A bill to be entitled

An act relating to prohibitions against discriminatory practices relating to 340B entities and 340B drugs; creating s. 499.0263, F.S.; providing definitions; prohibiting drug manufacturers from engaging in certain acts against the acquisitions of 340B drugs by and the delivery of such drugs to specified pharmacies; providing an exception; prohibiting drug manufacturers from interfering with pharmacies' rights to contract with 340B entities; providing that each commission of certain acts constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act and subjects the violator to certain actions and penalties; creating s. 626.8829, F.S.; defining terms; prohibiting certain acts by health insurance issuers, pharmacy benefit managers, or other third-party payors, or their agents, relating to reimbursement to a 340B entity for 340B drugs; providing applicability; prohibiting certain acts by manufacturers relating to interference with the acquisition of a 340B drug; prohibiting a manufacturer's interference with a pharmacy's right to contract with a 340B entity; providing that each commission of certain acts constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act and subjects the violator

to certain actions and penalties; creating ss. 627.64743, 627.65733, and 641.31543, F.S.; defining terms; prohibiting individual health insurers, group, blanket, and franchise health insurers, and health maintenance organizations, respectively, and pharmacy benefit managers on behalf of these insurers and health maintenance organizations, from engaging in certain acts against 340B entities for 340B drugs; providing applicability; providing that each commission of certain acts constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act and subjects the violator to certain actions and penalties; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.0263, Florida Statutes, is created to read:

499.0263 Prohibitions against manufacturers' discriminatory practices relating to 340B entities and 340B drugs.—

(1) As used in this section, the term:

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

U.S.C. s. 256b(a)(4).

(b) "340B entity" means an entity participating or authorized to participate in the 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(2) A manufacturer may not:

(a) Deny, restrict, prohibit, or otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by, or the 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.

(b) Interfere with a pharmacy's right to contract with a 340B entity.

(3) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act.

Section 2. Section 626.8829, Florida Statutes, is created to read:

626.8829 Prohibitions relating to 304B entities and drugs.—

(1) As used in this section, the term:

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

(b) "340B entity" means an entity participating or authorized to participate in the 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(c) "Health insurance issuer" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, which contracts, offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services. The term includes a sickness and accident insurance company, a health maintenance organization, a preferred provider organization or any similar entity, or any other entity providing a plan of health insurance or health benefits.

(d) "Manufacturer" means any person that is a manufacturer

of a prescription drug and that manufactures or distributes such prescription drug in this state.

(e) "Pharmacy" has the same meaning as in s. 465.003.

(f) "Pharmacy benefit manager" has the same meaning as in s. 626.88.

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

(a) Reimburse the 340B entity for 340B drugs at a rate lower than that paid for the same drug to non-340B entities or entities owned or operated by the pharmacy benefit manager on the basis that the claim is for a 340B drug.

(b) Impose any terms or conditions on the 340B entity which differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the 340B Drug Discount Program set forth in 42 U.S.C. s. 256b or that a drug is a 340B drug, including, but not limited to, any of the following terms or conditions relating to:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this subparagraph, the term "other adjustments" includes, but is not limited to, placing any additional requirements, restrictions, or unnecessary burdens on the 340B entity which result in administrative costs or fees to the 340B entity which are not placed on non-340B entities,

including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

2. Dispensation of fees that are less than such fees for non-340B entities.

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

4. Requirements relating to the frequency or scope of audits of inventory management systems.

5. 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 or the Agency for Health Care Administration for the administration of the Medicaid program.

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

(c) Require the 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.

(d) Base an action or contract requirement solely on the basis that the entity is a participant in the 340B Drug Discount Program in such a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the creation of a restriction or additional charge on

a patient who chooses to receive drugs from a 340B entity through direct dispensing, delivery, mail order, or administration of such drugs, regardless of the type of insurance coverage or medication. For purposes of this paragraph, it is considered a prohibited 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 on the 340B entity beyond that of any other pharmacy dispensing medications within the scope of Florida law, 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 or the Agency for Health Care Administration in administration of the Medicaid program.

(e) 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.

(f) Exclude the 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. s. 256b, or refuse to contract with the 340B entity for reasons other than those that

apply equally to non-340B entities.

