HOUSE BILL 357

C3 HB 1014/22 – HGO CF SB 898

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Introduced and read first time: January 26, 2023 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 5, 2023

CHAPTER _____

1 AN ACT concerning

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Pharmacy Benefits Managers – Definitions <u>Definition</u> of Carrier, ERISA, and Purchaser <u>and Alteration of Application of Law</u>

- FOR the purpose of repealing the definitions of "carrier" and "ERISA" and altering the 4 5 definition altering the definition of "purchaser" for the purpose of applying certain 6 provisions of State insurance law governing pharmacy benefits managers to eertain 7 persons that provide prescription drug coverage or benefits in the State through 8 plans or programs subject to the federal Employee Retirement Income Security Act 9 of 1974 (ERISA) exclude certain nonprofit health maintenance organizations; repealing a certain provision provisions that restricts restrict the applicability of 10 certain provisions of law to pharmacy benefits managers that provide pharmacy 11 benefits management services on behalf of a carrier; and generally relating to 12 13 pharmacy benefits managers.
- 14 BY repealing and reenacting, with amendments,
- 15 Article Insurance
- 16 Section 15–1601, 15–1606, 15–1611, 15–1611.1, 15–1612, 15–1613, 15–1622,
- 17 15-1628(a), 15-1628.3, 15-1629, and 15-1630, and 15-1633.1
- 18 Annotated Code of Maryland
- 19 (2017 Replacement Volume and 2022 Supplement)

20 BY repealing

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 2 3	Section 15–1633 Annotated Code of Maryland				
4	(2017 Replacement Volume and 2022 Supplement)				
5 6	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:				
7	Article - Insurance				
8	15–1601.				
9	(a) In this subtitle the following words have the meanings indicated.				
10 11	(b) "Agent" means a pharmacy, a pharmacist, a mail order pharmacy, or a nonresident pharmacy acting on behalf or at the direction of a pharmacy benefits manager				
12 13	(c) "Beneficiary" means an individual who receives prescription drug coverage or benefits from a purchaser.				
14 15 16	(d) $\{1\}$ "Carrier" means the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a health maintenance organization that:				
17	(i) provides prescription drug coverage or benefits in the State; and				
18 19	(ii) enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services.				
20 21 22 23	(2) "Carrier" does not include a person that provides prescription drug coverage or benefits through plans subject to ERISA and does not provide prescription drug coverage or benefits through insurance, unless the person is a multiple employer welfare arrangement as defined in § 514(b)(6)(A)(ii) of ERISA.				
24 25 26	(e) Compensation program" means a program, policy, or process through which sources and pricing information are used by a pharmacy benefits manager to determine the terms of payment as stated in a participating pharmacy contract.				
27 28	[(f)] (E) "Contracted pharmacy" means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:				
29	(1) the pharmacy benefits manager; or				
30 31	(2) a pharmacy services administration organization or a group purchasing organization.				
32	إ (g) "ERISA" has the meaning stated in § 8−301 of this article.				

- 1 **f**(h)**f (F)** "Formulary" means a list of prescription drugs used by a purchaser. 2 "Manufacturer payments" means any compensation **f**(i)**l** (G) 3 remuneration a pharmacy benefits manager receives from or on behalf of a pharmaceutical 4 manufacturer. 5 (2)"Manufacturer payments" includes: 6 payments received in accordance with agreements with pharmaceutical manufacturers for formulary placement and, if applicable, drug utilization; 7 8 (ii) rebates, regardless of how categorized; 9 (iii) market share incentives: 10 commissions; (iv) fees under products and services agreements; 11 (v) 12 (vi) any fees received for the sale of utilization data to a pharmaceutical manufacturer; and 13 14 (vii) administrative or management fees. 15 (3)"Manufacturer payments" does not include purchase discounts based on 16 invoiced purchase terms. 17 **f**(i)**ł (H)** "Nonprofit health maintenance organization" has the meaning stated in § 6–121(a) of this article. 18 "Nonresident pharmacy" has the meaning stated in § 12-403 of the 19 **{**(k)**∤ (I)** 20 Health Occupations Article. 21"Participating pharmacy contract" means a contract filed with the [(1)] (J) 22Commissioner in accordance with § 15–1628(b) of this subtitle. 23"Pharmacist" has the meaning stated in § 12-101 of the Health [(m)] (K) 24Occupations Article.
- 27 **{**(o)**} (M)** "Pharmacy and therapeutics committee" means a committee 28 established by a pharmacy benefits manager to:

