

COMMITTEE ON REGULATORY AFFAIRS
HOUSE OF REPRESENTATIVES AMENDMENTS TO S.B. 1164
(Reference to Senate engrossed bill)

- 1 Page 1, line 3, strike "section" insert "sections"; after "20-3335" insert
2 "and 20-3336"
- 3 Line 4, strike "coverage"
- 4 Line 5, strike "exemption determination process" insert "formulary change;
5 notice; exemption"
- 6 Line 6, strike "applicability;"
- 7 Line 18, strike "INSURER" insert "PLAN"
- 8 Line 22, after "INDIVIDUAL'S" insert "HEALTH CARE"
- 9 Strike lines 23 through 38, insert:
10 "B. A PHARMACY BENEFIT MANAGER OR HEALTH CARE INSURER MAY NOT CHANGE
11 A COVERED INDIVIDUAL FROM THE PREVIOUSLY COVERED PRESCRIPTION DRUG IF THE
12 COVERED INDIVIDUAL'S PRESCRIBING HEALTH CARE PROVIDER PROVIDES ELECTRONIC
13 OR WRITTEN NOTICE TO THE PHARMACY BENEFIT MANAGER OR HEALTH CARE INSURER
14 NOTIFYING THE PHARMACY BENEFIT MANAGER OR HEALTH CARE INSURER THAT IT WILL
15 CONTINUE ON THE CURRENT PRESCRIPTION DRUG."
- 16 Line 40, strike "DURING A PLAN YEAR" insert "THAT LIMITS OR EXCLUDES COVERAGE
17 OF A PRESCRIPTION DRUG"
- 18 Line 41, after "PROVIDE" insert "ELECTRONIC OR"; strike "FORMULARY" insert
19 "REMOVAL OF OR"
- 20 Page 2, line 1, after "CHANGE" insert a period strike remainder of line
21 Strike lines 2 through 12
- 22 Line 13, strike "APPROVE A CHANGE IN THE PRESCRIPTION DRUG." insert:
23 "D."
- 24 Line 14, strike "REQUEST"

1 Page 2, line 15, strike "A PRESCRIPTION DRUG COVERAGE EXEMPTION" insert "NOTIFY
2 THE PHARMACY BENEFIT MANAGER OR HEALTH CARE INSURER"

3 Strike lines 16 through 43

4 Strike page 3

5 Page 4, strike lines 1 through 10, insert "NONFORMULARY PRESCRIPTION DRUGS. THE
6 NOTICE SHALL ALSO INCLUDE NOTIFICATION TO THE PRESCRIBING HEALTH CARE
7 PROVIDER THAT IF THE HEALTH CARE PROVIDER NOTIFIES THE PHARMACY BENEFIT
8 MANAGER OR HEALTH CARE INSURER THAT THE ENROLLEE WILL CONTINUE ON THE
9 NONFORMULARY PRESCRIPTION DRUG FOR THE REMAINDER OF THE HEALTH CARE PLAN
10 YEAR, THE PROVIDER WILL NEED TO APPLY FOR A FORMULARY EXCEPTION PURSUANT TO
11 SECTION 20-3336 FOR THE CONTINUED USE OF THE NONFORMULARY PRESCRIPTION DRUG
12 ON RENEWAL OF THE HEALTH CARE PLAN.

13 E. THIS SECTION DOES NOT:

14 1. PREVENT A HEALTH CARE PROVIDER FROM PRESCRIBING ANOTHER
15 PRESCRIPTION DRUG COVERED BY THE HEALTH CARE INSURER OF THE PHARMACY
16 BENEFIT MANAGER IF THE HEALTH CARE PROVIDER DEEMS THE PRESCRIPTION DRUG
17 MEDICALLY NECESSARY FOR THE COVERED INDIVIDUAL.

18 2. PREVENT A HEALTH CARE INSURER OR PHARMACY BENEFIT MANAGER
19 CONTRACTED TO PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES FROM:

20 (a) ADDING A PRESCRIPTION DRUG TO ITS FORMULARY.

21 (b) REMOVING A PRESCRIPTION DRUG FROM ITS FORMULARY IF THE DRUG
22 MANUFACTURER HAS REMOVED THE PRESCRIPTION DRUG FOR SALE IN THE UNITED
23 STATES.

