HOUSE DOCKET, NO. 3592 FILED ON: 1/17/2025

HOUSE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Sean Reid

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 to protect 340B providers.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Sean Reid	*11th Essex*	*1/17/2025*

HOUSE DOCKET, NO. 3592 FILED ON: 1/17/2025

HOUSE . . . . . No.

[Pin Slip]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

An Act to protect 340B providers.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION XX. Chapter 32A of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after section 33, the following new section: -

Section 34.

(a) For purposes of this section:

(1) "340B drug" shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) "340B entity" shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) “Health insurance issuer” shall mean the group insurance commission or a “carrier” as defined in section 1 of chapter 176O.

(4) “Third party” shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term "other adjustment" includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

E. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B

entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third-party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a

340B entity unless the data is required by the United States Department of Health and Human Services.

SECTION XX. Chapter 175 of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after section 47TT, the following new section:-

Section 47UU.

(a) For purposes of this section:

(1) "340B drug" shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) "340B entity" shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) "Health insurance issuer" shall mean "carrier" as defined in section 1 of chapter 176O.

(4) "Third party" shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee

benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term "other adjustment" includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Restrictions or requirements regarding participation in standard or preferred pharmacy network.

E. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

F. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services.

SECTION XX. Chapter 176A of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after section 39, the following new section:-

Section 40.

(a) For purposes of this section:

(1) “340B drug” shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) “340B entity” shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) “Health insurance issuer” shall mean “carrier” as defined in section 1 of chapter 176O.

(4) “Third party” shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term “other adjustment” includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or

fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Restrictions or requirements regarding participation in standard or preferred pharmacy network.

E. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

F. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or

interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services.

SECTION XX. Chapter 176B of the General Laws, as appearing in the 2020 Official Edition, is hereby further amended by inserting after section 26 the following new section: -

Section 27.

(a) For purposes of this section:

(1) “340B drug” shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) “340B entity” shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) “Health insurance issuer” shall mean “carrier” as defined in section 1 of chapter 176O.

(4) “Third party” shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term “other adjustment” includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Restrictions or requirements regarding participation in standard or preferred pharmacy network.

E. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

F. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or

fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services.

SECTION XX. Chapter 176G of the General Laws, as appearing in the 2020 Official Edition, is hereby further amended by inserting after section 34 the following new section:-

Section 35.

(a) For purposes of this section:

(1) “340B drug” shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) “340B entity” shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) “Health insurance issuer” shall mean “carrier” as defined in section 1 of chapter 176O.

(4) “Third party” shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i)Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term “other adjustment” includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Restrictions or requirements regarding participation in standard or preferred pharmacy network.

E. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

F. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health

and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services.

SECTION XX. Chapter 176I of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after section 14 the following new section: -

Section 15.

(a) For purposes of this section:

(1) “340B drug” shall mean a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined by 42 U.S.C. 256b(a)(4).

(2) “340B entity” shall mean an entity participating or authorized to participate in the federal 340B drug discount program, as defined by 42 U.S.C. 256b, including its pharmacy, or

any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(3) “Health insurance issuer” shall mean “carrier” as defined in section 1 of chapter 176O.

(4) “Third party” shall mean a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

(5) “Manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug as defined in 247 CMR 2.00.

(6) “Pharmacy” incudes the definition of “pharmacy” and “retail drug business” as defined by section 1 of chapter 94C, and “Institutional pharmacy” as defined by section 39D of chapter 112.

(7) “Pharmacy benefit manager” shall have the same meaning as defined by section 226 of chapter 175.

(b) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third party payor, or their agents shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 U.S.C.256b or that a drug is a 340B drug including, without limitation, any of the following:

A. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this Subsection, the term "other adjustment" includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

B. Dispensing fees that are less than the dispensing fees for non-340B entities.

C. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

D. Restrictions or requirements regarding participation in standard or preferred pharmacy network.

E. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for

Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

F. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subsection, it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(v) Require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services,

Centers for Medicare and Medicaid Services, the executive office of health and human services, or the division of medical assistance.

(vi) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vii) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third party payor.

(viii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C.256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(ix) Nothing in this section applies to the division of medical assistance as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. 1396r-8(9k)).

(c) With respect to manufacturing or distribution of drugs related to 340B entities:

(i) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to

receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(ii) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

(iii) A manufacturer or distributor shall not require a 340B entity to submit any claims, utilization, patient, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the data is required by the United States Department of Health and Human Services.