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Legislative Document

No. 1487

H.P. 1094

House of Representatives, April 14, 2011

An Act To Assist Maine Pharmacies

Reference to the Committee on Labor, Commerce, Research and Economic Development suggested and ordered printed.

A handwritten signature in cursive script that reads "Heather J.R. Priest".

HEATHER J.R. PRIEST
Clerk

Presented by Representative BECK of Waterville.
Cosponsored by Senator BRANNIGAN of Cumberland and
Representatives: CAIN of Orono, GOODE of Bangor, MORRISON of South Portland,
SANBORN of Gorham, TREAT of Hallowell.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA §1711-E, sub-§1, ¶G**, as enacted by PL 2005, c. 589, §1, is
3 amended to read:

4 G. "Pharmacy benefits manager" has the same meaning as in Title 32, section ~~2699~~
5 13842, subsection ~~4~~, ~~paragraph F~~ 6.

6 **Sec. 2. 22 MRSA c. 603, sub-c. 4**, as amended, is repealed.

7 **Sec. 3. 22 MRSA §8702, sub-§8-B**, as amended by PL 2007, c. 695, Pt. A, §26,
8 is further amended to read:

9 **8-B. Pharmacy benefits manager.** "Pharmacy benefits manager" means an entity
10 that performs pharmacy benefits management as defined in Title 32, section ~~2699~~ 13842,
11 subsection ~~4~~, ~~paragraph E~~ 5.

12 **Sec. 4. 22 MRSA §8706, sub-§2, ¶C**, as amended by PL 2007, c. 136, §5, is
13 further amended to read:

14 C. The operations of the organization must be supported from 3 sources as provided
15 in this paragraph:

16 (1) Fees collected pursuant to paragraphs A and B;

17 (2) Annual assessments of not less than \$100 assessed against the following
18 entities licensed under Titles 24 ~~and~~ 24-A and 32: nonprofit hospital and medical
19 service organizations, health insurance carriers and health maintenance
20 organizations on the basis of the total annual health care premium; and 3rd-party
21 administrators, carriers that provide only administrative services for a plan
22 sponsor and pharmacy benefits managers that process and pay claims on the basis
23 of claims processed or paid for each plan sponsor. The assessments are to be
24 determined on an annual basis by the board. Health care policies issued for
25 specified disease, accident, injury, hospital indemnity, disability, long-term care
26 or other limited benefit health insurance policies are not subject to assessment
27 under this subparagraph. For purposes of this subparagraph, policies issued for
28 dental services are not considered to be limited benefit health insurance policies.
29 The total dollar amount of assessments under this subparagraph must equal the
30 assessments under subparagraph (3); and

31 (3) Annual assessments of not less than \$100 assessed by the organization
32 against providers. The assessments are to be determined on an annual basis by
33 the board. The total dollar amount of assessments under this subparagraph must
34 equal the assessments under subparagraph (2).

35 The aggregate level of annual assessments under subparagraphs (2) and (3) must be
36 an amount sufficient to meet the organization's expenditures authorized in the state
37 budget established under Title 5, chapter 149. The annual assessment may not
38 exceed \$1,346,904 in fiscal year 2002-03. In subsequent fiscal years, the annual
39 assessment may increase above \$1,346,904 by an amount not to exceed 5% per fiscal
40 year. The board may waive assessments otherwise due under subparagraphs (2) and

1 (3) when a waiver is determined to be in the interests of the organization and the
2 parties to be assessed.

3 **Sec. 5. 24-A MRSA §601, sub-§28**, as enacted by PL 2009, c. 581, §3, is
4 amended to read:

5 **28. Pharmacy benefits manager.** ~~Pharmacy~~ The annual filing fee for a pharmacy
6 benefits manager registration fees may not exceed: is \$1,000.

7 ~~A. Original issuance fee, \$100; and~~

8 ~~B. Annual renewal fee, \$100.~~

9 **Sec. 6. 24-A MRSA §1913**, as enacted by PL 2009, c. 581, §4, is amended to
10 read:

11 **§1913. Registration of pharmacy benefits managers**

12 Beginning April 1, 2011, a person may not act as a pharmacy benefits manager as
13 defined in Title ~~22~~ 32, section ~~2699~~ 13842, subsection ~~1, paragraph F~~ 6 in this State
14 without first paying the ~~registration~~ filing fee required under ~~Title 32, section 601~~ 13844,
15 subsection ~~28~~ 2, paragraph J. The superintendent may adopt routine technical rules
16 pursuant to Title 5, chapter 375, subchapter 2-A to administer and enforce the ~~registration~~
17 requirements of this section. The superintendent may enforce this section under sections
18 220 and 223 and other provisions of this Title.

