

ASSEMBLY, No. 1811

STATE OF NEW JERSEY

220th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2022 SESSION

Sponsored by:

Assemblywoman PAMELA R. LAMPITT

District 6 (Burlington and Camden)

Assemblyman DANIEL R. BENSON

District 14 (Mercer and Middlesex)

SYNOPSIS

Requires continued coverage of prescription drugs for certain medical conditions.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



1 **AN ACT** concerning prescription drug coverage for certain medical
2 conditions and supplementing various parts of the statutory law.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. a. As used in this section:

8 “Complex or chronic medical condition” means a physical,
9 behavioral, or developmental condition that does not have a known
10 cure or that can be severely debilitating or fatal if left untreated or
11 undertreated.

12 “Rare disease” means any disease or condition that affects less
13 than 200,000 persons in the United States.

14 b. Every group or individual hospital service corporation
15 contract delivered, issued, executed or renewed in this State, or
16 approved for issuance or renewal in this State, on or after the
17 effective date of this act, which provides for pharmacy services,
18 prescription drugs, or for participation in a prescription drug plan
19 shall continue to provide coverage for a drug for a covered person
20 with a complex or chronic medical condition or a rare disease, if the
21 drug was previously covered by the contract, while an appeal is at
22 any stage of the appeals process in situations in which a covered
23 person appeals a denial of coverage for the drug based on medical
24 necessity, except as provided for in subsection d. of this section.

25 c. With respect to a drug for a covered person with a complex
26 or chronic medical condition or a rare disease which meets the
27 conditions of subsection b. of this section in situations in which a
28 covered person appeals a denial of coverage for the drug based on
29 medical necessity, while the appeal is in any stage of the appeals
30 process, the provisions of a group or individual hospital service
31 corporation contract shall not apply so as to:

32 (1) set forth limitations on maximum coverage of prescription
33 drug benefits;

34 (2) subject the covered person to increased out-of-pocket costs;
35 or

36 (3) move a drug for a covered person to a more restrictive tier, if
37 the group or individual hospital service corporation contract uses a
38 formulary with tiers.

39 d. A hospital service corporation may only deny coverage
40 during the appeals process for a drug for a covered person with a
41 complex or chronic medical condition or a rare disease if:

42 (1) the prescribing provider has discontinued prescription of the
43 drug for the covered person;

44 (2) the United States Food and Drug Administration has issued a
45 notice, guidance, warning, announcement, or any other statement
46 about the drug which calls into question the clinical safety of the
47 drug; or

1 (3) the manufacturer of the drug has notified the United States
2 Food and Drug Administration of any manufacturing
3 discontinuance or potential discontinuance as required by 21
4 U.S.C.s.356c.

5
6 2. a. As used in this section:

7 “Complex or chronic medical condition” means a physical,
8 behavioral, or developmental condition that does not have a known
9 cure or that can be severely debilitating or fatal if left untreated or
10 undertreated.

11 “Rare disease” means any disease or condition that affects less
12 than 200,000 persons in the United States.

13 b. Every group or individual medical service corporation
14 contract delivered, issued, executed or renewed in this State, or
15 approved for issuance or renewal in this State, on or after the
16 effective date of this act, which provides for pharmacy services,
17 prescription drugs, or for participation in a prescription drug plan
18 shall continue to provide coverage for a drug for a covered person
19 with a complex or chronic medical condition or a rare disease, if the
20 drug was previously covered by the contract, while an appeal is at
21 any stage of the appeals process in situations in which a covered
22 person appeals a denial of coverage for the drug based on medical
23 necessity, except as provided for in subsection d. of this section.

24 c. With respect to a drug for a covered person with a complex
25 or chronic medical condition or a rare disease which meets the
26 conditions of subsection b. of this section in situations in which a
27 covered person appeals a denial of coverage for the drug based on
28 medical necessity, while the appeal is in any stage of the appeals
29 process, the provisions of a group or individual medical service
30 corporation contract shall not apply so as to:

31 (1) set forth limitations on maximum coverage of prescription
32 drug benefits;

33 (2) subject the covered person to increased out-of-pocket costs;
34 or

35 (3) move a drug for a covered person to a more restrictive tier, if
36 the group or individual medical service corporation contract uses a
37 formulary with tiers.

