C3 8lr2880 CF SB 1079

By: Delegates Anderton, Kipke, and Sample-Hughes Sample-Hughes, Adams, Pendergrass, Bromwell, Angel, Cullison, Hayes, Hill, Kelly, Krebs, Metzgar, Miele, Morales, Morgan, Pena-Melnyk, Platt, Rosenberg, Saab, Szeliga, West, and K. Young

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 13, 2018

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1 AN ACT concerning

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Pharmacy Benefits Managers - Revisions

FOR the purpose of altering the application fee for a pharmacy benefits manager to register with the Maryland Insurance Commissioner; requiring a pharmacy benefits manager applying to register to file a certain financial statement with the Commissioner; authorizing the Maryland Insurance Commissioner to require certain additional information from a pharmacy benefits manager in a certain application; altering the date on which the registration of a pharmacy benefits manager expires unless the registration is renewed; altering the length of the term for which a pharmacy benefits manager may renew a certain registration; altering the circumstances under which a pharmacy benefits manager may renew a registration; authorizing the Commissioner to impose certain fees under certain eircumstances; authorizing the Commissioner to require certain information or certain submissions from a pharmacy benefits manager for a certain purpose; authorizing a pharmacy benefits manager to pay a certain fee in lieu of a certain suspension under certain circumstances; authorizing a pharmacy benefits manager to reapply for a registration under certain circumstances; clarifying that certain actions of the Commissioner are subject to certain hearing provisions; providing that a certain provision prohibiting reimbursements in a certain amount does not apply to reimbursement for certain drugs or to certain chain pharmacies; prohibiting certain reimbursement from a pharmacy benefits manager to from reimbursing a pharmacy or pharmacist for a certain product or certain service in a certain amount;

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.



prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from providing a beneficiary with certain information regarding a certain retail price or certain cost share for a prescription drug; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from discussing with a beneficiary a certain retail price or certain cost share for a prescription drug; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from selling a certain alternative prescription drug under certain circumstances; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from offering and providing store direct delivery services as an ancillary service of the pharmacy; requiring each contract between a pharmacy benefits manager and a contracted pharmacy to include the methodology used to determine maximum allowable cost pricing; requiring a pharmacy benefits manager to disclose certain information to a contracted pharmacy under certain circumstances; requiring a pharmacy benefits manager to provide a certain means on its website by which certain contracted pharmacies may promptly review certain pricing updates, to use certain pricing information to calculate certain payments, and to disclose certain information in certain contracts; requiring a pharmacy benefits manager to disclose a certain maximum allowable cost list under certain circumstances: requiring a pharmacy benefits manager to establish a certain process by which a certain pharmacy has access to certain maximum allowable cost price lists in a certain format as updated in accordance with certain requirements; requiring a pharmacy benefits manager to use updated pricing information in calculating certain payments immediately after a certain update; altering a certain procedure that a pharmacy benefits manager is required to maintain; altering certain requirements that a pharmacy benefits manager must meet before placing a prescription drug on a certain list; prohibiting a pharmacy benefits manager from setting a maximum allowable cost for certain drugs, products, and devices that are placed on a certain list that is below a certain amount; altering a certain process that must be included in each contract between a pharmacy benefits manager and a contracted pharmacy; authorizing a contracted pharmacy to file a certain complaint with the Commissioner; requiring a contracted pharmacy to exhaust a certain appeal process before filing a certain complaint; requiring the Commissioner to hold a certain hearing and issue a certain order in accordance with certain procedures; providing that an appeal of a certain order may be taken in accordance with certain statutory provisions: prohibiting a pharmacy benefits manager from retaliating against a contracted pharmacy for exercising a certain right to appeal or filing a certain complaint; prohibiting a pharmacy benefits manager from charging a contracted pharmacy a certain fee; establishing a certain civil penalty for a violation of certain provisions of this Act; requiring the Commission to review a certain compensation program for a certain purpose and take certain action on appeal and order a pharmacy benefits manager to pay a certain claim under certain circumstances; providing that certain information is considered to be confidential and proprietary information and is not subject to disclosure under certain provisions of law; authorizing the Commissioner, under certain circumstances, to issue an order that requires a pharmacy benefits manager to pay a certain fine; authorizing the Commissioner to adopt certain regulations and establish a certain complaint process; defining a certain term; altering a certain definition; providing for the construction