19 **Sec. 7. 32 MRSA c. 117, sub-c. 14** is enacted to read:

20 **SUBCHAPTER 14**

21 **PRESCRIPTION DRUG PRACTICES**

22 **§13841. Short title**

23 This subchapter may be known and cited as "the Prescription Drug Practices Act."

24 **§13842. Definitions**

25 As used in this subchapter, unless the context otherwise indicates, the following
26 terms have the following meanings.

27 **1. Bureau.** "Bureau" means the Bureau of Insurance.

28 **2. Covered entity.** "Covered entity" means a nonprofit hospital or medical service
29 organization, insurer, health coverage plan or health maintenance organization licensed
30 pursuant to Title 24 or Title 24-A; a health program administered by the department or
31 the State in the capacity of provider of health coverage; or an employer, labor union or
32 other group of persons organized in the State that provides health coverage to covered
33 individuals who are employed or reside in the State. "Covered entity" does not include a
34 health plan that provides coverage only for accidental injury, specified disease, hospital

1 indemnity, Medicare supplement, disability income, long-term care or other limited
2 benefit health insurance policies and contracts.

3 **3. Covered individual.** "Covered individual" means a member, participant,
4 enrollee, contract holder or policyholder or beneficiary of a covered entity who is
5 provided health coverage by the covered entity. "Covered individual" includes a
6 dependent or other person provided health coverage through a policy, contract or plan for
7 a covered individual.

8 **4. Labeler.** "Labeler" means a person that receives prescription drugs from a
9 manufacturer or wholesaler and repackages those drugs for later retail sale and that has a
10 labeler code from the federal Food and Drug Administration under 21 Code of Federal
11 Regulations, Section 207.20 (2006).

12 **5. Pharmacy benefits management.** "Pharmacy benefits management" means the
13 arrangement for the procurement of prescription drugs at a negotiated rate for
14 dispensation within the State to covered individuals, the administration or management of
15 prescription drug benefits provided by a health insurance plan for the benefit of
16 beneficiaries or any of the following services provided with regard to the administration
17 of pharmacy benefits:

18 A. Mail order pharmacy services;

19 B. Claims processing, retail network management as defined by the bureau by rule
20 and payment of claims to pharmacies for prescription drugs dispensed to
21 beneficiaries;

22 C. Clinical formulary development and management services;

23 D. Rebate contracting and administration;

24 E. Certain patient compliance, therapeutic intervention and generic substitution
25 program services;

26 F. Disease management program services; and

27 G. Administration of drugs and immunizations.

28 **6. Pharmacy benefits manager.** "Pharmacy benefits manager" means a person that
29 performs pharmacy benefits management. "Pharmacy benefits manager" includes a
30 person acting for a pharmacy benefits manager in a contractual or employment
31 relationship in the performance of pharmacy benefits management for a covered entity
32 and includes mail order pharmacy services.

33 **7. Superintendent.** "Superintendent" means the Superintendent of Insurance.

34 **§13843. Certificate of compliance**

35 **1. Plan of operation submitted to the bureau.** A person seeking to become
36 certified under section 13844 in this State shall submit its plan of operation to the bureau
37 for review in a format determined by the bureau.

1 **2. Rules.** The bureau shall adopt rules that include but are not limited to a review of
2 the pharmacy benefits manager's plan of operation, the format required for submission of
3 the plan pursuant to subsection 1, the filing fee for a certificate of compliance, the
4 requirements for annual renewal under section 13844 and any other information that the
5 bureau may require to complete its review under this section. The fees collected must be
6 used for the purpose of regulating pharmacy benefits managers.

7 **3. Approval by the bureau.** If the plan of operation submitted pursuant to
8 subsection 1 is approved by the bureau, the bureau shall issue to the person a certificate
9 of compliance. The person shall file any subsequent material changes in the plan of
10 operation with the bureau.

11 **§13844. Certificate of authority**

12 **1. Certificate required.** A person may not act or operate as a pharmacy benefits
13 manager in this State without a valid certificate of authority issued by the bureau. The
14 certificate of authority must be renewed annually pursuant to section 13847. A violation
15 of this subsection is a civil violation for which a fine of not less than \$1,000 and not more
16 than \$10,000 may be adjudged.

