SENATE AMENDED

PRIOR PRINTER'S NOS. 2120, 2371, 3693, 3707 PRINTER'S NO. 3933

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 946 Session of 2015

INTRODUCED BY BAKER, FABRIZIO, D. COSTA, 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, M. QUINN, D. PARKER, DEASY, CUTLER AND BARBIN, AUGUST 18, 2015

SENATOR WHITE, BANKING AND INSURANCE, IN SENATE, AS AMENDED, SEPTEMBER 27, 2016

AN ACT

~~Providing for pharmacy audit procedures.~~ PROVIDING FOR PHARMACY AUDIT PROCEDURES, FOR REGISTRATION OF PHARMACY BENEFITS MANAGERS AND FOR MAXIMUM ALLOWABLE COST TRANSPARENCY. <--

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

~~Section 1. Short title.~~ <--

~~This act shall be known and may be cited as the Pharmacy Audit Integrity Act.~~

~~Section 2. Scope of act.~~

~~This act covers any audit of the records of a pharmacy conducted by a managed care company, third party payer, pharmacy benefits manager, a health program administered by a department of the Commonwealth or any entity that represents a company, group or department.~~

~~Section 3. Definitions.~~

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

~~"Auditing entity." A person, company or government entity that performs a pharmacy audit, including a plan sponsor, pharmacy benefit manager, managed care organization or third-party administrator.~~

~~"Business day." Any day of the week excluding Saturday, Sunday and any legal holiday.~~

~~"Department." The Insurance Department of the Commonwealth.~~

~~"Extrapolation." The practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors on any portion of claims submitted, based on the frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors actually measured in a sample of claims.~~

~~"Health care practitioner." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.~~

~~"Nonproprietary drug." As defined in section 2(7.1) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.~~

~~"Pharmacist." As defined in section 2(10) of the Pharmacy Act.~~

~~"Pharmacy." As defined in section 2(12) of the Pharmacy Act.~~

~~"Pharmacy audit." An audit, conducted on-site or remotely by or on behalf of an auditing entity of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy to beneficiaries of a health benefit plan. The term does not~~

include either of the following:

(1) A concurrent review or remote audit that is initiated within seven business days of the pharmacy's transmission of a claim to an auditing entity.

(2) A concurrent review or remote audit where no charge-back or recoupment is demanded by the auditing entity.

"Pharmacy benefits management." Any entity that performs any of the following:

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

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

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

(i) Mail-service pharmacy.

(ii) Claims processing.

(iii) Retail network management.

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

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

(vi) Rebate contracting and administration.

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

(viii) Disease management programs.

(ix) Setting pharmacy reimbursement pricing and

~~methodologies, including maximum allowable cost, and determining single or multiple source drugs.~~

~~"Pharmacy benefits manager" or "PBM." A person, business or other entity that performs pharmacy benefits management.~~

~~"Pharmacy record." Any record stored electronically or as a hard copy by a pharmacy that relates to the provision of prescription or nonproprietary drugs or pharmacy services or other component of pharmacist care that is included in the practice of pharmacy.~~

~~"Plan sponsor." Any of the following that pays for or processes a claim for payment for prescription drugs or pharmacy services:~~

~~(1) A health insuring corporation.~~

~~(2) A person authorized to engage in the business of sickness and accident.~~

~~(3) A person or government entity providing coverage of prescription or nonproprietary drugs or pharmacy services to individuals on a self-insurance basis.~~

~~(4) A group health plan, as defined in 29 U.S.C. § 1167 (relating to definitions and special rules).~~

~~(5) A service benefit plan, as referenced in 42 U.S.C. § 1396a(a)(25) (relating to state plans for medical assistance).~~

~~(6) A Medicaid managed care organization that has entered into a contract with the Commonwealth.~~

~~(7) Any other person or government entity that is by law, contract or agreement responsible for paying or processing a claim for payment for the provision of prescription or nonproprietary drugs or pharmacy services.~~

~~Section 4. Procedures for conducting pharmacy audits.~~

~~(a) Procedure.--An entity conducting a pharmacy audit under this act shall conform to the following rules:~~

~~(1) Except as otherwise provided by Federal or State law, an auditing entity conducting a pharmacy audit may have access to a pharmacy's previous audit report only if the report was prepared by an auditing entity.~~

~~(2) Any information collected during a pharmacy audit shall be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the pharmacy benefits manager and the plan sponsor, for which a pharmacy audit is being conducted.~~

