By: Delegates Kach, Bromwell, Elliott, and Olszewski Olszewski, Costa, Cullison, Donoghue, Hammen, Hubbard, A. Kelly, Kipke, Krebs, McDonough, Morhaim, Murphy, Nathan–Pulliam, Oaks, Pena–Melnyk, Pendergrass, Ready, Reznik, Tarrant, and V. Turner

Introduced and read first time: February 3, 2014 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 12, 2014

CHAPTER \_\_\_\_\_

#### 1 AN ACT concerning

C3

# Pharmacy Benefits Managers – Pharmacy Contracts – Payments Maximum <u>Allowable Cost Pricing</u>

4 FOR the purpose of requiring a pharmacy benefits manager to include in its contract  $\mathbf{5}$ with a pharmacy, a pharmacy services administration organization, or a group 6 purchasing organization the methodology used by the pharmacy benefits 7 manager to calculate a certain reimbursement paid for each drug, medical 8 product, and device that is a covered pharmacy benefit administered by the pharmacy benefits manager; requiring a pharmacy benefits manager to include 9 in its contract with a pharmacy, a pharmacy services administration 10 organization, or a group purchasing organization certain information and a 11 certain methodology, make available to a contracted pharmacy a certain list and 12 13 a certain maximum allowable cost, review and make certain adjustments to the maximum allowable cost, make available to a contracted pharmacy certain 14 15updates, allow a contracted pharmacy to resubmit a claim for payment under 16 <del>certain circumstances, and provide a process for a contracted pharmacy to</del> 17appeal the maximum allowable cost: establishing certain requirements for the appeal process; requiring a pharmacy benefits manager, if it denies an appeal, 18 to provide the reason for the denial and identify a certain national drug code 19 product; requiring a pharmacy benefits manager to adjust the maximum 2021allowable cost in a certain manner and provide a certain notice under certain circumstances; prohibiting a pharmacy benefits manager from requiring a 22

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

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

1	<del>pharmacy to dispense a prescription for a certain contractual reimbursement</del>
2	<del>amount; defining certain terms; providing for the application of this Act; and</del>
3	generally relating to pharmacy benefits managers and payments to pharmacies
4	for covered drugs, medical products, and devices each contract with a contracted
5	pharmacy, the sources used to determine maximum allowable cost pricing;
6	requiring the pharmacy benefits manager to update its pricing information with
7	a certain frequency and provide a means by which contracted pharmacies may
8	review pricing updates in a certain format; requiring a pharmacy benefits
9	<u>manager to maintain a procedure to eliminate products from a certain list for a</u>
10	certain purpose; requiring a pharmacy benefits manager to ensure that certain
11	conditions are met before placing a prescription drug on a maximum allowable
12	cost list; requiring each contract between a pharmacy benefits manager and a
13	contracted pharmacy to include a certain process for appealing, investigating,
$\begin{array}{c} 14 \\ 15 \end{array}$	and resolving disputes regarding maximum allowable cost pricing; defining
10 $16$	certain terms; providing for a delayed effective date; and generally relating to
10 $17$	<u>contracts between pharmacy benefits managers and contracted pharmacies and</u> maximum allowable cost pricing.
11	maximum anowable cost pricing.
18	BY adding to
19	Article – Insurance
$\overline{20}$	Section 15–1628.1 <del>and 15–1628.2</del>
$\frac{1}{21}$	Annotated Code of Maryland
22	(2011 Replacement Volume and 2013 Supplement)
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1PHARMACY FOR THE COST OF A DRUG, A MEDICAL PRODUCT, OR A DEVICE2DISPENSED TO A BENEFICIARY.

 3
 (II)
 "Drug product reimbursement" does not

 4
 INCLUDE A DISPENSING FEE OR A PROFESSIONAL FEE.

5 (4) (3) "MAXIMUM ALLOWABLE COST" MEANS THE MAXIMUM 6 AMOUNT THAT A PHARMACY BENEFITS MANAGER OR A PURCHASER WILL 7 REIMBURSE A CONTRACTED PHARMACY FOR THE COST OF A MULTISOURCE 8 GENERIC DRUG, A MEDICAL PRODUCT, OR A DEVICE.