38 d. A medical service corporation may only deny coverage
39 during the appeals process for a drug for a covered person with a
40 complex or chronic medical condition or a rare disease if:

41 (1) the prescribing provider has discontinued prescription of the
42 drug for the covered person;

43 (2) the United States Food and Drug Administration has issued a
44 notice, guidance, warning, announcement, or any other statement
45 about the drug which calls into question the clinical safety of the
46 drug; or

47 (3) the manufacturer of the drug has notified the United States
48 Food and Drug Administration of any manufacturing

1 discontinuance or potential discontinuance as required by 21
2 U.S.C.s.356c.

3

4 3. a. As used in this section:

5 “Complex or chronic medical condition” means a physical,
6 behavioral, or developmental condition that does not have a known
7 cure or that can be severely debilitating or fatal if left untreated or
8 undertreated.

9 “Rare disease” means any disease or condition that affects less
10 than 200,000 persons in the United States.

11 b. Every group or individual health service corporation contract
12 delivered, issued, executed or renewed in this State, or approved for
13 issuance or renewal in this State, on or after the effective date of
14 this act, which provides for pharmacy services, prescription drugs,
15 or for participation in a prescription drug plan shall continue to
16 provide coverage for a drug for a covered person with a complex or
17 chronic medical condition or a rare disease, if the drug was
18 previously covered by the contract, while an appeal is at any stage
19 of the appeals process in situations in which a covered person
20 appeals a denial of coverage for the drug based on medical
21 necessity, except as provided for in subsection d. of this section.

22 c. With respect to a drug for a covered person with a complex
23 or chronic medical condition or a rare disease which meets the
24 conditions of subsection b. of this section in situations in which a
25 covered person appeals a denial of coverage for the drug based on
26 medical necessity, while the appeal is in any stage of the appeals
27 process, the provisions of a group or individual health service
28 corporation contract shall not apply so as to:

29 (1) set forth limitations on maximum coverage of prescription
30 drug benefits;

31 (2) subject the covered person to increased out-of-pocket costs;
32 or

33 (3) move a drug for a covered person to a more restrictive tier, if
34 the group or individual health service corporation contract uses a
35 formulary with tiers.

36 d. A health service corporation may only deny coverage during
37 the appeals process for a drug for a covered person with a complex
38 or chronic medical condition or a rare disease if:

39 (1) the prescribing provider has discontinued prescription of the
40 drug for the covered person;

41 (2) the United States Food and Drug Administration has issued a
42 notice, guidance, warning, announcement, or any other statement
43 about the drug which calls into question the clinical safety of the
44 drug; or

45 (3) the manufacturer of the drug has notified the United States
46 Food and Drug Administration of any manufacturing
47 discontinuance or potential discontinuance as required by 21
48 U.S.C.s.356c.

1 4. a. As used in this section:

2 “Complex or chronic medical condition” means a physical,
3 behavioral, or developmental condition that does not have a known
4 cure or that can be severely debilitating or fatal if left untreated or
5 undertreated.

6 “Rare disease” means any disease or condition that affects less
7 than 200,000 persons in the United States.

8 b. Every individual health insurance policy or contract
9 delivered, issued, executed or renewed in this State, or approved for
10 issuance or renewal in this State, on or after the effective date of
11 this act, which provides for pharmacy services, prescription drugs,
12 or for participation in a prescription drug plan shall continue to
13 provide coverage for a drug for a covered person with a complex or
14 chronic medical condition or a rare disease, if the drug was
15 previously covered by the contract, while an appeal is at any stage
16 of the appeals process in situations in which a covered person
17 appeals a denial of coverage for the drug based on medical
18 necessity, except as provided for in subsection d. of this section.

19 c. With respect to a drug for a covered person with a complex
20 or chronic medical condition or a rare disease which meets the
21 conditions of subsection b. of this section in situations in which a
22 covered person appeals a denial of coverage for the drug based on
23 medical necessity, while the appeal is in any stage of the appeals
24 process, the provisions of an individual health insurance policy or
25 contract shall not apply so as to:

26 (1) set forth limitations on maximum coverage of prescription
27 drug benefits;

28 (2) subject the covered person to increased out-of-pocket costs;
29 or

30 (3) move a drug for a covered person to a more restrictive tier, if
31 the individual health insurance policy or contract uses a formulary
32 with tiers.

33 d. An individual health insurance policy or contract may only
34 deny coverage during the appeals process for a drug for a covered
35 person with a complex or chronic medical condition or a rare
36 disease if:

37 (1) the prescribing provider has discontinued prescription of the
38 drug for the covered person;

39 (2) the United States Food and Drug Administration has issued a
40 notice, guidance, warning, announcement, or any other statement
41 about the drug which calls into question the clinical safety of the
42 drug; or

43 (3) the manufacturer of the drug has notified the United States
44 Food and Drug Administration of any manufacturing
45 discontinuance or potential discontinuance as required by 21
46 U.S.C.s.356c.