~~(3) No auditing entity conducting a pharmacy audit shall solely compensate any of its employees or any contractor with which an auditing entity contracts to conduct a pharmacy audit, based on the amount claimed or the actual amount recouped by the pharmacy being audited.~~

~~(4) The entity shall provide the pharmacy being audited with at least 10 business days' prior written notice before conducting a pharmacy audit, unless both parties agree otherwise. The audit may be delayed for a period of up to 30 days at the request of the pharmacy, one time per year, and shall only be granted if there is good cause, including, but not limited to, a planned medical procedure or planned absence from work of a necessary pharmacist. If a delay is requested by the pharmacy, the pharmacy shall provide notice to the PBM at least five business days prior to the day the audit is to commence.~~

~~(5) (Reserved).~~

~~(6) The entity may not initiate or schedule a pharmacy audit during the first five business days of any month for~~

~~any pharmacy that averages in excess of 600 prescriptions filled per week, without the express consent of the pharmacy.~~

~~(7) The entity shall accept paper or electronic signature logs that document the delivery of prescription or nonproprietary drugs and pharmacist services to a health plan beneficiary or the agent of the beneficiary.~~

~~(8) The entity shall provide to the representative of the pharmacy, prior to leaving the pharmacy at the conclusion of the on-site portion of the pharmacy audit, a complete list of pharmacy records reviewed.~~

~~(9) Any pharmacy audit that involves clinical judgment shall be conducted by or in consultation with a pharmacist.~~

~~(10) No pharmacy audit shall cover:~~

~~(i) a period of more than 24 months after the date a claim was submitted by the pharmacy to the pharmacy benefits manager or plan sponsor unless a longer period is required by law; or~~

~~(ii) more than 250 prescriptions, provided that a refill shall not constitute a separate prescription for the purposes of this subparagraph.~~

~~(11) No auditing entity may use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by Federal requirements or Federal plans.~~

~~(12) No auditing entity shall include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill. As used in this paragraph, "misfill" means a prescription that was not dispensed, a prescription error, a prescription where the prescriber denied the authorization request or a prescription where an extra~~

dispensing fee was charged.

(13) A pharmacy may do any of the following when a pharmacy audit is performed:

(i) To validate the pharmacy record and delivery, a pharmacy may use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care practitioner with prescriptive authority.

(ii) To validate claims in connection with prescriptions or changes in prescriptions, or refills of prescription or nonproprietary drugs, a pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations or documented telephone calls from the prescribing health care practitioner or practitioner's agent. Documentation of an oral prescription order that has been verified by the prescribing health care practitioner shall meet the provisions of this subparagraph for the initial audit review.

(b) Written report.--An auditing entity shall provide the pharmacy with a written report of the pharmacy audit and comply with the following requirements:

(1) The preliminary pharmacy audit report must be delivered to the pharmacy or its corporate parent within 60 days after the completion of the pharmacy audit. The preliminary report shall include contact information for the individual who conducted the pharmacy audit, including

~~telephone number, facsimile number, e-mail and auditing firm, so that audit results, discrepancies and procedures can be reviewed. The preliminary pharmacy audit report shall include, but not be limited to, claim level information for any discrepancy found and total dollar amount of claims subject to recovery.~~

~~(2) A pharmacy shall be allowed 30 days following receipt of the preliminary audit report to respond to the findings of the preliminary report.~~

~~(3) A final audit report shall be delivered to the pharmacy or its corporate parent not later than 60 calendar days after any responses from the pharmacy or corporate parent are received by the auditing entity. The auditing entity shall issue a final pharmacy audit report that takes into consideration any responses provided to the auditing entity by the pharmacy or corporate parent.~~

~~(4) The final pharmacy audit report may be delivered electronically.~~

~~(5) No pharmacy shall be subject to a charge back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error, scrivener's error or computer error, unless the error resulted in overpayment to the pharmacy.~~

~~(6) No auditing entity conducting a pharmacy audit or person acting on behalf of the entity shall charge back or recoup or collect penalties from a pharmacy until the time period to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.~~

~~(7) If an identified discrepancy in a pharmacy audit~~

~~exceeds $25,000, future payments to the pharmacy in excess of that amount may be withheld pending adjudication of an appeal.~~

~~(8) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.~~

~~Section 5. Appeals process.~~

~~(a) General rule.--An auditing entity shall establish a written appeals process under which a pharmacy may appeal an unfavorable final audit report to the entity.~~

