SENATE No. 665

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:DISTRICT/ADDRESS:Jason M. LewisFifth Middlesex

SENATE DOCKET, NO. 982 FILED ON: 1/18/2023

SENATE No. 665

By Mr. Lewis, a petition (accompanied by bill, Senate, No. 665) of Jason M. Lewis for legislation relative to specialty medications and patient safety. Financial Services.

[SIMILAR MATTER FILED IN PREVIOUS SESSION SEE SENATE, NO. 695 OF 2021-2022.]

The Commonwealth of Massachusetts

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

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 is hereby amended by inserting after

2 section 17R the following new section:-

3 Section 17S. 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

management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed
by a specialty pharmacy may also require instruction and training on complex administration
processes and/or handling and storage considerations.

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

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

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

f) Any coverage offered by the commission to an active or retired employee of the commonwealth insured under the group insurance commission shall, when requiring the distribution of patient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic for administration, shall offer site neutral payment for such medication to the healthcare providers administering the medication. Such payment shall include the costs for the providers to intake, store and dispose of such medications. SECTION 2. Chapter 118E of the General Laws is hereby amended by inserting after
 section 10N the following new section:-

57 Section 10O. 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.

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

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

accountable care organizations may offer coverage for but shall not require the use of a home
infusion pharmacy to dispense sterile intravenous drugs ordered by physicians to patients in their
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 to the implementation of such a requirement; ii) a patient-specific expedited exception process 86 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

administration. A pharmacy owned or affiliated with a hospital may serve as a specialtypharmacy 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.

SECTION 3. Chapter 175 of the General Laws is hereby amended by inserting after
section 47PP the following new section:-

120 Section 47QQ. a) The following words as used in this section shall have the following121 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.

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

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

d) A policy, contract, agreement, plan or certificate of insurance issued, delivered or
renewed within the commonwealth that provides medical expense coverage shall, when requiring
the distribution of patient-specific medication from a specialty pharmacy to a physician's office,
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 to receive medication from a third party specialty pharmacy or to have the drug administered in 146 147 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.

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

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

SECTION 4. Chapter 176A of the General Laws is hereby amended by inserting after
section 8QQ the following new section:-

174 Section 8RR. a) The following words as used in this section shall have the following175 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.

b) Any contracts, except contracts providing supplemental coverage to Medicare or other
governmental programs, between a subscriber and the corporation under an individual or group
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.

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

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

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

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

SECTION 5. Chapter 176B of the General Laws is hereby amended by inserting after
 section 4QQ the following new section:-

233 Section 4RR. a) The following words as used in this section shall have the following234 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, which239 involves drugs used to treat chronic or specific diseases and conditions that require frequent240 communication with other health care providers, extensive patient monitoring and case241 management, and comprehensive counseling with the patient and/or caregiver. Drugs dispensed242 by a specialty pharmacy may also require instruction and training on complex administration243 processes and/or handling and storage considerations.

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

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

d) Any subscription certificate under an individual or group medical service agreement
 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 of a medication's pedigree to certify to the hospital pharmacy that the drug was handled 263 264 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.

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

federally controlled substance, to be distributed from a specialty pharmacy to a physician'soffice, hospital or clinic for administration.

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

SECTION 6. Chapter 176G of the General Laws is hereby amended by inserting after
 section 4II the following new section:-

287 Section 4JJ. a) The following words as used in this section shall have the following288 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. b) Any individual or group health maintenance contract shall not require a specialty
pharmacy to dispense a medication directly to a patient with the intention that the patient will
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.

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

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

334 SECTION 7. Chapter 176I of the General Laws is hereby amended by inserting after
 335 section 13 the following new section:-

336 Section 14. a) The following words as used in this section shall have the following337 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.

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

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

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

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

383 SECTION 8. Chapter 176Q of the General Laws is hereby amended in section 1 by
 384 inserting after the definition of "Rating factor", the following definitions:-

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

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

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

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

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

g) Health plans offered through the connector shall when requiring the distribution of
patient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic
for administration, require: i) at least 60 days' notice to providers and patients from the insurer

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

h) No health plans offered through the connector shall require a medication requiring
sterile compounding by health system pharmacy staff or a medication with a patient-specific
dosage requirement dependent upon lab or test results on the day of the clinic visit to be
distributed from a specialty pharmacy to a physician's office, hospital or clinic for
administration.

i) Health plans offered through the connector shall, when requiring the distribution ofpatient-specific medication from a specialty pharmacy to a physician's office, hospital or clinic

- 430 for administration, offer site neutral payment for such medication to the healthcare providers
- 431 administering the medication. Such payment shall include the costs for the providers to intake,
- 432 store and dispose of such medications.