47

48 5. a. As used in this section:

1 “Complex or chronic medical condition” means a physical,
2 behavioral, or developmental condition that does not have a known
3 cure or that can be severely debilitating or fatal if left untreated or
4 undertreated.

5 “Rare disease” means any disease or condition that affects less
6 than 200,000 persons in the United States.

7 b. Every group health insurance policy or contract delivered,
8 issued, executed or renewed in this State, or approved for issuance
9 or renewal in this State, on or after the effective date of this act,
10 which provides for pharmacy services, prescription drugs, or for
11 participation in a prescription drug plan shall continue to provide
12 coverage for a drug for a covered person with a complex or chronic
13 medical condition or a rare disease, if the drug was previously
14 covered by the contract, while an appeal is at any stage of the
15 appeals process in situations in which a covered person appeals a
16 denial of coverage for the drug based on medical necessity, except
17 as provided for in subsection d. of this section.

18 c. With respect to a drug for a covered person with a complex
19 or chronic medical condition or a rare disease which meets the
20 conditions of subsection b. of this section in situations in which a
21 covered person appeals a denial of coverage for the drug based on
22 medical necessity, while the appeal is in any stage of the appeals
23 process, the provisions of a group health insurance policy or
24 contract shall not apply so as to:

25 (1) set forth limitations on maximum coverage of prescription
26 drug benefits;

27 (2) subject the covered person to increased out-of-pocket costs;
28 or

29 (3) move a drug for a covered person to a more restrictive tier, if
30 the group health insurance policy or contract uses a formulary with
31 tiers.

32 d. A group health insurance policy or contract may only deny
33 coverage during the appeals process for a drug for a covered person
34 with a complex or chronic medical condition or a rare disease if:

35 (1) the prescribing provider has discontinued prescription of the
36 drug for the covered person;

37 (2) the United States Food and Drug Administration has issued a
38 notice, guidance, warning, announcement, or any other statement
39 about the drug which calls into question the clinical safety of the
40 drug; or

41 (3) the manufacturer of the drug has notified the United States
42 Food and Drug Administration of any manufacturing
43 discontinuance or potential discontinuance as required by 21
44 U.S.C.s.356c.

45

46 6. a. As used in this section:

47 “Complex or chronic medical condition” means a physical,
48 behavioral, or developmental condition that does not have a known

1 cure or that can be severely debilitating or fatal if left untreated or
2 undertreated.

3 “Rare disease” means any disease or condition that affects less
4 than 200,000 persons in the United States.

5 b. Every certificate of authority to establish and operate a
6 health maintenance organization delivered, issued, executed or
7 renewed in this State, or approved for issuance or renewal in this
8 State, on or after the effective date of this act, which provides for
9 pharmacy services, prescription drugs, or for participation in a
10 prescription drug plan shall continue to provide coverage for a drug
11 for a covered person with a complex or chronic medical condition
12 or a rare disease, if the drug was previously covered by the contract,
13 while an appeal is at any stage of the appeals process in situations
14 in which a covered person appeals a denial of coverage for the drug
15 based on medical necessity, except as provided for in subsection d.
16 of this section.

17 c. With respect to a drug for a covered person with a complex
18 or chronic medical condition or a rare disease which meets the
19 conditions of subsection b. of this section in situations in which a
20 covered person appeals a denial of coverage for the drug based on
21 medical necessity, while the appeal is in any stage of the appeals
22 process, the provisions of an enrollee agreement shall not apply so
23 as to:

24 (1) set forth limitations on maximum coverage of prescription
25 drug benefits;

26 (2) subject the covered person to increased out-of-pocket costs;
27 or

28 (3) move a drug for a covered person to a more restrictive tier, if
29 the health maintenance organization uses a formulary with tiers.

30 d. A health maintenance organization may only deny coverage
31 during the appeals process for a drug for a covered person with a
32 complex or chronic medical condition or a rare disease if:

33 (1) the prescribing provider has discontinued prescription of the
34 drug for the covered person;

35 (2) the United States Food and Drug Administration has issued a
36 notice, guidance, warning, announcement, or any other statement
37 about the drug which calls into question the clinical safety of the
38 drug; or

39 (3) the manufacturer of the drug has notified the United States
40 Food and Drug Administration of any manufacturing
41 discontinuance or potential discontinuance as required by 21
42 U.S.C.s.356c.