1 2	of certain provisions of this Act; providing for the application of this Act; providing for a delayed effective date; and generally relating to pharmacy benefits managers.		
3 4 5 6 7	BY repealing and reenacting, with amendments, Article – Insurance Section 15–1604, 15–1605, 15–1607, 15–1628.1, and 15–1642(e) 15–1642 Annotated Code of Maryland (2017 Replacement Volume)		
8 9 10 11 12	Article – Insurance Section 15–1611 , 15–1612, and 15–1613 Annotated Code of Maryland		
13 14	· · · · · · · · · · · · · · · · · · ·		
15	Article - Insurance		
16	15–1604.		
17 18 19	(a) A pharmacy benefits manager shall register with the Commissioner as a pharmacy benefits manager before providing pharmacy benefits management services in the State to purchasers.		
20	(b) An applicant for registration shall:		
21 22	(1) file with the Commissioner an application on the form that the Commissioner provides; $\{and\}$		
23 24	(2) pay to the Commissioner a registration fee {set by the Commissioner} OF \$1,000; AND		
25 26 27 28 29	(3) FILE WITH THE COMMISSIONER A FINANCIAL STATEMENT, CERTIFIED BY A CERTIFIED PUBLIC ACCOUNTANT WITHIN THE IMMEDIATELY PRECEDING 6 MONTHS, THAT PRESENTS, IN ACCORDANCE WITH GENERALLY ACCEPTED ACCOUNTING PRINCIPLES, THE FINANCIAL POSITION OF THE APPLICANT AND CONTAINS THE INFORMATION THAT THE COMMISSIONER REQUIRES.		
30 31	(C) THE COMMISSIONER MAY REQUIRE ANY ADDITIONAL INFORMATION OR SUBMISSIONS FROM A PHARMACY BENEFITS MANAGER THAT MAY BE REASONABLY		

Subject to the provisions of § 15–1607 of this part, the Commissioner shall register each pharmacy benefits manager that meets the requirements of this section.

NECESSARY TO VERIFY THE INFORMATION CONTAINED IN THE APPLICATION.

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- 1 15–1605.
- 2 (a) A pharmacy benefits manager registration expires on { the second } September 3 30 after its effective date unless it is renewed as provided under this section.
- 4 (b) A pharmacy benefits manager may renew its registration for an additional 5 **{**2-year**} 1-YEAR** term, if the pharmacy benefits manager:
- 6 (1) otherwise is entitled to be registered;
- 7 (2) files with the Commissioner a renewal application on the form that the 8 Commissioner requires; {and}
- 9 (3) pays to the Commissioner a renewal fee [set by the Commissioner] OF 10 **\$1,000;** AND
- 11 (4) FILES WITH THE COMMISSIONER A FINANCIAL STATEMENT
 12 CERTIFIED BY A CERTIFIED PUBLIC ACCOUNTANT WITHIN THE IMMEDIATELY
 13 PRECEDING 6 MONTHS, THAT PRESENTS, IN ACCORDANCE WITH GENERALLY
 14 ACCEPTED ACCOUNTING PRINCIPLES, THE FINANCIAL POSITION OF THE APPLICANT
 15 AND CONTAINS THE INFORMATION THAT THE COMMISSIONER REQUIRES.
- 16 (c) An application for renewal of a pharmacy benefits manager registration shall 17 be considered made in a timely manner if it is postmarked on or before the date the 18 pharmacy benefits manager's registration expires.
- 19 (D) IF A PHARMACY BENEFITS MANAGER FAILS TO PAY THE RENEWAL FEE
 20 REQUIRED UNDER SUBSECTION (B)(3) OF THIS SECTION WHEN THE PHARMACY
 21 BENEFITS MANAGER SUBMITS AN APPLICATION FOR RENEWAL, THE COMMISSIONER
 22 MAY IMPOSE AN ADDITIONAL APPLICATION FEE OF \$500.
- Subject to the provisions of § 15–1607 of this part, the Commissioner shall renew the registration of each pharmacy benefits manager that meets the requirements of this section.
- 26 (F) (E) THE COMMISSIONER MAY REQUIRE ANY ADDITIONAL INFORMATION OR SUBMISSIONS FROM A PHARMACY BENEFITS MANAGER THAT MAY BE REASONABLY NECESSARY TO VERIFY THE INFORMATION CONTAINED IN THE APPLICATION.
- 30 15–1607.
- 31 (a) (1) Subject to PARAGRAPH (2) OF THIS SUBSECTION AND the 32 APPLICABLE hearing provisions of Title 2 of this article, the Commissioner may deny a