~~(b) Adjudication.--The adjudication of a claim may not be appealed through the audit process.~~

~~Section 6. Limitations.~~

~~(a) General rule.--The provisions of this act shall not apply to an audit of pharmacy records when:~~

~~(1) fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or~~

~~(2) other investigative methods indicate a pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.~~

~~(b) Federal law.--This act does not supersede any audit requirements established by Federal law.~~

~~Section 7. Enforcement.~~

~~The department shall have enforcement authority and take action or impose penalties to bring noncomplying entities into full compliance with this act, including the promulgation of any regulations necessary to carry out this act.~~

~~Section 8. Effective date.~~

~~This act shall take effect in 90 days.~~

CHAPTER 1 <--

PRELIMINARY PROVISIONS

SECTION 101. SHORT TITLE.

THIS ACT SHALL BE KNOWN AND MAY BE CITED AS THE PHARMACY AUDIT INTEGRITY AND TRANSPARENCY ACT.

SECTION 102. SCOPE OF ACT.

THIS ACT COVERS ANY AUDIT OF THE RECORDS OF A PHARMACY CONDUCTED BY A MANAGED CARE COMPANY, THIRD-PARTY PAYER, PHARMACY BENEFITS MANAGER, A HEALTH PROGRAM ADMINISTERED BY A DEPARTMENT OF THE COMMONWEALTH OR ANY ENTITY THAT REPRESENTS A COMPANY, GROUP OR DEPARTMENT.

SECTION 103. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS ACT SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

"AUDITING ENTITY." A PERSON, COMPANY OR GOVERNMENT ENTITY THAT PERFORMS A PHARMACY AUDIT, INCLUDING A PLAN SPONSOR, PHARMACY BENEFIT MANAGER, MANAGED CARE ORGANIZATION OR THIRD-PARTY ADMINISTRATOR.

"BUSINESS DAY." ANY DAY OF THE WEEK EXCLUDING SATURDAY, SUNDAY AND ANY LEGAL HOLIDAY.

"COVERED ENTITY." A MEMBER, PARTICIPANT, ENROLLEE, CONTRACT HOLDER OR POLICY HOLDER PROVIDING PHARMACY BENEFITS TO A COVERED INDIVIDUAL UNDER A HEALTH COVERAGE PLAN PURSUANT TO A CONTRACT ADMINISTERED BY A PHARMACY BENEFIT MANAGER.

"COVERED INDIVIDUAL." A MEMBER, PARTICIPANT, ENROLLEE, CONTRACT HOLDER OR POLICYHOLDER OR BENEFICIARY OF A COVERED ENTITY WHO IS PROVIDED HEALTH COVERAGE BY THE COVERED ENTITY. THE TERM INCLUDES A DEPENDENT OR OTHER PERSON PROVIDED HEALTH COVERAGE THROUGH THE POLICY, CONTRACT OR PLAN OF A COVERED

INDIVIDUAL.

"DEPARTMENT." THE INSURANCE DEPARTMENT OF THE COMMONWEALTH.

"EXTRAPOLATION." THE PRACTICE OF INFERRING A FREQUENCY OF DOLLAR AMOUNT OF OVERPAYMENTS, UNDERPAYMENTS, NONVALID CLAIMS OR OTHER ERRORS ON ANY PORTION OF CLAIMS SUBMITTED, BASED ON THE FREQUENCY OF DOLLAR AMOUNT OF OVERPAYMENTS, UNDERPAYMENTS, NONVALID CLAIMS OR OTHER ERRORS ACTUALLY MEASURED IN A SAMPLE OF CLAIMS.

"GENERIC DRUG LIST." A LIST OF DRUGS, MEDICAL PRODUCTS OR DEVICES, OR BOTH, FOR WHICH A MAXIMUM ALLOWABLE COST HAS BEEN ESTABLISHED BY A PHARMACY BENEFITS MANAGER.

"HEALTH CARE PRACTITIONER." AS DEFINED IN SECTION 103 OF THE ACT OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE HEALTH CARE FACILITIES ACT.

"MAXIMUM ALLOWABLE COST." THE MAXIMUM AMOUNT THAT A PHARMACY BENEFITS MANAGER WILL REIMBURSE A PHARMACY FOR THE COST OF A DRUG OR A MEDICAL PRODUCT OR DEVICE.

