

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 947 Session of 2015

INTRODUCED BY FABRIZIO, BAKER, D. COSTA, V. BROWN, STAATS, LONGIETTI, DAVIS, GIBBONS, PICKETT, PASHINSKI, CRUZ, GROVE, McNEILL, YOUNGBLOOD, M. K. KELLER, KILLION, P. COSTA, COHEN, THOMAS, EVERETT, CARROLL, FARRY, SCHLOSSBERG, PHILLIPS-HILL, M. DALEY, WARD, READSHAW, HARKINS, SAYLOR, GOODMAN, GALLOWAY, BARRAR, BOYLE, MICCARELLI, DeLUCA, NEUMAN, MATZIE, TOEPEL, WATSON, KNOWLES, O'BRIEN, SANTARSIERO, PETRI, QUINN, RAVENSTAHL, D. PARKER AND DEASY, AUGUST 18, 2015

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, JUNE 30, 2016

AN ACT

1 Providing for registration of pharmacy benefits managers and for
2 maximum allowable cost transparency.

3 The General Assembly of the Commonwealth of Pennsylvania
4 hereby enacts as follows:

5 Section 1. Short title.

6 This act shall be known and may be cited as the
7 Pharmaceutical Transparency Act.

8 Section 2. Definitions.

9 The following words and phrases when used in this act shall
10 have the meanings given to them in this section unless the
11 context clearly indicates otherwise:

12 "Covered individual." A member, participant, enrollee,
13 contract holder or policyholder or beneficiary of a covered
14 entity who is provided health coverage by the covered entity.

1 The term includes a dependent or other person provided health  
2 coverage through the policy, contract or plan of a covered  
3 individual.

4 "Covered entity." A member, participant, enrollee, contract  
5 holder or policy holder providing pharmacy benefits to a covered  
6 individual under a health coverage plan pursuant to a contract  
7 administered by a pharmacy benefit manager.

8 "Department." ~~The Department of Health of the Commonwealth~~ <--  
9 INSURANCE DEPARTMENT OF THE COMMONWEALTH. <--

10 "Maximum allowable cost." The maximum amount that a pharmacy  
11 benefits manager will reimburse a pharmacy for the cost of a  
12 drug or a medical product or device.

13 ~~"Maximum allowable cost list." A list of drugs, medical~~ <--  
14 ~~products or devices, or both, for which a maximum allowable cost~~  
15 ~~has been established by a pharmacy benefits manager.~~

16 "Multiple source drug." A covered outpatient drug for which  
17 there is at least one other drug product that is rated as  
18 therapeutically equivalent under the Food and Drug  
19 Administration's most recent publication of "Approved Drug  
20 Products with Therapeutic Equivalence Evaluations."

21 "MULTIPLE SOURCE GENERIC LIST." A LIST OF DRUGS, MEDICAL <--  
22 PRODUCTS OR DEVICES, OR BOTH, FOR WHICH A MAXIMUM ALLOWABLE COST  
23 HAS BEEN ESTABLISHED BY A PHARMACY BENEFITS MANAGER.

24 "Network." A pharmacy or group of pharmacies that agree to  
25 provide prescription services to covered individuals on behalf  
26 of a covered entity or group of covered entities in exchange for  
27 payment for its services by a pharmacy benefits manager or  
28 pharmacy services administration organization. The term includes  
29 a pharmacy that generally dispenses outpatient prescriptions to  
30 covered individuals or dispenses particular types of

1 prescriptions, provides pharmacy services to particular types of  
2 covered individuals or dispenses prescriptions in particular  
3 health care settings, including networks of specialty,  
4 institutional or long-term care facilities.

5 "Pharmacy." As defined in section 2(12) of the act of  
6 September 27, 1961 (P.L.1700, No.699), known as the Pharmacy  
7 Act.

8 "Pharmacy benefits manager" or "PBM." A person, business or  
9 other entity that performs pharmacy benefits management for  
10 covered entities.

11 "Pharmacy benefits management." Performing any of the  
12 following:

13 (1) The procurement of prescription drugs at a  
14 negotiated contracted rate for dispensation within this  
15 Commonwealth to covered individuals.

16 (2) The administration or management of prescription  
17 drug benefits provided by a covered entity for the benefit of  
18 covered individuals.

19 (3) The provision of any of the following services in  
20 conjunction with the administration of pharmacy benefits:

21 (i) Mail-service pharmacy.