"Pharmacy" has the meaning stated in § 12-101 of the Health

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f(n)**] (L)**

Occupations Article.

1	(1)	objec	tively appraise and evaluate prescription drugs; and		
2 3	(2) make recommendations to a purchaser regarding the selection of drugs for the purchaser's formulary.				
4	{ (p) } (N)	(1)	"Pharmacy benefits management services" means:		
5 6	dispensation with	(i) ain the S	the procurement of prescription drugs at a negotiated rate for State to beneficiaries;		
7 8	(ii) the administration or management of prescription drug coverage provided by a purchaser for beneficiaries; and				
9 10	administration of	(iii) prescri	any of the following services provided with regard to the ption drug coverage:		
11			1. mail service pharmacy;		
12 13	2. claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;				
14			3. clinical formulary development and management services;		
15			4. rebate contracting and administration;		
16 17	substitution progr	rams; o	5. patient compliance, therapeutic intervention, and generic		
18			6. disease management programs.		
19 20 21	(2) provided by a non provided that the	nprofit l	rmacy benefits management services" does not include any service nealth maintenance organization that operates as a group model, :		
22 23	maintenance orga	(i) inizatio	is provided solely to a member of the nonprofit health n; and		
24 25	nonprofit health r	(ii) mainter	is furnished through the internal pharmacy operations of the nance organization.		
26 27	f (q) f (O) benefits managen		rmacy benefits manager" means a person that performs pharmacy vices.		
28	[(r)] (P)	"Prop	orietary information" means:		
29	(1)	a tra	de secret;		

1	(2)	confidential commercial information; or
2	(3)	confidential financial information.
3 4 5 6	=	e State Employee and Retiree Health and Welfare Benefits Program, AN NPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE
7	[(1)]	(I) provides prescription drug coverage or benefits in the State; and
8 9	= 1 / =	(II) enters into an agreement with a pharmacy benefits manager for armacy benefits management services.
10 11	(2) MAINTENANCE OI	"PURCHASER" DOES NOT INCLUDE A NONPROFIT HEALTH RGANIZATION THAT:
12		(I) OPERATES AS A GROUP MODEL;
13 14	THE NONPROFIT	(II) PROVIDES SERVICES SOLELY TO MEMBERS OR PATIENTS OF HEALTH MAINTENANCE ORGANIZATION; AND
15 16	OPERATIONS OF T	(III) FURNISHES SERVICES THROUGH THE INTERNAL PHARMACY THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION.
17 18 19		"Rebate sharing contract" means a contract between a pharmacy and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser.
18	benefits manager a	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one
18 19 20	benefits manager a share manufacture	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one
18 19 20 21	benefits manager a share manufacture {(u)} (S) prescription drug t	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one to another.
18 19 20 21 22	benefits manager a share manufacture {(u)} (S) prescription drug t	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one to another. "Therapeutic interchange" does not include:
18 19 20 21 22 23	benefits manager a share manufacture {(u)} (S) prescription drug t	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one to another. "Therapeutic interchange" does not include: (i) a change initiated pursuant to a drug utilization review;
18 19 20 21 22 23 24 25	benefits manager a share manufacture {(u)} (S) prescription drug t (2) prescribed drug;	and a purchaser under which the pharmacy benefits manager agrees to er payments with the purchaser. (1) "Therapeutic interchange" means any change from one to another. "Therapeutic interchange" does not include: (i) a change initiated pursuant to a drug utilization review; (ii) a change initiated for patient safety reasons;

prescribed drug is not covered by the beneficiary's formulary or plan.

