A bill to be entitled

An act relating to prescription drug price transparency; amending s. 499.012, F.S.; prohibiting permits for prescription drug manufacturers and nonresident prescription drug manufacturers and for certain wholesale distributors of prescription drugs from being renewed unless specified requirements are met; authorizing the Department of Business and Professional Regulation to suspend or revoke manufacturer permits and wholesale distributor permits under specified circumstances; amending s. 499.0121, F.S.; defining the term "price"; providing reporting requirements for certain entities that engage in wholesale distributions of prescription drugs; authorizing the department to request certain documentation and information; requiring the department to prescribe by rule specified timeframes; authorizing the department to extend specified timeframes; specifying what constitutes violations of specified laws; providing penalties and fines for violations; providing disposition of such fines; creating s. 499.026, F.S.; providing definitions; providing requirements for notifications by manufacturers of prescription drug price increases under certain circumstances; providing reporting

requirements; requiring the department to compile a list of specified drugs; authorizing the department to request certain documentation and information; requiring the department to prescribe by rule specified timeframes; authorizing the department to extend specified timeframes; providing duties of the department; specifying what constitutes violations of specified laws; prohibiting certain prescription drugs from being included in specified drug formularies; providing an exception; providing penalties and fines for violations; providing disposition of such fines; requiring the department to adopt rules; amending s. 499.05, F.S.; requiring the department to adopt rules; conforming provisions to changes made by the act; amending s. 624.490, F.S.; providing definitions; providing reporting requirements for registered pharmacy benefit managers; authorizing the Office of Insurance Regulation to request certain documentation and information; requiring the Financial Services Commission to prescribe by rule specified timeframes; authorizing the office to extend specified timeframes; requiring registered pharmacy benefit managers to maintain a website for a specified purpose and to update the information on the website under certain circumstances; specifying what constitutes violations

of specified laws; providing penalties and fines for violations; providing disposition of such fines; creating ss. 627.42384 and 641.3131, F.S.; requiring certain health insurers and health maintenance organizations, respectively, to submit and update contact information for single points of contact for a specified use; requiring the office to maintain and publish such points of contact; requiring such health insurers and health maintenance organizations to notify certain insureds and subscribers, respectively, within a specified timeframe of drug formulary changes; providing applicability; amending ss. 627.64741, 627.6572, and 641.314, F.S.; defining the term "net price"; providing additional requirements for contracts between pharmacy benefit managers and individual health insurers, group health insurers, and health maintenance organizations, respectively; providing applicability; amending ss. 110.12315, 409.815, 409.91195, 409.912, and 499.067, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Paragraph (f) is added to subsection (1) of

section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.—

(1)

(f)1. A permit for a prescription drug manufacturer or nonresident prescription drug manufacturer may not be renewed unless the prescription drug manufacturer or nonresident prescription drug manufacturer meets the requirements of s. 499.026. The department may suspend or revoke the permit of a manufacturer that fails to comply with the requirements of s. 499.026.

2. A permit for a prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, veterinary prescription drug wholesale distributor, or limited prescription drug veterinary wholesale distributor may not be renewed unless the wholesale distributor meets the requirements of s. 499.0121(16). The department may suspend or revoke the permit of a wholesale distributor that fails to comply with the requirements of s. 499.0121(16).

Section 2. Subsection (16) is added to section 499.0121, Florida Statutes, to read:

499.0121 Storage and handling of prescription drugs; recordkeeping; prescription drug price report requirements; penalties for noncompliance.—The department shall adopt rules to implement this section as necessary to protect the public

health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(16) PRESCRIPTION DRUG PRICE REPORT AND PENALTIES FOR NONCOMPLIANCE.—

(a) As used in this subsection, the term "price" means the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(b) By July 1 of each year, each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, prescription drug wholesale distributor, veterinary prescription drug wholesale distributor, or limited prescription drug veterinary wholesale distributor, or each manufacturer or repackager that engages in the wholesale distribution of prescription drugs, shall submit a report to the department on each prescription drug for which the price, during the previous calendar year:

1. Was $100 or more for a 30-day supply or for a course of treatment lasting less than 30 days; or

2. Increased by at least 10 percent over the previous price.

(c) The report must include, at a minimum, the following information:

1. The name and the price at the time of the report of each prescription drug specified in paragraph (b) and the cumulative percentage price increase during the previous calendar year.

