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A bill to be entitled An act relating to prescribed drug services and audits; creating s. 465.1871, F.S.; prohibiting attorneys from engaging in misleading advertisement related to medicinal drugs; providing causes of action; providing penalties; providing timeframes for actions for recovery; amending s. 465.1885, F.S.; providing definitions; providing applicability; providing requirements for pharmacy contracts and auditing entities; revising the timeframe for notice of audit; revising the rights that pharmacies have if audits are conducted; prohibiting audits from considering as fraud any clerical and recordkeeping error; limiting charge-backs and recoupments; excluding dispensing fees from calculations of overpayment; requiring auditing entities to be responsible for costs associated with audits; prohibiting auditing entities from compensating certain employees or contractors; providing penalties; requiring auditing entities to state the reason for the audits under certain circumstances; revising the timeframes of audit periods; revising the timeframe for the delivery of the preliminary audit report; revising the requirements for pharmacies to address discrepancies or audit findings; requiring the Office

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of Insurance Regulation to establish an appeals process; creating s. 624.491, F.S.; providing definitions; requiring pharmacy benefit managers to provide the office with an annual report; providing report requirements; prohibiting publication or disclosure of certain information; requiring the office to publish certain information; creating s. 624.495, F.S.; providing a definition; requiring registration of pharmacy services administration organizations with the office; requiring registration fees; providing registration and reporting requirements; requiring the office to issue registration certificates under certain circumstances; requiring rulemaking; amending s. 627.42392, F.S.; providing a definition; revising the circumstances under which health insurers and pharmacy benefit managers are required to use prior authorization forms for specified purposes; requiring health insurers and pharmacy benefit managers to establish and offer an online prior authorization process; providing requirements for the process; creating s. 627.42393, F.S.; providing definitions; requiring health insurers to publish and provide to insureds a procedure for exemptions from first fail policies; providing requirements for the procedure; providing requirements

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for authorization or denial of policy exemptions; amending ss. 627.64741, 627.6572, and 641.314, F.S.; requiring pharmacy benefit managers to publish a list of certain drugs on their websites; providing requirements for the publication; extending the applicability date; creating ss. 627.64742, 627.66998, and 641.3924, F.S.; providing definitions; requiring health insurers and health maintenance organizations to disclose to enrollees and prospective enrollees or to subscribers and prospective subscribers, respectively, that they are subject to excess cost sharing under certain circumstances; providing duties for health insurers and health maintenance organizations; prohibiting disclosure of specified information; providing an effective date. Be It Enacted by the Legislature of the State of Florida: Section 1. Section 465.1871, Florida Statutes, is created to read: 465.1871 Attorney liability for misleading advertisement.-(1) An attorney may not engage in misleading legal services advertisement related to medicinal drugs. A legal services advertisement is misleading if the advertisement does

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CODING: Words stricken are deletions; words underlined are additions.

any of the following:

(a) Fails to disclose at the beginning of the advertisement: "This is a paid advertisement for legal services."

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- (b) Presents the advertisement as a "medical alert,"

  "health alert," "consumer alert," or "public service

  announcement," or in any similar term.
- (c) Displays the logo of a federal or state government agency in a manner that suggests an affiliation with the agency or the sponsorship of that agency.
- (d) Uses the word "recall" when referring to a product that has not been recalled either by a government agency or through an agreement between the manufacturer and a government agency.
  - (e) Fails to identify the sponsor of the advertisement.
- (f) Fails to indicate the identity of the attorney or law firm that will represent the client, or how cases will be referred to an attorney or law firm that will represent the client if the sponsor of the advertisement may not represent persons responding to the advertisement.
- (2) A person who ceases to follow medical advice relating to medicinal drugs because of misleading legal services advertising as described in subsection (1) has a cause of action for double the amount of actual damages against the attorney who engaged in the misleading legal services advertisement.
  - (3) A person who ceases to follow medical advice relating

