

PROPOSED

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:

1 "D."

2 Page 2, line 14, strike "REQUEST"

3 Line 15, strike "A PRESCRIPTION DRUG COVERAGE EXEMPTION" insert "NOTIFY THE  
4 PHARMACY BENEFIT MANAGER OR HEALTH CARE INSURER"

5 Strike lines 16 through 43

6 Strike page 3

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

15 E. THIS SECTION DOES NOT:

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

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

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

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

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

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

1 G. FOR THE PURPOSES OF THIS SECTION:  
2 1. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION  
3 20-2501.  
4 2. "LIMIT OR EXCLUDE COVERAGE" MEANS TO:  
5 (a) LIMIT OR REDUCE THE MAXIMUM COVERAGE OF PRESCRIPTION DRUG  
6 BENEFITS.  
7 (b) INCREASE COST SHARING FOR A COVERED PRESCRIPTION DRUG.  
8 (c) REQUIRE AN ADDITIONAL PRIOR AUTHORIZATION FOR A PATIENT  
9 CURRENTLY APPROVED FOR THE DRUG BASED SOLELY ON THE MOVEMENT OF A DRUG TO A  
10 MORE RESTRICTIVE FORMULARY TIER.  
11 (d) REMOVE A PRESCRIPTION DRUG FROM A FORMULARY UNLESS EITHER OF THE  
12 FOLLOWING APPLIES:  
13 (i) THE UNITED STATES FOOD AND DRUG ADMINISTRATION REVOKES APPROVAL  
14 FOR OR REMOVES A PRESCRIPTION DRUG FROM THE PRESCRIPTION DRUG MARKET.  
15 (ii) THE PRESCRIPTION DRUG MANUFACTURER NOTIFIES THE UNITED STATES  
16 FOOD AND DRUG ADMINISTRATION OF A MANUFACTURING DISCONTINUATION OR A  
17 POTENTIAL DISCONTINUATION AS REQUIRED BY SECTION 506C OF THE FEDERAL FOOD,  
18 DRUG, AND COSMETIC ACT (21 UNITED STATES CODE SECTION 356c).  
19 3. "UTILIZATION REVIEW AGENT" HAS THE SAME MEANING PRESCRIBED IN  
20 SECTION 20-2530.  
21 20-3336. Pharmacy benefit managers; prescribing; formulary  
22 exception process requirements; exception;  
23 enforcement; definitions  
24 A. ON RENEWAL OF A HEALTH CARE PLAN, A HEALTH CARE INSURER, PHARMACY  
25 BENEFIT MANAGER OR UTILIZATION REVIEW AGENT THAT IS CONTRACTED TO PROVIDE  
26 PHARMACY BENEFIT MANAGEMENT SERVICES FOR THE HEALTH CARE INSURER SHALL  
27 PROVIDE A COVERED INDIVIDUAL AND PRESCRIBING HEALTH CARE PROVIDER WITH  
28 ACCESS TO A CLEAR AND CONVENIENT PROCESS TO REQUEST A FORMULARY EXCEPTION  
29 PROCESS. THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION  
30 REVIEW AGENT MAY USE ITS EXISTING FORMULARY EXCEPTION PROCESS TO SATISFY

1 THIS REQUIREMENT IF THE MEDICAL EXCEPTIONS PROCESS IS CONSISTENT WITH THE  
2 REQUIREMENTS PRESCRIBED IN THIS SECTION.

3 B. A HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION  
4 REVIEW AGENT SHALL FOLLOW THE PROCESS AND RESPOND TO A FORMULARY EXCEPTION  
5 DETERMINATION REQUEST IN ACCORDANCE WITH 45 CODE OF FEDERAL REGULATIONS  
6 SECTION 156.122.

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

14 1. THE COVERED INDIVIDUAL HAS TRIED A FORMULARY EQUIVALENT  
15 PRESCRIPTION DRUG THAT WAS A PART OF THE COVERED INDIVIDUAL'S PRESCRIPTION  
16 DRUG BENEFIT AT THE TIME OF THE TRIAL, THE FORMULARY EQUIVALENT  
17 PRESCRIPTION DRUG WAS NOT EFFECTIVE IN THE TREATMENT OF THE COVERED  
18 INDIVIDUAL'S MEDICAL CONDITION AND THE HEALTH CARE PROVIDER SPECIFIES THE  
19 CONTRAINDICATION OR ADVERSE OR HARMFUL REACTION IN THE COVERED INDIVIDUAL.

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

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

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

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

3           2. WHETHER THE FORMULARY PRESCRIPTION DRUG IS NOT IN THE BEST  
4 INTEREST OF THE COVERED INDIVIDUAL BASED ON MEDICAL NECESSITY BECAUSE THE  
5 COVERED INDIVIDUAL'S USE OF THE FORMULARY PRESCRIPTION DRUG IS EXPECTED TO  
6 CAUSE EITHER OF THE FOLLOWING:

7           (a) A NEGATIVE IMPACT ON THE COVERED INDIVIDUAL'S COMORBID  
8 CONDITION.

