior to the implementation of such a requirement; ii) a  
202 patient-specific expedited exception process for cases in which a provider certifies that it is  
203 unsafe for a patient to receive medication from a third party specialty pharmacy or to have the  
204 drug administered in the home setting; iii) same day delivery of medications; iv) 24 hour per day,  
205 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or  
206 other ability to ensure that a drug remains at the appropriate temperature through all stages of  
207 supply and storage; vi) the provision of a medication's pedigree to certify to the hospital  
208 pharmacy that the drug was handled appropriately through the supply chain; vii) demonstration  
209 of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA  
210 reporting requirements; viii) demonstrated accreditation from a national accreditation

211 organization; ix) demonstrated ability to deliver medications to a health system pharmacy in a  
212 ready-to-administer dosage form and clinically appropriate dosage; and x) third-party specialty  
213 pharmacies to establish agreements with hospitals responsible for receiving and administering  
214 medications dispensed by the specialty pharmacy to ensure proper receipt, transfer, handling, and  
215 storage of the medication prior to administration. A pharmacy owned or affiliated with a hospital  
216 may serve as specialty pharmacy for the purposes of this paragraph.

217 e) Any contracts, except contracts providing supplemental coverage to Medicare or other  
218 governmental programs, between a subscriber and the corporation under an individual or group  
219 hospital service plan which is delivered, issued or renewed in the commonwealth shall not  
220 require a medication requiring sterile compounding by health system pharmacy staff or a  
221 medication with a patient-specific dosage requirement dependent upon lab or test results on the  
222 day of the clinic visit, or a federally controlled substance, to be distributed from a specialty  
223 pharmacy to a physician's office, hospital or clinic for administration.

224 f) Any contracts, except contracts providing supplemental coverage to Medicare or other  
225 governmental programs, between a subscriber and the corporation under an individual or group  
226 hospital service plan which is delivered, issued or renewed in the commonwealth shall, when  
227 requiring the distribution of patient-specific medication from a specialty pharmacy to a  
228 physician's office, hospital or clinic for administration, offer site neutral payment for such  
229 medication to the healthcare providers administering the medication. Such payment shall include  
230 the costs for the providers to intake, store and dispose of such medications.

231 SECTION 5. Chapter 176B of the General Laws, as appearing in the 2018 Official  
232 Edition, is hereby amended by inserting after section 4K the following new section:-

233 Section 4KK. a) The following words as used in this section shall have the following  
234 meanings:

235 “Specialty pharmacy” means a pharmacy that is providing specialty pharmacy practice  
236 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
237 injury, illness, and disease are dispensed and compounded.

238 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
239 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
240 communication with other health care providers, extensive patient monitoring and case  
241 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
242 by a specialty pharmacy may also require instruction and training on complex administration  
243 processes and/or handling and storage considerations.

244 b) Any subscription certificate under an individual or group medical service agreement  
245 delivered, issued or renewed within the commonwealth shall not require a specialty pharmacy to  
246 dispense a medication directly to a patient with the intention that the patient will transport the  
247 medication to a healthcare provider for administration.

248 c) Any subscription certificate under an individual or group medical service agreement  
249 delivered, issued or renewed within the commonwealth may offer coverage for but shall not  
250 require the use of a home infusion pharmacy to dispense sterile intravenous drugs ordered by  
251 physicians to patient in their homes or the use of an infusion site external to a patient’s provider  
252 office or clinic..

253 d) Any subscription certificate under an individual or group medical service agreement  
254 delivered, issued or renewed within the commonwealth shall when requiring the distribution of

255 patient-specific medication from a specialty pharmacy to a physician’s office, hospital or clinic  
256 for administration, require: i) at least 60 days’ notice to providers and patients from the insurer  
257 prior to the implementation of such a requirement; ii) a patient-specific expedited exception  
258 process for cases in which a provider certifies that it is unsafe for a patient to receive medication  
259 from a third party specialty pharmacy or to have the drug administered in the home setting; iii)  
260 same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a  
261 pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug  
262 remains at the appropriate temperature through all stages of supply and storage; vi) the provision  
263 of a medication’s pedigree to certify to the hospital pharmacy that the drug was handled  
264 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk  
265 evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
266 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
267 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
268 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
269 with hospitals responsible for receiving and administering medications dispensed by the  
270 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
271 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
272 pharmacy for the purposes of this paragraph.

273 e) Any subscription certificate under an individual or group medical service agreement  
274 delivered, issued or renewed within the commonwealth shall not require a medication requiring  
275 sterile compounding by health system pharmacy staff or a medication with a patient-specific  
276 dosage requirement dependent upon lab or test results on the day of the clinic visit, , or a

277 federally controlled substance, to be distributed from a specialty pharmacy to a physician's  
278 office, hospital or clinic for administration.

