By Senator Wright

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A bill to be entitled An act relating to prescription drug coverage; amending s. 624.3161, F.S.; authorizing the Office of Insurance Regulation to examine pharmacy benefit managers; specifying that certain examination costs are payable by persons examined; transferring, renumbering, and amending s. 465.1885, F.S.; revising entities conducting pharmacy audits to which certain requirements and restrictions apply; authorizing audited pharmacies to appeal certain findings; providing that health insurers and health maintenance organizations that transfer a certain payment obligation to pharmacy benefit managers remain responsible for certain violations; creating s. 624.491, F.S.; providing applicability; requiring health insurers and health maintenance organizations, or pharmacy benefit managers on behalf of health insurers and health maintenance organizations, to annually report specified information to the office; requiring reporting pharmacy benefit managers to also provide the information to health insurers and health maintenance organizations they contract with; authorizing the Financial Services Commission to adopt rules; amending ss. 627.64741, 627.6572, and 641.314, F.S.; defining and redefining terms; specifying requirements relating to brand-name and generic drugs in contracts between pharmacy benefit managers and pharmacies or pharmacy services administration organizations; requiring an agreement for pharmacy

benefit managers to pass through certain financial benefits to the individual or group health insurer or health maintenance organization, respectively; authorizing the office to require health insurers or health maintenance organizations to submit certain contracts or contract amendments to the office; authorizing the office to order insurers or health maintenance organizations to cancel such contracts under certain circumstances; authorizing the commission to adopt rules; revising applicability; providing an effective date.

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

Section 1. Subsections (1) and (3) of section 624.3161, Florida Statutes, are amended to read:

624.3161 Market conduct examinations.

- (1) As often as it deems necessary, the office shall examine each pharmacy benefit manager, each licensed rating organization, each advisory organization, each group, association, carrier, as defined in s. 440.02, or other organization of insurers which engages in joint underwriting or joint reinsurance, and each authorized insurer transacting in this state any class of insurance to which the provisions of chapter 627 are applicable. The examination shall be for the purpose of ascertaining compliance by the person examined with the applicable provisions of chapters 440, 624, 626, 627, and 635.
  - (3) The examination may be conducted by an independent

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professional examiner under contract to the office, in which case payment shall be made directly to the contracted examiner by the insurer or person examined in accordance with the rates and terms agreed to by the office and the examiner.

Section 2. Section 465.1885, Florida Statutes, is transferred, renumbered as s. 624.491, Florida Statutes, and amended to read:

624.491 465.1885 Pharmacy audits; rights.-

- (1) A health insurer or health maintenance organization providing pharmacy benefits through a major medical individual or group health insurance policy or health maintenance contract, respectively, shall comply with the requirements of this section when the insurer or health maintenance organization or any entity acting on behalf of the insurer or health maintenance organization, including, but not limited to, a pharmacy benefit manager, audits the records of a pharmacy licensed under chapter 465. Such audit must comply with the following requirements If an audit of the records of a pharmacy licensed under this chapter is conducted directly or indirectly by a managed care company, an insurance company, a third-party payor, a pharmacy benefit manager, or an entity that represents responsible parties such as companies or groups, referred to as an "entity" in this section, the pharmacy has the following rights:
- (a) The pharmacy must  $\overline{\text{To}}$  be notified at least 7 calendar days before the initial onsite audit for each audit cycle.
- (b) An To have the onsite audit may not be scheduled during after the first 3 calendar days of a month unless the pharmacist consents otherwise.
  - (c) The scope of <del>To have</del> the audit period must be limited

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to 24 months after the date a claim is submitted to or adjudicated by the entity.

- (d)  $\overline{\text{To have}}$  An audit that requires clinical or professional judgment  $\underline{\text{must be}}$  conducted by or in consultation with a pharmacist.
- (e) A pharmacy may To use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.
- (f) A pharmacy must To be reimbursed for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.
- (g) A copy of To receive the preliminary audit report <u>must</u> be provided to the pharmacy within 120 days after the conclusion of the audit.
- (h) A pharmacy may  $\overline{\text{TO}}$  produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.
- (i) A copy of To receive the final audit report <u>must be</u> provided to the pharmacy within 6 months after <u>receipt of</u> receiving the preliminary audit report.
- (j) Any  $\overline{\text{To have}}$  recoupment or penalties  $\underline{\text{must be calculated}}$  based on actual overpayments and not according to the accounting practice of extrapolation.
  - (2) The rights contained in This section does do not apply

to:

(a) Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;

