

State of South Dakota

SEVENTY-NINTH SESSION
LEGISLATIVE ASSEMBLY, 2004

400J0774

HOUSE ENGROSSED NO. **HB 1311** - 02/12/2004

This bill has been extensively amended (hoghoused) and may no longer be consistent with the original intention of the sponsor.

Introduced by: The Committee on State Affairs at the request of the Governor

1 FOR AN ACT ENTITLED, An Act to provide for the regulation of pharmacy benefits
2 management.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

4 Section 1. Terms used in this Act mean:

5 (1) "Covered entity," a nonprofit hospital or medical service corporation, health insurer,
6 health benefit plan, or health maintenance organization; a health program
7 administered by a department or the state in the capacity of provider of health
8 coverage; or an employer, labor union, or other group of persons organized in the
9 state that provides health coverage to covered individuals who are employed or reside
10 in the state. The term does not include a self-funded plan that is exempt from state
11 regulation pursuant to ERISA, a plan issued for coverage for federal employees, or
12 a health plan that provides coverage only for accidental injury, specified disease,
13 hospital indemnity, medicare supplement, disability income, long- term care, or other
14 limited benefit health insurance policies and contracts;

15 (2) "Covered individual," a member, participant, enrollee, contract holder, policy holder,



1 or beneficiary of a covered entity who is provided health coverage by the covered
2 entity. The term includes a dependent or other person provided health coverage
3 through a policy, contract, or plan for a covered individual;

4 (3) "Director," the director of the Division of Insurance;

5 (4) "Generic drug," a chemically equivalent copy of a brand-name drug with an expired
6 patent;

7 (5) "Labeler," an entity or person that receives prescription drugs from a manufacturer
8 or wholesaler and repackages those drugs for later retail sale and that has a labeler
9 code from the federal Food and Drug Administration under 21 C.F.R. § 270.20
10 (1999);

11 (6) "Pharmacy benefits management," the procurement of prescription drugs at a
12 negotiated rate for dispensation within this state to covered individuals, the
13 administration or management of prescription drug benefits provided by a covered
14 entity for the benefit of covered individuals, or any of the following services provided
15 with regard to the administration of the following pharmacy benefits:

16 (a) Mail service pharmacy;

17 (b) Claims processing, retail network management, and payment of claims to
18 pharmacies for prescription drugs dispensed to covered individuals;

19 (c) Clinical formulary development and management services;

20 (d) Rebate contracting and administration;

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

23 (f) Disease management programs involving prescription drug utilization;

24 (7) "Pharmacy benefits manager," an entity that performs pharmacy benefits

1 management. The term includes a person or entity acting for a pharmacy benefits
2 manager in a contractual or employment relationship in the performance of pharmacy
3 benefits management for a covered entity and includes mail service pharmacy. The
4 term does not include a health carrier licensed pursuant to Title 58 when the health
5 carrier or its subsidiary is providing pharmacy benefits management to its own
6 insureds; or a public self-funded pool or a private single employer self-funded plan
7 that provides such benefits or services directly to its beneficiaries;

8 (8) "Proprietary information," information on pricing, costs, revenue, taxes, market
9 share, negotiating strategies, customers, and personnel held by private entities and
10 used for that private entity's business purposes;

11 (9) "Trade secret," information, including a formula, pattern, compilation, program,
12 device, method, technique, or process, that:

13 (a) Derives independent economic value, actual or potential, from not being
14 generally known to, and not being readily ascertainable by proper means by,
15 other persons who can obtain economic value from its disclosure or use; and

16 (b) Is the subject of efforts that are reasonable under the circumstances to
17 maintain its secrecy.

18 Section 2. No person or entity may perform or act as a pharmacy benefits manager in this
19 state without a valid license to operate as a third party administrator pursuant to chapter 58-29D.

20 Section 3. Each pharmacy benefits manager shall perform its duties exercising good faith
21 and fair dealing toward the covered entity.

22 Section 4. A covered entity may request that any pharmacy benefits manager with which it
23 has a pharmacy benefits management services contract disclose to the covered entity, the
24 amount of all rebate revenues and the nature, type, and amounts of all other revenues that the

1 pharmacy benefits manager receives from each pharmaceutical manufacturer or labeler with
2 whom the pharmacy benefits manager has a contract. The pharmacy benefits manager shall
3 disclose in writing:

4 (1) The aggregate amount, and for a list of drugs to be specified in the contract, the
5 specific amount, of all rebates and other retrospective utilization discounts received
6 by the pharmacy benefits manager directly or indirectly, from each pharmaceutical
7 manufacturer or labeler that are earned in connection with the dispensing of
8 prescription drugs to covered individuals of the health benefit plans issued by the
9 covered entity or for which the covered entity is the designated administrator;

10 (2) The nature, type, and amount of all other revenue received by the pharmacy benefits
11 manager directly or indirectly from each pharmaceutical manufacturer or labeler for
12 any other products or services provided to the pharmaceutical manufacturer or labeler
13 by the pharmacy benefits manager with respect to programs that the covered entity
14 offers or provides to its enrollees; and

15 (3) Any prescription drug utilization information requested by the covered entity relating
16 to covered individuals.