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101 to medicinal drugs because of legal services advertising related 102 to medicinal drugs, whether the advertisement is misleading or 103 not, has a cause of action against the attorney who engaged in 104 the legal services advertisement. 105 (4) An action under this section may be brought in any 106 court of competent jurisdiction to recover compensatory damages 107 against the attorney who engages in legal services advertising; 108 however, the plaintiff may not recover damages twice for the 109 same injury. An action for recovery under this section must commence within 2 years after the time the legal services 110 111 advertising last occurs. 112 Section 2. Section 465.1885, Florida Statutes, is amended to read: 113 114 (Substantial rewording of section. See s. 465.1885, F.S., for present text.) 115 116 465.1885 Pharmacy audits.— 117 (1) As used in this section, the term: 118 "Health benefit plan" means any individual or group (a) 119 plan, employee welfare benefit plan, policy, or contract for 120 health care services issued, delivered, issued for delivery, or renewed in this state by a health care insurer, health 121 122 maintenance organization, accident and sickness insurer, fraternal benefit society, nonprofit hospital service 123 124 corporation, nonprofit medical services corporation, health care 125 service plan, or any other person, firm, corporation, joint

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venture, or other similar business entity that pays for insureds or beneficiaries in this state.

- arrangement for the delivery of pharmacy services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacy services for an enrollee on a prepaid or insured basis that contains one or more incentive arrangements intended to influence the cost or level of pharmacy services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacy services.

  The pharmacy benefit management plan also requires or creates benefit payment differential for enrollees to use under contract with the pharmacy benefit manager.
- (c) "Pharmacy benefit manager" means a business that administers the prescription drug or device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions, and health maintenance organizations. The term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefit management for a managed care company, nonprofit hospital or medical services organization, insurance company, or other third-party payor.
- (d) "Pharmacy services" means offering for sale, compounding, or dispensing of drugs, chemicals, or poisons

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pursuant to a prescription. The term also includes the sale or provision of, fitting of, or counseling on medical devices, including prosthetics and durable medical equipment.

- (2) (a) This section applies to any audit of the records of a pharmacy, except Medicaid-related records, that is conducted by a managed care company, a nonprofit hospital or medical services organization, a health benefit plan, a third-party payor, a pharmacy benefit manager, a health program administered by an agency of the state, or any entity that represents those companies, groups, or agencies.
- (b) A health benefit plan located or domiciled outside of this state is subject to this section if it receives, processes, adjudicates, pays, or denies claims for health care services submitted by or on behalf of patients, insureds, or beneficiaries who reside in this state.
- (3) A pharmacy contract must identify and describe in detail the audit procedures, and the entity conducting an audit shall follow these procedures.
- (4) An entity conducting an audit must give the pharmacy written notice at least 4 weeks before conducting the initial audit for each audit cycle. If the auditing entity is a pharmacy benefit manager and if the auditing entity does not include its auditing guidelines in its provider manual, the notice must include a documented checklist of all items being audited and the manual, including the name, date, and edition or volume,

applicable to the audit and auditing guidelines. For onsite audits, a pharmacy benefit manager must also provide a list of materials that are copied or removed during the course of an audit. The pharmacy benefit manager may document these materials on a checklist or an audit acknowledgment form. The pharmacy must produce any items during the course of the audit or within 30 days after the audit.

- (5) An entity conducting an audit may not interfere with the delivery of pharmacy services to a patient and shall use every effort to minimize inconvenience and disruption to pharmacy operations during the audit process.
- (6) An audit that involves clinical or professional judgement shall be conducted by or in consultation with a pharmacist licensed in this state.
- (7) The audit may not consider as fraud any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record; however, such errors may be subject to recoupment if the errors resulted in overpayment to the pharmacy. The pharmacy has the right to submit amended claims through an online submission to correct clerical or recordkeeping errors in lieu of recoupment if no actual financial harm to the patient or plan has occurred and if the prescription was dispensed according to the prescription documentation requirements set forth in the Florida Pharmacy Act and within the plan limits. The pharmacy is

manager unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health insurance plan managed by the pharmacy benefit manager, or a consumer. A person is not subject to criminal penalties for errors provided for in this subsection without proof of intent to commit fraud, waste, or abuse.

- (a) Any amount to be charged back or recouped due to overpayment must not exceed the amount the pharmacy was overpaid.
- (b) The auditing entity may not include the dispensing fee in the calculation of an overpayment unless a prescription is a misfill. As used in this paragraph, the term "misfill" means a prescription that was not dispensed, a prescription in which the prescriber denied the authorization request, a prescription in which an additional dispensing fee was charged, or a prescription error by the pharmacy.
- (8) The auditing entity may not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal requirements or federal plans.
- (9) The auditing entity may not require any documentation that is not required by state and federal law. The information is considered valid if documented on the prescription,

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computerized treatment notes, pharmacy system, or other acceptable medical records.