- (b) Audits of claims paid for by federally funded programs; or
- (c) Concurrent reviews or desk audits that occur within 3 business days  $\underline{\text{after}}$  of transmission of a claim and where no chargeback or recoupment is demanded.
- (3) An entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice may dispense with the notice requirements of paragraph (1)(a) if such pharmacy has been a member of a credentialed provider network for less than 12 months.
- (4) Pursuant to s. 408.7057 and after receipt of the final audit report issued by the health insurer or health maintenance organization, a pharmacy may appeal the findings of the final audit as to whether a claim payment is due or the amount of a claim payment.
- (5) If a health insurer or health maintenance organization transfers to a pharmacy benefit manager through a contract the obligation to pay any pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of any insured or subscriber, the health insurer or health maintenance organization remains responsible for any violations of this section, s. 627.6131, or s. 641.3155.

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Section 3. Section 624.491, Florida Statutes, is created to read:

- 624.491 Health insurer, health maintenance organization, and pharmacy benefit manager reporting requirements.—
  - (1) This section applies to:
- (a) A health insurer or health maintenance organization issuing, delivering, or issuing for delivery comprehensive major medical individual or group insurance policies or health maintenance contracts, respectively, in this state; and
- (b) A pharmacy benefit manager providing pharmacy benefit management services on behalf of a health insurer or health maintenance organization described in paragraph (a) and managing prescription drug coverage under a contract with the health insurer or health maintenance organization.
- (2) By March 1 annually, a health insurer or health maintenance organization, or a pharmacy benefit manager on behalf of a health insurer or health maintenance organization, shall report, in a form and manner as prescribed by the commission, the following information to the office with respect to services provided by the health insurer or health maintenance organization, or the pharmacy benefit manager on behalf of the insurer or health maintenance organization, for the immediately preceding policy or contract year:
  - (a) The total number of prescriptions that were dispensed.
- (b) The number and percentage of all prescriptions that were provided through retail pharmacies compared to mail-order pharmacies. This paragraph applies to pharmacies licensed under chapter 465 which dispense drugs to the general public and which were paid by the health insurer, health maintenance

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organization, or pharmacy benefit manager under the contract.

(c) For retail pharmacies and mail-order pharmacies described in paragraph (b), the general dispensing rate, which is the number and percentage of prescriptions for which a generic drug was available and dispensed.

- (d) The aggregate amount and types of rebates, discounts, price concessions, or other earned revenues that the health insurer, health maintenance organization, or pharmacy benefit manager negotiated for and are attributable to patient utilization under the plan, excluding bona fide service fees that include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs.
- (e) If negotiated by the pharmacy benefit manager, the aggregate amount of the rebates, discounts, or price concessions under paragraph (d) which were passed through to the health insurer or health maintenance organization.
- (f) If the health insurer or health maintenance organization contracted with a pharmacy benefit manager, the aggregate amount of the difference between the amount the health insurer or health maintenance organization paid the pharmacy benefit manager and the amount the pharmacy benefit manager paid retail pharmacies and mail order pharmacies.
- (3) A pharmacy benefit manager that reports the information under subsection (2) to the office shall also provide the information to the health insurer or health maintenance organization with which the pharmacy benefit manager is under contract.

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(4) The commission may adopt rules to administer this section.

Section 4. Section 627.64741, Florida Statutes, is amended to read:

- 627.64741 Pharmacy benefit manager contracts.-
- (1) As used in this section, the term:
- (a) "Brand-name drug" means a drug that:
- 1. Is a brand drug described by Medi-Span and has a multisource code field containing an "M" (cobranded product), an "O" (originator brand), or an "N" (single-source brand), except for a drug with a multisource code of "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or
- 2. Has an equivalent brand drug designation in the First Databank FDB MedKnowledge database.
  - (b) "Generic drug" means a drug that:
- 1. Is a generic drug described by Medi-Span and has a multisource code field containing a "Y" (generic), or an "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or
- 2. Has an equivalent generic drug designation in the First Databank FDB MedKnowledge database.
- (c) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug:
- 1. As specified at the time of claim processing and directly or indirectly reported on the initial remittance advice of an adjudicated claim for a generic drug, brand-name drug, biological product, or specialty drug;
- 2. Which amount must be based on pricing published in the Medi-Span Master Drug Database, or, if the pharmacy benefit

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manager uses only First Databank FDB MedKnowledge, must be based on pricing published in First Databank FDB MedKnowledge; and