- registration to a pharmacy benefits manager applicant or refuse to renew, suspend, or 1 2 revoke the registration of a pharmacy benefits manager if the pharmacy benefits manager, or an officer, director, or employee of the pharmacy benefits manager: 3 4 **∮**(1)**∤ (1)** makes a material misstatement or misrepresentation in an 5 application for registration; 6 **{**(2)**} (Ⅲ)** fraudulently or deceptively obtains or attempts to obtain a 7 registration; 8 $\{(3)\}$ (III) in connection with the administration of pharmacy benefits 9 management services, commits fraud or engages in illegal or dishonest activities; or 10 $\{(4)\}$ violates any provision of this part or a regulation adopted under 11 this part. 12 SUBJECT TO THE APPROVAL OF THE COMMISSIONER, A 13 PHARMACY BENEFITS MANAGER MAY, IN LIEU OF PART OR ALL OF THE DAYS OF ANY SUSPENSION PERIOD IMPOSED BY THE COMMISSIONER, PAY A FEE OF \$1,000 PER 14 15 DAY OF THE SUSPENSION PERIOD. 16 IF THE COMMISSIONER'S DENIAL OR REVOCATION OF A PHARMACY 17 BENEFITS MANAGER'S REGISTRATION IS SUSTAINED BY THE COMMISSIONER AFTER A HEARING IN ACCORDANCE WITH TITLE 2 OF THIS ARTICLE, A PHARMACY BENEFITS 18 MANAGER MAY REAPPLY FOR A REGISTRATION NO EARLIER THAN 1 YEAR AFTER 19 20 THE DATE ON WHICH A DENIAL OR REVOCATION WAS SUSTAINED BY THE COMMISSIONER. 21 22 This section does not limit any other regulatory authority of the [(b)] (C) 23 Commissioner under this article. 15-1611. 2425 (A) THIS SECTION DOES NOT APPLY TO REIMBURSEMENT: 26 **(1)** FOR SPECIALTY DRUGS; **(2)** 27 FOR MAIL ORDER DRUGS; OR 28 **(3)** TO A CHAIN PHARMACY WITH MORE THAN 15 STORES OR A PHARMACIST WHO IS AN EMPLOYEE OF THE CHAIN PHARMACY. 29
- 30 <u>(B)</u> A PHARMACY BENEFITS MANAGER MAY NOT REIMBURSE A PHARMACY 31 OR PHARMACIST FOR A PHARMACEUTICAL PRODUCT OR PHARMACIST SERVICE IN 32 AN AMOUNT LESS THAN THE AMOUNT THAT THE PHARMACY BENEFITS MANAGER

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1	REIMBURSES ITSELF OR AN AFFILIATE FOR PROVIDING THE SAME PRODUCT OR
2	SERVICE.
3	15-1612.
4	IN ADDITION TO THE DECIGEDATION AND DENEMAL EFEC ECTARISHED
4 5	IN ADDITION TO THE REGISTRATION AND RENEWAL FEES ESTABLISHED LINDED SS 15 1604 AND 15 1605 OF THIS CURTIFIE THE COMMISSIONED MAY
6	UNDER §§ 15–1604 AND 15–1605 OF THIS SUBTITLE, THE COMMISSIONER MAY REQUIRE A PHARMACY BENEFITS MANAGER TO PAY A FEE SET BY THE
7	COMMISSIONER TO COVER THE COSTS OF IMPLEMENTATION AND ENFORCEMENT OF
8	THIS SUBTITLE, INCLUDING FEES TO COVER THE COSTS OF:
Ü	
9	(1) SALARIES AND BENEFITS PAID TO PERSONNEL ENGAGED IN THE
10	IMPLEMENTATION AND ENFORCEMENT OF THIS SUBTITLE;
11	(2) REASONABLE TECHNOLOGY COSTS RELATING TO THE
12	ENFORCEMENT OF THIS SUBTITLE, INCLUDING THE COSTS OF:
13	(I) SOFTWARE AND HARDWARE USED IN THE ENFORCEMENT
14	PROCESS: AND
15	(H) TRAINING PERSONNEL IN THE PROPER USE OF THE
16	SOFTWARE OR HARDWARE; AND
. –	
17	(3) EDUCATION AND TRAINING FOR PERSONNEL ENGAGED IN THE
18	ENFORCEMENT OF THIS SUBTITLE TO MAINTAIN PROFICIENCY AND COMPETENCE.
19	15-1613.
	10 1010.
20	(A) A PHARMACY BENEFITS MANAGER MAY NOT PROHIBIT A PHARMACY OR
21	PHARMACIST FROM:
22	(1) PROVIDING A BENEFICIARY WITH INFORMATION REGARDING THE
23	RETAIL PRICE FOR A PRESCRIPTION DRUG OR THE AMOUNT OF THE COST SHARE
24	FOR WHICH THE BENEFICIARY IS RESPONSIBLE FOR A PRESCRIPTION DRUG;
25	(2) DISCUSSING WITH A BENEFICIARY INFORMATION REGARDING
26	THE RETAIL PRICE FOR A PRESCRIPTION DRUG OR THE AMOUNT OF THE COST
27	SHARE FOR WHICH THE BENEFICIARY IS RESPONSIBLE FOR A PRESCRIPTION DRUG;
28	(3) IF A MORE AFFORDABLE DRUG IS AVAILABLE THAN ONE ON THE

