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

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. Lewis	*Fifth 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:

SECTION 1. Chapter 32A of the General Laws is hereby amended by inserting after section 17R the following new section:-

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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.

d) 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, 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 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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 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 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:-

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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) 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.

d) 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 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 prior to the implementation of such a requirement; ii) a patient-specific 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty pharmacy for the purposes of this paragraph.

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

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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) 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

from the insurer prior to the implementation of such a requirement; ii) a patient-specific 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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:-

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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 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 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 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..

d) 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, 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 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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:-

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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 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

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 prior to the implementation of such a requirement; ii) a patient-specific 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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's office, 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:-

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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 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.

c) Any individual or group health maintenance 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.

d) 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, 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 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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 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 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.

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

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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) 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.

d) 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, 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 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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.

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

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

"Specialty pharmacy practice" means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent 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.

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

prior to the implementation of such a requirement; ii) a patient-specific 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 the home setting; iii) same day delivery of medications; iv) 24 hour per day, 7 day per week on-call access to a pharmacist or nurse; v) provision of cold chain logistics or other ability to ensure that a drug 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 appropriately through the supply chain; vii) demonstration of expertise and reliability in risk evaluation and mitigation strategy to comply with USFDA 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 a specialty 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 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.