17 **2. Application.** A person seeking to obtain a certificate of authority under this
18 section must apply to the bureau on a form obtained from the bureau. In addition to the
19 disclosure required under section 13845, an application submitted to the bureau must
20 include or have attached the following:

21 **A.** All basic organizational documents of the pharmacy benefits manager, including,
22 but not limited to, the articles of incorporation, articles of association, bylaws,
23 partnership agreement, trade name certificate, trust agreement, shareholder agreement
24 and other applicable documents and all amendments to those documents;

25 **B.** The names, addresses, official positions and professional qualifications of the
26 individuals who are responsible for the conduct of the affairs of the pharmacy
27 benefits manager, including all members of the board of directors, board of trustees,
28 executive committee or any other governing board or committee, the principal
29 officers in the case of a corporation, the partners or members in the case of a
30 partnership or association and any other person who exercises control or influence
31 over the affairs of the pharmacy benefits manager;

32 **C.** A certificate of compliance issued by the bureau pursuant to section 13843
33 indicating that the pharmacy benefits manager's plan of operation is consistent with
34 any rules adopted by the bureau;

35 **D.** Annual statements or reports for the 3 most recent years or such other information
36 as the bureau may require in order to review the current financial condition of the
37 applicant;

38 **E.** If the applicant is not currently acting as a pharmacy benefits manager, a
39 statement of the amounts and sources of funds available for organization expenses
40 and the proposed arrangements for reimbursement and compensation of incorporators
41 or other principals;

- 1 F. The name and address of the agent for service of process in this State;
- 2 G. A detailed description of the claims processing services, pharmacy services,
- 3 insurance services, other prescription drug or device services, audit procedures for
- 4 network pharmacies or other administrative services to be provided;
- 5 H. All incentive arrangements and programs, including, but not limited to, rebates,
- 6 discounts, disbursements and any other similar financial arrangement or program
- 7 relating to income or consideration received or negotiated, directly or indirectly, with
- 8 any pharmaceutical company, that relate to prescription drug or device services,
- 9 including, at a minimum, information on the formula or other method for calculation
- 10 and amount of the incentive arrangements, rebates or other disbursements, the
- 11 identity of the associated drug or device and the dates and amounts of these
- 12 disbursements;
- 13 I. Other information as the bureau may require; and
- 14 J. A filing fee of \$1,000.

15 **3. Inspection.** An applicant for a certificate of authority under this section shall

16 make available for inspection by the bureau copies of all contracts with insurers,

17 pharmaceutical manufacturers or other persons using the services of the pharmacy

18 benefits manager for pharmacy benefits management.

19 **4. Denial of certificate.** The bureau may not issue a certificate of authority under

20 this section if it determines that the pharmacy benefits manager or any principal of the

21 pharmacy benefits manager is not competent, trustworthy, financially responsible or of

22 good personal and business reputation or has had an insurance license or pharmacy

23 license denied for cause by any state.

24 **5. Fidelity bond.** A pharmacy benefits manager shall maintain a fidelity bond equal

25 to at least 10% of the amount of the funds handled or managed annually by the pharmacy

26 benefits manager. The bureau may require that the amount of the bond be an amount in

27 excess of \$500,000, but the amount required may not be more than 10% of the amount of

28 the funds handled or managed annually by the pharmacy benefits manager. A copy of the

29 bond must be provided to the bureau.

30 **§13845. Disclosure required**

31 **1. Disclosure of ownership interests and affiliations required.** A pharmacy

32 benefits manager shall disclose to the bureau any ownership interest or affiliation of any

33 kind with:

34 A. Any insurance company responsible for providing benefits directly or through

35 reinsurance to any plan for which the pharmacy benefits manager provides services;

36 or

37 B. Any parent company, subsidiary, other entity or business relating to the provision

38 of pharmacy services or other prescription drug or device services or pharmaceutical

39 manufacturer.

1 **2. Material changes in ownership.** A pharmacy benefits manager shall notify the
2 bureau in writing within 5 calendar days of any material change in its ownership.