2. The length of time the prescription drug has been on the market.

3. The factors that contributed to the price increase.

4. The name of any generic version of the prescription drug available on the market.

5. The total sales revenue for the prescription drug during the previous calendar year.

6. The introductory price of the prescription drug when it was approved by the United States Food and Drug Administration and the cumulative yearly increase, by calendar year, in the price of the drug during the previous 5 years or during the number of years the drug has been on the market, whichever is less.

7. Any prompt pay or discount, rebate, or reduction in price provided by the reporting wholesale distributor or manufacturer or repackager that engages in the wholesale distribution of prescription drugs when selling a prescription

drug to a manufacturer, pharmacy, pharmacy benefit manager, and other entities.

8. The documentation necessary to support the information reported under this paragraph.

(d) The department may make a written request to the reporting wholesale distributor, manufacturer, or repackager for supporting documentation or additional information concerning the report. The department shall prescribe by rule the timeframes for the department's request for documentation or information and for the response by the reporting wholesale distributor, manufacturer, or repackager. The department may extend the timeframe, if necessary, for the response by the wholesale distributor, manufacturer, or repackager.

(e) A wholesale distributor, or a manufacturer or repackager that engages in the wholesale distribution of prescription drugs, violates this subsection if the wholesale distributor, manufacturer, or repackager:

1. Fails to timely submit the report required under this subsection;

2. Fails to provide information required under this subsection;

3. Fails to timely respond to a written request by the department with regard to the report required under this subsection; or

4. Provides inaccurate or incomplete information in the

report required under this subsection.

(f)1. The department may deny an application for a renewal permit or registration or suspend or revoke a registration certificate or a permit of a prescription drug wholesale distributor, or a manufacturer or repackager that engages in the wholesale distribution of prescription drugs, for violating this subsection.

2.a. The department may also impose an administrative fine, not to exceed $5,000 per violation per day, for a violation of this subsection or a rule adopted to administer this subsection. Each day the violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine.

b. In determining the amount of fine to be levied for a violation of this subsection, the department must consider the following factors:

(I) The severity of the violation.

(II) Any action taken by the permittee to correct the violation or to remedy complaints.

(III) Any previous violation.

c. All fines collected under this subparagraph shall be deposited into the Public Medical Assistance Trust Fund administered by the Agency for Health Care Administration, to be used to help the uninsured pay for health care.

Section 3. Section 499.026, Florida Statutes, is created

to read:

499.026 Prescription drug price transparency.—

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Division" means the Division of Consumer Services of the Department of Agriculture and Consumer Services.

(c) "Drug" means a prescription drug.

(d) "Health insurer" means a health insurer issuing major medical coverage through an individual or group policy or a health maintenance organization issuing major medical coverage through an individual or group contract, regulated under chapter 627 or chapter 641.

(e) "Medicaid" means the Agency for Health Care Administration Medicaid program.

(f) "Office" means the Office of Insurance Regulation of the Financial Services Commission.

(g) "Price" means the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(2)(a) At least 120 days before the effective date of any single manufacturer increase of at least 10 percent in the price

of a drug, a manufacturer must provide notice of the upcoming drug price increase to:

1. The department, the Department of Health, the agency, the division, and the office.

2. Every health insurer that covers the drug. The manufacturer shall use the contact list published by the office under ss. 627.42384 and 641.3131 to provide notice to health insurers. Notification shall be presumed to occur on the date that the manufacturer attempts to communicate with the applicable point of contact published by the office.

(b) The notices must include, at a minimum, the following information:

1. The name and current price of the drug.

2. The date that the increase will become effective.

3. The dollar amount of the intended increase in the price of the drug.

4. The percentage price increase.

5. A statement of whether the price increase is necessitated by a change or improvement of the drug and, if so, a description of the change or improvement.

6. A description of any other factors that contributed to the price increase.

7. The documentation necessary to support the information reported under subparagraphs 5. and 6.

(3)(a) By July 1 of each year, a manufacturer shall submit

a report to the department, the Department of Health, the agency, the division, and the office on each drug for which the price, during the previous calendar year:

1. Was $100 or more for a 30-day supply or for a course of treatment lasting less than 30 days; or

2. Increased by at least 10 percent over the previous price in a single manufacturer price.

(b) The report must include, at a minimum, the following information:

1. The name and the price at the time of the report of each drug specified in paragraph (a) and the cumulative percentage price increase during the previous calendar year.

2. The length of time the drug has been on the market.

3. The factors that contributed to the price increase.

4. The name of any generic version of the drug available on the market.

5. The research and development costs associated with the drug that were paid using public funds.

6. The direct costs incurred by the manufacturer to manufacture, market, and distribute the drug and to ensure ongoing safety and effectiveness research associated with the drug.

