

MAINE STATE LEGISLATURE

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121st MAINE LEGISLATURE

FIRST REGULAR SESSION-2003

Legislative Document

No. 554

S.P. 194

In Senate, February 6, 2003

An Act To Protect Against Unfair Prescription Drug Practices

Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Joy J. O'Brien".

JOY J. O'BRIEN
Secretary of the Senate

Presented by Senator TREAT of Kennebec.
Cosponsored by Representative LEMOINE of Old Orchard Beach and
Senators: HALL of Lincoln, HATCH of Somerset, LaFOUNTAIN of York, MAYO of
Sagadahoc, STANLEY of Penobscot, Representatives: CANAVAN of Waterville, KANE of
Saco, O'NEIL of Saco.

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

4 Sec. 1. 22 MRSA c. 603, sub-c. 4 is enacted to read:

6 **SUBCHAPTER 4**

8 **PRESCRIPTION DRUG PRACTICES**

10 **§2699. Prescription drug practices**

12 Pharmacy benefits managers shall and contracts for pharmacy
14 benefits management must comply with the requirements of this
16 section.

18 I. Definitions. As used in this chapter, unless the
20 context otherwise indicates, the following terms have the
22 following meanings.

24 A. "Covered entity" means a nonprofit hospital or medical
26 service organization, insurer, health coverage plan or
28 health maintenance organization licensed pursuant to Title
30 24 or 24-A; a health program administered by the department
32 or the State in the capacity of provider of health coverage;
34 or an employer, labor union or other group of persons
36 organized in the State that provides health coverage to
38 covered individuals who are employed or reside in the
40 State. "Covered entity" does not include a health plan that
42 provides coverage only for accidental injury, specified
44 disease, hospital indemnity, Medicare supplement, disability
46 income or other long-term care.

48 B. "Covered individual" means a member, participant,
50 enrollee, contract holder or policy holder or beneficiary of
a covered entity who is provided health coverage by the
covered entity. "Covered individual" includes a dependent
or other person provided health coverage through a policy,
contract or plan for a covered individual.

C. "ERISA" means the Employee Retirement Income Security
Act of 1974, 29 United States Code, Sections 1001 to 1461
(1988).

D. "Generic drug" means a chemically equivalent copy of a
brand-name drug with an expired patent.

E. "Labeler" means an entity or person that receives
prescription drugs from a manufacturer or wholesaler and
repackages those drugs for later retail sale and that has a
labeler code from the federal Food and Drug Administration
under 21 Code of Federal Regulations, 270.20 (1999).

2 F. "Pharmacy benefits management" means the procurement of
4 prescription drugs at a negotiated rate for dispensation
6 within this State to covered individuals, the administration
8 or management of prescription drug benefits provided by a
covered entity for the benefit of covered individuals or any
of the following services provided with regard to the
administration of pharmacy benefits:

10 (1) Mail service pharmacy;

12 (2) Claims processing, retail network management and
14 payment of claims to pharmacies for prescription drugs
dispensed to covered individuals;

16 (3) Clinical management formulary development and
18 management services;

20 (4) Rebate contracting and administration;

22 (5) Certain patient compliance, therapeutic
intervention and generic substitution programs; and

24 (6) Disease management programs.

26 G. "Pharmacy benefits manager" means an entity that
28 performs pharmacy benefits management. "Pharmacy benefits
30 manager" includes a person or entity acting for a pharmacy
benefits manager in a contractual or employment relationship
in the performance of pharmacy benefits management for a
covered entity and includes mail service pharmacy.

32 **2. Required practices.** A pharmacy benefits manager owes a
34 fiduciary duty to a covered entity and covered individuals and
shall discharge that duty in accordance with the provisions of
36 ERISA, state and federal law and this section.

38 A. A pharmacy benefits manager shall perform its duties
40 with care, skill, prudence and diligence and in accordance
with the standards of conduct applicable to a fiduciary in
42 an enterprise of a like character and with like aims.

44 B. A pharmacy benefits manager shall discharge its duties
with respect to the covered entity and covered individuals
solely in the interests of the covered individuals and for
46 the primary purpose of providing benefits to covered
individuals and defraying reasonable expenses of
48 administering health plans.

50 C. A pharmacy benefits manager shall notify the covered

2 entity in writing of any activity, policy or practice of the
3 pharmacy benefits manager that directly or indirectly
4 presents any conflict of interest with the duties imposed by
5 this subsection.