3 **3. Disclosure of agreements.** A pharmacy benefits manager shall disclose to the
4 bureau the following agreements and practices:

5 A. An agreement with a pharmaceutical manufacturer to favor the manufacturer's
6 products over a competitor's products, to place the manufacturer's drug on the
7 pharmacy benefits manager's preferred list or formulary or to substitute the drug
8 prescribed by a patient's health care provider with a drug agreed to by the pharmacy
9 benefits manager and the manufacturer;

10 B. An agreement with a pharmaceutical manufacturer to share manufacturer rebates
11 and discounts with the pharmacy benefits manager or to pay money or other
12 economic benefits to the pharmacy benefits manager;

13 C. An agreement or practice to bill a health plan for prescription drugs at a cost
14 higher than the pharmacy benefits manager pays the pharmacy;

15 D. An agreement to share revenue with a mail order or Internet pharmacy company;
16 and

17 E. Any agreement to sell prescription drug data, including data concerning the
18 prescribing practices of health care providers in this State.

19 **§13846. Records**

20 **1. Maintenance of records.** A pharmacy benefits manager shall maintain for the
21 duration of any written agreement or contract and for 2 years thereafter books and records
22 of all transactions between pharmacy benefits managers and insurers, covered entities,
23 covered individuals, pharmacists and pharmacies.

24 **2. Access to records.** The bureau may access books and records maintained by a
25 pharmacy benefits manager for the purposes of examination, audit and inspection. The
26 information contained in the books and records is confidential and may not be disclosed,
27 except that the bureau may use this information in any proceeding instituted against a
28 pharmacy benefits manager or insurer.

29 **3. Financial examinations.** The superintendent shall conduct periodic financial
30 examinations of a pharmacy benefits manager. The pharmacy benefits manager shall pay
31 the cost of the examination. The examination fee must be used to offset expenses for the
32 regulation, supervision and examination of all persons subject to regulation under this
33 subchapter.

34 **§13847. Annual statement; fee**

35 **1. Annual statement.** A pharmacy benefits manager shall file with the bureau an
36 annual statement and filing fee for renewing a certificate of authority under section 13844
37 on or before March 1st. The statement must be in the form and contain such information
38 as the bureau prescribes for the previous calendar year, including the total number of
39 persons subject to management by the pharmacy benefits manager, the number of persons

1 terminated, the number of persons covered at the end of the year and the dollar value of
2 claims processed.

3 **2. Disclosure of incentive arrangements.** The annual statement under subsection 1
4 must disclose all incentive arrangements and programs, including, but not limited to,
5 rebates, discounts, disbursements and any other similar financial arrangement or program
6 relating to income or consideration received or negotiated, directly or indirectly, with any
7 pharmaceutical company, that relate to prescription drug or device services, including, at
8 a minimum, information on the formula or other method for calculation and the amount
9 of the incentive arrangements, rebates or other disbursements, the identity of the
10 associated drug or device and the dates and amounts of these disbursements.

11 **§13848. Contracts; prohibited provisions**

12 **1. Contract required.** A pharmacy benefits manager may not act as a pharmacy
13 benefits manager without a written contract between a covered entity or a covered
14 individual and the pharmacy benefits manager.

15 **2. Participation in contracts.** A pharmacy benefits manager may not require a
16 pharmacist or pharmacy to participate in one contract in order to participate in another
17 contract. The pharmacy benefits manager may not exclude an otherwise qualified
18 pharmacist or pharmacy from participation in a particular network solely because the
19 pharmacist or pharmacy declined to participate in another plan or network managed by
20 the pharmacy benefits manager.

21 A pharmacy benefits manager that provides coverage for prescription drugs as part of a
22 health plan may not refuse to contract with a pharmacy that is qualified and is willing to
23 meet the terms and conditions of the pharmacy benefits manager's criteria for pharmacy
24 participation as stipulated in the pharmacy benefits manager's contractual agreement with
25 its pharmacy.

26 This subsection may not be construed to limit a pharmacy benefits manager's ability to
27 offer a covered individual incentives, including variations in premiums, deductibles,
28 copayments or coinsurance or variations in the quantities of medications available to the
29 covered individual, to encourage the use of certain preferred pharmacies as long as the
30 pharmacy benefits manager makes the terms applicable to the preferred pharmacies
31 available to all pharmacies. For purposes of this subsection, "preferred pharmacy" means
32 any pharmacy willing to meet the specified terms, conditions and price that the pharmacy
33 benefits manager may require for its preferred pharmacies.