7. The total sales revenue for the drug during the previous calendar year.

8. The manufacturer's profit attributable to the drug

during the previous calendar year.

9. The introductory price of the drug when it was approved by the United States Food and Drug Administration and the cumulative yearly increase, by calendar year, in the price of the drug during the previous 5 years or during the number of years the drug has been on the market, whichever is less.

10. The 10 highest prices paid for the drug during the previous year in other countries.

11. The documentation necessary to support the information reported under this paragraph.

(4)(a) Before reviewing the data in the report filed under subsection (3), the department, in consultation with the Department of Health, the agency, and the office, shall compile a list of drugs that have a significant cost to the state or that are designated as being critical to public health. Such drugs may be sourced from the Medicaid drug utilization data and drug spending data, the division's drug spending data, and the drug spending data of health insurers and health plans and their pharmacy benefit managers.

(b) After receiving the report required under subsection (3), the department:

1. May make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the timeframes for the department's request for documentation or

information and for the manufacturer's response to the request. The department may extend the timeframe, if necessary, for the manufacturer's response.

2. Shall review the costs and the factors contributing to each drug price or drug price increase in the report.

3. Shall review the price and price increase of each drug on the list compiled under paragraph (a) and each drug on the lists reported by wholesale distributors and other entities engaged in wholesale distribution of prescription drugs and by registered pharmacy benefit managers under ss. 499.0121(16) and 624.490(6)(b), respectively, to make sure that any drug on the compiled and reported lists which fits the criterion in subparagraph (3)(a)1. or subparagraph (3)(a)2. is also reported by the drug's manufacturer under subsection (3).

4. Shall, in consultation with the Department of Health, the division, and the office, determine whether the manufacturer has violated this section.

(5) A manufacturer violates this section if the manufacturer:

(a) Fails to timely submit notices or reports required under this section;

(b) Fails to provide information required under this section;

(c) Fails to timely respond to a written request by the department with regard to the notices or report required under

this section; or

(d) Provides inaccurate or incomplete information in the notices or report required under this section.

(6) A drug for which the manufacturer does not comply with the notification or reporting requirements under this section may not be included in the Medicaid's and state group health insurance's drug formularies unless the drug is the most clinically appropriate, clinically effective, and lowest net-cost drug.

(7)(a) The department may deny an application for a renewal permit or suspend or revoke a permit of a prescription drug manufacturer or nonresident prescription drug manufacturer for violating this section.

(b)1. The department may also impose an administrative fine, not to exceed $5,000 per violation per day, for a violation of this section or a rule adopted under this section. Each day the violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine.

2. In determining the amount of fine to be levied for a violation of this section, the department, in consultation with the Department of Health, the agency, the division, and the office, must consider the following factors:

a. The severity of the violation.

b. Any action taken by the permittee to correct the

violation or to remedy complaints.

c. Any previous violation.

3. All fines collected under this section shall be deposited into the Public Medical Assistance Trust Fund administered by the agency, to be used to help the uninsured pay for health care.

(8) The department shall adopt rules to administer this section.

Section 4. Paragraph (m) of subsection (1) of section 499.05, Florida Statutes, is amended, and paragraph (o) is added to that subsection, to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter with respect to:

(m) Wholesale distributor reporting requirements of s. 499.0121(14) and (16) ~~s. 499.0121(14)~~.

(o) Manufacturer notification and reporting requirements of s. 499.026(2) and (3).

Section 5. Subsection (6) of section 624.490, Florida Statutes, is renumbered as subsection (7), and a new subsection (6) is added to that section, to read:

624.490 Registration of pharmacy benefit managers; prescription drug price report and public access requirements; penalties for noncompliance.—

(6)(a) As used in this subsection, the term:

1. "Negotiated price" means the value at which a prescription drug is sold by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy, under a prescription drug benefits coverage administered by a pharmacy benefit manager, before any tax or cost is added and any discount, rebate, or reduction in price, including a rebate offered to the pharmacy benefit manager, is subtracted.

2. "Net price" means the value at which a prescription drug is sold by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy, under a prescription drug benefits coverage administered by a pharmacy benefit manager, after all taxes and other costs are added and all discounts, rebates, and reductions in price are subtracted, including any rebate offered to the pharmacy benefit manager which is passed on to the health insurer or health maintenance organization.