- (10) Unless superseded by state or federal law, auditors may have access only to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefit manager, health plan, or insurer. An auditing vendor contracting with multiple pharmacy benefit managers or health insurance plans may not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefit manager or health insurance plan.
- (11) Audit results shall be disclosed to the health benefit plan in a manner pursuant to contract terms.
- (12) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for the purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.
- (13) (a) If the pharmacy benefit manager or its representative conducts an audit, the sample size must not be greater than 150 prescriptions. A refill does not constitute a separate prescription for the purposes of this subsection.
- (b) The audit must be a true representation of the billing of the pharmacy to the pharmacy benefit manager. The sampling

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for the audit must be random, with the average cost per prescription audited, and may not be more than the average prescription billed to the pharmacy benefit manager during that period. The random process of how these prescriptions were selected must be provided to the pharmacy.

- (14) Reasonable costs associated with the audit must be the responsibility of the auditing entity if the claims sample exceeds 100 unique prescription hard copies.
- (15) (a) The auditing entity may not compensate an employee or contractor with which the auditing entity contracts to conduct the pharmacy audit based on the amount claimed or the actual amount recouped by the pharmacy being audited.
- (b) The license of any auditing entity that violates paragraph (a) may be denied, suspended, or revoked upon proof of such violation.
- (16) A finding of an overpayment must not include the cost of the drugs that were dispensed in accordance with the prescriber's orders, if the prescription was dispensed according to prescription documentation requirements set forth by the Florida Pharmacy Act and within the plan limits. A finding of an overpayment may not include the dispensing fee, as specified in paragraph (7)(b).
- (17) For a finding of an underpayment due to package size or other clerical error, the pharmacy benefit manager shall make the pharmacy whole and shall allow the pharmacy to reprocess for

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276 underpayment.

- (18) (a) Each pharmacy must be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity and must be audited under rules applicable to the contractor and time period of the prescription.
- (b) If the auditing entity is a pharmacy benefit manager, the entity must state, as requested by the Office of Insurance Regulation, the reason for which the audit was initiated, such as random or suspected fraud.
- (19) Where not superseded by state or federal law, the period covered by an audit must not exceed 6 months after the date on which the claim was submitted to or adjudicated by a managed care company, a nonprofit hospital or medical services organization, a health benefit plan, a third-party payor, a pharmacy benefit manager, a health program administered by an agency of the state, or any entity that represents those companies, groups, or agencies. An audit may not be conducted 6 months after the date on which the pharmacy benefit management plan terminated its contract to adjudicate claims with a pharmacy benefit manager, health plan administrator, or any other entity representing those companies.
- (20) An audit may not be initiated or scheduled during the first 5 calendar days of any month.
- (21) The auditing entity shall provide the pharmacy with a written report of the audit and shall comply with all of the

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## following requirements:

- (a) The preliminary audit report shall be delivered to the pharmacy within 30 days after the conclusion of the audit, with a reasonable extension to be granted upon request.
- (b) The pharmacy shall be allowed at least 60 days after receipt of the preliminary audit report to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request.
- (c) The auditing entity shall deliver the final report to the pharmacy within 30 days after sending out the preliminary audit report or within 30 days after receiving a final appeal, whichever is later.
- (d) The auditor or auditors assigned to the audit shall sign the audit documents. The auditor shall sign the acknowledgment or receipt, and the audit report must contain clear contact information of the representative of the auditing organization.
- (22) Recoupment of any disputed funds, or repayment of funds to the entity by the pharmacy if permitted pursuant to contractual agreement, must occur after final internal disposition of the audit, including the appeals process.
- (a) Recoupment shall be billed to the pharmacy, and the pharmacy shall be given reasonable time to make interest-free payment, not to exceed 2 years after final disposition of the audit.