"MULTIPLE SOURCE DRUG." A COVERED OUTPATIENT DRUG FOR WHICH THERE IS AT LEAST ONE OTHER DRUG PRODUCT THAT IS RATED AS THERAPEUTICALLY EQUIVALENT UNDER THE FOOD AND DRUG ADMINISTRATION'S MOST RECENT PUBLICATION OF "APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS."

"NETWORK." A PHARMACY OR GROUP OF PHARMACIES THAT AGREE TO PROVIDE PRESCRIPTION SERVICES TO COVERED INDIVIDUALS ON BEHALF OF A COVERED ENTITY OR GROUP OF COVERED ENTITIES IN EXCHANGE FOR PAYMENT FOR ITS SERVICES BY A PHARMACY BENEFITS MANAGER OR PHARMACY SERVICES ADMINISTRATION ORGANIZATION. THE TERM INCLUDES A PHARMACY THAT GENERALLY DISPENSES OUTPATIENT PRESCRIPTIONS TO COVERED INDIVIDUALS OR DISPENSES PARTICULAR TYPES OF PRESCRIPTIONS, PROVIDES PHARMACY SERVICES TO PARTICULAR TYPES OF

COVERED INDIVIDUALS OR DISPENSES PRESCRIPTIONS IN PARTICULAR HEALTH CARE SETTINGS, INCLUDING NETWORKS OF SPECIALTY, INSTITUTIONAL OR LONG-TERM CARE FACILITIES.

"NONPROPRIETARY DRUG." AS DEFINED IN SECTION 2(7.1) OF THE ACT OF SEPTEMBER 27, 1961 (P.L.1700, NO.699), KNOWN AS THE PHARMACY ACT.

"PHARMACIST." AS DEFINED IN SECTION 2(10) OF THE PHARMACY ACT.

"PHARMACY." AS DEFINED IN SECTION 2(12) OF THE PHARMACY ACT.

"PHARMACY AUDIT." AN AUDIT, CONDUCTED ON-SITE BY OR ON BEHALF OF AN AUDITING ENTITY OF ANY RECORDS OF A PHARMACY FOR PRESCRIPTION OR NONPROPRIETARY DRUGS DISPENSED BY A PHARMACY TO BENEFICIARIES OF A HEALTH BENEFIT PLAN.

"PHARMACY BENEFITS MANAGEMENT." ANY ENTITY THAT PERFORMS ANY OF THE FOLLOWING:

(1) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A NEGOTIATED CONTRACTED RATE FOR DISPENSATION WITHIN THIS COMMONWEALTH TO COVERED INDIVIDUALS.

(2) THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG BENEFITS PROVIDED BY A COVERED ENTITY FOR THE BENEFIT OF COVERED INDIVIDUALS.

(3) THE PROVISION OF ANY OF THE FOLLOWING IN CONJUNCTION WITH THE ADMINISTRATION OF PHARMACY BENEFITS:

(I) MAIL-SERVICE PHARMACY.

(II) CLAIMS PROCESSING.

(III) RETAIL NETWORK MANAGEMENT.

(IV) PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION DRUGS DISPENSED TO COVERED INDIVIDUALS VIA RETAIL OR MAIL-ORDER PHARMACY.

(V) CLINICAL FORMULARY DEVELOPMENT AND MANAGEMENT

SERVICES, INCLUDING, BUT NOT LIMITED TO, UTILIZATION MANAGEMENT AND QUALITY ASSURANCE PROGRAMS.

(VI) REBATE CONTRACTING AND ADMINISTRATION.

(VII) CERTAIN PATIENT COMPLIANCE, THERAPEUTIC INTERVENTION AND GENERIC SUBSTITUTION PROGRAMS.

(VIII) DISEASE MANAGEMENT PROGRAMS.

(IX) SETTING PHARMACY REIMBURSEMENT PRICING AND METHODOLOGIES, INCLUDING MAXIMUM ALLOWABLE COST, AND DETERMINING SINGLE OR MULTIPLE SOURCE DRUGS.

"PHARMACY BENEFITS MANAGER" OR "PBM." A PERSON, BUSINESS OR OTHER ENTITY THAT PERFORMS PHARMACY BENEFITS MANAGEMENT FOR COVERED ENTITIES.

"PHARMACY RECORD." ANY RECORD STORED ELECTRONICALLY OR AS A HARD COPY BY A PHARMACY THAT RELATES TO THE PROVISION OF PRESCRIPTION OR NONPROPRIETARY DRUGS OR PHARMACY SERVICES OR OTHER COMPONENT OF PHARMACIST CARE THAT IS INCLUDED IN THE PRACTICE OF PHARMACY.