3. "Rebate offered to a pharmacy benefit manager" means a direct payment by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy to a pharmacy benefit manager for a prescription drug dispensed to an insured or subscriber. Such payment serves an incentive for the pharmacy benefit manager to promote use of the prescription drug, and the pharmacy benefit manager may choose to keep the payment or to pass it on, in full or in part, to the health insurer or health maintenance organization.

(b)1. By July 1 of each year, a registered pharmacy benefit manager shall submit a report to the office on each prescription drug for which the negotiated price, during the previous calendar year:

a. Was $100 or more for a 30-day supply or for a course of treatment lasting less than 30 days; or

b. Increased by at least 10 percent over the previous negotiated price.

2. The report must include, at a minimum, the following information:

a. The name and the negotiated price at the time of the report of each prescription drug specified in subparagraph 1. and the cumulative percentage negotiated price increase during the previous calendar year.

b. The name of any generic version of the prescription drug available on the market.

c. The total sales revenue of the pharmacy benefit manager for the prescription drug during the previous calendar year.

d. The documentation necessary to support the information reported under this paragraph.

3. The office may make a written request to the pharmacy benefit manager for supporting documentation or additional information concerning the report. The commission shall prescribe by rule the timeframes for the office's request for documentation or information and for the pharmacy benefit

manager's response to the request. The office may extend the timeframe, if necessary, for the pharmacy benefit manager's response.

(c) A registered pharmacy benefit manager shall maintain a website that provides public access to the net price of each prescription drug. The registered pharmacy benefit manager shall update the net price of a prescription drug on the website at least 90 days before the net price of the prescription drug changes.

(d) A registered pharmacy benefit manager violates this subsection if the registered pharmacy benefit manager:

1. Fails to timely submit the report required under paragraph (b);

2. Fails to provide information required under paragraph (b);

3. Fails to timely respond to a written request by the office with regard to the report required under paragraph (b);

4. Provides inaccurate or incomplete information in the report required under paragraph (b); or

5. Fails to maintain a website for access to net prices of prescription drugs or to update the net prices on the website, as required under paragraph (c).

(e)1. The office may deny an application for renewal registration or suspend or revoke a registration certificate of a pharmacy benefit manager for violating this subsection.

2.a. The office may also impose an administrative fine, not to exceed $5,000 per violation per day, for a violation of this subsection or a rule adopted to administer this subsection. Each day the violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine.

b. In determining the amount of fine to be levied for a violation of this subsection, the office must consider the following factors:

(I) The severity of the violation.

(II) Any action taken by the pharmacy benefit manager to correct the violation or to remedy complaints.

(III) Any previous violation.

c. All fines collected under this subsection shall be deposited into the Public Medical Assistance Trust Fund administered by the Agency for Health Care Administration, to be used to help the uninsured pay for health care.

Section 6. Section 627.42384, Florida Statutes, is created to read:

627.42384 Formulary changes resulting from drug price increases.—

(1) A health insurer issuing a major medical individual or group policy shall submit, and update as necessary, contact information for a single point of contact for use by prescription drug manufacturers to comply with s. 499.026. The

office shall maintain and publish on its website a list of such points of contact.

(2) A health insurer issuing a major medical individual or group policy must provide written notice to each affected insured and each prescribing health care provider at least 90 days before making a drug formulary change that results from a prescription drug price increase reported by a drug manufacturer under s. 499.026(2).

(3) This section applies to policies entered into or renewed on or after January 1, 2023.

Section 7. Paragraph (b) of subsection (1) of section 627.64741, Florida Statutes, is redesignated as paragraph (c), subsection (5) is amended, a new paragraph (b) is added to subsection (1), and paragraphs (c) through (f) are added to subsection (2) of that section, to read:

627.64741 Pharmacy benefit manager contracts.—

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

(b) "Net price" means the value at which a prescription drug is sold by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy, under a prescription drug benefits coverage administered by a pharmacy benefit manager, after all taxes and other costs are added and all discounts, rebates, and reductions in price are subtracted, including any rebate offered to the pharmacy benefit manager which is passed on to the health insurer.

(2) A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(c) Maintain a website that provides public access to the net price of each covered prescription drug and update the net price of a covered prescription drug on the website at least 90 days before the net price of the covered prescription drug changes.

(d) Provide written notice to each affected insured and each prescribing health care provider at least 90 days before making a change in the drug formulary or in the net price of a covered prescription drug, including a change that results from a price increase of a covered prescription drug reported by a drug manufacturer under s. 499.026(2).

(e) Inform an affected insured, in writing, of the net price of each covered prescription drug for which the insured has made a payment.

