

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, QUINN, D. PARKER, DEASY AND CUTLER, AUGUST 18, 2015

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

AN ACT

1 Providing for pharmacy audit procedures.

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

4 ~~Section 1. Short title.~~

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

7 ~~Section 2. Scope of act.~~

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

13 ~~Section 3. Definitions.~~

14 ~~The following words and phrases when used in this act shall~~

1 ~~have the meanings given to them in this section unless the~~
2 ~~context clearly indicates otherwise:~~

3 ~~"Audit." A review of one or more pharmacy records conducted~~
4 ~~by an auditing entity for payment for the provision of~~
5 ~~prescription or nonproprietary drugs or pharmacy services.~~

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

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

12 ~~"Department." The Department of Health of the Commonwealth.~~

13 ~~"Health care practitioner." As defined in section 102 of the~~
14 ~~act of July 19, 1979 (P.L.130, No.48), known as the Health Care~~
15 ~~Facilities Act.~~

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

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

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

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

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

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

30 ~~(i) Mail service pharmacy.~~

1 ~~(ii) Claims processing.~~

2 ~~(iii) Retail network management.~~

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

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

9 ~~(vi) Rebate contracting and administration.~~

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

12 ~~(viii) Disease management programs.~~

13 ~~(ix) Setting pharmacy reimbursement pricing and~~
14 ~~methodologies, including maximum allowable cost, and~~
15 ~~determining single or multiple source drugs.~~

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

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

23 ~~"Pharmacy Services Administration Organization" or "PSAO."~~
24 ~~Any entity that contracts with pharmacies to assist with third~~
25 ~~party payer interactions and can provide a variety of other~~
26 ~~administrative services. Administrative services may include,~~
27 ~~but are not limited to, contracting with PBMs on behalf of~~
28 ~~pharmacies and managing pharmacies' claims payments from third~~
29 ~~party payers.~~

30 ~~"Plan sponsor." Any of the following that pays for or~~

1 ~~processes a claim for payment for prescription drugs or pharmacy~~
2 ~~services:~~

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

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

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

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

11 ~~(5) A service benefit plan, as referenced in 42 U.S.C. §~~
12 ~~1396a(a)(25) (relating to state plans for medical~~
13 ~~assistance).~~

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

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

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

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

23 ~~(1) The pharmacy contract between a PBM and a pharmacy,~~
24 ~~or alternatively, a PBM and a pharmacy's contracting~~
25 ~~representative or agent shall identify and describe in detail~~
26 ~~the audit procedures.~~

27 ~~(2) The entity conducting an audit shall give the~~
28 ~~pharmacy written notice at least 30 days prior to conducting~~
29 ~~an onsite audit or requesting records for any audit conducted~~
30 ~~offsite. The audit may be delayed 30 days at the request of~~

1 ~~the pharmacy, one time per year, and shall only be granted if~~
2 ~~there is good cause, including, but not limited to, a planned~~
3 ~~medical procedure or planned absence from work of a necessary~~
4 ~~pharmacist. If a delay is requested by the pharmacy, the~~
5 ~~pharmacy shall provide notice to the PBM 10 business days~~
6 ~~prior to the day the audit is to commence.~~

7 ~~(3) The entity conducting the audit shall audit no more~~
8 ~~than 100 prescription records per onsite audit.~~

9 ~~(4) A pharmacy may do any of the following when an audit~~
10 ~~is performed:~~

11 ~~(i) Validate a pharmacy record by using an original~~
12 ~~or photocopied record of a hospital or health care~~
13 ~~practitioner for drugs or medicinal supplies written or~~
14 ~~transmitted electronically for purposes of validating the~~
15 ~~pharmacy record with respect to orders of prescription~~
16 ~~drugs.~~

17 ~~(ii) Validate one or more claims for payment for the~~
18 ~~provision of prescription or nonproprietary drugs or~~
19 ~~pharmacy services by using either of the following:~~

20 ~~(A) an original pharmacy record or photocopy of~~
21 ~~the record; or~~

22 ~~(B) any legal prescription complying with the~~
23 ~~Board of Pharmacy requirements may be used to~~
24 ~~validate claims in connection with prescriptions,~~
25 ~~refills or changes in prescriptions. This shall~~
26 ~~include prescription records in an electronic form or~~
27 ~~otherwise contained digital media.~~