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- 1 **f**(v)**f** (T) "Therapeutic interchange solicitation" means any communication by a pharmacy benefits manager for the purpose of requesting a therapeutic interchange.
- 3 **(w)** "Trade secret" has the meaning stated in § 11–1201 of the Commercial 4 Law Article.
- 5 15-1606.
- 6 A [carrier] PURCHASER-may not enter into an agreement with a pharmacy benefits manager that has not registered with the Commissioner.
- 8 15–1611.
- 9 (a) [This section applies only to a pharmacy benefits manager that provides 10 pharmacy benefits management services on behalf of a carrier.
- 11 (b) A pharmacy benefits manager may not prohibit a pharmacy or pharmacist 12 from:
- 13 (1) providing a beneficiary with information regarding the retail price for 14 a prescription drug or the amount of the cost share for which the beneficiary is responsible 15 for a prescription drug;
- 16 (2) discussing with a beneficiary information regarding the retail price for 17 a prescription drug or the amount of the cost share for which the beneficiary is responsible 18 for a prescription drug; or
- 19 (3) if a more affordable drug is available than one on the purchaser's 20 formulary and the requirements for a therapeutic interchange under §§ $\{15-1633.1\}$ 21 $\{15-1633\}$ through 15–1639 of this subtitle are met, selling the more affordable alternative 22 to the beneficiary.
- [(c)] (B) This section may not be construed to alter the requirements for a therapeutic interchange under §§ \frac{1}{4}5-1633.1\frac{1}{45-1633} \text{ through } 15-1639 \text{ of this subtitle.}
- 25 15–1611.1.
- 26 (a) [This section applies only to a pharmacy benefits manager that provides 27 pharmacy benefits management services on behalf of a carrier.
- 28 (b) Except as provided in subsection [(c)] (B) of this section, a pharmacy benefits 29 manager may not require that a beneficiary use a specific pharmacy or entity to fill a 30 prescription if:

- 1 (1) the pharmacy benefits manager or a corporate affiliate of the pharmacy 2 benefits manager has an ownership interest in the pharmacy or entity; or
- 3 (2) the pharmacy or entity has an ownership interest in the pharmacy 4 benefits manager or a corporate affiliate of the pharmacy benefits manager.
- 5 **[(c)] (B)** A pharmacy benefits manager may require a beneficiary to use a specific pharmacy or entity for a specialty drug as defined in § 15–847 of this title.
- 7 15–1612.
- 8 (a) [This section applies only to a pharmacy benefits manager that provides 9 pharmacy benefits management services on behalf of a carrier.
- 10 (b) This section does not apply to reimbursement:
- 11 (1) for specialty drugs;
- 12 (2) for mail order drugs; or
- 13 (3) to a chain pharmacy with more than 15 stores or a pharmacist who is 14 an employee of the chain pharmacy.
- [(c)] (B) A pharmacy benefits manager may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount that the pharmacy benefits manager reimburses itself or an affiliate for providing the same product or service.
- 19 15–1613.
- A pharmacy and therapeutics committee established by a pharmacy benefits manager performing pharmacy benefits management services [on behalf of a carrier] shall meet the requirements of this part.
- 23 15–1622.
- [(a) Except as provided for in subsection (b) of this section, the provisions of §§ 15–1623 and 15–1624 of this subtitle apply only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.
- 27 (b)] The provisions of §§ 15–1623 and 15–1624 of this part do not apply to a pharmacy benefits manager when providing pharmacy benefits management services to a purchaser that is affiliated with the pharmacy benefits manager through common ownership within an insurance holding company.

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15–1629.