43

44 7. a. As used in this section:

45 “Complex or chronic medical condition” means a physical,
46 behavioral, or developmental condition that does not have a known
47 cure or that can be severely debilitating or fatal if left untreated or
48 undertreated.

1 “Rare disease” means any disease or condition that affects less
2 than 200,000 persons in the United States.

3 b. Every individual health benefits plan delivered, issued,
4 executed or renewed in this State, or approved for issuance or
5 renewal in this State, on or after the effective date of this act, which
6 provides for pharmacy services, prescription drugs, or for
7 participation in a prescription drug plan shall continue to provide
8 coverage for a drug for a covered person with a complex or chronic
9 medical condition or a rare disease, if the drug was previously
10 covered by the contract, while an appeal is at any stage of the
11 appeals process in situations in which a covered person appeals a
12 denial of coverage for the drug based on medical necessity, except
13 as provided for in subsection d. of this section.

14 c. With respect to a drug for a covered person with a complex
15 or chronic medical condition or a rare disease which meets the
16 conditions of subsection b. of this section in situations in which a
17 covered person appeals a denial of coverage for the drug based on
18 medical necessity, while the appeal is in any stage of the appeals
19 process, the provisions of an individual health benefits plan shall
20 not apply so as to:

21 (1) set forth limitations on maximum coverage of prescription
22 drug benefits;

23 (2) subject the covered person to increased out-of-pocket costs;
24 or

25 (3) move a drug for a covered person to a more restrictive tier, if
26 the individual health benefits plan uses a formulary with tiers.

27 d. An individual health benefits plan may only deny coverage
28 during the appeals process for a drug for a covered person with a
29 complex or chronic medical condition or a rare disease if:

30 (1) the prescribing provider has discontinued prescription of the
31 drug for the covered person;

32 (2) the United States Food and Drug Administration has issued a
33 notice, guidance, warning, announcement, or any other statement
34 about the drug which calls into question the clinical safety of the
35 drug; or

36 (3) the manufacturer of the drug has notified the United States
37 Food and Drug Administration of any manufacturing
38 discontinuance or potential discontinuance as required by 21
39 U.S.C.s.356c.

40

41 8. a. As used in this section:

42 “Complex or chronic medical condition” means a physical,
43 behavioral, or developmental condition that does not have a known
44 cure or that can be severely debilitating or fatal if left untreated or
45 undertreated.

46 “Rare disease” means any disease or condition that affects less
47 than 200,000 persons in the United States.

1 b. Every small employer health benefits plan delivered, issued,
2 executed or renewed in this State, or approved for issuance or
3 renewal in this State, on or after the effective date of this act, which
4 provides for pharmacy services, prescription drugs, or for
5 participation in a prescription drug plan shall continue to provide
6 coverage for a drug for a covered person with a complex or chronic
7 medical condition or a rare disease, if the drug was previously
8 covered by the contract, while an appeal is at any stage of the
9 appeals process in situations in which a covered person appeals a
10 denial of coverage for the drug based on medical necessity, except
11 as provided for in subsection d. of this section.

12 c. With respect to a drug for a covered person with a complex
13 or chronic medical condition or a rare disease which meets the
14 conditions of subsection b. of this section in situations in which a
15 covered person appeals a denial of coverage for the drug based on
16 medical necessity, while the appeal is in any stage of the appeals
17 process, the provisions of a small employer health benefits plan
18 shall not apply so as to:

19 (1) set forth limitations on maximum coverage of prescription
20 drug benefits;

21 (2) subject the covered person to increased out-of-pocket costs;
22 or

23 (3) move a drug for a covered person to a more restrictive tier, if
24 the small employer health benefits plan uses a formulary with tiers.

25 d. A small employer health benefits plan may only deny
26 coverage during the appeals process for a drug for a covered person
27 with a complex or chronic medical condition or a rare disease if:

28 (1) the prescribing provider has discontinued prescription of the
29 drug for the covered person;

30 (2) the United States Food and Drug Administration has issued a
31 notice, guidance, warning, announcement, or any other statement
32 about the drug which calls into question the clinical safety of the
33 drug; or

34 (3) the manufacturer of the drug has notified the United States
35 Food and Drug Administration of any manufacturing
36 discontinuance or potential discontinuance as required by 21
37 U.S.C.s.356c.