(3) Subsection (2) does not apply to the Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. s. 1396r-8(k).

(4) A manufacturer may not deny, restrict, prohibit, or otherwise interfere with, directly or indirectly, the acquisition of a 340B drug by, or the 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.

(5) A manufacturer may not interfere with a pharmacy's right to contract with a 340B entity.

(6) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act.

Section 3. Section 627.64743, Florida Statutes, is created to read:

627.64743 Reimbursement of 340B entities for 340B drugs.—

(1) As used in this section, the term:

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

(b) "340B entity" means an entity participating or authorized to participate in the 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(c) "Pharmacy" has the same meaning as in s. 465.003.

(d) "Pharmacy benefit manager" has the same meaning as in s. 627.64741(1).

(2) With respect to reimbursement to a 340B entity for 340B drugs, an insurer issuing, delivering, or renewing an individual health insurance policy in this state which provides prescription drug coverage, or a pharmacy benefit manager on behalf of such insurer, may not do any of the following:

(a) Reimburse the 340B entity for 340B drugs at a rate lower than that paid for the same drug to non-340B entities on the basis that the claim is for a 340B drug.

(b) Impose any terms or conditions on the 340B entity which differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the 340B

Drug Discount Program set forth in 42 U.S.C. s. 256b or that a drug is a 340B drug, including, but not limited to, any of the following terms or conditions relating to:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this subparagraph, the term "other adjustments" includes, but is not limited to, placing any additional requirements, restrictions, or unnecessary burdens on the 340B entity which result in administrative costs or fees to the 340B entity which are not placed on non-340B entities, including affiliate pharmacies or in-network pharmacies of the insurer or of the pharmacy benefit manager.

2. Dispensation of fees that are less than such fees for non-340B entities.

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

4. Requirements relating to the frequency or scope of audits of inventory management systems.

5. 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 or the Agency for Health Care Administration for the administration of the Medicaid program.

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

(c) Require the 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.

(d) Base an action or contract requirement solely on the basis that the entity is a participant in the 340B Drug Discount Program in such a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity through direct dispensing, delivery, mail order, or administration of such drugs, regardless of the type of insurance coverage or medication. For purposes of this paragraph, it is considered a prohibited practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if the insurer, or the pharmacy benefit manager on behalf of the insurer, places any additional requirements, restrictions, or unnecessary burdens on the 340B entity beyond that of any other pharmacy dispensing medications within the scope of Florida law, 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 or the Agency for Health Care Administration in administration of

the Medicaid program.

(e) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to the insurer or the pharmacy benefit manager.

(f) Exclude the 340B entity from the network of the insurer or pharmacy benefit manager on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C. s. 256b, or refuse to contract with the 340B entity for reasons other than those that apply equally to non-340B entities.

(3) Subsection (2) does not apply to the Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. s. 1396r-8(k).

(4) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act.

Section 4. Section 627.65733, Florida Statutes, is created to read:

627.65733 Reimbursement of 340B entities for 340B drugs.—

(1) As used in this section, the term:

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

(b) "340B entity" means an entity participating or authorized to participate in the 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(c) "Pharmacy" has the same meaning as in s. 465.003.

(d) "Pharmacy benefit manager" has the same meaning as in s. 627.6572(1).

(2) With respect to reimbursement to a 340B entity for 340B drugs, an insurer issuing, delivering, or renewing a group, blanket, or franchise health insurance policy in this state which provides prescription drug coverage, or a pharmacy benefit manager on behalf of such insurer, may not do any of the following:

(a) Reimburse the 340B entity for 340B drugs at a rate lower than that paid for the same drug to non-340B entities on the basis that the claim is for a 340B drug.

(b) Impose any terms or conditions on the 340B entity which differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the 340B Drug Discount Program set forth in 42 U.S.C. s. 256b or that a

drug is a 340B drug, including, but not limited to, any of the following terms or conditions relating to:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this subparagraph, the term "other adjustments" includes, but is not limited to, placing any additional requirements, restrictions, or unnecessary burdens on the 340B entity which result in administrative costs or fees to the 340B entity which are not placed on non-340B entities, including affiliate pharmacies or in-network pharmacies of the insurer or of the pharmacy benefit manager.