"PHARMACY SERVICES ADMINISTRATION ORGANIZATION" OR "PSAO." ANY ENTITY THAT CONTRACTS WITH PHARMACIES TO ASSIST WITH THIRD-PARTY PAYER INTERACTIONS AND CAN PROVIDE A VARIETY OF OTHER ADMINISTRATIVE SERVICES. THE ADMINISTRATIVE SERVICES VARY BUT MAY INCLUDE CONTRACTING WITH PBMS ON BEHALF OF PHARMACIES AND MANAGING PHARMACIES' CLAIMS PAYMENTS FROM THIRD-PARTY PAYERS.

"PLAN SPONSOR." ANY OF THE FOLLOWING THAT PAYS FOR OR PROCESSES A CLAIM FOR PAYMENT FOR PRESCRIPTION DRUGS OR PHARMACY SERVICES:

(1) A HEALTH INSURING CORPORATION.

(2) A PERSON AUTHORIZED TO ENGAGE IN THE BUSINESS OF SICKNESS AND ACCIDENT.

(3) A PERSON OR GOVERNMENT ENTITY PROVIDING COVERAGE OF

PRESCRIPTION OR NONPROPRIETARY DRUGS OR PHARMACY SERVICES TO INDIVIDUALS ON A SELF-INSURANCE BASIS.

(4) A GROUP HEALTH PLAN, AS DEFINED IN 29 U.S.C. § 1167 (RELATING TO DEFINITIONS AND SPECIAL RULES).

(5) A SERVICE BENEFIT PLAN, AS REFERENCED IN 42 U.S.C. § 1396A(A)(25) (RELATING TO STATE PLANS FOR MEDICAL ASSISTANCE).

(6) A MEDICAID MANAGED CARE ORGANIZATION THAT HAS ENTERED INTO A CONTRACT WITH THE COMMONWEALTH.

(7) ANY OTHER PERSON OR GOVERNMENT ENTITY THAT IS BY LAW, CONTRACT OR AGREEMENT RESPONSIBLE FOR PAYING OR PROCESSING A CLAIM FOR PAYMENT FOR THE PROVISION OF PRESCRIPTION OR NONPROPRIETARY DRUGS OR PHARMACY SERVICES.

CHAPTER 3

PHARMACY AUDITS

SECTION 301. PROCEDURES FOR CONDUCTING PHARMACY AUDITS.

(A) PROCEDURE.--AN ENTITY CONDUCTING A PHARMACY AUDIT UNDER THIS CHAPTER SHALL CONFORM TO THE FOLLOWING RULES:

(1) EXCEPT AS OTHERWISE PROVIDED BY FEDERAL OR STATE LAW, AN AUDITING ENTITY CONDUCTING A PHARMACY AUDIT MAY HAVE ACCESS TO A PHARMACY'S PREVIOUS AUDIT REPORT ONLY IF THE REPORT WAS PREPARED BY AN AUDITING ENTITY.

(2) ANY INFORMATION COLLECTED DURING A PHARMACY AUDIT SHALL BE CONFIDENTIAL BY LAW, EXCEPT THAT THE AUDITING ENTITY CONDUCTING THE PHARMACY AUDIT MAY SHARE THE INFORMATION WITH THE PHARMACY BENEFITS MANAGER AND THE PLAN SPONSOR, FOR WHICH A PHARMACY AUDIT IS BEING CONDUCTED.

(3) NO AUDITING ENTITY CONDUCTING A PHARMACY AUDIT SHALL SOLELY COMPENSATE ANY OF ITS EMPLOYEES OR ANY CONTRACTOR WITH WHICH AN AUDITING ENTITY CONTRACTS TO CONDUCT A PHARMACY

AUDIT, BASED ON THE AMOUNT CLAIMED OR THE ACTUAL AMOUNT RECOUPED BY THE PHARMACY BEING AUDITED.

(4) THE ENTITY SHALL PROVIDE THE PHARMACY BEING AUDITED WITH AT LEAST 14 CALENDAR DAYS' PRIOR WRITTEN NOTICE BEFORE CONDUCTING A PHARMACY AUDIT, UNLESS BOTH PARTIES AGREE OTHERWISE. IF A DELAY IS REQUESTED BY THE PHARMACY, THE PHARMACY SHALL PROVIDE NOTICE TO THE PBM WITHIN 72 HOURS OF RECEIVING NOTICE OF THE AUDIT.