1	(a) (1)	At the time of entering into a contract with a pharmacy or a pharmacist,
2		vorking days before any contract change, a pharmacy benefits manager
3	shall disclose to t	he pharmacy or pharmacist:
4		(i) the applicable terms, conditions, and reimbursement rates;
5		(ii) the process and procedures for verifying pharmacy benefits and
6	beneficiary eligib	llity;
7		(iii) the dispute resolution and audit appeals process; and
8		(iv) the process and procedures for verifying the prescription drugs
9	included on the fo	ermularies used by the pharmacy benefits manager.
10	(2)	(i) This paragraph does not apply to a requirement that a specialty
11	pharmacy obtain	national certification to be considered a specialty pharmacy in a pharmacy
12	benefits manager	's or [carrier's] PURCHASER'S network.
13		(ii) For purposes of credentialing a pharmacy or a pharmacist as a
14	condition for part	icipating in a pharmacy benefits manager's OR PURCHASER'S network
15		e pharmacy benefits manager OR PURCHASER may not:
16		1. require a pharmacy or pharmacist to renew credentialing
17	more frequently t	han once every 3 years; or
18		2. charge a pharmacy or pharmacist a fee for the initial
19	eredentialing or r	enewing credentialing.
20	15-1628.3.	
21	(a) A ph	armacy benefits manager or a [carrier] PURCHASER may not directly or
22		a contracted pharmacy, or hold a contracted pharmacy responsible for, a
23		ce-based reimbursement related to the adjudication of a claim or an
24	incentive program	1.
25	(b) A pl	narmacy benefits manager or [carrier] PURCHASER may not make or
26	allow any reducti	on in payment for pharmacy services by a pharmacy benefits manager or
27	[carrier] PURCH.	ASER or directly or indirectly reduce a payment for a pharmacy service
28	under a reconcili	ation process to an effective rate of reimbursement, including generic
29		and effective rates, direct and indirect remuneration fees, or any other
30	reduction or aggr	egate reduction of payments.

- 1 (a) [This section applies only to a pharmacy benefits manager that provides 2 pharmacy benefits management services on behalf of a carrier.
- 3 (b)] This section does not apply to an audit that involves probable or potential 4 fraud or willful misrepresentation by a pharmacy or pharmacist.
- 5 **[(c)] (B)** A pharmacy benefits manager shall conduct an audit of a pharmacy or pharmacist under contract with the pharmacy benefits manager in accordance with this section.
- 8 [(d)] (C) A pharmacy benefits manager may not schedule an onsite audit to begin 9 during the first 5 calendar days of a month unless requested by the pharmacy or 10 pharmacist.
- 11 **[(e)] (D)** When conducting an audit, a pharmacy benefits manager shall:
- 12 (1) if the audit is onsite, provide written notice to the pharmacy or pharmacist at least 2 weeks before conducting the initial onsite audit for each audit cycle;
- 14 (2) employ the services of a pharmacist if the audit requires the clinical or 15 professional judgment of a pharmacist;
- 16 (3) permit its auditors to enter the prescription area of a pharmacy only when accompanied by or authorized by a member of the pharmacy staff;
- 18 (4) allow a pharmacist or pharmacy to use any prescription, or authorized 19 change to a prescription, that meets the requirements of COMAR 10.34.20.02 to validate 20 claims submitted for reimbursement for dispensing of original and refill prescriptions;
- 21 (5) for purposes of validating the pharmacy record with respect to orders 22 or refills of a drug, allow the pharmacy or pharmacist to use records of a hospital or a 23 physician or other prescriber authorized by law that are:
- 24 (i) written; or
- 25 (ii) transmitted electronically or by any other means of 26 communication authorized by contract between the pharmacy and the pharmacy benefits 27 manager;
- 28 (6) audit each pharmacy and pharmacist under the same standards and 29 parameters as other similarly situated pharmacies or pharmacists audited by the 30 pharmacy benefits manager;
- 31 (7) only audit claims submitted or adjudicated within the 2-year period 32 immediately preceding the audit, unless a longer period is authorized under federal or State 33 law;

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pharmacy benefits manager.