6 D. A pharmacy benefits manager shall provide to a covered
7 entity all financial and utilization information requested
8 by the covered entity relating to the provision of benefits
9 to covered individuals through that covered entity and all
10 financial and utilization information relating to services
11 to that covered entity. A pharmacy benefits manager
12 providing information under this paragraph may designate
13 that material as confidential. Information designated as
14 confidential by a pharmacy benefits manager and provided to
15 a covered entity under this paragraph may not be disclosed
16 to any person without the consent of the pharmacy benefits
17 manager, except that disclosure may be made in a court
18 filing under the Maine Unfair Trade Practices Act or when
19 authorized by that Act or ordered by a court of this State
20 for good cause shown.

21 E. With regard to the dispensation of a substitute
22 prescription drug for a prescribed drug to a covered
23 individual the following provisions apply.

24
25 (1) The pharmacy benefits manager may substitute a
26 lower-priced generic drug for a higher-priced
27 prescribed drug.

28
29 (2) The pharmacy benefits manager may not substitute a
30 higher-priced generic drug for a lower-priced
31 prescribed drug.

32
33 (3) The pharmacy benefits manager shall consult with
34 the prescribing health professional or that person's
35 authorized representative and shall:

36
37 (a) Disclose the costs of both drugs to the
38 covered individual and the covered entity and any
39 benefit or payment directly or indirectly accruing
40 to the pharmacy benefits manager as a result of
41 the substitution; and

42
43 (b) Obtain the approval of the prescribing health
44 professional or that person's authorized
45 representative for the substitution.

46
47 (4) The pharmacy benefits manager shall transfer in
48 full to the covered entity or covered individuals any
49 benefit or payment received in any form by the pharmacy
50

2 benefits manager as a result of the prescription drug
3 substitution.

4 F. A pharmacy benefits manager that derives any payment or
5 benefit for the dispensation of prescription drugs within
6 the State based on volume of sales for certain prescription
7 drugs or classes or brands of drugs within the State shall
8 pass that payment or benefit on in full to the covered
9 entity or covered individuals.

10 G. A pharmacy benefits manager shall disclose to the
11 covered entity all financial terms and arrangements for
12 remuneration of any kind that apply between the pharmacy
13 benefits manager and any prescription drug manufacturer or
14 labeler, including, without limitation, formulary management
15 and drug-switch programs, educational support, claims
16 processing and pharmacy network fees that are charged from
17 retail pharmacies and data sales fees.

18 3. Prohibition. A pharmacy benefits manager may not in a
19 contract with a covered entity or a prescription drug
20 manufacturer or labeler accept or agree to an obligation that is
21 inconsistent with the fiduciary duties imposed by subsection 2,
22 ERISA or other state or federal law.

23 4. Waiver prohibited. Any agreement to waive the
24 provisions of this section is against public policy and void.

25 5. Enforcement. A violation of this section is a violation
26 of the Maine Unfair Trade Practices Act. Compliance with this
27 section may be enforced through private action or action by the
28 Attorney General.

29 A. A covered entity, covered individual or other person
30 injured as a result of a violation of this section is
31 eligible to bring a private action as a person pursuant to
32 the Unfair Trade Practices Act.

33 B. An action by the Attorney General pursuant to this
34 subsection is subject to the provisions of this paragraph
35 and the Maine Unfair Trade Practices Act. Each violation of
36 this section is a civil violation for which the Attorney
37 General may obtain, in addition to other remedies,
38 injunctive relief and a fine in an amount not to exceed
39 \$10,000 per violation, plus the costs of suit, including
40 necessary and reasonable investigative costs, reasonable
41 expert fees and reasonable attorney's fees.

42

2

SUMMARY

4 This bill specifies the fiduciary duties of pharmacy
benefits managers and the obligation to serve the covered
6 entities with whom they contract and the covered individuals
provided health care benefits by the covered entities. The bill
8 prohibits contractual terms that are inconsistent with the
pharmacy benefits manager's fiduciary duties. The bill requires
10 payment to a pharmacy benefits manager based on volume of certain
drugs or as a result of substitution of drugs to be passed on to
12 the covered entity or covered individuals. The bill requires
disclosure of financial terms that apply between a pharmacy
14 benefits manager and a manufacturer or labeler. The bill
requires consultation with and agreement of the prescribing
16 health professional or a representative of that professional
before a pharmacy benefits manager may switch a prescription drug
18 to be dispensed to a covered individual. The bill prohibits
agreements to waive provisions of the law. Violations of the law
20 are violations of the Maine Unfair Trade Practices Act and are
enforceable by private action or the Attorney General.