(5) (RESERVED).

(6) THE ENTITY MAY NOT INITIATE OR SCHEDULE A PHARMACY AUDIT DURING THE FIRST FIVE BUSINESS DAYS OF ANY MONTH FOR ANY PHARMACY THAT AVERAGES IN EXCESS OF 600 PRESCRIPTIONS FILLED PER WEEK, WITHOUT THE EXPRESS CONSENT OF THE PHARMACY.

(7) THE ENTITY SHALL ACCEPT PAPER OR ELECTRONIC SIGNATURE LOGS THAT DOCUMENT THE DELIVERY OF PRESCRIPTION OR NONPROPRIETARY DRUGS AND PHARMACIST SERVICES TO A HEALTH PLAN BENEFICIARY OR THE BENEFICIARY'S CAREGIVER OR GUARDIAN.

(8) THE ENTITY SHALL PROVIDE TO THE REPRESENTATIVE OF THE PHARMACY, PRIOR TO LEAVING THE PHARMACY AT THE CONCLUSION OF THE ON-SITE PORTION OF THE PHARMACY AUDIT, A COMPLETE LIST OF PHARMACY RECORDS REVIEWED.

(9) ANY PHARMACY AUDIT THAT INVOLVES CLINICAL JUDGMENT SHALL BE CONDUCTED BY OR IN CONSULTATION WITH A PHARMACIST.

(10) NO PHARMACY AUDIT SHALL COVER:

(I) A PERIOD OF MORE THAN 24 MONTHS AFTER THE DATE A CLAIM WAS SUBMITTED BY THE PHARMACY TO THE PHARMACY BENEFITS MANAGER OR PLAN SPONSOR UNLESS A LONGER PERIOD IS REQUIRED BY LAW; OR

(II) MORE THAN 250 PRESCRIPTIONS, PROVIDED THAT A REFILL SHALL NOT CONSTITUTE A SEPARATE PRESCRIPTION FOR

THE PURPOSES OF THIS SUBPARAGRAPH.

(11) NO AUDITING ENTITY MAY USE EXTRAPOLATION TO CALCULATE PENALTIES OR AMOUNTS TO BE CHARGED BACK OR RECOUPED UNLESS OTHERWISE REQUIRED BY FEDERAL REQUIREMENTS OR FEDERAL PLANS.

(12) NO AUDITING ENTITY SHALL INCLUDE DISPENSING FEES IN THE CALCULATION OF OVERPAYMENTS UNLESS A PRESCRIPTION IS CONSIDERED A MISFILL. AS USED IN THIS PARAGRAPH, "MISFILL" MEANS A PRESCRIPTION THAT WAS NOT DISPENSED, A PRESCRIPTION ERROR, A PRESCRIPTION WHERE THE PRESCRIBER DENIED THE AUTHORIZATION REQUEST OR A PRESCRIPTION WHERE AN EXTRA DISPENSING FEE WAS CHARGED.

(13) A PHARMACY MAY DO ANY OF THE FOLLOWING WHEN A PHARMACY AUDIT IS PERFORMED:

(I) TO VALIDATE THE PHARMACY RECORD AND DELIVERY, A PHARMACY MAY USE AUTHENTIC AND VERIFIABLE STATEMENTS OR RECORDS, INCLUDING, BUT NOT LIMITED TO, MEDICATION ADMINISTRATION RECORDS OF A NURSING HOME, ASSISTED LIVING FACILITY, HOSPITAL OR HEALTH CARE PRACTITIONER WITH PRESCRIPTIVE AUTHORITY.

(II) TO VALIDATE CLAIMS IN CONNECTION WITH PRESCRIPTIONS OR CHANGES IN PRESCRIPTIONS, OR REFILLS OF PRESCRIPTION OR NONPROPRIETARY DRUGS, A PHARMACY MAY USE ANY VALID PRESCRIPTION, INCLUDING, BUT NOT LIMITED TO, MEDICATION ADMINISTRATION RECORDS, FACSIMILES, ELECTRONIC PRESCRIPTIONS, ELECTRONICALLY STORED IMAGES OF PRESCRIPTIONS, ELECTRONICALLY CREATED ANNOTATIONS OR DOCUMENTED TELEPHONE CALLS FROM THE PRESCRIBING HEALTH CARE PRACTITIONER OR PRACTITIONER'S AGENT. DOCUMENTATION OF AN ORAL PRESCRIPTION ORDER THAT HAS BEEN VERIFIED BY

THE PRESCRIBING HEALTH CARE PRACTITIONER SHALL MEET THE PROVISIONS OF THIS SUBPARAGRAPH FOR THE INITIAL AUDIT REVIEW.