30 INTERCHANGE UNDER §§ 15–1633 THROUGH 15–1639 OF THIS SUBTITLE ARE MET, 31 SELLING THE MORE AFFORDABLE ALTERNATIVE TO THE BENEFICIARY; OR

PURCHASER'S FORMULARY AND THE REQUIREMENTS FOR A THERAPEUTIC

10 THIS SECTION MAY NOT BE CONSTRUCTED TO ALTER REQUIREMENTS FOR A THERAPEUTIC INTERCHANGE UNDER §§ 15–1633 THRO 15–1639 OF THIS SUBTITLE. 15–1628.1. (a) (1) In this section the following words have the meanings indicated. (2) "Contracted pharmacy" means a pharmacy that participates in network of a pharmacy benefits manager through a contract with: (i) the pharmacy benefits manager; or (ii) a pharmacy services administration organization or a gourchasing organization. (3) "DRUG SHORTAGE LIST" MEANS A LIST OF DRUG PRODUCTS AT A DISCOUNT WITH AN EXPIRATION DATE OF LESS THAN 1 YEAR FROM THE SOF PURCHASE BY THE CONTRACTED PHARMACY LISTED ON THE FEDERAL FOOD DRUG ADMINISTRATION'S DRUG SHORTAGES WEBSITE. [(3)] (4) (1) "Maximum allowable cost" means the maximum and that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy of a multisource generic drug, a medical product, or a device. (II) "MAXIMUM ALLOWABLE COST" DOES NOT INCLUDISPENSING FEES. [(4)] (5) "Maximum allowable cost list" means a list of multis generic drugs, medical products, and devices for which a maximum allowable cost has established by a pharmacy benefits manager or a purchaser.		HOUSE BILL 1349
(B) THIS SECTION MAY NOT BE CONSTRUCTED TO ALTER REQUIREMENTS FOR A THERAPEUTIC INTERCHANGE UNDER §\$ 15–1633 THREE 15–1639 OF THIS SUBTITLE. (a) (1) In this section the following words have the meanings indicated. (2) "Contracted pharmacy" means a pharmacy that participates in network of a pharmacy benefits manager through a contract with: (i) the pharmacy benefits manager; or (ii) a pharmacy services administration organization or a gourchasing organization. (3) "DRUG SHORTAGE LIST" MEANS A LIST OF DRUG PRODUCTS of TA A DISCOUNT WITH AN EXPIRATION DATE OF LESS THAN 1 YEAR FROM THE OF PURCHASE BY THE CONTRACTED PHARMACY LISTED ON THE FEDERAL FOOD DRUG ADMINISTRATION'S DRUG SHORTAGES WEBSITE. [(3)] (4) (1) "Maximum allowable cost" means the maximum and that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy for the cost of a multisource generic drug, a medical product, or a device. (II) "MAXIMUM ALLOWABLE COST" DOES NOT INCIDISPENSING FEES. [(4)] (5) "Maximum allowable cost list" means a list of multisgeneric drugs, medical products, and devices for which a maximum allowable cost has established by a pharmacy benefits manager or a purchaser.	1	(4) OFFERING AND PROVIDING STORE DIRECT DELIVERY SERVICES
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[(4)] (5) "Maximum allowable cost list" means a list of multis generic drugs, medical products, and devices for which a maximum allowable cost has established by a pharmacy benefits manager or a purchaser.	20	(II) "MAXIMUM ALLOWABLE COST" DOES NOT INCLUDE
generic drugs, medical products, and devices for which a maximum allowable cost has established by a pharmacy benefits manager or a purchaser.	21	DISPENSING FEES.
established by a pharmacy benefits manager or a purchaser.	22	[(4)] (5) "Maximum allowable cost list" means a list of multisource
25 (h) In each contract between a pharmacy banefits manager and a contr		generic drugs, medical products, and devices for which a maximum allowable cost has been established by a pharmacy benefits manager or a purchaser.
•	25	(b) In each contract between a pharmacy benefits manager and a contracted pharmacy the pharmacy benefits manager shall include the METHODOLOGY AND sources

28 (C) (1) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE 29 CONTRACTED PHARMACY WHETHER THE PHARMACY BENEFITS MANAGER IS USING 30 AN IDENTICAL MAXIMUM ALLOWABLE COST LIST WITH ANY OTHER CONTRACTED 31 PHARMACY.

used to determine maximum allowable cost pricing.