(f) Provide in writing to each insured and each prescribing health care provider the address of the pharmacy benefit manager's website where the list of the net prices of all prescription drugs is posted.

(5) This section applies to contracts entered into or renewed on or after July 1, 2022 ~~July 1, 2018~~.

Section 8. Paragraph (b) of subsection (1) of section 627.6572, Florida Statutes, is redesignated as paragraph (c), subsection (5) is amended, a new paragraph (b) is added to

subsection (1), and paragraphs (c) through (f) are added to subsection (2) of that section, to read:

627.6572 Pharmacy benefit manager contracts.—

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

(b) "Net price" means the value at which a prescription drug is sold by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy, under a prescription drug benefits coverage administered by a pharmacy benefit manager, after all taxes and other costs are added and all discounts, rebates, and reductions in price are subtracted, including any rebate offered to the pharmacy benefit manager which is passed on to the health insurer.

(2) A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(c) Maintain a website that provides public access to the net price of each covered prescription drug and update the net price of a covered prescription drug on the website at least 90 days before the net price of the covered prescription drug changes.

(d) Provide written notice to each affected insured and each prescribing health care provider at least 90 days before making a change in the drug formulary or in the net price of a covered prescription drug, including a change that results from a price increase of a covered prescription drug reported by a drug manufacturer under s. 499.026(2).

(e) Inform an insured, in writing, of the net price of each covered prescription drug for which the insured has made a payment.

(f) Provide in writing to each insured and each prescribing health care provider the address of the pharmacy benefit manager's website where the list of the net prices of all covered prescription drugs is posted.

(5) This section applies to contracts entered into or renewed on or after July 1, 2022 ~~July 1, 2018~~.

Section 9. Section 641.3131, Florida Statutes, is created to read:

641.3131 Formulary changes resulting from drug price increases.—

(1) A health maintenance organization issuing a major medical or other comprehensive coverage contract shall submit, and update as necessary, contact information for a single point of contact for use by prescription drug manufacturers to comply with s. 499.026. The office shall maintain and publish on its website a list of such points of contact.

(2) A health maintenance organization issuing a major medical or other comprehensive coverage contract must provide written notice to each affected subscriber and each prescribing health care provider at least 90 days before making a drug formulary change that results from a prescription drug price increase reported by a drug manufacturer under s. 499.026(2).

(3) This section applies to contracts entered into or renewed on or after January 1, 2023.

Section 10. Paragraph (b) of subsection (1) of 641.314, Florida Statutes, is redesignated as paragraph (c), subsection (5) is amended, a new paragraph (b) is added to subsection (1), and paragraphs (c) through (f) are added to subsection (2) of that section, to read:

641.314 Pharmacy benefit manager contracts.—

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

(b) "Net price" means the value at which a prescription drug is sold by a prescription drug manufacturer, prescription drug wholesale distributor, or pharmacy, under a prescription drug benefits coverage administered by a pharmacy benefit manager, after all taxes and other costs are added and all discounts, rebates, and reductions in price are subtracted, including any rebate offered to the pharmacy benefit manager which is passed on to the health maintenance organization.

(2) A contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:

(c) Maintain a website that provides public access to the net price of each covered prescription drug and update the net price of a covered prescription drug on the website at least 90 days before the net price of the covered prescription drug changes.

(d) Provide written notice to each affected subscriber and each prescribing health care provider at least 90 days before making a change in the drug formulary or in the net price of a covered prescription drug, including a change that results from a price increase of a covered prescription drug reported by a drug manufacturer under s. 499.026(2).

(e) Inform a subscriber in writing of the net price of each covered prescription drug for which the subscriber has made a payment.

(f) Provide in writing to each subscriber and each prescribing health care provider the address of the pharmacy benefit manager's website where the list of the net prices of all prescription drugs is posted.

(5) This section applies to contracts entered into or renewed on or after July 1, 2022 ~~July 1, 2018~~.

Section 11. Subsections (3) and (4) and paragraph (a) of subsection (9) of section 110.12315, Florida Statutes, are amended to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(3) The department shall maintain the generic, preferred

brand name, and the nonpreferred brand name lists of drugs and supplies to be used in the administration of the state employees' prescription drug program. These lists may not include a prescription drug for which the prescription drug manufacturer does not comply with the requirements of s. 499.026 unless the prescription drug is the most clinically appropriate, clinically effective, and lowest net-cost prescription drug.