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(b) If the identified discrepancy for an individual audit
exceeds \$25,000, future payments in excess of that amount to the
pharmacy may be withheld pending finalization of the audit.
(23) Interest must not accrue during the audit period.
(24) The auditing entity shall provide a copy of the final
audit report, after completion of any review process, to the
plan sponsor in a manner pursuant to a contract.
(25) The Office of Insurance Regulation shall establish a
written appeals process under which a pharmacy may appeal an
unfavorable preliminary audit report to the entity. Following
<pre>the appeal:</pre>
(a) If the auditing entity finds that an unfavorable audit
report or any portion thereof is unsubstantiated, the entity
shall dismiss the audit report or that portion without the
necessity of any further action.
(b) If any of the issues raised in the appeal are not
resolved to the satisfaction of either party, that party may ask
the Office of Insurance Regulation to enforce the provisions of
the insurance code and applicable rules as they relate to the
review of policy contracts and associated rates. The cost of
mediation shall be borne by agreement of the parties or by the
decision of the office.
Section 3. Section 624.491, Florida Statutes, is created
to read:

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624.491 Pharmacy benefit manager disclosures.—

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(d)

(1) As used in this section, the term: "Administrative fee" means a fee paid or a payment made by a pharmaceutical manufacturer to a pharmacy benefit manager or its designee, or a fee or payment retained by a pharmacy benefit manager or its designee, pursuant to a contract between the pharmacy benefit manager and the pharmaceutical manufacturer in connection with the pharmacy benefit manager's administering, invoicing, allocating, and collecting rebates. "Aggregate retained-rebate percentage" means the percentage of all rebates received by a pharmacy benefit manager from all pharmaceutical manufacturers which is not passed on to the pharmacy benefit manager's health plan or issuer clients. The percentage is calculated by dividing the aggregate dollar amount of rebates that the pharmacy benefit manager received during the prior calendar year from all pharmaceutical manufacturers that was not passed on to the pharmacy benefit manager's health plan or issuer clients by the aggregate dollar amount of rebates that the pharmacy benefit manager received during the prior calendar year from all pharmaceutical manufacturers. (c) "Health plan" means a policy, contract, certification, or agreement offered or issued by an issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health services.

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"Issuer" means an authorized health insurer or health

maintenance organization that offers one or more health plans delivered or issued to deliver to any person in this state.

- (e) "Issuer administrative service fee" means a fee paid or a payment made by an issuer or its designee to a pharmacy benefit manager, or a fee or payment retained by a pharmacy benefit manager, pursuant to a contract between the pharmacy benefit manager and the issuer or the issuer's designee in connection with the pharmacy benefit manager's managing or administering the pharmacy benefit and administering, invoicing, allocating, and collecting rebates.
- (f) "Pharmacy benefit manager" has the same meaning as in s. 624.490.
- (g) "Rebate" means a rebate, discount, or price concession that is based on the use or price of a prescription drug and that is paid by the pharmaceutical manufacturer or an entity other than the patient, directly or indirectly, to a pharmacy benefit manager after the pharmacy benefit manager adjudicates the claim. Rebates include price protection rebates and a reasonable estimate of volume-based discounts or other discounts.
- (2) Beginning January 1, 2020, and by January 1 of each year thereafter, a pharmacy benefit manager shall provide the office with a report containing all of the following information from the prior calendar year:
  - (a) The aggregate dollar amount of all administrative fees

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that the pharmacy benefit manager received.

- (b) The aggregate dollar amount of all administrative fees that the pharmacy benefit manager received and did not pass on to health plans or issuers.
- (c) The aggregate dollar amount of all issuer administrative service fees that the pharmacy benefit manager received.
- (d) The aggregate dollar amount of rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers.
- (e) The aggregate dollar amount of rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers and did not pass on to health plans or issuers.
  - (f) The aggregate retained-rebate percentage.
- (g) Across all of the pharmacy benefit manager's contractual relationships or other relationships with all health plans or issuers, the highest aggregate retained-rebate percentage and the lowest aggregate retained-rebate percentage.
- (3) The pharmacy benefit manager may not publish or otherwise disclose any information that would reveal the identity of a specific health plan, the price charged for a specific drug or class of drugs, or the amount of any rebates provided for a specific drug or class of drugs. Any such information is protected from disclosure as confidential and proprietary information and is not subject to public records

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requirements under s. 119.07(1) or s. 24(a), Art. I of the State

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limited to:

42/	Constitution.
428	(4) The office shall publish in a timely manner the
429	information that it receives under subsection (2) on a publicly
430	available website. However, the office may not publish or
431	disclose any information that is considered a trade secret under
432	s. 624.4213.
433	Section 4. Section 624.495, Florida Statutes, is created
434	to read:
435	624.495 Registration of pharmacy services administration
436	organizations.—
437	(1) As used in this section, the term "pharmacy services
438	administration organization" or "PSAO" means a person or entity
439	doing business in this state which contracts with independent
440	pharmacies to represent these pharmacies or provide them with a
441	broad range of services Services provided by PSAOs are intended

(a) Negotiating and contracting with third-party payers on behalf of member pharmacies.

defined in s. 624.490. PSAO's services may include, but are not

to achieve administrative efficiencies, including contract and

payers, or third-party payers' pharmacy benefit managers, as

payment efficiencies, for both member pharmacies and third-party

(b) Contracting with pharmacy benefit managers that are used by third-party payers.