2. Dispensation of fees that are less than such fees for non-340B entities.

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

4. Requirements relating to the frequency or scope of audits of inventory management systems.

5. 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 or the Agency for Health Care Administration for the administration of the Medicaid program.

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

(c) Require the 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.

(d) Base an action or contract requirement solely on the basis that the entity is a participant in the 340B Drug Discount Program in such a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity through direct dispensing, delivery, mail order, or administration of such drugs, regardless of the type of insurance coverage or medication. For purposes of this paragraph, it is considered a prohibited practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if the insurer, or the pharmacy benefit manager on behalf of the insurer, places any additional requirements, restrictions, or unnecessary burdens on the 340B entity beyond that of any other pharmacy dispensing medications within the scope of Florida law, 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 or the Agency for Health Care Administration in administration of the Medicaid program.

(e) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to the insurer or the pharmacy benefit manager.

(f) Exclude the 340B entity from the network of the insurer or pharmacy benefit manager on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C. s. 256b, or refuse to contract with the 340B entity for reasons other than those that apply equally to non-340B entities.

(3) Subsection (2) does not apply to the Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. s. 1396r-8(k).

(4) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act.

Section 5. Section 641.31543, Florida Statutes, is created to read:

641.31543 Reimbursement of 340B entities for 340B drugs.—

(1) As used in this section, the term:

(a) "340B drug" means a drug that has been subject to any

offer for reduced prices by a manufacturer pursuant to 42 U.S.C. s. 256b and is purchased by a covered entity as defined in 42 U.S.C. s. 256b(a)(4).

(b) "340B entity" means an entity participating or authorized to participate in the 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(c) "Pharmacy" has the same meaning as in s. 465.003.

(d) "Pharmacy benefit manager" has the same meaning as in s. 641.314(1).

(2) With respect to reimbursement to a 340B entity for 340B drugs, a health maintenance organization issuing, delivering, or renewing a health maintenance contract in this state which provides prescription drug coverage, or a pharmacy benefit manager on behalf of such health maintenance organization, may not do any of the following:

(a) Reimburse the 340B entity for 340B drugs at a rate lower than that paid for the same drug to non-340B entities on the basis that the claim is for a 340B drug.

(b) Impose any terms or conditions on the 340B entity which differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the 340B Drug Discount Program set forth in 42 U.S.C. s. 256b or that a drug is a 340B drug, including, but not limited to, any of the

following terms or conditions relating to:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this subparagraph, the term "other adjustments" includes, but is not limited to, placing any additional requirements, restrictions, or unnecessary burdens on the 340B entity which result in administrative costs or fees to the 340B entity which are not placed on non-340B entities, including affiliate pharmacies or in-network pharmacies of the health maintenance organization or of the pharmacy benefit manager.

2. Dispensation of fees that are less than such fees for non-340B entities.

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

4. Requirements relating to the frequency or scope of audits of inventory management systems.

5. 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 or the Agency for Health Care Administration for the administration of the Medicaid program.

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

(c) Require the 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.

(d) Base an action or contract requirement solely on the basis that the entity is a participant in the 340B Drug Discount Program in such a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity through direct dispensing, delivery, mail order, or administration of such drugs, regardless of the type of insurance coverage or medication. For purposes of this paragraph, it is considered a prohibited practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if the health maintenance organization, or the pharmacy benefit manager on behalf of the health maintenance organization, places any additional requirements, restrictions, or unnecessary burdens on the 340B entity beyond that of any other pharmacy dispensing medications within the scope of Florida law, 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 or the Agency for Health Care Administration in administration of the Medicaid

program.

(e) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to the health maintenance organization or the pharmacy benefit manager.

(f) Exclude the 340B entity from the network of the health maintenance organization or pharmacy benefit manager on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C. s. 256b, or refuse to contract with the 340B entity for reasons other than those that apply equally to non-340B entities.

(3) Subsection (2) does not apply to the Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. s. 1396r-8(k).

(4) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act.

Section 6. This act shall take effect July 1, 2025.