22 (ii) Claims processing.

23 (iii) Retail network management.

24 (iv) Payment of claims to pharmacies for  
25 prescription drugs dispensed to covered individuals via  
26 retail or mail-order pharmacy.

27 (v) Clinical formulary development and management  
28 services, including, but not limited to, utilization  
29 management and quality assurance programs.

30 (vi) Rebate contracting and administration.

1 (vii) Certain patient compliance, therapeutic  
2 intervention and generic substitution programs.

3 (viii) Disease management programs.

4 (ix) Setting pharmacy reimbursement pricing and  
5 methodologies, including maximum allowable cost, and  
6 determining single or multiple source drugs.

7 "Pharmacy Services Administration Organization" or "PSAO."  
8 Any entity that contracts with pharmacies to assist with third-  
9 party payer interactions and can provide a variety of other  
10 administrative services. The administrative services vary but  
11 may include contracting with PBMs on behalf of pharmacies and  
12 managing pharmacies' claims payments from third-party payers.  
13 Section 3. PBM registration.

14 (a) General rule.--To conduct business in this Commonwealth,  
15 a PBM must register with the department. ~~annually by:~~ <--

16 ~~(1) Submitting the registration form prescribed under~~  
17 ~~subsection (c).~~

18 ~~(2) Paying a registration fee promulgated by the~~  
19 ~~department.~~

20 ~~(b) Registration renewal. The department shall prescribe~~  
21 ~~rules for the annual renewal of a PBM registration, and the~~  
22 ~~following shall apply:~~

23 ~~(1) A PBM shall pay a renewal fee adopted by the~~  
24 ~~department.~~

25 ~~(2) Any lapse in registration under this section shall~~  
26 ~~be subject to penalties or late fees, or both, as established~~  
27 ~~by the department.~~

28 ~~(c) Registration form. The department shall develop a~~  
29 ~~registration form, which a PBM shall submit to the department.~~  
30 ~~The form must contain the following information, along with any~~

1 ~~additional requirements as may be established by the department:~~

2 ~~(1) The identity, address and telephone number of the~~  
3 ~~PBM.~~

4 ~~(2) The name, business address and telephone number of~~  
5 ~~the contact person for the PBM.~~

6 ~~(3) When applicable, the Federal employer identification~~  
7 ~~number for the PBM.~~

8 ~~(4) For a PBM that maintains a mail order pharmacy that~~  
9 ~~ships or mails prescription drugs to residents of this~~  
10 ~~Commonwealth, the identity, business address and telephone~~  
11 ~~number of the licensed pharmacist in charge and the license~~  
12 ~~number of any mail order pharmacy owned by the PBM to the~~  
13 ~~department.~~

14 ~~(d) Inspection. The department may conduct announced or~~  
15 ~~unannounced random inspections annually of a registered PBM,~~  
16 ~~which shall encompass the following:~~

17 ~~(1) The operation of the PBM.~~

18 ~~(2) Review of records as selected by the department.~~

19 ~~(3) Adherence to other requirements of this act.~~

20 ~~(e) Revocation, suspension, denial or restriction. The~~  
21 ~~department may revoke, suspend, deny or restrict registration of~~  
22 ~~a PBM for violation of this section or on other grounds or~~  
23 ~~violations of Federal or State laws or regulations as determined~~  
24 ~~necessary or appropriate by the department. THE DEPARTMENT SHALL <--~~  
25 ~~PROMULGATE REGULATIONS TO IMPLEMENT THIS SECTION.~~

26 Section 4. ~~Maximum allowable cost~~ MULTIPLE SOURCE GENERIC list <--  
27 and reimbursement.

28 (a) General rule.--~~Before a PBM places a drug on a maximum~~ <--  
29 ~~allowable cost list, the PBM must ensure that:~~

30 ~~(1) the drug is listed as "A" or "AB" rated in the most~~

1 ~~recent version of the Food and Drug Administration's~~  
2 ~~"Approved Drug Products with Therapeutic Equivalence~~  
3 ~~Evaluations" or is an authorized generic;~~

4 ~~(2) two or more therapeutically equivalent, multiple~~  
5 ~~source drugs or authorized generics available for purchase by~~  
6 ~~network retail pharmacies from wholesalers servicing this~~  
7 ~~Commonwealth; and~~