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- 1 (2) IF A PHARMACY BENEFITS MANAGER USES A DIFFERENT
 2 MAXIMUM ALLOWABLE COST LIST WITH ANOTHER CONTRACTED PHARMACY, THE
 3 PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE CONTRACT PHARMACY
 4 ANY DIFFERENCES BETWEEN THE AMOUNT PAID TO ANY CONTRACTED PHARMACY
 5 AND THE AMOUNT CHARGED TO THE PURCHASER.
- 6 $\{(c)\}$ (D) A pharmacy benefits manager shall:
- 7 (1) update its pricing information at least every 7 days and provide a means ON THE PHARMACY BENEFITS MANAGER'S WEBSITE by which ALL contracted pharmacies may promptly review pricing updates in a format that is readily available and accessible AT THE TIME THE PHARMACY BENEFITS MANAGER UPDATES THE LIST FOR 11 ITS OWN USE:
- 12 (2) ESTABLISH A REASONABLE PROCESS BY WHICH A CONTRACTED
 13 PHARMACY HAS ACCESS TO THE CURRENT AND APPLICABLE MAXIMUM ALLOWABLE
 14 COST PRICE LISTS IN AN ELECTRONIC FORMAT AS UPDATED IN ACCORDANCE WITH
 15 THE REQUIREMENTS OF THIS SECTION; AND
- 16 (2) (3) IMMEDIATELY AFTER A PRICING INFORMATION UPDATE
 17 UNDER ITEM (1) OF THIS SUBSECTION, USE THE UPDATED PRICING INFORMATION
 18 IN CALCULATING THE PAYMENTS MADE TO ALL CONTRACTED PHARMACIES; AND.
- 19 (3) DISCLOSE IN EACH CONTRACT BETWEEN THE PHARMACY
 20 BENEFITS MANAGER AND A CONTRACTED PHARMACY WHETHER THE PHARMACY
 21 BENEFITS MANAGER USES A DIFFERENT MAXIMUM ALLOWABLE COST LIST FOR
 22 DRUGS, PRODUCTS, OR DEVICES DISPENSED AT RETAIL PHARMACIES THAN FOR
 23 DRUGS, PRODUCTS, OR DEVICES DISPENSED BY MAIL.
- 24 (E) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO A CONTRACTED
 25 PHARMACY A MAXIMUM ALLOWABLE COST LIST USED BY THE PHARMACY BENEFITS
 26 MANAGER FOR DRUGS, PRODUCTS, OR DEVICES DISPENSED BY MAIL IF THE
 27 MAXIMUM ALLOWABLE COST LIST IS:
- 28 (1) DIFFERENT THAN THE MAXIMUM ALLOWABLE COST LIST USED BY
 29 THE PHARMACY BENEFITS MANAGER FOR DRUGS, PRODUCTS, OR DEVICES
 30 DISPENSED AT RETAIL PHARMACIES; AND
- 31 (2) ADOPTED BY THE PHARMACY BENEFITS MANAGER AFTER 32 EXECUTING A CONTRACT WITH THE CONTRACTED PHARMACY.
- 4 (d) (T) (1) A pharmacy benefits manager shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing [in a timely manner] AS NECESSARY to:

(I) nome in consistent with puicing about got
(I) remain consistent with pricing changes;
(II) REMOVE FROM THE LIST DRUGS THAT NO LONGER MEET
THE REQUIREMENTS OF SUBSECTION (G) (E) OF THIS SECTION; AND
(III) ENSURE THE REFLECT THE CURRENT AVAILABILITY OF DRUGS in the marketplace.
(2) A PRODUCT ON THE MAXIMUM ALLOWABLE COST LIST SHALL BE ELIMINATED FROM THE LIST BY THE PHARMACY BENEFITS MANAGER WITHIN 24 HOURS 7 DAYS AFTER THE PHARMACY BENEFITS MANAGER KNOWS OR SHOULD HAVE KNOWN OF A CHANGE IN THE PRICING OR AVAILABILITY OF THE PRODUCT.
{ (e) } (G) Before placing a prescription drug on a maximum allowable cost list, a pharmacy benefits manager shall ensure that:
(1) the drug is listed as "A" or "B" rated in the most recent version of the U.S. Food and Drug Administration's approved drug products with therapeutic equivalence evaluations, also known as the Orange Book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; [and]
(2) (I) IF A DRUG IS MANUFACTURED BY MORE THAN ONE
MANUFACTURER, the drug is fgenerally available IN AT LEAST THREE GENERICALLY
EQUIVALENT OR BIOEQUIVALENT VERSIONS for purchase by contracted pharmacies,
INCLUDING CONTRACTED RETAIL PHARMACIES, in the State from a [national or
regional] wholesale distributor [and is not obsolete] WITH A PERMIT IN THE STATE; OR
(II) IF A DRUG IS MANUFACTURED BY ONLY ONE
MANUFACTURER, THE DRUG IS GENERALLY AVAILABLE FOR PURCHASE BY
CONTRACTED PHARMACIES, INCLUDING CONTRACTED RETAIL PHARMACIES, IN THE
STATE FROM AT LEAST TWO WHOLESALE DISTRIBUTORS WITH A PERMIT IN THE
STATE; AND
(3) THE DRUG IS NOT OBSOLETE, TEMPORARILY UNAVAILABLE, OR
LISTED ON A DRUG SHORTAGE LIST AS CURRENTLY IN SHORTAGE.
(H) A PHARMACY BENEFITS MANAGER MAY NOT SET THE MAXIMUM
ALLOWABLE COST FOR ANY DRUG, PRODUCT, OR DEVICE IT PLACES ON A MAXIMUM
ALLOWABLE COST LIST IN AN AMOUNT THAT IS BELOW THE AMOUNT ESTABLISHED
IN THE SOURCE USED BY THE PHARMACY BENEFITS MANAGER TO SET THE MAXIMUM
ALLOWABLE COST FOR THE DRUG, PRODUCT, OR DEVICE.

- Each contract between a pharmacy benefits manager and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:
- 4 (1) a requirement that an appeal be filed **BY THE CONTRACT PHARMACY** 5 no later than 21 days after the date of the initial **ADJUDICATED** claim;
- 6 (2) a requirement that [an appeal be investigated and resolved], within 7 [21] 7 days after the date the appeal is filed, THE PHARMACY BENEFITS MANAGER 8 INVESTIGATE AND RESOLVE THE APPEAL AND REPORT TO THE CONTRACTED 9 PHARMACY ON THE PHARMACY BENEFITS MANAGER'S DETERMINATION ON THE 10 APPEAL;
- 11 (3) A REQUIREMENT THAT A PHARMACY BENEFITS MANAGER MAKE 12 AVAILABLE ON ITS WEBSITE INFORMATION ABOUT THE APPEAL PROCESS, 13 INCLUDING:
- 14 (I) a DIRECT telephone number at which the contracted pharmacy
 15 may DIRECTLY contact the DEPARTMENT OR OFFICE RESPONSIBLE FOR PROCESSING
 16 APPEALS FOR pharmacy benefits manager to speak to an individual SPECIFICALLY OR
 17 LEAVE A MESSAGE FOR AN INDIVIDUAL WHO IS responsible for processing appeals;
- 18 <u>(II) AN E-MAIL ADDRESS OF THE DEPARTMENT OR OFFICE</u> 19 <u>RESPONSIBLE FOR PROCESSING APPEALS TO WHICH AN INDIVIDUAL WHO IS</u> 20 <u>RESPONSIBLE FOR PROCESSING APPEALS HAS ACCESS; AND</u>
- 21 (III) A NOTICE INDICATING THAT THE INDIVIDUAL
 22 SPECIFICALLY RESPONSIBLE FOR PROCESSING APPEALS SHALL RETURN CALLS A
 23 CALL OR AN E-MAIL MADE BY A CONTRACTED PHARMACY TO THE INDIVIDUAL
 24 WITHIN 3 BUSINESS DAYS OR LESS OF RECEIVING THE CALL OR E-MAIL;
- 25 (4) a requirement that a pharmacy benefits manager provide:
- 26 (i) a reason for any appeal denial; and
- 27 (ii) the national drug code of a drug that IS READILY AVAILABLE
 28 FOR PURCHASE AND THE NAME OF THE WHOLESALE DISTRIBUTOR FROM WHICH THE
 29 DRUG may be purchased by the contracted pharmacy WAS AVAILABLE ON THE DATE THE
 30 CLAIM WAS ADJUDICATED at a price at or below the [benchmark price] MAXIMUM
 31 ALLOWABLE COST determined by the pharmacy benefits manager; and
- 32 (5) if an appeal is upheld, a requirement that a pharmacy benefits 33 manager:

1	(i) make the change in the maximum allowable cost no later than 1
2	business day after the date of determination on the appeal; and
3	(ii) permit the appealing contracting pharmacy to reverse and rebill
4	the claim, and any subsequent similar claims.
5	(I) FOR THE APPEALING PHARMACY:
9	(I) FOR THE ATTEALING THARMACT.
6	1. ADJUST THE MAXIMUM ALLOWABLE COST FOR THE
7	DRUG AS OF THE DATE OF THE ORIGINAL CLAIM FOR PAYMENT; AND
8	2. WITHOUT REQUIRING THE APPEALING PHARMACY TO
9	REVERSE AND REBILL THE CLAIMS, PROVIDE REIMBURSEMENT FOR THE CLAIM AND
10	ANY SUBSEQUENT AND SIMILAR CLAIMS UNDER SIMILARLY APPLICABLE
11	CONTRACTS WITH THE PHARMACY BENEFITS MANAGER:
12	A. FOR THE ORIGINAL CLAIM, IN THE FIRST REMITTANCE
13	TO THE PHARMACY AFTER THE DATE THE APPEAL WAS DETERMINED; AND
14	B. FOR SUBSEQUENT AND SIMILAR CLAIMS UNDER
15	SIMILARLY APPLICABLE CONTRACTS, IN THE SECOND REMITTANCE TO THE
16	PHARMACY AFTER THE DATE THE APPEAL WAS DETERMINED; AND
17	(II) FOR A SIMILARLY SITUATED CONTRACTED PHARMACY IN
18	THE STATE:
1.0	1
19	1. ADJUST THE MAXIMUM ALLOWABLE COST FOR THE
20	DRUG AS OF THE DATE THE APPEAL WAS DETERMINED; AND
21	2. PROVIDE NOTICE TO THE PHARMACY OR PHARMACY'S
22	CONTRACTED AGENT THAT:
44	CONTRACTED AGENT THAT.
23	A. AN APPEAL HAS BEEN UPHELD; AND
20	ANALI EAL HAS BEEN ULITELD, AND
24	B. WITHOUT FILING A SEPARATE APPEAL, THE
25	PHARMACY OR THE PHARMACY'S CONTRACTED AGENT MAY REVERSE AND REBILL A
26	SIMILAR CLAIM.
20	SIMILATE OLIMINA
27	(J) (1) WITHIN 30 CALENDAR DAYS AFTER A PHARMACY BENEFITS
28	MANAGER DENIES AN APPEAL BY A CONTRACTED PHARMACY UNDER SUBSECTION
29	(I) OF THIS SECTION, THE CONTRACTED PHARMACY MAY FILE A COMPLAINT WITH
30	THE COMMISSIONER FOR REVIEW OF THE DECISION BY THE PHARMACY BENEFITS
31	MANAGER.

1	(2) A CONTRACTED PHARMACY SHALL EXHAUST THE APPEAL
2	PROCESS ESTABLISHED BY THE PHARMACY BENEFITS MANAGER UNDER
3	SUBSECTION (I) OF THIS SECTION BEFORE FILING A COMPLAINT WITH THE
4	COMMISSIONER UNDER THIS SUBSECTION.