17 A pharmacy benefits manager shall provide such information requested by the covered entity
18 for such disclosure within thirty days of receipt of the request. If requested, the information shall
19 be provided no less than once each year. The contract entered into between the pharmacy
20 benefits manager and the covered entity shall set forth any fees to be charged for drug utilization
21 reports requested by the covered entity.

22 Section 5. A pharmacy benefits manager, unless authorized pursuant to the terms of its
23 contract with a covered entity, may not contact any covered individual without express written
24 permission of the covered entity.

1 Section 6. Except for utilization information, a covered entity shall maintain any information
2 disclosed in response to a request pursuant to section 4 of this Act as confidential and
3 proprietary information, and may not use such information for any other purpose or disclose
4 such information to any other person except as provided in this Act or in the pharmacy benefits
5 management services contract between the parties. Any covered entity who discloses
6 information in violation of this section is subject to an action for injunctive relief and is liable
7 for any damages which are the direct and proximate result of such disclosure. Nothing in this
8 section prohibits a covered entity from disclosing confidential or proprietary information to the
9 director, upon request. Any such information obtained by the director is confidential and
10 privileged and is not open to public inspection or disclosure.

11 Section 7. The covered entity may have the pharmacy benefits manager's books and records
12 related to the rebates or other information described in subdivisions (1), (2), and (3) of section
13 4 of this Act, to the extent the information relates directly or indirectly to such covered entity's
14 contract, audited in accordance with the terms of the pharmacy benefits management services
15 contract between the parties. However, if the parties have not expressly provided for audit rights
16 and the pharmacy benefits manger has advised the covered entity that other reasonable options
17 are available and subject to negotiation, the covered entity may have such books and records
18 audited as follows:

- 19 (1) Such audits may be conducted no more frequently than once in each twelve-month
20 period upon not less than thirty business days' written notice to the pharmacy benefits
21 manager;
- 22 (2) The covered entity may select an independent firm to conduct such audit, and such
23 independent firm shall sign a confidentiality agreement with the covered entity and
24 the pharmacy benefits manager ensuring that all information obtained during such

1 audit will be treated as confidential. The firm may not use, disclose, or otherwise
2 reveal any such information in any manner or form to any person or entity except as
3 otherwise permitted under the confidentiality agreement. The covered entity shall
4 treat all information obtained as a result of the audit as confidential, and may not use
5 or disclose such information except as may be otherwise permitted under the terms
6 of the contract between the covered entity and the pharmacy benefits manager or if
7 ordered by a court of competent jurisdiction for good cause shown;

8 (3) Any such audit shall be conducted at the pharmacy benefits manager's office where
9 such records are located, during normal business hours, without undue interference
10 with the pharmacy benefits manager's business activities, and in accordance with
11 reasonable audit procedures.

12 Section 8. With regard to the dispensation of a substitute prescription drug for a prescribed
13 drug to a covered individual, when the pharmacy benefits manager requests a substitution, the
14 following provisions apply:

15 (1) The pharmacy benefits manager may request the substitution of a lower-priced
16 generic and therapeutically equivalent drug for a higher-priced prescribed drug;

17 (2) With regard to substitutions in which the substitute drug's net cost is more for the
18 covered individual or the covered entity than the prescribed drug, the substitution
19 must be made only for medical reasons that benefit the covered individual. If a
20 substitution is being requested pursuant to this subdivision, the pharmacy benefits
21 manager shall obtain the approval of the prescribing health professional.

22 Section 9. The Division of Insurance shall promulgate rules, pursuant to chapter 1-26, to
23 carry out the issuance of the license required by section 2 of this Act and the enforcement
24 provisions of this Act. The rules may include the following:

- 1 (1) Definition of terms;
- 2 (2) Use of prescribed forms;
- 3 (3) Reporting requirements;
- 4 (4) Enforcement procedures; and
- 5 (5) Protection of proprietary information and trade secrets.

6 Section 10. Any covered entity may bring a civil action to enforce the provisions of this Act
7 or to seek civil damages for the violation of its provisions.

8 Section 11. The provisions of this Act apply only to pharmacy benefits management services
9 contracts entered into or renewed after June 30, 2004.