28 ~~(iii) Resubmit a disputed or denied claim for~~
29 ~~payment using any commercially reasonable method of~~
30 ~~resubmission, including resubmission by facsimile, mail~~

1 ~~or electronic means, provided that the period of time~~
2 ~~when a claim may be resubmitted has not expired as~~
3 ~~mutually agreed upon by the contracting parties.~~

4 ~~(5) An audit must be conducted applying only the~~
5 ~~applicable Federal or Pennsylvania laws and regulations.~~

6 ~~(6) A clerical or recordkeeping error, such as a~~
7 ~~typographical error, scrivener's error or computer error~~
8 ~~regarding a required document or record does not constitute~~
9 ~~fraud, and claims relating thereto shall be subject to~~
10 ~~neither recoupment nor criminal penalties without proof of~~
11 ~~intent to commit fraud or absent an indication there was an~~
12 ~~error in dispensing the prescribed drug.~~

13 ~~(7) The finding of an overpayment shall not include the~~
14 ~~dispensing fee amount. This provision specifically does not~~
15 ~~include the payment of multiple dispensing fees for the same~~
16 ~~prescription, exclusive of refills.~~

17 ~~(8) The period of time covered by an audit may not be~~
18 ~~more than 12 months from the scheduled date of the audit.~~

19 ~~(9) An onsite audit may not be initiated or scheduled~~
20 ~~during the first three business days of any month unless~~
21 ~~consented to by the pharmacy.~~

22 ~~(10) The auditing entity may not receive payment, by~~
23 ~~contract, based on a percentage of the amount recovered.~~

24 ~~(11) An entity conducting an audit under this act shall~~
25 ~~not use the accounting practice of extrapolation in~~
26 ~~calculating recoupments or penalties for audits. An~~
27 ~~extrapolation audit means an audit of a sample of~~
28 ~~prescription drug benefit claims submitted by a pharmacy to~~
29 ~~the entity conducting the audit that is then used to estimate~~
30 ~~audit results for a larger group of claims not reviewed by~~

1 ~~the auditor.~~

2 ~~(12) When calculating for days' supply for topical and~~
3 ~~ophthalmic products, the pharmacist's reasonable,~~
4 ~~professional judgment based on communication with the patient~~
5 ~~or prescriber shall take precedence.~~

6 ~~(13) The auditing entity shall not recoup payment for a~~
7 ~~prescription which has been used by the patient in accordance~~
8 ~~with the prescriber's instructions even if the prescriber's~~
9 ~~instructions are different than the manufacturer's suggested~~
10 ~~use.~~

11 ~~(14) When directions for use include variable dosing~~
12 ~~instructions, the highest prescribed dose must be used to~~
13 ~~calculate day's supply, copay and allowable refill date and~~
14 ~~quantity.~~

15 ~~(15) The pharmacy's usual and customary price for~~
16 ~~compounded medications shall be considered the reimbursable~~
17 ~~cost unless the pricing methodology is published in the~~
18 ~~provider contract and mutually agreed upon by the contracting~~
19 ~~parties.~~

20 ~~(16) A pharmacy shall be permitted to utilize~~
21 ~~information regarding the availability of third party~~
22 ~~resources provided by a PBM and shall not be liable to repay~~
23 ~~any amount for which a third party is liable only if a~~
24 ~~pharmacy has actual knowledge regarding the availability of~~
25 ~~third party resources available to a claimant for pharmacy~~
26 ~~benefits. PBMs and prescription drug plans may pursue claims~~
27 ~~for such third party resources.~~

28 ~~(17) With the exception of overpayments, if a PBM~~
29 ~~approves a claim through adjudication, the auditor may not~~
30 ~~retroactively deny or modify the claim based upon~~

1 ~~retroactively obtained ineligibility information, unless the~~
2 ~~claim was fraudulent.~~

3 ~~(18) An auditor may not deny or reject any claim~~
4 ~~retroactively through audits in the event that the PBM or~~
5 ~~auditor has subsequently become aware of another payer~~
6 ~~responsible for payment of the claim following adjudication~~
7 ~~or payment of the claim.~~