1 deliver the preliminary audit report to the pharmacy or pharmacist 2 within 120 calendar days after the completion of the audit, with reasonable extensions 3 allowed: 4 in accordance with subsection [(k)] (J) of this section, allow a pharmacy (9)5 or pharmacist to produce documentation to address any discrepancy found during the audit; 6 and 7 deliver the final audit report to the pharmacy or pharmacist: (10)8 (i) within 6 months after delivery of the preliminary audit report if 9 the pharmacy or pharmacist does not request an internal appeal under subsection [(k)] (J) of this section; or 10 11 (ii) within 30 days after the conclusion of the internal appeals 12 process under subsection [(k)] (J) of this section if the pharmacy or pharmacist requests 13 an internal appeal. 14 [(f)] **(E)** If a contract between a pharmacy or pharmacist and a pharmacy benefits manager specifies a period of time in which a pharmacy or pharmacist is allowed 15 16 to withdraw and resubmit a claim and that period of time expires before the pharmacy benefits manager delivers a preliminary audit report that identifies discrepancies, the 17 pharmacy benefits manager shall allow the pharmacy or pharmacist to withdraw and 18 19 resubmit a claim within 30 days after: 20 (1)the preliminary audit report is delivered if the pharmacy or pharmacist 21does not request an internal appeal under subsection [(k)] (J) of this section; or 22 (2)the conclusion of the internal appeals process under subsection [(k)] (J) 23of this section if the pharmacy or pharmacist requests an internal appeal. 24[(g)] **(F)** During an audit, a pharmacy benefits manager may not disrupt the 25provision of services to the customers of a pharmacy. 26 [(h)] (G) A pharmacy benefits manager may not: (1) 27 (i) use the accounting practice of extrapolation to calculate 28overpayments or underpayments; or 29 Except as provided in paragraph (2) of this subsection: (ii) 30 1. share information from an audit with another pharmacy 31 benefits manager; or 32 2. use information from an audit conducted by another

- 1 (2) Paragraph (1)(ii) of this subsection does not apply to the sharing of 2 information: 3 (i) required by federal or State law; 4 (ii) in connection with an acquisition or merger involving the pharmacy benefits manager; or 5 6 at the payor's request or under the terms of the agreement (iii) 7 between the pharmacy benefits manager and the payor. 8 [(i)] **(H)** The recoupment of a claims payment from a pharmacy or pharmacist 9 by a pharmacy benefits manager shall be based on an actual overpayment or denial of an 10 audited claim unless the projected overpayment or denial is part of a settlement agreed to 11 by the pharmacy or pharmacist. In this subsection, "overpayment" means a payment by the 12 [(j)] (I) (1) 13 pharmacy benefits manager to a pharmacy or pharmacist that is greater than the rate or 14 terms specified in the contract between the pharmacy or pharmacist and the pharmacy 15 benefits manager at the time that the payment is made. 16 A clerical error, record-keeping error, typographical error, or scrivener's error in a required document or record may not constitute fraud or grounds for 17 recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits 18 19 manager if the prescription was otherwise legally dispensed and the claim was otherwise 20 materially correct. 21Notwithstanding paragraph (2) of this subsection, claims remain 22subject to recoupment of overpayment or payment of any discovered underpayment by the 23pharmacy benefits manager. 24A pharmacy benefits manager shall establish an internal appeals [(k)] (J) (1) process under which a pharmacy or pharmacist may appeal any disputed claim in a 2526 preliminary audit report. 27 Under the internal appeals process, a pharmacy benefits manager shall allow a pharmacy or pharmacist to request an internal appeal within 30 working days after 2829 receipt of the preliminary audit report, with reasonable extensions allowed. 30 (3)The pharmacy benefits manager shall include in its preliminary audit
 - (4) The decision of the pharmacy benefits manager on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist shall be reflected in the final audit report.

and telephone number of the person to whom an internal appeal should be addressed.