24 (c) MAKING ANY FORMULARY CHANGES FOR PATIENTS WHO ARE NOT ON A
25 PREVIOUSLY APPROVED PRESCRIPTION DRUG.

26 F. IF A HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
27 REVIEW AGENT THAT IS CONTRACTED TO PROVIDE PHARMACY BENEFIT MANAGEMENT
28 SERVICES VIOLATES THIS SECTION, THE DIRECTOR MAY ENFORCE THIS SECTION
29 PURSUANT TO SECTION 20-3333.

30 G. FOR THE PURPOSES OF THIS SECTION:

31 1. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION
32 20-2501.

- 1 2. "LIMIT OR EXCLUDE COVERAGE" MEANS TO:
- 2 (a) LIMIT OR REDUCE THE MAXIMUM COVERAGE OF PRESCRIPTION DRUG
- 3 BENEFITS.
- 4 (b) INCREASE COST SHARING FOR A COVERED PRESCRIPTION DRUG.
- 5 (c) MOVE A PRESCRIPTION DRUG TO A MORE RESTRICTIVE FORMULARY TIER.
- 6 (d) REMOVE A PRESCRIPTION DRUG FROM A FORMULARY UNLESS EITHER OF THE
- 7 FOLLOWING APPLIES:
- 8 (i) THE UNITED STATES FOOD AND DRUG ADMINISTRATION REVOKES APPROVAL
- 9 FOR OR REMOVES A PRESCRIPTION DRUG FROM THE PRESCRIPTION DRUG MARKET.
- 10 (ii) THE PRESCRIPTION DRUG MANUFACTURER NOTIFIES THE UNITED STATES
- 11 FOOD AND DRUG ADMINISTRATION OF A MANUFACTURING DISCONTINUATION OR A
- 12 POTENTIAL DISCONTINUATION AS REQUIRED BY SECTION 506C OF THE FEDERAL FOOD,
- 13 DRUG, AND COSMETIC ACT (21 UNITED STATES CODE SECTION 356c).
- 14 3. "UTILIZATION REVIEW AGENT" HAS THE SAME MEANING PRESCRIBED IN
- 15 SECTION 20-2530.
- 16 20-3336. Pharmacy benefit managers; prescribing; formulary
- 17 exception process requirements; exception;
- 18 enforcement; definitions
- 19 A. ON RENEWAL OF A HEALTH CARE PLAN, A HEALTH CARE INSURER, PHARMACY
- 20 BENEFIT MANAGER OR UTILIZATION REVIEW AGENT THAT IS CONTRACTED TO PROVIDE
- 21 PHARMACY BENEFIT MANAGEMENT SERVICES FOR THE HEALTH CARE INSURER SHALL
- 22 PROVIDE A COVERED INDIVIDUAL AND PRESCRIBING HEALTH CARE PROVIDER WITH
- 23 ACCESS TO A CLEAR AND CONVENIENT PROCESS TO REQUEST A FORMULARY EXCEPTION
- 24 PROCESS. THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
- 25 REVIEW AGENT MAY USE ITS EXISTING FORMULARY EXCEPTION PROCESS TO SATISFY
- 26 THIS REQUIREMENT IF THE MEDICAL EXCEPTIONS PROCESS IS CONSISTENT WITH THE
- 27 REQUIREMENTS PRESCRIBED IN THIS SECTION.
- 28 B. A HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
- 29 REVIEW AGENT SHALL FOLLOW THE PROCESS AND RESPOND TO A FORMULARY EXCEPTION
- 30 DETERMINATION REQUEST IN ACCORDANCE WITH 45 CODE OF FEDERAL REGULATIONS
- 31 SECTION 156.122.