- 3. au Excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (d) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer to residents of this state.
- (2) A health insurer may contract only with a pharmacy benefit manager that A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:
- (a) <u>Updates</u> <del>Update</del> maximum allowable cost pricing information at least every 7 calendar days.
- (b) Maintains Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.
- (c) (3) Does not limit A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.
- (d) (4) Does not require A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that

exceeds the lesser of:

- 1.(a) The applicable cost-sharing amount; or
- 2.(b) The retail price of the drug in the absence of prescription drug coverage.
- (3) A drug identified as a brand-name drug must be considered a brand-name drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy services administration organization on behalf of the pharmacy. A single-source generic drug with only one manufacturer must be reimbursed as if it were a brand-name drug.
- (4) A drug identified as a generic drug must be considered a generic drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy services administrative organization acting on behalf of the pharmacy. The pharmacy benefit manager and the pharmacy, or a pharmacy services administrative organization on behalf of the pharmacy, shall agree that if the pharmacy benefit manager is provided any rebate or other financial benefit for any drug identified as a generic drug, the pharmacy benefit manager must pass through all such rebates or other financial benefits to the health insurer.
- (5) The office may require a health insurer to submit to the office any contract, or amendments to a contract, for the administration or management of prescription drug benefits by a pharmacy benefit manager on behalf of the insurer.
- (6) After review of a contract under subsection (5), the office may order the insurer to cancel the contract in accordance with the terms of the contract and applicable law if

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14-01655-20 20201338 the office determines that any of the following conditions 292 exist: 293 (a) The fees to be paid by the insurer are so unreasonably 294 high as compared with similar contracts entered into by 295 insurers, or as compared with similar contracts entered into by 296 other insurers in similar circumstances, that the contract is detrimental to the policyholders of the insurer. (b) The contract does not comply with the Florida Insurance 299 Code. (c) The pharmacy benefit manager is not registered with the office pursuant to s. 624.490. (7) The commission may adopt rules to administer this 303 section. (8) (5) This section applies to contracts entered into, 305 amended, or renewed on or after July 1, 2020 2018. Section 5. Section 627.6572, Florida Statutes, is amended to read: 627.6572 Pharmacy benefit manager contracts.-(1) As used in this section, the term: (a) "Brand-name drug" means a drug that: 1. Is a brand drug described by Medi-Span and has a 312 multisource code field containing an "M" (cobranded product), an "O" (originator brand), or an "N" (single-source brand), except 313 for a drug with a multisource code of "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or 2. Has an equivalent brand drug designation in the First 317 Databank FDB MedKnowledge database. (b) "Generic drug" means a drug that:

1. Is a generic drug described by Medi-Span and has a

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multisource code field containing a "Y" (generic), or an "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or

- 2. Has an equivalent generic drug designation in the First Databank FDB MedKnowledge database.
- (c) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug:
- 1. As specified at the time of claim processing and directly or indirectly reported on the initial remittance advice of an adjudicated claim for a generic drug, brand-name drug, biological product, or specialty drug;
- 2. Which amount must be based on pricing published in the Medi-Span Master Drug Database, or, if the pharmacy benefit manager uses only First Databank FDB MedKnowledge, must be based on pricing published in First Databank FDB MedKnowledge; and
- 3.  $\tau$  Excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (d) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer to residents of this state.
- (2) A health insurer may contract only with a pharmacy benefit manager that A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:
- (a) <u>Updates</u> <del>Update</del> maximum allowable cost pricing information at least every 7 calendar days.
- (b)  $\underline{\text{Maintains}}$   $\underline{\text{Maintain}}$  a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or

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modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

- (c) (3) Does not limit A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.
- (d) (4) Does not require A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:
  - 1.<del>(a)</del> The applicable cost-sharing amount; or
- 2.(b) The retail price of the drug in the absence of prescription drug coverage.
- (3) A drug identified as a brand-name drug must be considered a brand-name drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and pharmacy, or a pharmacy services administration organization on behalf of the pharmacy. A single-source generic drug with only one manufacturer must be reimbursed as if it were a brand-name drug.
- (4) A drug identified as a generic drug must be considered a generic drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy services administrative organization acting on behalf of the pharmacy. The pharmacy benefit manager

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and the pharmacy, or a pharmacy services administrative organization on behalf of the pharmacy, shall agree that if the pharmacy benefit manager is provided any rebate or other financial benefit for any drug identified as a generic drug, the pharmacy benefit manager must pass through all such rebates or other financial benefits to the health insurer.