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451	(c) Communicating information to member pharmacies
452	regarding contractual and regulatory requirements.
453	(d) Providing general and claims-specific assistance to
454	member pharmacies by means of a help-desk or a dedicated staff
455	person.
456	(e) Providing other services to help member pharmacies
457	interact with third-party payers or with third-party payers'
458	pharmacy benefit managers, such as managing and analyzing
459	payment and drug-dispensing data to identify claims that are
460	unpaid or incorrectly paid by third-party payers.
461	(2) Effective January 1, 2021, to conduct business in this
462	state, a pharmacy services administration organization must
463	register with the office. To initially register or renew a
464	registration, a PSAO must submit:
465	(a) A nonrefundable fee not to exceed \$500.
466	(b) A copy of the registrant's corporate charter, articles
467	of incorporation, or other charter document.
468	(c) A completed registration form adopted by the
469	commission containing:
470	1. The name and address of the registrant.
471	2. The name, address, and official position of each
472	officer and director of the registrant.
473	(3) The registrant shall report any change in information
474	required by subsection (2) to the office in writing within 60

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CODING: Words stricken are deletions; words underlined are additions.

days after the change occurs.

476	(4) Upon receipt of a completed registration form, the
477	required documents, and the registration fee, the office shall
478	issue a registration certificate. The certificate may be in
479	paper or electronic form and must clearly indicate the
480	expiration date of the registration. Registration certificates
481	are nontransferable.
482	(5) A registration certificate is valid for 2 years after
483	its date of issuance. The commission shall adopt by rule an
484	initial registration fee not to exceed \$500 and a registration
485	renewal fee not to exceed \$500, both of which are nonrefundable.
486	Total fees may not exceed the cost of administering this
487	section.
488	(6) The commission shall adopt rules necessary to
489	implement this section.
490	Section 5. Section 627.42392, Florida Statutes, is amended
491	to read:
492	627.42392 Prior authorization.—
493	(1) As used in this section, the term:
494	(a) "Electronic prior authorization process" does not
495	include transmissions through a facsimile machine.
496	(b) "Health insurer" means an authorized insurer offering
497	health insurance as defined in s. 624.603, a managed care plan
498	as defined in s. 409.962(10), or a health maintenance
499	organization as defined in s. 641.19(12).
500	(2) Notwithstanding any other provision of law, effective

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January 1, 2017, or 6  $\frac{1}{100}$  months after the effective date of the rule adopting the prior authorization form, whichever is later, a health insurer, or a pharmacy benefit benefits manager on behalf of the health insurer, which does not provide an electronic prior authorization process for use by its contracted providers, shall only use the prior authorization form that has been approved by the Financial Services Commission for granting a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form may not exceed two pages in length, excluding any instructions or quiding documentation, and must include all clinical documentation necessary for the health insurer to make a decision. At a minimum, the form must include: (a) (1) Sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number; (b) (2) The provider's provider name, address, and phone number; (c)  $\frac{3}{3}$  The medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed; (d) (4) Any laboratory documentation required; and (e) $\frac{(5)}{(5)}$  An attestation that all information provided is true and accurate. The Financial Services Commission in consultation with (3)

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the Agency for Health Care Administration shall adopt by rule

guidelines for all prior authorization forms which ensure the general uniformity of such forms.