279 f) Any subscription certificate under an individual or group medical service agreement  
280 delivered, issued or renewed within the commonwealth shall, when requiring the distribution of  
281 patient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic  
282 for administration, offer site neutral payment for such medication to the healthcare providers  
283 administering the medication. Such payment shall include the costs for the providers to intake,  
284 store and dispose of such medications.

285 SECTION 6. Chapter 176G of the General Laws, as appearing in the 2018 Official  
286 Edition, is hereby amended by inserting after section 4D the following new section:-

287 Section 4DD. a) The following words as used in this section shall have the following  
288 meanings:

289 "Specialty pharmacy" means a pharmacy that is providing specialty pharmacy practice  
290 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
291 injury, illness, and disease are dispensed and compounded.

292 "Specialty pharmacy practice" means the provision of pharmacist care services, which  
293 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
294 communication with other health care providers, extensive patient monitoring and case  
295 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
296 by a specialty pharmacy may also require instruction and training on complex administration  
297 processes and/or handling and storage considerations.

298           b) Any individual or group health maintenance contract shall not require a specialty  
299 pharmacy to dispense a medication directly to a patient with the intention that the patient will  
300 transport the medication to a healthcare provider for administration.

301           c) Any individual or group health maintenance contract may offer coverage for but shall  
302 not require the use of a home infusion pharmacy to dispense sterile intravenous drugs ordered by  
303 physicians to patient in their homes or the use of an infusion site external to a patient’s provider  
304 office or clinic.

305           d) Any individual or group health maintenance contract shall when requiring the  
306 distribution of patient-specific medication from a specialty pharmacy to a physician’s office,  
307 hospital or clinic for administration, require: i) at least 60 days’ notice to providers and patients  
308 from the insurer prior to the implementation of such a requirement; ii) a patient-specific  
309 expedited exception process for cases in which a provider certifies that it is unsafe for a patient  
310 to receive medication from a third party specialty pharmacy or to have the drug administered in  
311 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-  
312 call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure  
313 that a drug remains at the appropriate temperature through all stages of supply and storage; vi)  
314 the provision of a medication’s pedigree to certify to the hospital pharmacy that the drug was  
315 handled appropriately through the supply chain; vii) demonstration of expertise and reliability in  
316 risk evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
317 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
318 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
319 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
320 with hospitals responsible for receiving and administering medications dispensed by the



321 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
322 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
323 pharmacy for the purposes of this paragraph.

324 e) Any individual or group health maintenance contract shall not require a medication  
325 requiring sterile compounding by health system pharmacy staff or a medication with a patient-  
326 specific dosage requirement dependent upon lab or test results on the day of the clinic visit, or a  
327 federally controlled substance, to be distributed from a specialty pharmacy to a physician's  
328 office, hospital or clinic for administration.

329 f) Any individual or group health maintenance contract shall when requiring the  
330 distribution of patient-specific medication from a specialty pharmacy to a physician's office,  
331 hospital or clinic for administration, offer site neutral payment for such medication to the  
332 healthcare providers administering the medication. Such payment shall include the costs for the  
333 providers to intake, store and dispose of such medications.

334 SECTION 7. Chapter 176I of the General Laws, as appearing in the 2018 Official  
335 Edition, is hereby amended by inserting after section 12 the following new section:-

336 Section 13. a) The following words as used in this section shall have the following  
337 meanings:

338 "Specialty pharmacy" means a pharmacy that is providing specialty pharmacy practice  
339 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
340 injury, illness, and disease are dispensed and compounded.

341 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
342 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
343 communication with other health care providers, extensive patient monitoring and case  
344 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
345 by a specialty pharmacy may also require instruction and training on complex administration  
346 processes and/or handling and storage considerations.

347 b) An organization entering into a preferred provider contract shall not require a specialty  
348 pharmacy to dispense a medication directly to a patient with the intention that the patient will  
349 transport the medication to a healthcare provider for administration.

350 c) An organization entering into a preferred provider contract may offer coverage for but  
351 shall not require the use of a home infusion pharmacy to dispense sterile intravenous drugs  
352 ordered by physicians to patient in their homes or the use of an infusion site external to a  
353 patient’s provider office or clinic.