8 ~~(3) dispensing fees are not included in the calculation~~  
9 ~~of maximum allowable cost price reimbursement to pharmacy~~  
10 ~~providers.~~

11 ~~(b) Removal from listing. If a drug that has been placed on~~  
12 ~~a maximum allowable cost list no longer meets the requirements~~  
13 ~~of subsection (a), the drug shall be removed from the maximum~~  
14 ~~allowable cost list by the PBM within seven business days after~~  
15 ~~the date that the PBM becomes aware that the drug no longer~~  
16 ~~meets the requirements of subsection (a).~~ IN ORDER TO PLACE A <--  
17 PARTICULAR DRUG ON A MULTIPLE SOURCE GENERIC LIST, A PBM SHALL,  
18 AT A MINIMUM, ENSURE THAT:

19 (1) THE DRUG IS LISTED AS "A," "B," "NR" OR "NA" RATED  
20 IN THE MOST RECENT VERSION OF THE FOOD AND DRUG  
21 ADMINISTRATION'S "APPROVED DRUG PRODUCTS WITH THERAPEUTIC  
22 EQUIVALENCE EVALUATIONS," COMMONLY KNOWN AS THE ORANGE BOOK;  
23 AND

24 (2) THE DRUG IS AVAILABLE FOR PURCHASE BY ALL PHARMACIES  
25 IN THIS STATE FROM NATIONAL OR REGIONAL WHOLESALERS AND IS  
26 NOT OBSOLETE OR TEMPORARILY UNAVAILABLE.

27 (B) REMOVAL FROM LISTING.--A PBM MUST MAINTAIN A PROCEDURE  
28 TO ELIMINATE DRUGS FROM THE LIST OF DRUGS SUBJECT TO MULTIPLE  
29 SOURCE DRUG PRICING OR MODIFY THE MAXIMUM ALLOWABLE COST IN A  
30 TIMELY FASHION.

1 (C) SUBSTITUTIONS.--A PBM MAY NOT PENALIZE A PHARMACIST OR  
2 PHARMACY ON AUDIT IF THE PHARMACIST OR PHARMACY PERFORMS A  
3 GENERIC SUBSTITUTION PURSUANT TO THE ACT OF NOVEMBER 24, 1976  
4 (P.L.1163, NO.259), REFERRED TO AS THE GENERIC EQUIVALENT DRUG  
5 LAW.

6 Section 5. Availability of the ~~maximum allowable cost~~ MULTIPLE <--  
7 SOURCE GENERIC list.

8 (A) GENERAL RULE.--Upon each contract execution or renewal, <--  
9 a PBM shall ~~make available~~, with respect to contracts between a <--  
10 PBM and a pharmacy, or alternatively, a PBM and a pharmacy's  
11 contracting ~~representative or agent such as PSAO, the following:~~ <--

12 ~~(1) The criteria used to determine the maximum allowable~~  
13 ~~costs for the drugs and medical products and devices on each~~  
14 ~~maximum allowable cost list.~~

15 ~~(2) The current maximum allowable cost list used by that~~  
16 ~~PBM for covered individuals served by that contracted~~  
17 ~~pharmacy.~~

18 ~~(3) Upon request, every maximum allowable cost list used~~  
19 ~~by that PBM for covered individuals served by that contracted~~  
20 ~~pharmacy.~~

21 ~~(4) In the event there are multiple lists under the same~~  
22 ~~contract, the contract shall identify which maximum allowable~~  
23 ~~cost lists are appropriately applicable.~~

24 ~~Section 6. Updating maximum allowable cost list.~~

25 ~~A PBM shall:~~

26 ~~(1) Update each maximum allowable cost list at least~~  
27 ~~once every seven business days.~~

28 ~~(2) Make the updated lists available to every pharmacy~~  
29 ~~with which the PBM has a contract, directly or through a~~  
30 ~~PSAO, in a readily accessible, secure and usable publicly~~

1 ~~accessible Internet website or other comparable format or~~  
2 ~~process.~~

3 ~~(3) Utilize the updated maximum allowable costs to~~  
4 ~~calculate the payments made to the contracted pharmacies~~  
5 ~~within three business days.~~