- (4) Electronic prior authorization approvals do not preclude benefit verification or medical review by the insurer under either the medical or pharmacy benefits.
- (5) Beginning January 1, 2020, a health insurer, or a pharmacy benefit manager on behalf of the health insurer, must establish and offer a secure, interactive online electronic prior authorization process for accepting electronic prior authorization forms. The process must allow a person seeking prior authorization the ability to upload documentation if such documentation is required by the health insurer or pharmacy benefit manager to adjudicate the prior authorization request.
- Section 6. Section 627.42393, Florida Statutes, is created to read:
  - 627.42393 Fail first policies.-

- (1) As used in this section, the term:
- (a) "Fail first policy" means a written protocol that specifies the order in which a medical procedure, course of treatment, or prescription drug must be used to treat an insured's condition.
- (b) "Health insurer" has the same meaning as in s. 627.42392.
- (c) "Policy exemption" means a determination by a health insurer that a fail first policy is not medically appropriate or

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indicated for treatment for an insured's condition and that the health insurer authorizes the use of another medical procedure, course of treatment, or prescription prescribed or recommended by the treating health care provider for the insured's condition.

- (d) "Preceding prescription drug or medical treatment"

  means a medical procedure, course of treatment, or prescription

  drug that must be used pursuant to a health insurer's fail first

  policy as a condition of coverage under a health insurance

  policy or a health maintenance contract to treat an insured's

  condition.
- (e) "Urgent care situation" means an injury or condition of an insured which, if medical care and treatment are not provided earlier than the time generally considered by the medical profession to be reasonable for a nonurgent situation, in the opinion of the insured's treating health care provider, would:
- 1. Seriously jeopardize the insured's life, health, or ability to regain maximum function; or
- 2. Subject the insured to severe pain that cannot be adequately managed.
- (2) A health insurer must publish on its website and provide to an insured in writing a procedure for an insured and health care provider to request a policy exemption. The procedure must include:

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(	a) A	descripti	lon o	f the	manr	ner	in	which	the	insured	or
health	care	provider	may	reques	st a	pol	icy	exemp	otior	l .	

- (b) The manner and timeframe in which the health insurer is required to authorize or deny a policy exemption request or respond to an appeal of the health insurer's denial of a request.
- (c) The conditions under which the policy exemption must be granted.
- (3) (a) The health insurer must authorize or deny a policy exemption request or respond to an appeal of the health insurer's authorization or denial of a request within:
- 1. Seventy-two hours after obtaining a completed prior authorization form for a nonurgent care situation.
- 2. Twenty-four hours after obtaining a completed prior authorization form for an urgent care situation.
- (b) An authorization of the request must specify the approved medical procedure, course of treatment, or prescription drug benefits. The health insurer must grant a policy exemption request if the insured has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action, and such drug or treatment lacked efficacy or effectiveness or adversely affected the insured.
- (c) A denial of the request must include a detailed, written explanation of the reason for the denial, the clinical

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rationale that supports the denial, and the procedure to appeal the health insurer's determination.

- (4) The health insurer may request a copy of relevant documentation from the insured's medical record in support of a policy exemption request.
- Section 7. Subsection (5) of section 627.64741, Florida Statutes, is renumbered as subsection (6) and amended, and a new subsection (5) is added to that section, to read:
  - 627.64741 Pharmacy benefit manager contracts.-
- (5) Beginning July 1, 2020, for all the plans it manages for health insurers or health maintenance organizations, a pharmacy benefit manager must publish an up-to-date, accurate, and complete list of all covered drugs on the plans' formulary drug lists, including any tiered structure that it has adopted and any restriction on the manner in which a drug can be obtained. The formulary drug list must be easily accessible to the general public for viewing.
- (a) The list must be on the pharmacy benefit manager's website and must be easily accessible through a clearly identifiable link or tab, without requiring an individual to create or access an account or enter a policy number.
- (b) If the pharmacy benefit manager manages more than one plan for one or more health maintenance organizations or health insurers, an individual can easily discern which formulary drug list applies to which plan.

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626	(6) (5) This section applies to contracts entered into or
627	renewed on or after <u>July 1, 2020</u> <del>July 1, 2018</del> .
628	Section 8. Section 627.64742, Florida Statutes, is created
629	to read:
630	627.64742 Cost-sharing fairness.—
631	(1) As used in this section, the term:
632	(a) "Enrollee" means an individual who is covered under a
633	health insurance policy.
634	(b) "Excess cost sharing" means a deductible, copayment,
635	or coinsurance amount charged to an enrollee for a covered
636	prescription drug that is greater than the amount that the
637	enrollee's health insurance policy issuer would pay absent that
638	enrollee's cost sharing, after accounting for rebates.
639	(c) "Health insurance policy" means a policy, contract,
640	certification, or agreement offered or issued by an issuer to
641	provide, deliver, arrange for, pay for, or reimburse any of the
642	costs of health services.
643	(d) "Issuer" means an authorized health insurer that
644	offers one or more health insurance policies to any person in
645	this state.
646	(e) "Rebate" means:
647	1. A negotiated price concession, including, but not
648	limited to, a base rebate and a reasonable estimate of price
649	protection rebates and performance-based rebates, that may
650	accrue directly or indirectly to the issuer during the coverage