9           (b) A CLINICALLY PREDICTABLE NEGATIVE DRUG INTERACTION.

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

12          E. DENIAL OF COVERAGE FOR A HEALTH CARE INSURER'S OR PHARMACY  
13 BENEFIT MANAGER'S DENIAL OF COVERAGE FOR A NONFORMULARY PRESCRIPTION DRUG  
14 SHALL BE MADE IN WRITING BY A LICENSED PHARMACIST OR MEDICAL DIRECTOR. THE  
15 WRITTEN DENIAL SHALL CONTAIN AN EXPLANATION OF THE DENIAL THAT INCLUDES THE  
16 MEDICAL OR PHARMACOLOGICAL REASONS WHY THE AUTHORIZATION WAS DENIED AND A  
17 SIGNATURE BY THE LICENSED PHARMACIST OR MEDICAL DIRECTOR WHO MADE THE  
18 DECISION TO DENY COVERAGE. THE HEALTH CARE INSURER, PHARMACY BENEFIT  
19 MANAGER OR UTILIZATION REVIEW AGENT SHALL SEND A COPY OF THE WRITTEN DENIAL  
20 TO THE COVERED INDIVIDUAL'S TREATING HEALTH CARE PROVIDER WHO REQUESTED THE  
21 FORMULARY EXCEPTION. THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR  
22 UTILIZATION REVIEW AGENT SHALL MAINTAIN COPIES OF ALL WRITTEN DENIALS AND  
23 SHALL MAKE THE COPIES AVAILABLE TO THE DEPARTMENT FOR INSPECTION. A  
24 COVERED INDIVIDUAL OR THE COVERED INDIVIDUAL'S AUTHORIZED REPRESENTATIVE  
25 MAY APPEAL ANY DETERMINATION TO DENY A FORMULARY EXCEPTION UNDER CHAPTER  
26 15, ARTICLE 2 OF THIS TITLE. THE WRITTEN NOTIFICATION SHALL INCLUDE THE  
27 PROCESS IN WHICH A COVERED INDIVIDUAL MAY APPEAL THE DETERMINATION.

28          F. IF THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR  
29 UTILIZATION REVIEW AGENT AUTHORIZES A FORMULARY EXCEPTION FOR A COVERED  
30 INDIVIDUAL PURSUANT TO THIS SECTION, THAT AUTHORIZATION SHALL BE IN EFFECT  
31 UNTIL THE END OF THE COVERED INDIVIDUAL'S PLAN YEAR. THE APPROVAL OF A

1 FORMULARY EXCEPTION SHALL BE IN WRITING AND DELIVERED TO THE COVERED  
2 INDIVIDUAL AND THE COVERED INDIVIDUAL'S TREATING HEALTH CARE PROVIDER.

3 G. THIS SECTION DOES NOT:

4 1. PREVENT A HEALTH CARE PROVIDER FROM PRESCRIBING ANOTHER  
5 PRESCRIPTION DRUG COVERED BY THE HEALTH CARE INSURER OR THE PHARMACY  
6 BENEFIT MANAGER IF THE HEALTH CARE PROVIDER DEEMS THE PRESCRIPTION DRUG  
7 MEDICALLY NECESSARY FOR THE COVERED INDIVIDUAL.

8 2. PREVENT A HEALTH CARE INSURER OR PHARMACY BENEFIT MANAGER  
9 CONTRACTED TO PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES FROM MANAGING  
10 ITS FORMULARY IN COMPLIANCE WITH THIS SECTION, INCLUDING:

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

12 (b) REMOVING A PRESCRIPTION DRUG FROM ITS FORMULARY IF THE DRUG  
13 MANUFACTURER HAS REMOVED THE PRESCRIPTION DRUG FOR SALE IN THE UNITED  
14 STATES.

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

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

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

23 J. FOR THE PURPOSES OF THIS SECTION:

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

26 2. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION  
27 20-2501.

28 3. "HEALTH CARE PLAN" MEANS A POLICY, CONTRACT OR EVIDENCE OF  
29 COVERAGE THAT A HEALTH CARE INSURER ISSUES TO AN INSURED, ENROLLEE OR  
30 SUBSCRIBER.

1                   4. "UTILIZATION REVIEW AGENT" HAS THE SAME MEANING PRESCRIBED IN  
2           SECTION 20-2530."  
3 Page 4, line 12, after the "contracts" insert ", policies or evidences of  
4           coverage that are"  
5 Amend title to conform

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03/22/2024  
08:27 AM  
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