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

11 ~~(1) The preliminary audit report must be delivered to~~
12 ~~the pharmacy or its corporate parent within 60 days after the~~
13 ~~completion of the audit. The preliminary report shall include~~
14 ~~contact information for the individual who conducted the~~
15 ~~audit, including telephone number, facsimile number, e mail~~
16 ~~and auditing firm, so that audit results, discrepancies and~~
17 ~~procedures can be reviewed. The preliminary audit report~~
18 ~~shall include, but is not limited to, claim level information~~
19 ~~for any discrepancy found and total dollar amount of claims~~
20 ~~subject to recovery.~~

21 ~~(2) A pharmacy shall be allowed at least 60 days~~
22 ~~following receipt of the preliminary audit report to produce~~
23 ~~documentation to address any discrepancy found during the~~
24 ~~audit. This shall include prescriptions not initially~~
25 ~~provided in the audit.~~

26 ~~(3) A final audit report shall be delivered to the~~
27 ~~pharmacy or its corporate parent within 120 days after~~
28 ~~receipt of the preliminary audit report or final appeal.~~

29 ~~(4) The audit report must be signed and include the~~
30 ~~signature of any pharmacist participating in the audit.~~

1 ~~(5) Any recoupments of disputed funds shall only occur~~
2 ~~after final internal disposition of the audit. Any recoupment~~
3 ~~shall be provided in writing to the pharmacy for payment.~~

4 ~~(6) Interest shall not accerue during the audit period.~~

5 ~~(7) Each entity conducting an audit shall provide a copy~~
6 ~~of the final audit report, after completion of any review~~
7 ~~process, to the plan sponsor. The final audit report may be~~
8 ~~delivered electronically.~~

9 ~~Section 5. Appeals process.~~

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

13 ~~(b) Adjudication. The adjudication of a claim cannot be~~
14 ~~appealed through the audit process.~~

15 ~~Section 6. Limitations.~~

16 ~~(a) Exceptions. Any rights derived from this act shall not~~
17 ~~apply to:~~

18 ~~(1) Audits which are the result of a complaint to the~~
19 ~~PBM or Board of Pharmacy in which suspected fraudulent~~
20 ~~activity or other intentional and willful misrepresentation~~
21 ~~is evidenced by a physical review, review of claims data or~~
22 ~~statements or other investigative methods.~~

23 ~~(2) Concurrent reviews or desk audits that occur within~~
24 ~~three business days of transmission of a claim where no~~
25 ~~chargeback or recoupment is demanded.~~

26 ~~(b) Federal law. This act does not supersede any audit~~
27 ~~requirements established by Federal law, including extrapolation~~
28 ~~audits when required.~~

29 ~~Section 7. Enforcement.~~

30 ~~The department shall have enforcement authority and shall~~

1 ~~take action or impose penalties to bring noncomplying entities~~
2 ~~into full compliance with this act, including the promulgation~~
3 ~~of any regulations necessary to carry out this act.~~

4 ~~Section 8. Effective date.~~

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

6 SECTION 1. SHORT TITLE.

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

9 SECTION 2. SCOPE OF ACT.

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

15 SECTION 3. DEFINITIONS.

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

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

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

25 "DEPARTMENT." THE INSURANCE DEPARTMENT OF THE COMMONWEALTH.

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

1 CLAIMS.

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

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

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

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

11 "PHARMACY AUDIT." AN AUDIT, CONDUCTED ON-SITE OR REMOTELY BY
12 OR ON BEHALF OF AN AUDITING ENTITY OF ANY RECORDS OF A PHARMACY
13 FOR PRESCRIPTION OR NONPROPRIETARY DRUGS DISPENSED BY A PHARMACY
14 TO BENEFICIARIES OF A HEALTH BENEFIT PLAN. THE TERM DOES NOT
15 INCLUDE EITHER OF THE FOLLOWING:

16 (1) A CONCURRENT REVIEW OR REMOTE AUDIT THAT IS
17 INITIATED WITHIN SEVEN BUSINESS DAYS OF THE PHARMACY'S
18 TRANSMISSION OF A CLAIM TO AN AUDITING ENTITY.