34 **3. Prohibition.** The written contract between a covered entity or a covered
35 individual and the pharmacy benefits manager may not provide that the pharmacist or
36 pharmacy is responsible for the actions of the insurer or the pharmacy benefits manager.

37 **4. Pharmacy benefits manager duties.** All contracts must provide that, when the
38 pharmacy benefits manager receives payment for the services of the pharmacist or
39 pharmacy, the pharmacy benefits manager shall distribute the funds in accordance with
40 the time frames provided in this subchapter.

1 **§13849. Termination of contracts**

2 **1. Complaints, grievances and appeals.** A pharmacy benefits manager may not
3 terminate the contract of or penalize a pharmacist or pharmacy solely as a result of the
4 pharmacist's or pharmacy's filing of a complaint, grievance or appeal.

5 **2. Denial or limitation of benefits.** A pharmacy benefits manager may not
6 terminate the contract of or penalize a pharmacist or pharmacy for expressing
7 disagreement with the pharmacy benefits manager's decision to deny or limit benefits to a
8 covered individual or because the pharmacist or pharmacy assists the covered individual
9 to seek reconsideration of the pharmacy benefits manager's decision or because the
10 pharmacist or pharmacy discusses alternative medications.

11 **3. Written notice required.** At least 30 days before terminating a pharmacy's or
12 pharmacist's participation in a plan or network, the pharmacy benefits manager shall give
13 the pharmacy or pharmacist a written explanation of the reason for the termination, unless
14 the termination is based on:

15 A. The loss of the pharmacy's license or the pharmacist's license to practice
16 pharmacy or cancellation of professional liability insurance; or

17 B. A conviction of fraud.

18 **§13850. Medication reimbursement costs**

19 A pharmacy benefits manager shall use a current and nationally recognized
20 benchmark on which to base the reimbursement paid to network pharmacies for
21 medications and products. The reimbursement must be determined as follows:

22 **1. Average wholesale price.** For brand-name or single-source products, the average
23 wholesale price, as listed in standard industry references as determined by the bureau by
24 rule, that is correct and current on the date of service provided, must be used; and

25 **2. Criteria for reimbursement.** For generic drug or multisource products, the
26 maximum allowable cost must be established by referencing the baseline price in
27 standard industry references as determined by the bureau by rule. Only products that are
28 compliant with federal pharmacy laws as equivalent and generically interchangeable may
29 be reimbursed from a maximum allowable cost price methodology. If a multisource
30 product has no baseline price, then it must be treated as a single-source drug for the
31 purpose of determining reimbursement. Upon written request, a pharmacy benefits
32 manager shall disclose its pricing source and date for determining a disputed maximum
33 allowable cost price.

34 **§13850-A. Processing of clean claims; audits**

35 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
36 following terms have the following meanings.

37 A. "Applicable number of calendar days" means:

38 (1) With respect to claims submitted electronically, 21 days; and

1 (2) With respect to claims submitted otherwise, 30 days.

2 B. "Clean claim" means a claim that has no defect or impropriety, including a lack of
3 required substantiating documentation, or particular circumstance requiring special
4 treatment that prevents payment within the applicable number of calendar days from
5 being made on the claim under this section.

6 **2. Payment of claims.** A pharmacy benefits manager shall pay or deny a clean
7 claim pursuant to this subsection.

8 A. A pharmacy benefits manager shall pay or deny a clean claim submitted by a
9 pharmacy within the applicable number of calendar days.

10 A pharmacy benefits manager that fails to pay or deny a clean claim in accordance
11 with this subsection shall pay a penalty to the bureau for the delinquent payment
12 period, which is the period beginning on the 45th day after receipt of the clean claim
13 and ending on the clean claim payment date. The penalty is calculated as follows: the
14 amount of the clean claim payment multiplied by 10% per annum multiplied by the
15 number of days in the delinquent payment period divided by 365.

16 B. A contract entered into by a pharmacy benefits manager with a pharmacy with
17 respect to a prescription drug plan offered by a pharmacy benefits manager must
18 provide that payment be issued, mailed or otherwise transmitted with respect to all
19 clean claims submitted by a pharmacy, other than a pharmacy that dispenses drugs by
20 mail order only or a pharmacy located in, or under contract with, a long-term care
21 facility, within the applicable number of calendar days after the date on which the
22 claim is received. For purposes of this subsection, a claim is considered to have been
23 received:

24 (1) With respect to claims submitted electronically, on the date on which the
25 claim is transferred; and

26 (2) With respect to claims submitted otherwise, on the 5th day after the postmark
27 date of the claim or the date specified in the time stamp of the transmission of the
28 claim.