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year from a manufacturer, dispensing pharmacy, or other party to the transaction; and

2. A reasonable estimate of any fee and administrative cost that are passed on to the issuer and serve to reduce the issuer's prescription drug liabilities for the coverage year.

- (2) An issuer that plans to charge enrollees cost-sharing amounts that could result in excess cost sharing for a covered prescription drug must disclose to enrollees and prospective enrollees the fact that enrollees could be subject to such excess cost sharing. Such notice must be provided in health insurance policy documents, including, but not limited to, in evidence of coverage materials, formulary or preferred drug guides, and all marketing materials.
- (3) An issuer must strive to make available to enrollees at the point of sale an amount greater than 50 percent of the rebates.
- (4) An issuer shall annually report to the office whether it made more than 50 percent of the rebates available to the enrollees during the prior benefit year.
- (5) In making the required disclosures and in offering certifications under this section, an issuer may not publish or otherwise reveal information regarding the amount of rebates it receives, including, but not limited to, information regarding the amount of rebates it receives on a product-, manufacturer-, or pharmacy-specific basis. Such information is protected as a

records requirements under s. 119.07(1) or s. 24(a), Art. I of the State Constitution, and may not be disclosed directly or indirectly. An issuer shall impose the confidentiality protections of this subsection on a vendor or downstream third party that performs health care or administrative services on behalf of the issuer and may receive or have access to rebate information.

Section 9. Subsection (5) of section 627.6572, Florida Statutes, is renumbered as subsection (6) and amended, and a new subsection (5) is added to that section, to read:

- 627.6572 Pharmacy benefit manager contracts.-
- (5) Beginning July 1, 2020, for all the plans it manages for health insurers or health maintenance organizations, a pharmacy benefit manager must publish an up-to-date, accurate, and complete list of all covered drugs on the plans' formulary drug lists, including any tiered structure that it has adopted and any restriction on the manner in which a drug can be obtained. The formulary drug list must be easily accessible to the general public for viewing.
- (a) The list must be on the pharmacy benefit manager's website and must be easily accessible through a clearly identifiable link or tab, without requiring an individual to create or access an account or enter a policy number.
  - (b) If the pharmacy benefit manager manages more than one

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701	plan for one or more health maintenance organizations or health
702	insurers, an individual can easily discern which formulary drug
703	list applies to which plan.
704	(6) (5) This section applies to contracts entered into or
705	renewed on or after <u>July 1, 2020</u> <del>July 1, 2018</del> .
706	Section 10. Section 627.66998, Florida Statutes, is
707	created to read:
708	627.66998 Cost-sharing fairness.—
709	(1) As used in this section, the term:
710	(a) "Enrollee" means an individual who is covered under a
711	health benefit plan policy.
712	(b) "Excess cost sharing" means a deductible, copayment,
713	or coinsurance amount charged to an enrollee for a covered
714	prescription drug that is greater than the amount that the
715	enrollee's health benefit plan issuer would pay absent that
716	enrollee's cost sharing, after accounting for rebates.
717	(c) "Health benefit plan" means a policy, contract,
718	certification, or agreement offered or issued by an issuer to
719	provide, deliver, arrange for, pay for, or reimburse any of the
720	costs of health services.
721	(d) "Issuer" means an authorized health insurer that
722	offers one or more health benefit plans to any person in this
723	state.

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A negotiated price concession, including, but not

CODING: Words stricken are deletions; words underlined are additions.