6 ~~(4) A PBM shall provide a contractual commitment to~~  
7 ~~deliver a particular average reimbursement rate for generics.~~  
8 ~~The average reimbursement rate for generics shall be~~  
9 ~~calculated using the actual amount paid to the pharmacy,~~  
10 ~~excluding the dispensing fee, and shall not be calculated~~  
11 ~~solely according to the amount allowed by the plan and shall~~  
12 ~~include all generics dispensed, regardless of whether they~~  
13 ~~are subject to maximum allowable cost pricing. The contract~~  
14 ~~shall set forth the types of claims to be excluded from the~~  
15 ~~methodologies to be used in the calculation of the average~~  
16 ~~reimbursement rate.~~

17 ~~(5) Maintain a procedure to eliminate products from the~~  
18 ~~list of drugs subject to such pricing or modify maximum~~  
19 ~~allowable cost rates within seven business days when such~~  
20 ~~drugs do not meet the standards and requirements of this act~~  
21 ~~as set forth in order to remain consistent with pricing~~  
22 ~~changes in the marketplace.~~

23 ~~Section 7. Maximum allowable cost appeals process.~~

24 ~~(a) Process to be established. All contracts between a~~  
25 ~~pharmacy and a PBM or a pharmacy contracted directly with a~~  
26 ~~contracting representative or agent such as a PSAO shall include~~  
27 ~~a process to appeal, investigate and resolve disputes regarding~~  
28 ~~the listed maximum allowable cost for a particular drug or~~  
29 ~~medical product or device. The process shall be made available~~  
30 ~~on the PBM's publicly accessible Internet website and contain~~



1 ~~information about the appeals process, including, but not~~  
2 ~~limited to, a telephone number or process that a pharmacy may~~  
3 ~~use to submit maximum allowable cost appeals.~~

4 ~~(b) Grounds. A pharmacy may base an appeal on either of the~~  
5 ~~following:~~

6 ~~(1) the maximum allowable cost established for a~~  
7 ~~particular drug or medical product or device is below cost at~~  
8 ~~which the drug is available for purchase by that pharmacy in~~  
9 ~~this Commonwealth from national or regional wholesalers; or~~

10 ~~(2) the PBM has placed a drug on the list in violation~~  
11 ~~of section 4.~~

12 ~~(c) Time period for filing. The right to appeal shall be~~  
13 ~~limited to 30 days following the reimbursement for a drug by a~~  
14 ~~PBM.~~

15 ~~(d) Determination. A PBM shall make a final determination~~  
16 ~~within seven business days of receiving an appeal and shall~~  
17 ~~notify the appealing party of the determination.~~

18 ~~(e) Denial. If a PBM denies an appeal, the PBM shall state~~  
19 ~~the reason for the denial and provide the national drug code of~~  
20 ~~an equivalent drug that is available for purchase by network-~~  
21 ~~retail pharmacies in the Commonwealth from wholesalers at a~~  
22 ~~price that is equal to or less than the maximum cost for that~~  
23 ~~drug.~~

24 ~~(f) Filing of grievance. A pharmacy may file a grievance~~  
25 ~~with the department should a disagreement over denial between a~~  
26 ~~PBM and a pharmacy occur. The department shall investigate the~~  
27 ~~grievance and report its findings to the pharmacy within 30~~  
28 ~~business days.~~

29 ~~(g) Approval. If a PBM grants an appeal, the PBM shall~~  
30 ~~adjust the maximum allowable cost of the drug for the appealing~~

1 ~~pharmacy, along with all network pharmacies. The adjustment~~  
2 ~~shall be paid to the pharmacy within one business day of the~~  
3 ~~determination. The PBM shall notify all similarly situated~~  
4 ~~network pharmacy providers as defined by the plan sponsor.~~

5 REPRESENTATIVE OR AGENT SUCH AS PSAO: <--

6 (1) INCLUDE IN THE CONTRACT THE SOURCES UTILIZED TO  
7 DETERMINE MULTIPLE SOURCE DRUG PRICING, INCLUDING, IF  
8 APPLICABLE, THE MAXIMUM ALLOWABLE COST OR ANY SUCCESSIVE  
9 PRICING FORMULA OF THE PBM.

10 (2) UPDATE THE PRICING INFORMATION EVERY SEVEN CALENDAR  
11 DAYS.

12 (3) ESTABLISH A REASONABLE PROCESS BY WHICH PHARMACIES  
13 HAVE A METHOD TO ACCESS RELEVANT OR CURRENT MAXIMUM ALLOWABLE  
14 COST PRICING LISTS IN EFFECT AND ANY SUCCESSIVE PRICING  
15 FORMULAS IN A TIMELY FASHION.