38

39 9. a. As used in this section:

40 “Complex or chronic medical condition” means a physical,
41 behavioral, or developmental condition that does not have a known
42 cure or that can be severely debilitating or fatal if left untreated or
43 undertreated.

44 “Rare disease” means any disease or condition that affects less
45 than 200,000 persons in the United States.

46 b. Every prepaid prescription service organization contract
47 delivered, issued, executed or renewed in this State, or approved for
48 issuance or renewal in this State, on or after the effective date of

1 this act, shall continue to provide coverage for a drug for a covered
2 person with a complex or chronic medical condition or a rare
3 disease, if the drug was previously covered by the contract, while
4 an appeal is at any stage of the appeals process in situations in
5 which a covered person appeals a denial of coverage for the drug
6 based on medical necessity, except as provided for in subsection d.
7 of this section.

8 c. With respect to a drug for a covered person with a complex
9 or chronic medical condition or a rare disease which meets the
10 conditions of subsection b. of this section in situations in which a
11 covered person appeals a denial of coverage for the drug based on
12 medical necessity, while the appeal is in any stage of the appeals
13 process, the provisions of a prepaid prescription service
14 organization contract shall not apply so as to:

15 (1) set forth limitations on maximum coverage of prescription
16 drug benefits;

17 (2) subject the covered person to increased out-of-pocket costs;
18 or

19 (3) move a drug for a covered person to a more restrictive tier, if
20 the prepaid prescription service organization contract uses a
21 formulary with tiers.

22 d. A prepaid prescription service organization may only deny
23 coverage during the appeals process for a drug for a covered person
24 with a complex or chronic medical condition or a rare disease if:

25 (1) the prescribing provider has discontinued prescription of the
26 drug for the covered person;

27 (2) the United States Food and Drug Administration has issued a
28 notice, guidance, warning, announcement, or any other statement
29 about the drug which calls into question the clinical safety of the
30 drug; or

31 (3) the manufacturer of the drug has notified the United States
32 Food and Drug Administration of any manufacturing
33 discontinuance or potential discontinuance as required by 21
34 U.S.C.s.356c.

35
36 10. a. As used in this section:

37 “Complex or chronic medical condition” means a physical,
38 behavioral, or developmental condition that does not have a known
39 cure or that can be severely debilitating or fatal if left untreated or
40 undertreated.

41 “Rare disease” means any disease or condition that affects less
42 than 200,000 persons in the United States.

43 b. The State Health Benefits Commission shall ensure that
44 every contract purchased by the State Health Benefits Program, on
45 or after the effective date of this act, which provides for pharmacy
46 services, prescription drugs, or for participation in a prescription
47 drug plan shall continue to provide coverage for a drug for a
48 covered person with a complex or chronic medical condition or a

1 rare disease, if the drug was previously covered by the contract,
2 while an appeal is at any stage of the appeals process in situations
3 in which a covered person appeals a denial of coverage for the drug
4 based on medical necessity, except as provided for in subsection d.
5 of this section.

6 c. With respect to a drug for a covered person with a complex
7 or chronic medical condition or a rare disease which meets the
8 conditions of subsection b. of this section in situations in which a
9 covered person appeals a denial of coverage for the drug based on
10 medical necessity, while the appeal is in any stage of the appeals
11 process, the provisions of the State Health Benefits Program
12 contract shall not apply so as to:

13 (1) set forth limitations on maximum coverage of prescription
14 drug benefits;

15 (2) subject the covered person to increased out-of-pocket costs;
16 or

17 (3) move a drug for a covered person to a more restrictive tier, if
18 the State Health Benefits Program contract uses a formulary with
19 tiers.

20 d. The State Health Benefits Commission may only deny
21 coverage during the appeals process for a drug for a covered person
22 with a complex or chronic medical condition or a rare disease if:

23 (1) the prescribing provider has discontinued prescription of the
24 drug for the covered person;

25 (2) the United States Food and Drug Administration has issued a
26 notice, guidance, warning, announcement, or any other statement
27 about the drug which calls into question the clinical safety of the
28 drug; or

29 (3) the manufacturer of the drug has notified the United States
30 Food and Drug Administration of any manufacturing
31 discontinuance or potential discontinuance as required by 21
32 U.S.C.s.356c.

33

34 11. a. As used in this section:

35 “Complex or chronic medical condition” means a physical,
36 behavioral, or developmental condition that does not have a known
37 cure or that can be severely debilitating or fatal if left untreated or
38 undertreated.