(4) The department shall maintain a list of maintenance drugs and supplies. The list may not include a drug for which the prescription drug manufacturer does not comply with the requirements of s. 499.026 unless the prescription drug is the most clinically appropriate, clinically effective, and lowest net-cost prescription drug.

(a) Preferred provider organization health plan members may have prescriptions for maintenance drugs and supplies filled up to three times as a supply for up to 30 days through a retail pharmacy; thereafter, prescriptions for the same maintenance drug or supply must be filled for up to 90 days either through the department's contracted mail order pharmacy or through a retail pharmacy.

(b) Health maintenance organization health plan members may have prescriptions for maintenance drugs and supplies filled for up to 90 days either through a mail order pharmacy or through a retail pharmacy.

(9)(a) Beginning with the 2020 plan year, the department

must implement formulary management for prescription drugs and supplies. Such management practices must require prescription drugs to be subject to formulary inclusion or exclusion and, beginning with the 2023 plan year, must require a prescription drug for which the prescription drug manufacturer does not comply with the requirements of s. 499.026 to be subject to formulary exclusion, but may not restrict access to the most clinically appropriate, clinically effective, and lowest net-cost prescription drugs and supplies. Drugs excluded from the formulary must be available for inclusion if a physician, advanced practice registered nurse, or physician assistant prescribing a pharmaceutical clearly states on the prescription that the excluded drug is medically necessary. Prescription drugs and supplies first made available in the marketplace after January 1, 2020, may not be covered by the prescription drug program until specifically included in the list of covered prescription drugs and supplies.

Section 12. Paragraph (n) of subsection (2) of section 409.815, Florida Statutes, is amended to read:

409.815 Health benefits coverage; limitations.—

(2) BENCHMARK BENEFITS.—In order for health benefits coverage to qualify for premium assistance payments for an eligible child under ss. 409.810-409.821, the health benefits coverage, except for coverage under Medicaid and Medikids, must include the following minimum benefits, as medically necessary.

(n) Prescribed drugs.—

1. Coverage shall include drugs prescribed for the treatment of illness or injury when prescribed by a licensed health practitioner acting within the scope of his or her practice.

2. Prescribed drugs may be limited to generics if available and brand name products if a generic substitution is not available, unless the prescribing licensed health practitioner indicates that a brand name is medically necessary.

3. Prescribed drugs covered under this section shall include all prescribed drugs covered under the Florida Medicaid program.

4. Prescribed drugs may not include a prescription drug for which the manufacturer does not comply with the requirements of s. 499.026 unless the prescription drug is the most clinically appropriate, clinically effective, and lowest net-cost prescription drug or unless a physician, advanced practice registered nurse, or physician assistant prescribing the drug clearly states on the prescription that the excluded drug is medically necessary.

Section 13. Subsection (8) of section 409.91195, Florida Statutes, is amended to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.—There is created a Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of

developing a Medicaid preferred drug list.

(8) The committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product and the manufacturer's prescription drug price transparency, as required under s. 499.012.

Section 14. Paragraph (a) of subsection (5) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to

minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without

limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(5)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the

Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Drugs for which the manufacturer does not comply with the requirements of s. 499.026 are excluded from the preferred list, unless the drug is the most clinically appropriate, clinically effective, and lowest net-cost prescription drug. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior

authorization by telephone or other telecommunication device within 24 hours after receipt of a request for prior authorization; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. A provider of prescribed drugs is reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the Centers for Medicare and Medicaid Services National Average Drug Acquisition Cost pricing files plus a professional dispensing fee, the wholesale acquisition cost plus a professional dispensing fee, the state maximum allowable cost plus a professional dispensing fee, or the usual and customary charge billed by the provider.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients,

patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that

requires Medicaid practitioners who issue written prescriptions for medicinal drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by prescribers who issue written prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The

agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality

of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential

medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

9. The agency shall implement a Medicaid prescription drug management system.

a. The agency may contract with a vendor that has experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best

practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

10. The agency may contract for drug rebate administration, including, but not limited to, calculating

rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

11. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

12. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of

certain medications subject to prior authorization.

13. The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

14. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the

agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

15. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency

shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

Section 15. Subsection (9) of section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(9)(a) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

(b) The department may deny an application for a renewal permit or suspend or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(16).

(c) The department may deny an application for a renewal permit or suspend or revoke a permit if it finds the permittee has not complied with the notification or reporting requirements of, or knowingly made a false statement in a notice or report required by, s. 499.026(2) or (3), respectively.

Section 16. This act shall take effect July 1, 2022.