- 5 (3) THE COMMISSIONER SHALL HOLD A HEARING ON THE
 6 COMPLAINT AND ISSUE AN ORDER IN ACCORDANCE WITH THE HEARING AND REVIEW
 7 PROCEDURES ESTABLISHED UNDER §§ 2–210 THROUGH 2–214 OF THIS ARTICLE.
- 8 (4) An Appeal of an order of the Commissioner under this 9 Subsection may be taken in accordance with \$ 2-215 of this article.
- 10 (5) (G) A PHARMACY BENEFITS MANAGER MAY NOT RETALIATE
 11 AGAINST A CONTRACTED PHARMACY FOR EXERCISING ITS RIGHT TO APPEAL UNDER
 12 THIS SECTION OR FILING A COMPLAINT WITH THE COMMISSIONER UNDER THIS
 13 SUBSECTION.
- 14 (K) (H) A PHARMACY BENEFITS MANAGER MAY NOT CHARGE A
 15 CONTRACTED PHARMACY A FEE RELATED TO AN ADJUDICATION OF A CLAIM UNDER
 16 THE READJUDICATION OF A CLAIM OR CLAIMS RESULTING FROM CARRYING OUT
 17 THE REQUIREMENT OF A CONTRACT SPECIFIED IN SUBSECTION (F)(5) OF THIS
 18 SECTION OR THE UPHOLDING OF AN APPEAL UNDER SUBSECTION (I) OF THIS
 19 SECTION.
- 20 (L) (1) A PHARMACY BENEFITS MANAGER THAT VIOLATES THIS SECTION 21 IS SUBJECT TO A CIVIL PENALTY OF NOT LESS THAN \$1,000 FOR EACH VIOLATION.
- 22 **(2)** EACH DAY THAT A VIOLATION CONTINUES SHALL BE A SEPARATE 23 VIOLATION.
- 24 (I) (1) IF A PHARMACY BENEFITS MANAGER DENIES AN APPEAL AND A
 25 CONTRACTED PHARMACY FILES A COMPLAINT WITH THE COMMISSIONER, THE
 26 COMMISSIONER SHALL:
- 27 (I) REVIEW THE COMPENSATION PROGRAM OF THE PHARMACY
 28 BENEFITS MANAGER TO ENSURE THAT THE REIMBURSEMENT FOR PHARMACY
 29 BENEFITS MANAGEMENT SERVICES PAID TO THE PHARMACIST OR A PHARMACY
 30 COMPLIES WITH THIS SUBTITLE AND THE TERMS OF THE CONTRACT; AND
- 31 (II) BASED ON A DETERMINATION MADE BY THE COMMISSIONER
 32 UNDER ITEM (I) OF THIS PARAGRAPH, DISMISS THE APPEAL OR UPHOLD THE APPEAL
 33 AND ORDER THE PHARMACY BENEFITS MANAGER TO PAY THE CLAIM OR CLAIMS IN
 34 ACCORDANCE WITH THE COMMISSIONER'S FINDINGS.

1 2 3	(2) ALL PRICING INFORMATION AND DATA COLLECTED BY THE COMMISSIONER DURING A REVIEW REQUIRED BY PARAGRAPH (1) OF THIS SUBSECTION:
4 5	(I) IS CONSIDERED TO BE CONFIDENTIAL AND PROPRIETARY INFORMATION; AND
6 7	(II) IS NOT SUBJECT TO DISCLOSURE UNDER THE PUBLIC INFORMATION ACT.
8	15–1642.
9 10 11	(a) If the Commissioner determines that a pharmacy benefits manager has violated any provision of this subtitle or any regulation adopted under this subtitle, the Commissioner may issue an order that requires the pharmacy benefits manager to:
12 13	(1) cease and desist from the identified violation and further similar violations;
14	(2) take specific affirmative action to correct the violation; [or]
15 16	(3) make restitution of money, property, or other assets to a person that has suffered financial injury because of the violation; OR
17	(4) PAY A FINE IN AN AMOUNT DETERMINED BY THE COMMISSIONER.
18 19 20	(b) (1) An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is registered under Part II of this subtitle in the manner provided in § 2–204 of this article.
21 22 23 24	(2) An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is not registered under Part II of this subtitle in the manner provided in § 4–206 or § 4–207 of this article for service on an unauthorized insurer that does an act of insurance business in the State.
25 26 27	(3) A request for a hearing on any order issued under this section does not stay that portion of the order that requires the pharmacy benefits manager to cease and desist from conduct identified in the order.
28 29 30	(4) The Commissioner may file a petition in the circuit court of any county to enforce an order issued under this section, whether or not a hearing has been requested or, if requested, whether or not a hearing has been held.
31 32 33	(5) If the Commissioner prevails in an action brought under this section, the Commissioner may recover, for the use of the State, reasonable attorney's fees and the costs of the action.

1 2 3	(c) In addition to any other enforcement action taken by the Commissioner under this section AND SUBJECT TO § 15—1628.1(L) OF THIS SUBTITLE, the Commissioner may impose a civil penalty not exceeding \$10,000 for each violation of this subtitle.
4	(D) THE COMMISSIONER MAY ADOPT REGULATIONS:
5	(1) TO CARRY OUT THIS SUBTITLE; AND
6 7	(2) TO ESTABLISH A COMPLAINT PROCESS TO ADDRESS GRIEVANCES AND APPEALS BROUGHT IN ACCORDANCE WITH THIS SUBTITLE.
8 9	[(d)](E) This section does not limit any other regulatory authority of the Commissioner under this article.
10 11 12	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all contracts between a pharmacy benefits manager and a pharmacy entered into, modified, amended, or renewed on or after January 1, 2019.
13 14	SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2019.
	Approved:
	Governor.
	Speaker of the House of Delegates.
	President of the Senate.