(e) "Rebate" means:

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limited to, a base rebate and a reasonable estimate of price protection rebates and performance-based rebates, that may accrue directly or indirectly to the issuer during the coverage year from a manufacturer, dispensing pharmacy, or other party to the transaction; and

- 2. A reasonable estimate of any fee and administrative cost that are passed on to the issuer and serve to reduce the issuer's prescription drug liabilities for the coverage year.
- (2) An issuer that plans to charge enrollees cost-sharing amounts that could result in excess cost sharing for a covered prescription drug must disclose to enrollees and prospective enrollees the fact that enrollees could be subject to such excess cost sharing. Such notice must be provided in health benefit plan documents, including, but not limited to, in evidence of coverage materials, formulary or preferred drug guides, and all marketing materials.
- (3) An issuer must strive to make available to enrollees at the point of sale an amount greater than 50 percent of the rebates.
- (4) An issuer shall annually report to the office whether it made more than 50 percent of the rebates available to the enrollees during the prior benefit year.
- (5) In making the required disclosures and in offering certifications under this section, an issuer may not publish or otherwise reveal information regarding the amount of rebates it

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receives, including, but not limited to, information regarding the amount of rebates it receives on a product-, manufacturer-, or pharmacy-specific basis. Such information is protected as a trade secret under applicable law, is not subject to public records requirements under s. 119.07(1) or s. 24(a), Art. I of the State Constitution, and may not be disclosed directly or indirectly. An issuer shall impose the confidentiality protections of this subsection on a vendor or downstream third party that performs health care or administrative services on behalf of the issuer and may receive or have access to rebate information.

Section 11. Subsection (5) of section 641.314, Florida Statutes, is renumbered as subsection (6) and amended, and a new subsection (5) is added to that section, to read:

- 641.314 Pharmacy benefit manager contracts.-
- (5) Beginning July 1, 2020, for all the plans it manages for health insurers or health maintenance organizations, a pharmacy benefit manager must publish an up-to-date, accurate, and complete list of all covered drugs on the plans' formulary drug lists, including any tiered structure that it has adopted and any restriction on the manner in which a drug can be obtained. The formulary drug list must be easily accessible to the general public for viewing.
- (a) The list must be on the pharmacy benefit manager's website and must be easily accessible through a clearly

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776 identifiable link or tab, without requiring an individual to create or access an account or enter a policy number.

- (b) If the pharmacy benefit manager manages more than one plan for one or more health maintenance organizations or health insurers, an individual can easily discern which formulary drug list applies to which plan.
- (6) This section applies to contracts entered into or renewed on or after July 1, 2020 July 1, 2018.
- Section 12. Section 641.3924, Florida Statutes, is created to read:
  - 641.3924 Cost-sharing fairness.-
  - (1) As used in this section, the term:
- (a) "Excess cost sharing" means a deductible, copayment, or coinsurance amount charged to a subscriber for a covered prescription drug that is greater than the amount that the subscriber's health benefit plan issuer would pay absent that subscriber's cost sharing, after accounting for rebates.
- "Issuer" means a health maintenance organization that offers one or more health benefit plans to any person in this state.
  - (c) "Rebate" means:

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1. A negotiated price concession, including, but not limited to, a base rebate and a reasonable estimate of price protection rebates and performance-based rebates, that may accrue directly or indirectly to the issuer during the coverage

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year from a manufacturer, dispensing pharmacy, or other party to
the transaction; and

2. A reasonable estimate of any fee and administrative cost that are passed on to the issuer and serve to reduce the issuer's prescription drug liabilities for the coverage year.

- sharing amounts that could result in excess cost sharing for a covered prescription drug must disclose to subscribers and prospective subscribers the fact that subscribers could be subject to such excess cost sharing. Such notice must be provided in health maintenance contract documents, including, but not limited to, in evidence of coverage materials, formulary or preferred drug guides, and all marketing materials.
- (3) An issuer must strive to make available to subscribers at the point of sale an amount greater than 50 percent of the rebates.
- (4) An issuer shall annually report to the office whether it made more than 50 percent of the rebates available to the subscribers during the prior benefit year.
- (5) In making the required disclosures under this section, an issuer may not publish or otherwise reveal information regarding the amount of rebates it receives, including, but not limited to, information regarding the amount of rebates it receives on a product-, manufacturer-, or pharmacy-specific basis. Such information is protected as a trade secret under

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applicable law, is not subject to public records requirements
under s. 119.07(1) or s. 24(a), Art. I of the State
Constitution, and may not be disclosed directly or indirectly.
An issuer shall impose the confidentiality protections of this
subsection on a vendor or downstream third party that performs
health care or administrative services on behalf of the issuer
and may receive or have access to rebate information.
Section 13. This act shall take effect January 1, 2020.

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