354 d) An organization entering into a preferred provider contract shall when requiring the  
355 distribution of patient-specific medication from a specialty pharmacy to a physician’s office,  
356 hospital or clinic for administration, require: i) at least 60 days’ notice to providers and patients  
357 from the insurer prior to the implementation of such a requirement; ii) a patient-specific  
358 expedited exception process for cases in which a provider certifies that it is unsafe for a patient  
359 to receive medication from a third party specialty pharmacy or to have the drug administered in  
360 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-  
361 call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure  
362 that a drug remains at the appropriate temperature through all stages of supply and storage; vi)

363 the provision of a medication's pedigree to certify to the hospital pharmacy that the drug was  
364 handled appropriately through the supply chain; vii) demonstration of expertise and reliability in  
365 risk evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
366 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
367 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
368 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
369 with hospitals responsible for receiving and administering medications dispensed by the  
370 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
371 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
372 pharmacy for the purposes of this paragraph.

373 e) An organization entering into a preferred provider contract shall not require a  
374 medication requiring sterile compounding by health system pharmacy staff or a medication with  
375 a patient-specific dosage requirement dependent upon lab or test results on the day of the clinic  
376 visit, or a federally controlled substance, to be distributed from a specialty pharmacy to a  
377 physician's office, hospital or clinic for administration.

378 f) An organization entering into a preferred provider contract shall, when requiring the  
379 distribution of patient-specific medication from a specialty pharmacy to a physician's office,  
380 hospital or clinic for administration, offer site neutral payment for such medication to the  
381 healthcare providers administering the medication. Such payment shall include the costs for the  
382 providers to intake, store and dispose of such medications.

383 SECTION 8. Chapter 176Q of the General Laws, as appearing in the 2018 Official  
384 Edition, is hereby amended in section 1 by inserting after the definition of “Rating factor”, the  
385 following definitions:-

386 “Specialty pharmacy” means a pharmacy that is providing specialty pharmacy practice  
387 services and where drugs, devices, and other materials used in the diagnosis and treatment of  
388 injury, illness, and disease are dispensed and compounded.

389 “Specialty pharmacy practice” means the provision of pharmacist care services, which  
390 involves drugs used to treat chronic or specific diseases and conditions that require frequent  
391 communication with other health care providers, extensive patient monitoring and case  
392 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed  
393 by a specialty pharmacy may also require instruction and training on complex administration  
394 processes and/or handling and storage considerations.

395 SECTION 9. Chapter 176Q of the General Laws, as appearing in the 2018 Official  
396 Edition, is hereby amended in section 5 by inserting after subsection d the following 5 new  
397 subsections:-

398 e) No health plans offered through the connector shall require a specialty pharmacy to  
399 dispense a medication directly to a patient with the intention that the patient will transport the  
400 medication to a healthcare provider for administration.

401 f) Health plans offered through the connector may offer coverage for but shall not require  
402 the use of a home infusion pharmacy to dispense sterile intravenous drugs ordered by physicians  
403 to patient in their homes or the use of an infusion site external to a patient’s provider office or  
404 clinic.

405 g) Health plans offered through the connector shall when requiring the distribution of  
406 patient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic  
407 for administration, require: i) at least 60 days' notice to providers and patients from the insurer  
408 prior to the implementation of such a requirement; ii) a patient-specific expedited exception  
409 process for cases in which a provider certifies that it is unsafe for a patient to receive medication  
410 from a third party specialty pharmacy or to have the drug administered in the home setting; iii)  
411 same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a  
412 pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug  
413 remains at the appropriate temperature through all stages of supply and storage; vi) the provision  
414 of a medication's pedigree to certify to the hospital pharmacy that the drug was handled  
415 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk  
416 evaluation and mitigation strategy to comply with USFDA reporting requirements; viii)  
417 demonstrated accreditation from a national accreditation organization; ix) demonstrated ability to  
418 deliver medications to a health system pharmacy in a ready-to-administer dosage form and  
419 clinically appropriate dosage; and x) third-party specialty pharmacies to establish agreements  
420 with hospitals responsible for receiving and administering medications dispensed by the  
421 specialty pharmacy to ensure proper receipt, transfer, handling, and storage of the medication  
422 prior to administration. A pharmacy owned or affiliated with a hospital may serve as a specialty  
423 pharmacy for the purposes of this paragraph.

424 h) No health plans offered through the connector shall require a medication requiring  
425 sterile compounding by health system pharmacy staff or a medication with a patient-specific  
426 dosage requirement dependent upon lab or test results on the day of the clinic visit to be

427 distributed from a specialty pharmacy to a physician's office, hospital or clinic for  
428 administration.

429 i) Health plans offered through the connector shall, when requiring the distribution of  
430 patient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic  
431 for administration, offer site neutral payment for such medication to the healthcare providers  
432 administering the medication. Such payment shall include the costs for the providers to intake,  
433 store and dispose of such medications.