9 (5) (4) "MAXIMUM ALLOWABLE COST LIST" MEANS A LIST OF
10 MULTISOURCE GENERIC DRUGS, MEDICAL PRODUCTS, AND DEVICES FOR WHICH
11 A MAXIMUM ALLOWABLE COST HAS BEEN ESTABLISHED BY A PHARMACY
12 BENEFITS MANAGER OR A PURCHASER.

13 (B) A PHARMACY BENEFITS MANAGER SHALL INCLUDE IN ITS
 14 CONTRACT WITH A PHARMACY, A PHARMACY SERVICES ADMINISTRATION
 15 ORGANIZATION, OR A GROUP PURCHASING ORGANIZATION THE METHODOLOGY
 16 USED BY THE PHARMACY BENEFITS MANAGER TO CALCULATE THE DRUG
 17 PRODUCT REIMBURSEMENT PAID FOR EACH DRUG, MEDICAL PRODUCT, AND
 18 DEVICE THAT IS A COVERED PHARMACY BENEFIT ADMINISTERED BY THE
 19 PHARMACY BENEFITS MANAGER.

20 (C) A PHARMACY BENEFITS MANAGER SHALL:

21 (1) INCLUDE IN ITS CONTRACT WITH A PHARMACY, A PHARMACY
 22 SERVICES ADMINISTRATION ORGANIZATION, OR A GROUP PURCHASING
 23 ORGANIZATION, FOR EVERY DRUG, MEDICAL PRODUCT, AND DEVICE FOR WHICH
 24 THE PHARMACY BENEFITS MANAGER ESTABLISHES A MAXIMUM ALLOWABLE
 25 COST TO DETERMINE THE DRUG PRODUCT REIMBURSEMENT:

26 (I) INFORMATION IDENTIFYING THE NATIONAL DRUG
 27 PRICING COMPENDIA OR OTHER SOURCE USED TO OBTAIN THE DRUG, MEDICAL
 28 PRODUCT, AND DEVICE PRICE DATA; AND

29(II)THEMETHODOLOGYUSEDTOCALCULATETHE30MAXIMUM ALLOWABLE COST;

31 (2) MAKE AVAILABLE TO A CONTRACTED PHARMACY:

 32
 (I)
 THE
 MAXIMUM
 ALLOWABLE
 COST
 LIST
 OF
 THE

 33
 PHARMACY BENEFITS MANAGER; AND

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1	<del>(II)</del> <del>THE MAXIMUM ALLOWABLE COST FOR EACH DRUG,</del>
2	MEDICAL PRODUCT, AND DEVICE ON THE MAXIMUM ALLOWABLE COST LIST;
3	(3) AT LEAST EVERY 7 DAYS, REVIEW AND MAKE ANY NECESSARY
4	ADJUSTMENTS TO:
<b>5</b>	(I) THE DRUGS, MEDICAL PRODUCTS, AND DEVICES ON THE
6	MAXIMUM ALLOWABLE COST LIST; AND
7	(II) THE MAXIMUM ALLOWABLE COST OF EACH DRUG,
8	MEDICAL PRODUCT, AND DEVICE ON THE MAXIMUM ALLOWABLE COST LIST TO
9 10	REFLECT THE CURRENT MANUFACTURER PRICE FOR THE DRUG, MEDICAL PRODUCT, AND DEVICE;
11	(4) AFTER REVIEWING AND MAKING NECESSARY ADJUSTMENTS,
12	MAKE AVAILABLE TO A CONTRACTED PHARMACY WEEKLY UPDATES OF:
13	(I) THE MAXIMUM ALLOWABLE COST LIST; AND
14	<del>(II)</del> THE MAXIMUM ALLOWABLE COST FOR EACH DRUG,
15	MEDICAL PRODUCT, AND DEVICE ON THE MAXIMUM ALLOWABLE COST LIST;
16	(5) ALLOW A CONTRACTED PHARMACY TO RESUBMIT A CLAIM
17	FOR PAYMENT AT THE MAXIMUM ALLOWABLE COST IN EFFECT ON THE DATE OF
18	THE ORIGINAL CLAIM SUBMISSION IF THE PHARMACY'S CLAIM WAS ORIGINALLY
19 20	SUBMITTED AT A MAXIMUM ALLOWABLE COST THAT CHANGED ON OR BEFORE
20	THE ORIGINAL CLAIM SUBMISSION DATE; AND
21	(6) PROVIDE A PROCESS FOR A CONTRACTED PHARMACY TO
22	APPEAL A MAXIMUM ALLOWABLE COST.
23	(D) THE APPEAL PROCESS REQUIRED UNDER SUBSECTION (C)(6) OF
24	THIS SECTION SHALL:
25	(1) ALLOW A CONTRACTED PHARMACY TO APPEAL A MAXIMUM
26	ALLOWABLE COST WITHIN 60 DAYS AFTER THE DATE OF THE ORIGINAL CLAIM
27	SUBMISSION; AND
28	(2) REQUIRE A PHARMACY BENEFITS MANAGER TO INVESTIGATE
29	AND MAKE A DECISION ON AN APPEAL WITHIN 7 BUSINESS DAYS AFTER
30	RECEIVING THE APPEAL.
31	(E) IF A PHARMACY BENEFITS MANAGER DENIES AN APPEAL, THE
32	PHARMACY BENEFITS MANAGER SHALL:

1	(1) PROVIDE THE REASON FOR THE DENIAL; AND
2	(2) IDENTIFY THE NATIONAL DRUG CODE PRODUCT AVAILABLE
3	TO PHARMACIES IN THE STATE THAT MAY BE PURCHASED AT A PRICE AT OR
4	BELOW THE MAXIMUM ALLOWABLE COST.
5	(F) IF, AS A RESULT OF AN APPEAL, A PHARMACY BENEFITS MANAGER
6	DETERMINES THAT THE MAXIMUM ALLOWABLE COST HAS BEEN APPLIED
7	INCORRECTLY, THE PHARMACY BENEFITS MANAGER SHALL:
8	(1) ADJUST THE MAXIMUM ALLOWABLE COST RETROACTIVE TO
9	THE DATE OF THE ORIGINAL CLAIM; AND
10	(2) NOTIFY THE CONTRACTED PHARMACY THAT ALL PAYMENT
11	CLAIMS SUBMITTED AFTER THE EFFECTIVE DATE OF THE MAXIMUM ALLOWABLE
12	COST ADJUSTMENT MAY BE RESUBMITTED, AT NO ADDITIONAL COST TO THE
13	CONTRACTED PHARMACY, FOR PAYMENT AT THE ADJUSTED MAXIMUM
14	ALLOWABLE COST.
15	$\frac{15-1628.2}{1000000000000000000000000000000000000$
16	A pharmacy benefits manager may not require a pharmacy to
17	DISPENSE A PRESCRIPTION FOR A CONTRACTUAL REIMBURSEMENT AMOUNT
18	THAT IS BELOW THE PHARMACY'S ACQUISITION COST.
19	(B) IN EACH CONTRACT BETWEEN A PHARMACY BENEFITS MANAGER
20	AND A CONTRACTED PHARMACY, THE PHARMACY BENEFITS MANAGER SHALL
21	INCLUDE THE SOURCES USED TO DETERMINE MAXIMUM ALLOWABLE COST
22	PRICING.
23	(C) A PHARMACY BENEFITS MANAGER SHALL UPDATE ITS PRICING
24	INFORMATION AT LEAST EVERY 7 DAYS AND PROVIDE A MEANS BY WHICH
25	CONTRACTED PHARMACIES MAY PROMPTLY REVIEW PRICING UPDATES IN A
26	FORMAT THAT IS READILY AVAILABLE AND ACCESSIBLE.
27	(D) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A PROCEDURE
28	TO ELIMINATE PRODUCTS FROM THE LIST OF DRUGS SUBJECT TO MAXIMUM
29	ALLOWABLE COST PRICING IN A TIMELY MANNER TO REMAIN CONSISTENT WITH
30	PRICING CHANGES IN THE MARKETPLACE.
31	(E) <b>BEFORE PLACING A PRESCRIPTION DRUG ON A MAXIMUM</b>
32	ALLOWABLE COST LIST, A PHARMACY BENEFITS MANAGER SHALL ENSURE

