

HOUSE No. 1199

The Commonwealth of Massachusetts

PRESENTED BY:

Jon Santiago

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:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Jon Santiago</i>	<i>9th Suffolk</i>	<i>2/19/2021</i>
<i>James J. O'Day</i>	<i>14th Worcester</i>	<i>2/26/2021</i>
<i>David Allen Robertson</i>	<i>19th Middlesex</i>	<i>3/17/2021</i>

HOUSE No. 1199

By Mr. Santiago of Boston, a petition (accompanied by bill, House, No. 1199) of Jon Santiago, James J. O'Day and David Allen Robertson relative to specialty medications and patient safety. Financial Services.

The Commonwealth of Massachusetts

**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.