(B) WRITTEN REPORT.--AN AUDITING ENTITY SHALL PROVIDE THE PHARMACY WITH A WRITTEN REPORT OF THE PHARMACY AUDIT AND COMPLY WITH THE FOLLOWING REQUIREMENTS:

(1) THE PRELIMINARY PHARMACY AUDIT REPORT MUST BE DELIVERED TO THE PHARMACY OR ITS CORPORATE PARENT WITHIN 60 DAYS AFTER THE COMPLETION OF THE PHARMACY AUDIT. THE PRELIMINARY REPORT SHALL INCLUDE CONTACT INFORMATION FOR THE AUDITING ENTITY WHO CONDUCTED THE PHARMACY AUDIT AND AN APPROPRIATE AND ACCESSIBLE POINT OF CONTACT, INCLUDING TELEPHONE NUMBER, FACSIMILE NUMBER, E-MAIL, AND AUDITING FIRM, SO THAT AUDIT RESULTS, DISCREPANCIES AND PROCEDURES CAN BE REVIEWED. THE PRELIMINARY PHARMACY AUDIT REPORT SHALL INCLUDE, BUT NOT BE LIMITED TO, CLAIM LEVEL INFORMATION FOR ANY DISCREPANCY FOUND AND TOTAL DOLLAR AMOUNT OF CLAIMS SUBJECT TO RECOVERY.

(2) A PHARMACY SHALL BE ALLOWED 30 DAYS FOLLOWING RECEIPT OF THE PRELIMINARY AUDIT REPORT TO RESPOND TO THE FINDINGS OF THE PRELIMINARY REPORT.

(3) A FINAL AUDIT REPORT SHALL BE DELIVERED TO THE PHARMACY OR ITS CORPORATE PARENT NOT LATER THAN 60 CALENDAR DAYS AFTER ANY RESPONSES FROM THE PHARMACY OR CORPORATE PARENT ARE RECEIVED BY THE AUDITING ENTITY. THE AUDITING ENTITY SHALL ISSUE A FINAL PHARMACY AUDIT REPORT THAT TAKES INTO CONSIDERATION ANY RESPONSES PROVIDED TO THE AUDITING ENTITY BY THE PHARMACY OR CORPORATE PARENT.

(4) THE FINAL PHARMACY AUDIT REPORT MAY BE DELIVERED ELECTRONICALLY.

(5) NO PHARMACY SHALL BE SUBJECT TO A CHARGE-BACK OR RECOUPMENT FOR A CLERICAL OR RECORDKEEPING ERROR IN A REQUIRED DOCUMENT OR RECORD, INCLUDING A TYPOGRAPHICAL ERROR, SCRIVENER'S ERROR OR COMPUTER ERROR, UNLESS THE ERROR RESULTED IN OVERPAYMENT TO THE PHARMACY.

(6) NO AUDITING ENTITY CONDUCTING A PHARMACY AUDIT OR PERSON ACTING ON BEHALF OF THE ENTITY SHALL CHARGE-BACK OR RECOUP OR COLLECT PENALTIES FROM A PHARMACY UNTIL THE TIME PERIOD TO FILE AN APPEAL OF A FINAL PHARMACY AUDIT REPORT HAS PASSED OR THE APPEALS PROCESS HAS BEEN EXHAUSTED, WHICHEVER IS LATER.

(7) IF AN IDENTIFIED DISCREPANCY IN A PHARMACY AUDIT EXCEEDS $25,000, FUTURE PAYMENTS TO THE PHARMACY IN EXCESS OF THAT AMOUNT MAY BE WITHHELD PENDING ADJUDICATION OF AN APPEAL.

(8) NO INTEREST SHALL ACCRUE FOR ANY PARTY DURING THE AUDIT PERIOD, BEGINNING WITH THE NOTICE OF THE PHARMACY AUDIT AND ENDING WITH THE CONCLUSION OF THE APPEALS PROCESS.

SECTION 302. APPEALS PROCESS.