19 (2) A CONCURRENT REVIEW OR REMOTE AUDIT WHERE NO CHARGE-
20 BACK OR RECOUPMENT IS DEMANDED BY THE AUDITING ENTITY.

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

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

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

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

1 (I) MAIL-SERVICE PHARMACY.
2 (II) CLAIMS PROCESSING.
3 (III) RETAIL NETWORK MANAGEMENT.
4 (IV) PAYMENT OF CLAIMS TO PHARMACIES FOR
5 PRESCRIPTION DRUGS DISPENSED TO COVERED INDIVIDUALS VIA
6 RETAIL OR MAIL-ORDER PHARMACY.

7 (V) CLINICAL FORMULARY DEVELOPMENT AND MANAGEMENT
8 SERVICES, INCLUDING, BUT NOT LIMITED TO, UTILIZATION
9 MANAGEMENT AND QUALITY ASSURANCE PROGRAMS.

10 (VI) REBATE CONTRACTING AND ADMINISTRATION.

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

13 (VIII) DISEASE MANAGEMENT PROGRAMS.

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

17 "PHARMACY BENEFITS MANAGER" OR "PBM." A PERSON, BUSINESS OR
18 OTHER ENTITY THAT PERFORMS PHARMACY BENEFITS MANAGEMENT.

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

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

27 (1) A HEALTH INSURING CORPORATION.

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

30 (3) A PERSON OR GOVERNMENT ENTITY PROVIDING COVERAGE OF

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

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

5 (5) A SERVICE BENEFIT PLAN, AS REFERENCED IN 42 U.S.C. §
6 1396A(A) (25) (RELATING TO STATE PLANS FOR MEDICAL
7 ASSISTANCE).

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

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

14 SECTION 4. PROCEDURES FOR CONDUCTING PHARMACY AUDITS.

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

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

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

26 (3) NO AUDITING ENTITY CONDUCTING A PHARMACY AUDIT SHALL
27 SOLELY COMPENSATE ANY OF ITS EMPLOYEES OR ANY CONTRACTOR WITH
28 WHICH AN AUDITING ENTITY CONTRACTS TO CONDUCT A PHARMACY
29 AUDIT, BASED ON THE AMOUNT CLAIMED OR THE ACTUAL AMOUNT
30 RECOUPED BY THE PHARMACY BEING AUDITED.

1 (4) THE ENTITY SHALL PROVIDE THE PHARMACY BEING AUDITED
2 WITH AT LEAST 10 BUSINESS DAYS' PRIOR WRITTEN NOTICE BEFORE
3 CONDUCTING A PHARMACY AUDIT, UNLESS BOTH PARTIES AGREE
4 OTHERWISE. THE AUDIT MAY BE DELAYED FOR A PERIOD OF UP TO 30
5 DAYS AT THE REQUEST OF THE PHARMACY, ONE TIME PER YEAR, AND
6 SHALL ONLY BE GRANTED IF THERE IS GOOD CAUSE, INCLUDING, BUT
7 NOT LIMITED TO, A PLANNED MEDICAL PROCEDURE OR PLANNED
8 ABSENCE FROM WORK OF A NECESSARY PHARMACIST. IF A DELAY IS
9 REQUESTED BY THE PHARMACY, THE PHARMACY SHALL PROVIDE NOTICE
10 TO THE PBM AT LEAST FIVE BUSINESS DAYS PRIOR TO THE DAY THE
11 AUDIT IS TO COMMENCE.

12 (5) (RESERVED).

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

17 (7) THE ENTITY SHALL ACCEPT PAPER OR ELECTRONIC
18 SIGNATURE LOGS THAT DOCUMENT THE DELIVERY OF PRESCRIPTION OR
19 NONPROPRIETARY DRUGS AND PHARMACIST SERVICES TO A HEALTH PLAN
20 BENEFICIARY OR THE AGENT OF THE BENEFICIARY.