29 C. If payment is not issued, mailed or otherwise transmitted by the pharmacy
30 benefits manager within the applicable number of calendar days after a clean claim is
31 received, the pharmacy benefits manager shall pay interest to the pharmacy at the rate
32 of 18% per annum.

33 D. A claim is considered to be a clean claim if the pharmacy benefits manager
34 involved does not provide notice to the pharmacy of any deficiency in the claim
35 within 10 days after the date on which an electronically submitted claim is received
36 or within 15 days after the date on which a claim submitted otherwise is received.

37 E. If a pharmacy benefits manager determines that a submitted claim is not a clean
38 claim, the pharmacy benefits manager shall immediately notify the pharmacy of the
39 determination. The notice must specify all defects or improprieties in the claim and
40 list all additional information or documents necessary for the proper processing and
41 payment of the claim. If a pharmacy receives notice from a pharmacy benefits
42 manager that a claim has been determined not to be a clean claim, the pharmacy shall

1 take steps to correct that claim and then resubmit the claim to the pharmacy benefits
2 manager for payment.

3 F. A claim resubmitted to a pharmacy benefits manager with additional information
4 pursuant to paragraph E is considered to be a clean claim if the pharmacy benefits
5 manager does not provide notice to the pharmacy of any defect or impropriety in the
6 claim within 10 days of the date on which additional information is received if the
7 claim is resubmitted electronically or within 15 days of the date on which additional
8 information is received if the claim is resubmitted otherwise.

9 G. A claim submitted to a pharmacy benefits manager that is not paid by the
10 pharmacy benefits manager or contested by the covered entity within the applicable
11 number of calendar days after the date on which the claim is received by the
12 pharmacy benefits manager is considered to be a clean claim and must be paid by the
13 pharmacy benefits manager.

14 H. Payment of a clean claim under this subsection is considered to have been made
15 on the date on which the payment is transferred with respect to claims paid
16 electronically and on the date on which the payment is submitted to the United States
17 Postal Service or a common carrier for delivery with respect to claims paid otherwise.

18 I. A pharmacy benefits manager shall pay all clean claims submitted electronically
19 by electronic transfer of funds if the pharmacy so requests or has so requested
20 previously.

21 J. Beginning October 1, 2015, the bureau shall adopt rules that outline the collection
22 procedures for the outstanding interest from claims under paragraph A. The bureau
23 shall also adopt rules that transfer the remaining interest to the General Fund.

24 **3. Exception.** This section does not apply to any medical assistance or public health
25 programs administered by the Department of Health and Human Services, including, but
26 not limited to, the Medicaid program and the elderly low-cost drug program under Title
27 22, section 254-D.

28 **4. Adjustment of payments.** Within 24 hours of a price increase notification by a
29 pharmaceutical manufacturer or supplier, a pharmacy benefits manager shall adjust its
30 payments to pharmacists or pharmacies consistent with the price increase.

31 **5. Retroactive denial of claims prohibited.** A claim paid by a pharmacy benefits
32 manager may not be retroactively denied or adjusted after 7 days from payment of the
33 claim except as provided in subsection 6. In no case may an acknowledgement of
34 eligibility be retroactively reversed.

35 **6. Retroactive denial or adjustment allowed.** A pharmacy benefits manager may
36 retroactively deny or adjust a claim if:

37 A. The original claim was submitted fraudulently;

38 B. The original claim payment was incorrect because the pharmacist or pharmacy
39 was already paid for services rendered; or

40 C. The services were not rendered by the pharmacist or pharmacy.

1 **7. Audits.** A pharmacy benefits manager's books and records relating to rebates and
2 other information must be made available for audit by a covered entity or its agent. The
3 auditor shall comply with the following requirements.

4 A. A finding of overpayment or underpayment must be based on the actual
5 overpayment or underpayment and not a projection based on the number of patients
6 served having a similar diagnosis or on the number of similar orders or refills for
7 similar drugs.