1 C. FOR A COVERED INDIVIDUAL RENEWING THE SAME HEALTH CARE PLAN, A
2 HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT
3 SHALL APPROVE A FORMULARY EXCEPTION FOR A COVERED INDIVIDUAL WHO HAS BEEN
4 PREVIOUSLY APPROVED TO RECEIVE THE NONFORMULARY PRESCRIPTION DRUG UNDER THE
5 SAME HEALTH CARE PLAN IF THE PRESCRIBING HEALTH CARE PROVIDER USES THE
6 FORMULARY EXCEPTION PROCESS AND PROVIDES RELEVANT CLINICAL DOCUMENTATION TO
7 CERTIFY ALL OF THE FOLLOWING:

8 1. THE COVERED INDIVIDUAL HAS TRIED A FORMULARY EQUIVALENT
9 PRESCRIPTION DRUG THAT WAS A PART OF THE COVERED INDIVIDUAL'S PRESCRIPTION
10 DRUG BENEFIT AT THE TIME OF THE TRIAL, THE FORMULARY EQUIVALENT
11 PRESCRIPTION DRUG WAS NOT EFFECTIVE IN THE TREATMENT OF THE COVERED
12 INDIVIDUAL'S MEDICAL CONDITION AND THE HEALTH CARE PROVIDER SPECIFIES THE
13 CONTRAINDICATION OR ADVERSE OR HARMFUL REACTION IN THE COVERED INDIVIDUAL.

14 2. THE COVERED INDIVIDUAL HAS EXPERIENCED A POSITIVE THERAPEUTIC
15 OUTCOME ON THE REQUESTED DRUG FOR MORE THAN NINETY DAYS.

16 3. FORMULARY EQUIVALENT PRESCRIPTION DRUGS ARE CONTRAINDICATED OR
17 WILL LIKELY CAUSE A SERIOUS ADVERSE REACTION.

18 D. IF A COVERED INDIVIDUAL DOES NOT QUALIFY FOR A FORMULARY
19 EXCEPTION PURSUANT TO SUBSECTION C OF THIS SECTION, THE COVERED INDIVIDUAL
20 MAY STILL APPLY FOR A FORMULARY EXCEPTION USING THE HEALTH CARE INSURER'S,
21 PHARMACY BENEFIT MANAGER'S OR UTILIZATION REVIEW AGENT'S FORMULARY
22 EXCEPTION PROCESS. WHEN EVALUATING WHETHER THE COVERED INDIVIDUAL SHOULD
23 QUALIFY FOR A FORMULARY EXCEPTION TO CONTINUE ON A NONFORMULARY
24 PRESCRIPTION DRUG, THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR
25 UTILIZATION AGENT SHALL CONSIDER THE FOLLOWING FACTORS:

26 1. WHETHER THE COVERED INDIVIDUAL HAS EXPERIENCED A POSITIVE
27 THERAPEUTIC OUTCOME ON THE PREVIOUSLY APPROVED DRUG.

28 2. WHETHER THE FORMULARY PRESCRIPTION DRUG IS NOT IN THE BEST
29 INTEREST OF THE COVERED INDIVIDUAL BASED ON MEDICAL NECESSITY BECAUSE THE
30 COVERED INDIVIDUAL'S USE OF THE FORMULARY PRESCRIPTION DRUG IS EXPECTED TO
31 CAUSE EITHER OF THE FOLLOWING:

1 (a) A NEGATIVE IMPACT ON THE COVERED INDIVIDUAL'S COMORBID
2 CONDITION.

3 (b) A CLINICALLY PREDICTABLE NEGATIVE DRUG INTERACTION.

4 3. WHETHER THE FORMULARY PRESCRIPTION DRUG IS CONTRAINDICATED OR
5 WILL LIKELY CAUSE A SERIOUS ADVERSE REACTION.

6 E. DENIAL OF COVERAGE FOR A HEALTH CARE INSURER'S OR PHARMACY
7 BENEFIT MANAGER'S DENIAL OF COVERAGE FOR A NONFORMULARY PRESCRIPTION DRUG
8 SHALL BE MADE IN WRITING BY A LICENSED PHARMACIST OR MEDICAL DIRECTOR. THE
9 WRITTEN DENIAL SHALL CONTAIN AN EXPLANATION OF THE DENIAL THAT INCLUDES THE
10 MEDICAL OR PHARMACOLOGICAL REASONS WHY THE AUTHORIZATION WAS DENIED AND A
11 SIGNATURE BY THE LICENSED PHARMACIST OR MEDICAL DIRECTOR WHO MADE THE
12 DECISION TO DENY COVERAGE. THE HEALTH CARE INSURER, PHARMACY BENEFIT
13 MANAGER OR UTILIZATION REVIEW AGENT SHALL SEND A COPY OF THE WRITTEN DENIAL
14 TO THE COVERED INDIVIDUAL'S TREATING HEALTH CARE PROVIDER WHO REQUESTED THE
15 FORMULARY EXCEPTION. THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR
16 UTILIZATION REVIEW AGENT SHALL MAINTAIN COPIES OF ALL WRITTEN DENIALS AND
17 SHALL MAKE THE COPIES AVAILABLE TO THE DEPARTMENT FOR INSPECTION. A
18 COVERED INDIVIDUAL OR THE COVERED INDIVIDUAL'S AUTHORIZED REPRESENTATIVE
19 MAY APPEAL ANY DETERMINATION TO DENY A FORMULARY EXCEPTION UNDER CHAPTER
20 15, ARTICLE 2 OF THIS TITLE. THE WRITTEN NOTIFICATION SHALL INCLUDE THE
21 PROCESS IN WHICH A COVERED INDIVIDUAL MAY APPEAL THE DETERMINATION.