39 “Rare disease” means any disease or condition that affects less
40 than 200,000 persons in the United States.

41 b. The School Employees’ Health Benefits Commission shall
42 ensure that every contract purchased by the School Employees’
43 Health Benefits Program on or after the effective date of this act,
44 which provides for pharmacy services, prescription drugs, or for
45 participation in a prescription drug plan shall continue to provide
46 coverage for a drug for a covered person with a complex or chronic
47 medical condition or a rare disease, if the drug was previously
48 covered by the contract, while an appeal is at any stage of the

1 appeals process in situations in which a covered person appeals a
2 denial of coverage for the drug based on medical necessity, except
3 as provided for in subsection d. of this section.

4 c. With respect to a drug for a covered person with a complex
5 or chronic medical condition or a rare disease which meets the
6 conditions of subsection b. of this section in situations in which a
7 covered person appeals a denial of coverage for the drug based on
8 medical necessity, while the appeal is in any stage of the appeals
9 process, the provisions of the School Employees' Health Benefits
10 contract shall not apply so as to:

11 (1) set forth limitations on maximum coverage of prescription
12 drug benefits;

13 (2) subject the covered person to increased out-of-pocket costs;
14 or

15 (3) move a drug for a covered person to a more restrictive tier, if
16 the School Employees' Health Benefits contract uses a formulary
17 with tiers.

18 d. The School Employees' Health Benefits Commission may
19 only deny coverage during the appeals process for a drug for a
20 covered person with a complex or chronic medical condition or a
21 rare disease if:

22 (1) the prescribing provider has discontinued prescription of the
23 drug for the covered person;

24 (2) the United States Food and Drug Administration has issued a
25 notice, guidance, warning, announcement, or any other statement
26 about the drug which calls into question the clinical safety of the
27 drug; or

28 (3) the manufacturer of the drug has notified the United States
29 Food and Drug Administration of any manufacturing
30 discontinuance or potential discontinuance as required by 21
31 U.S.C.s.356c.

32
33 12. This act shall take effect on the 90th day next following 9
34 enactment.

35

36

37

STATEMENT

38

39 This bill requires health insurance carriers to provide continued
40 coverage of prescription drugs for covered persons diagnosed with a
41 complex or chronic medical condition or a rare disease during a
42 coverage appeal based on medical necessity.

43 The bill defines "complex or chronic medical condition" as a
44 physical, behavioral, or developmental condition that does not have a
45 known cure or that can be severely debilitating or fatal if left untreated
46 or undertreated. "Rare disease" is defined as any disease or condition
47 that affects less than 200,000 persons in the United States.

1 The bill requires hospital, medical and health service corporations,
2 commercial insurers, health maintenance organizations, health benefits
3 plans issued pursuant to the New Jersey Individual Health Coverage
4 and Small Employer Health Benefits Programs, prepaid prescription
5 service organizations, and plans provided by the State Health Benefits
6 Commission and the School Employees' Health Benefits Commission
7 to continue to provide coverage for a drug for a covered person with a
8 complex or chronic medical condition or a rare disease, if the drug was
9 previously covered by the policy or contract, while an appeal is at any
10 stage of the appeals process in situations in which a covered person
11 appeals a denial of coverage for the drug based on medical necessity,
12 except under certain circumstances.

13 With respect to a drug for a covered person with a complex or
14 chronic medical condition or a rare disease in situations in which a
15 covered person appeals a denial of coverage for the drug based on
16 medical necessity, while the appeal is in any stage of the appeals
17 process, the bill provides the provisions of the policy or contract shall
18 not apply so as to:

19 (1) set forth limitations on maximum coverage of prescription drug
20 benefits;

21 (2) subject the covered person to increased out-of-pocket costs; or

22 (3) move a drug for a covered person to a more restrictive tier, if
23 the policy or contract uses a formulary with tiers.

24 The bill further provides that a policy or contract may only deny
25 coverage during the appeals process for a drug for a covered person
26 with a complex or chronic medical condition or a rare disease if:

27 (1) the prescribing provider has discontinued prescription of the
28 drug for the covered person;

29 (2) the United States Food and Drug Administration has issued a
30 notice, guidance, warning, announcement, or any other statement
31 about the drug which calls into question the clinical safety of the drug;
32 or

33 (3) the manufacturer of the drug has notified the United States
34 Food and Drug Administration of any manufacturing discontinuance
35 or potential discontinuance as required by 21 U.S.C.s.356c.