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

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

27 (10) NO PHARMACY AUDIT SHALL COVER:

28 (I) A PERIOD OF MORE THAN 24 MONTHS AFTER THE DATE A
29 CLAIM WAS SUBMITTED BY THE PHARMACY TO THE PHARMACY
30 BENEFITS MANAGER OR PLAN SPONSOR UNLESS A LONGER PERIOD

1 IS REQUIRED BY LAW; OR

2 (II) MORE THAN 250 PRESCRIPTIONS, PROVIDED THAT A
3 REFILL SHALL NOT CONSTITUTE A SEPARATE PRESCRIPTION FOR
4 THE PURPOSES OF THIS SUBPARAGRAPH.

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

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

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

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

24 (II) TO VALIDATE CLAIMS IN CONNECTION WITH
25 PRESCRIPTIONS OR CHANGES IN PRESCRIPTIONS, OR REFILLS OF
26 PRESCRIPTION OR NONPROPRIETARY DRUGS, A PHARMACY MAY USE
27 ANY VALID PRESCRIPTION, INCLUDING, BUT NOT LIMITED TO,
28 MEDICATION ADMINISTRATION RECORDS, FACSIMILES, ELECTRONIC
29 PRESCRIPTIONS, ELECTRONICALLY STORED IMAGES OF
30 PRESCRIPTIONS, ELECTRONICALLY CREATED ANNOTATIONS OR

1 DOCUMENTED TELEPHONE CALLS FROM THE PRESCRIBING HEALTH
2 CARE PRACTITIONER OR PRACTITIONER'S AGENT. DOCUMENTATION
3 OF AN ORAL PRESCRIPTION ORDER THAT HAS BEEN VERIFIED BY
4 THE PRESCRIBING HEALTH CARE PRACTITIONER SHALL MEET THE
5 PROVISIONS OF THIS SUBPARAGRAPH FOR THE INITIAL AUDIT
6 REVIEW.

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

10 (1) THE PRELIMINARY PHARMACY AUDIT REPORT MUST BE
11 DELIVERED TO THE PHARMACY OR ITS CORPORATE PARENT WITHIN 60
12 DAYS AFTER THE COMPLETION OF THE PHARMACY AUDIT. THE
13 PRELIMINARY REPORT SHALL INCLUDE CONTACT INFORMATION FOR THE
14 INDIVIDUAL WHO CONDUCTED THE PHARMACY AUDIT, INCLUDING
15 TELEPHONE NUMBER, FACSIMILE NUMBER, E-MAIL AND AUDITING FIRM,
16 SO THAT AUDIT RESULTS, DISCREPANCIES AND PROCEDURES CAN BE
17 REVIEWED. THE PRELIMINARY PHARMACY AUDIT REPORT SHALL
18 INCLUDE, BUT NOT BE LIMITED TO, CLAIM LEVEL INFORMATION FOR
19 ANY DISCREPANCY FOUND AND TOTAL DOLLAR AMOUNT OF CLAIMS
20 SUBJECT TO RECOVERY.

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

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

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

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

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

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

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

21 SECTION 5. APPEALS PROCESS.

22 (A) GENERAL RULE.--AN AUDITING ENTITY SHALL ESTABLISH A
23 WRITTEN APPEALS PROCESS UNDER WHICH A PHARMACY MAY APPEAL AN
24 UNFAVORABLE FINAL AUDIT REPORT TO THE ENTITY.

25 (B) ADJUDICATION.--THE ADJUDICATION OF A CLAIM MAY NOT BE
26 APPEALED THROUGH THE AUDIT PROCESS.

27 SECTION 6. LIMITATIONS.

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

30 (1) FRAUD, WASTE, ABUSE OR OTHER INTENTIONAL MISCONDUCT

1 IS INDICATED BY PHYSICAL REVIEW OR REVIEW OF CLAIMS DATA OR
2 STATEMENTS; OR

3 (2) OTHER INVESTIGATIVE METHODS INDICATE A PHARMACY IS
4 OR HAS BEEN ENGAGED IN CRIMINAL WRONGDOING, FRAUD OR OTHER
5 INTENTIONAL OR WILLFUL MISREPRESENTATION.

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

8 SECTION 7. ENFORCEMENT.

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

13 SECTION 8. EFFECTIVE DATE.

14 THIS ACT SHALL TAKE EFFECT IN 90 DAYS.