THAT:

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$     \begin{array}{c}       1 \\       2 \\       3 \\       4 \\       5     \end{array} $	(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
6	(2) THE DRUG IS GENERALLY AVAILABLE FOR PURCHASE BY
7	CONTRACTED PHARMACIES IN THE STATE FROM A NATIONAL OR REGIONAL
8	WHOLESALE DISTRIBUTOR AND IS NOT OBSOLETE.
9	(F) EACH CONTRACT BETWEEN A PHARMACY BENEFITS MANAGER AND
10	A CONTRACTED PHARMACY MUST INCLUDE A PROCESS TO APPEAL,
11	INVESTIGATE, AND RESOLVE DISPUTES REGARDING MAXIMUM ALLOWABLE
12	COST PRICING THAT INCLUDES:
13	(1) A REQUIREMENT THAT AN APPEAL BE FILED NO LATER THAN
14	<b>21 DAYS AFTER THE DATE OF THE INITIAL CLAIM;</b>
15	(2) <u>A REQUIREMENT THAT AN APPEAL BE INVESTIGATED AND</u>
16	RESOLVED WITHIN 21 DAYS AFTER THE DATE THE APPEAL IS FILED;
17	(3) A TELEPHONE NUMBER AT WHICH THE CONTRACTED
18	PHARMACY MAY CONTACT THE PHARMACY BENEFITS MANAGER TO SPEAK TO AN
19	INDIVIDUAL RESPONSIBLE FOR PROCESSING APPEALS;
2.0	
$\begin{array}{c} 20 \\ 21 \end{array}$	(4) <u>A REQUIREMENT THAT A PHARMACY BENEFITS MANAGER</u>
41	PROVIDE:
22	(I) <u>A REASON FOR ANY APPEAL DENIAL; AND</u>
	/>
23	(II) <u>THE NATIONAL DRUG CODE OF A DRUG THAT MAY BE</u>
24	PURCHASED BY THE CONTRACTED PHARMACY AT A PRICE AT OR BELOW THE
25	BENCHMARK PRICE DETERMINED BY THE PHARMACY BENEFITS MANAGER; AND
26	(5) IF AN APPEAL IS UPHELD, A REQUIREMENT THAT A
$\frac{1}{27}$	PHARMACY BENEFITS MANAGER:
28	(I) MAKE THE CHANGE IN THE MAXIMUM ALLOWABLE COST
29	<u>NO LATER THAN 1 BUSINESS DAY AFTER THE DATE OF DETERMINATION ON THE</u>
30	APPEAL; AND
31	(II) PERMIT THE APPEALING CONTRACTING PHARMACY TO
32	REVERSE AND REBILL THE CLAIM, AND ANY SUBSEQUENT SIMILAR CLAIMS.

1SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all2contracts between a pharmacy benefits manager and a pharmacy, a pharmacy services3administration organization, or a group purchasing organization entered into or4renewed on or after July 1, 2014.

5 SECTION <del>3.</del> <u>2.</u> AND BE IT FURTHER ENACTED, That this Act shall take 6 effect <u>July 1, 2014</u> January 1, 2015.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.