A PHARMACY MAY APPEAL A FINAL AUDIT REPORT IN ACCORDANCE WITH THE PROCEDURES ESTABLISHED BY THE ENTITY CONDUCTING THE PHARMACY AUDIT.

SECTION 303. LIMITATIONS.

(A) GENERAL RULE.--THE PROVISIONS OF THIS CHAPTER SHALL NOT APPLY TO AN AUDIT OF PHARMACY RECORDS WHEN:

(1) FRAUD, WASTE, ABUSE OR OTHER INTENTIONAL MISCONDUCT IS INDICATED BY PHYSICAL REVIEW OR REVIEW OF CLAIMS DATA OR STATEMENTS; OR

(2) OTHER INVESTIGATIVE METHODS INDICATE A PHARMACY IS OR HAS BEEN ENGAGED IN CRIMINAL WRONGDOING, FRAUD OR OTHER

INTENTIONAL OR WILLFUL MISREPRESENTATION.

(B) FEDERAL LAW.--THIS CHAPTER DOES NOT SUPERSEDE ANY AUDIT REQUIREMENTS ESTABLISHED BY FEDERAL LAW.

SECTION 304. ENFORCEMENT.

THE DEPARTMENT SHALL HAVE ENFORCEMENT AUTHORITY AND TAKE ACTION OR IMPOSE PENALTIES TO BRING NONCOMPLYING ENTITIES INTO FULL COMPLIANCE WITH THIS CHAPTER, INCLUDING THE PROMULGATION OF ANY REGULATIONS NECESSARY TO CARRY OUT THIS CHAPTER.

CHAPTER 5

PBM REQUIREMENTS

SECTION 501. PBM REGISTRATION.

TO CONDUCT BUSINESS IN THIS COMMONWEALTH, A PBM MUST REGISTER WITH THE DEPARTMENT. THE DEPARTMENT SHALL PROMULGATE REGULATIONS TO IMPLEMENT THIS SECTION.

SECTION 502. GENERIC DRUG LIST AND REIMBURSEMENT.

(A) GENERAL RULE.--IN ORDER TO PLACE A PARTICULAR DRUG ON A GENERIC DRUG LIST, A PBM SHALL, AT A MINIMUM, ENSURE THAT:

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

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

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

(C) SUBSTITUTIONS.--A PBM MAY NOT PENALIZE A PHARMACIST OR

PHARMACY ON AUDIT IF THE PHARMACIST OR PHARMACY PERFORMS A GENERIC SUBSTITUTION PURSUANT TO THE ACT OF NOVEMBER 24, 1976 (P.L.1163, NO.259), REFERRED TO AS THE GENERIC EQUIVALENT DRUG LAW.

SECTION 503. AVAILABILITY OF GENERIC DRUG LIST.

(A) GENERAL RULE.--UPON EACH CONTRACT EXECUTION OR RENEWAL, A PBM SHALL, WITH RESPECT TO CONTRACTS BETWEEN A PBM AND A PHARMACY, OR ALTERNATIVELY, A PBM AND A PHARMACY'S CONTRACTING REPRESENTATIVE OR AGENT SUCH AS A PSAO:

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

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

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

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

SECTION 504. MULTIPLE SOURCE DRUG PRICING APPEALS PROCESS.

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

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

(2) THE APPEAL SHALL BE INVESTIGATED AND RESOLVED BY THE PBM THROUGH AN INTERNAL PROCESS WITHIN 14 CALENDAR DAYS OF RECEIPT OF THE APPEAL BY THE PBM.

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

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

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

SECTION 505. ENFORCEMENT.

THE DEPARTMENT SHALL ENFORCE THE PROVISIONS OF THIS CHAPTER AND SHALL TAKE ACTION OR IMPOSE PENALTIES TO BRING NONCOMPLYING ENTITIES INTO FULL COMPLIANCE WITH THIS CHAPTER.

SECTION 506. DEPARTMENT AUTHORITY.

THE DEPARTMENT SHALL PROMULGATE REGULATIONS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS CHAPTER.

SECTION 507. APPLICABILITY.

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

CHAPTER 11

MISCELLANEOUS PROVISIONS

SECTION 1101. EFFECTIVE DATE.

THIS ACT SHALL TAKE EFFECT AS FOLLOWS:

(1) THE ADDITION OF CHAPTER 5 SHALL TAKE EFFECT IN 90 DAYS.

(2) THE REMAINDER OF THIS ACT SHALL TAKE EFFECT IN 60 DAYS.