8 B. Calculations of overpayments may not include dispensing fees.

9 C. The auditor may not use extrapolation in calculating recoupments or penalties.

10 D. The auditor may not receive payment based on a percentage of the amount
11 recovered.

12 E. Interest may not accrue during the audit period.

13 F. To the extent that an audit results in the identification of any clerical or record-
14 keeping errors in a document or record required by the auditor, the pharmacy is not
15 subject to recoupment of funds by the pharmacy benefits manager unless the
16 pharmacy benefits manager can provide proof of intent to commit fraud or such error
17 results in actual financial harm to the pharmacy benefits manager, a covered entity or
18 a covered individual.

19 **8. Audit information and reports.** A preliminary audit report must be delivered to
20 the pharmacy within 60 days after the conclusion of the audit under subsection 7. A
21 pharmacy must be allowed at least 30 days following receipt of the preliminary audit to
22 provide documentation to address any discrepancy found in the audit. A final audit report
23 must be delivered to the pharmacy within 90 days after receipt of the preliminary audit
24 report or final appeal, whichever is later. A charge-back, recoupment or other penalty
25 may not be assessed until the appeal process established by the bureau by rule has been
26 exhausted and the final report issued. Except as provided by state or federal law, audit
27 information may not be shared. Auditors may have access only to previous audit reports
28 on a particular pharmacy conducted by that same entity.

29 **§13850-B. Disclosures to covered persons; authorization for substitutions**

30 **1. Written notice to covered persons.** When the services of a pharmacy benefits
31 manager are used, the pharmacy benefits manager shall provide a written notice approved
32 by the insurer to a covered individual advising the individual of the identity of and
33 relationship between the pharmacy benefits manager, the insurer and the covered
34 individual.

35 **2. Notice requirements.** The notice under subsection 1 must contain a statement
36 advising the covered individual that the pharmacy benefits manager is regulated by the
37 bureau and that the individual has the right to file a complaint, appeal or grievance with
38 the bureau concerning the pharmacy benefits manager. The notice must include the toll-
39 free telephone number, mailing address and e-mail address of the bureau. The notice
40 must be written in plain English, understandable by the average citizen, and a copy must
41 be provided to the bureau and to each pharmacist and pharmacy participating in the
42 network.

1 **3. Substitute prescription.** When a pharmacy benefits manager requests a
2 substitute prescription for a prescribed drug for a covered individual, the following
3 provisions apply.

4 A. The pharmacy benefits manager may substitute a lower-priced generic and
5 therapeutically equivalent drug for a higher-priced prescribed drug.

6 B. With regard to substitutions in which the substitute drug costs more than the
7 prescribed drug, the substitution must be made for medical reasons that benefit the
8 covered individual. To make a substitution under this paragraph, the pharmacy
9 benefits manager shall obtain the approval of the prescribing health professional or
10 that person's authorized representative after disclosing to the covered individual the
11 cost of both drugs and any benefit or payment directly or indirectly accruing to the
12 pharmacy benefits manager as a result of the substitution and any potential effects on
13 a patient's health and safety, including side effects.

14 C. The pharmacy benefits manager shall transfer in full to the covered entity or the
15 covered individual any benefit or payment received in any form by the pharmacy
16 benefits manager as a result of a prescription drug substitution under paragraph A or
17 B.

18 **§13850-C. Complaints**

19 1. Adoption of procedures. The bureau shall adopt procedures for formal
20 investigations of complaints concerning the failure of a pharmacy benefits manager to
21 comply with this subchapter.

22 2. Transfer of complaints. The bureau shall refer a complaint received under this
23 subchapter to the board if the complaint involves a pharmacy professional or patient
24 health or safety issue.

25 **§13850-D. Responsibilities to the covered entity**

26 1. Disclosure of arrangements. A pharmacy benefits manager shall disclose to the
27 covered entity all financial terms and arrangements for remuneration of any kind that
28 apply between the pharmacy benefits manager and any manufacturer or labeler,
29 including, but not limited to, rebates, formulary management and drug substitution
30 programs, educational support, claims processing and pharmacy network fees and data
31 sales fees.

32 2. Price differentials. A pharmacy benefits manager shall disclose to a covered
33 entity whether there is a difference between the amount paid to the retail pharmacy and
34 the amount billed to the covered entity for a purchase.

35 3. Audits. The covered entity may audit the pharmacy benefits manager's books and
36 records related to the rebates or other information provided in subsections 1 and 2.

37 4. Good faith. A pharmacy benefits manager shall perform its duties exercising
38 good faith and fair dealing toward the covered entity and covered individual.