22 F. IF THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR
23 UTILIZATION REVIEW AGENT AUTHORIZES A FORMULARY EXCEPTION FOR A COVERED
24 INDIVIDUAL PURSUANT TO THIS SECTION, THAT AUTHORIZATION SHALL BE IN EFFECT
25 UNTIL THE END OF THE COVERED INDIVIDUAL'S PLAN YEAR. THE APPROVAL OF A
26 FORMULARY EXCEPTION SHALL BE IN WRITING AND DELIVERED TO THE COVERED
27 INDIVIDUAL AND THE COVERED INDIVIDUAL'S TREATING HEALTH CARE PROVIDER.

28 G. THIS SECTION DOES NOT:

29 1. PREVENT A HEALTH CARE PROVIDER FROM PRESCRIBING ANOTHER
30 PRESCRIPTION DRUG COVERED BY THE HEALTH CARE INSURER OR THE PHARMACY
31 BENEFIT MANAGER IF THE HEALTH CARE PROVIDER DEEMS THE PRESCRIPTION DRUG
32 MEDICALLY NECESSARY FOR THE COVERED INDIVIDUAL.

1 2. PREVENT A HEALTH CARE INSURER OR PHARMACY BENEFIT MANAGER
2 CONTRACTED TO PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES FROM:

3 (a) ADDING A PRESCRIPTION DRUG TO ITS FORMULARY.

4 (b) REMOVING A PRESCRIPTION DRUG FROM ITS FORMULARY IF THE DRUG
5 MANUFACTURER HAS REMOVED THE PRESCRIPTION DRUG FOR SALE IN THE UNITED
6 STATES.

7 (c) SETTING THE COST SHARING FOR NONFORMULARY PRESCRIPTION DRUGS.

8 H. IF A HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
9 REVIEW AGENT THAT IS CONTRACTED TO PROVIDE PHARMACY BENEFIT MANAGEMENT
10 SERVICES VIOLATES THIS SECTION, THE DIRECTOR MAY ENFORCE THIS SECTION
11 PURSUANT TO SECTION 20-3333.

12 I. A POLICY THAT IS ISSUED OR RENEWED BY A DISABILITY INSURER DOES
13 NOT INCLUDE A POLICY THAT PROVIDES LIMITED BENEFIT COVERAGE AS DEFINED IN
14 SECTION 20-1137.

15 J. FOR THE PURPOSES OF THIS SECTION:

16 1. "FORMULARY EXCEPTION" MEANS THAT HEALTH PLAN COVERAGE OF A HEALTH
17 CARE PROVIDER'S SELECTED PRESCRIPTION DRUG IS GRANTED.

18 2. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION
19 20-2501.

20 3. "HEALTH CARE PLAN" MEANS A POLICY, CONTRACT OR EVIDENCE OF
21 COVERAGE THAT A HEALTH CARE INSURER ISSUES TO AN INSURED, ENROLLEE OR
22 SUBSCRIBER.

23 4. "UTILIZATION REVIEW AGENT" HAS THE SAME MEANING PRESCRIBED IN
24 SECTION 20-2530."

25 Page 4, line 12, after the "contracts" insert ", policies or evidences of
26 coverage that are"

27 Amend title to conform

And, as so amended, it do pass

LAURIN HENDRIX
CHAIRMAN

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