- (5) The office may require a health insurer to submit to the office any contract, or amendments to a contract, for the administration or management of prescription drug benefits by a pharmacy benefit manager on behalf of the insurer.
- (6) After review of a contract under subsection (5), the office may order the insurer to cancel the contract in accordance with the terms of the contract and applicable law if the office determines that any of the following conditions exist:
- (a) The fees to be paid by the insurer are so unreasonably high as compared with similar contracts entered into by insurers, or as compared with similar contracts entered into by other insurers in similar circumstances, that the contract is detrimental to the policyholders of the insurer.
- (b) The contract does not comply with the Florida Insurance Code.
- (c) The pharmacy benefit manager is not registered with the office pursuant to s. 624.490.
- $\underline{\mbox{(7)}}$  The commission may adopt rules to administer this section.
- (8) (5) This section applies to contracts entered into, amended, or renewed on or after July 1, 2020 2018.
  - Section 6. Section 641.314, Florida Statutes, is amended to

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641.314 Pharmacy benefit manager contracts.-

- (1) As used in this section, the term:
- (a) "Brand-name drug" means a drug that:
- 1. Is a brand drug described by Medi-Span and has a multisource code field containing an "M" (cobranded product), an "O" (originator brand), or an "N" (single-source brand), except for a drug with a multisource code of "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or
- 2. Has an equivalent brand drug designation in the First Databank FDB MedKnowledge database.
  - (b) "Generic drug" means a drug that:
- 1. Is a generic drug described by Medi-Span and has a multisource code field containing a "Y" (generic), or an "O" and a Dispense as Written code of 3, 4, 5, 6, or 9; or
- 2. Has an equivalent generic drug designation in the First Databank FDB MedKnowledge database.
- (c) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug:
- 1. As specified at the time of claim processing and directly or indirectly reported on the initial remittance advice of an adjudicated claim for a generic drug, brand-name drug, biological product, or specialty drug;
- 2. Which amount must be based on pricing published in the Medi-Span Master Drug Database, or, if the pharmacy benefit manager uses only First Databank FDB MedKnowledge, must be based on pricing published in First Databank FDB MedKnowledge; and
  - $\underline{\text{3.}}$   $\tau$  Excluding dispensing fees, prior to the application of

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copayments, coinsurance, and other cost-sharing charges, if any.

(d) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health maintenance organization to residents of this state.

- (2) A health maintenance organization may contract only with a pharmacy benefit manager that A contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:
- (a) <u>Updates</u> <del>Update</del> maximum allowable cost pricing information at least every 7 calendar days.
- (b) Maintains Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.
- (c) (3) Does not limit A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.
- (d) (4) Does not require A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:
  - 1. (a) The applicable cost-sharing amount; or

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2.(b) The retail price of the drug in the absence of prescription drug coverage.

- (3) A drug identified as a brand-name drug must be considered a brand-name drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy services administration organization on behalf of the pharmacy. A single-source generic drug with only one manufacturer must be reimbursed as if it were a brand-name drug.
- (4) A drug identified as a generic drug must be considered a generic drug for all purposes under an agreement, contract, or amendment to a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy services administrative organization acting on behalf of the pharmacy. The pharmacy benefit manager and the pharmacy, or a pharmacy services administrative organization on behalf of the pharmacy, shall agree that if the pharmacy benefit manager is provided any rebate or other financial benefit for any drug identified as a generic drug, the pharmacy benefit manager must pass through all such rebates or other financial benefits to the health maintenance organization.
- (5) The office may require a health maintenance organization to submit to the office any contract, or amendments to a contract, for the administration or management of prescription drug benefits by a pharmacy benefit manager on behalf of the health maintenance organization.
- (6) After review of a contract under subsection (5), the office may order the health maintenance organization to cancel the contract in accordance with the terms of the contract and applicable law if the office determines that any of the

following conditions exist:

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- (a) The fees to be paid by the health maintenance organization are so unreasonably high as compared with similar contracts entered into by health maintenance organizations, or as compared with similar contracts entered into by other health maintenance organizations in similar circumstances, that the contract is detrimental to the subscribers of the health maintenance organization.
- (b) The contract does not comply with the Florida Insurance Code.
- (c) The pharmacy benefit manager is not registered with the office pursuant to s. 624.490.
- (7) The commission may adopt rules to administer this section.
- (8) (5) This section applies to <u>pharmacy benefit manager</u> contracts entered into, <u>amended</u>, or renewed on or after July 1, 2020 2018.
  - Section 7. This act shall take effect July 1, 2020.