16 (B) CONFIDENTIALITY PROVISION.--NOTHING IN THIS SECTION MAY  
17 PROHIBIT A PBM FROM ESTABLISHING A REASONABLE CONFIDENTIALITY  
18 PROVISION WITH A PHARMACY'S OR PHARMACIST'S CONTRACTING  
19 REPRESENTATIVE AGENT SUCH AS A PSAO.

20 SECTION 6. MULTIPLE SOURCE GENERIC DRUG PRICING APPEALS  
21 PROCESS.

22 (A) PROCESS TO BE ESTABLISHED.--ALL CONTRACTS BETWEEN A PBM  
23 OR A PHARMACY, OR ALTERNATIVELY, A PHARMACY'S CONTRACTING AGENT,  
24 SUCH A PSAO, SHALL INCLUDE A PROCESS TO APPEAL, INVESTIGATE AND  
25 RESOLVE DISPUTES REGARDING MULTIPLE SOURCE DRUG PRICING. THE  
26 CONTRACT PROVISION ESTABLISHING THE PROCESS SHALL INCLUDE THE  
27 FOLLOWING:

28 (1) THE RIGHT TO APPEAL SHALL BE LIMITED TO 14 CALENDAR  
29 DAYS FOLLOWING THE INITIAL CLAIM.

30 (2) THE APPEAL SHALL BE INVESTIGATED AND RESOLVED BY THE

1 PBM THROUGH AN INTERNAL PROCESS WITHIN 14 CALENDAR DAYS OF  
2 RECEIPT OF THE APPEAL BY THE PBM.

3 (3) A TELEPHONE NUMBER AT WHICH A PHARMACY MAY CONTACT  
4 THE PBM AND SPEAK WITH AN INDIVIDUAL WHO IS INVOLVED IN THE  
5 APPEALS PROCESS.

6 (B) DENIAL.--IF A PBM DENIES AN APPEAL, THE PBM SHALL  
7 PROVIDE THE REASON FOR THE DENIAL AND IDENTIFY THE NATIONAL DRUG  
8 CODE OF AN EQUIVALENT DRUG THAT IS AVAILABLE FOR PURCHASE BY  
9 NETWORK RETAIL PHARMACIES IN THIS COMMONWEALTH FROM WHOLESALERS  
10 AT A PRICE THAT IS EQUAL TO OR LESS THAN THE MAXIMUM ALLOWABLE  
11 COST FOR THE APPEALED DRUG AS DETERMINED BY THE PBM.

12 (C) APPROVAL.--IF A PBM GRANTS AN APPEAL, THE PBM SHALL MAKE  
13 THE PRICE CORRECTION, PERMIT THE REPORTING PHARMACY TO REVERSE  
14 AND REBILL THE APPEALED CLAIM AND MAKE THE PRICE CORRECTION  
15 EFFECTIVE FOR ALL SIMILARLY SITUATED PHARMACIES FROM THE DATE OF  
16 THE APPROVED APPEAL.

17 Section 8 7. Enforcement. <--

18 ~~(a) Action by the department.~~ The department shall enforce <--  
19 the provisions of this act and shall take action or impose  
20 penalties to bring noncomplying entities into full compliance  
21 with this act.

22 ~~(b) Violation of Unfair Trade Practices and Consumer <--~~  
23 Protection Law. A violation of this act shall constitute a  
24 violation of the act of December 17, 1968 (P.L.1224, No.387),  
25 known as the Unfair Trade Practices and Consumer Protection Law.

26 ~~(c) Financial penalties. A violation of this act may <--~~  
27 subject the PBM to financial penalties as determined by the  
28 department. Additionally, the department may subject a pharmacy  
29 to financial penalties if the department finds the pharmacy has  
30 engaged in conduct that would constitute an abuse of the appeal

1 ~~process.~~

2 Section 9 8. Department authority.

<--

3 The department shall promulgate regulations necessary to  
4 implement the provisions of this act.

5 SECTION 9. APPLICABILITY.

<--

6 THIS ACT SHALL APPLY TO ALL CONTRACTS AND AGREEMENTS FOR  
7 PHARMACY BENEFITS MANAGEMENT SERVICES EXECUTED OR RENEWED ON OR  
8 AFTER THE EFFECTIVE DATE OF THIS SECTION.

9 Section 10. Effective date.

10 This act shall take effect in 90 days.