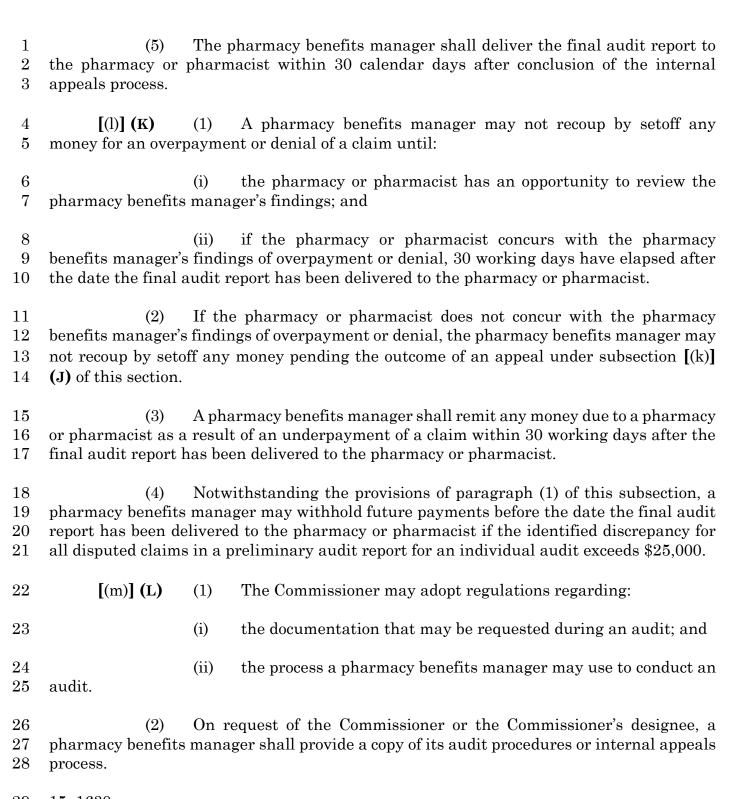
report a written explanation of the internal appeals process, including the name, address,

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29 15–1630.

30 (a) [This section applies only to a pharmacy benefits manager that provides 31 pharmacy benefits management services on behalf of a carrier.

- 1 (b)] A pharmacy benefits manager shall establish a reasonable internal review 2 process for a pharmacy to request the review of a failure to pay the contractual 3 reimbursement amount of a submitted claim.
- 4 **[(c)] (B)** A pharmacy may request a pharmacy benefits manager to review a failure to pay the contractual reimbursement amount of a claim within 180 calendar days after the date the submitted claim was paid by the pharmacy benefits manager.
- 7 **[(d)] (C)** The pharmacy benefits manager shall give written notice of its review 8 decision within 90 calendar days after receipt of a request for review from a pharmacy 9 under this section.
- [(e)] (D) If the pharmacy benefits manager determines through the internal review process established under subsection [(b)] (A) of this section that the pharmacy benefits manager underpaid a pharmacy, the pharmacy benefits manager shall pay any money due to the pharmacy within 30 working days after completion of the internal review process.
- [(f)] (E) This section may not be construed to limit the ability of a pharmacy and a pharmacy benefits manager to contractually agree that a pharmacy may have more than 180 calendar days to request an internal review of a failure of the pharmacy benefits manager to pay the contractual amount of a submitted claim.
- 19 [15-1633.
- The provisions of §§ 15–1633.1 through 15–1639 of this subtitle apply only to a pharmacy benefits manager performing pharmacy benefits management services on behalf of a carrier.
- 23 [15-1633.1.] **15-1633.**
- 24 A pharmacy benefits manager or its agent may not request a therapeutic interchange 25 unless:
- 26 (1) the proposed therapeutic interchange is for medical reasons that benefit 27 the beneficiary; or
- 28 (2) the proposed therapeutic interchange will result in financial savings 29 and benefits to the purchaser or the beneficiary.
- 30 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 31 January 1, 2024.