

MAINE STATE LEGISLATURE

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BANKING AND INSURANCE

Reported by:

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**STATE OF MAINE
SENATE
118TH LEGISLATURE
SECOND REGULAR SESSION**

COMMITTEE AMENDMENT "*A*" to S.P. 761, L.D. 2068, Bill, "An Act to Permit Off-label Use of Prescription Drugs for Cancer, HIV or AIDS"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting in its place the following:

Sec. 1. 24 MRSA §§2320-F and 2320-G are enacted to read:

§2320-F. Off-label use of prescription drugs for cancer

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Medically accepted indication" includes any use of a drug that has been approved by the federal Food and Drug Administration and includes another use of the drug if that use is supported by one or more citations in the standard reference compendia or if the nonprofit hospital and medical service organization involved, based upon guidance provided by the federal Department of Health and Human Services Medicare program pursuant to 42 United States Code, Section 1395x(t), determines that that use is medically accepted based on supportive clinical evidence in peer-reviewed medical literature.

B. "Off-label use" means the prescription and use of drugs for medically accepted indications other than those stated in the labeling approved by the federal Food and Drug Administration.

2 C. "Peer-reviewed medical literature" means scientific
3 studies published in at least 2 articles from major
4 peer-reviewed medical journals that present data that
5 supports the proposed off-label use as generally safe and
6 effective.

8 D. "Standard reference compendia" means:

10 (1) The United States Pharmacopeia Drug Information or
11 information published by its successor organization; or

12 (2) The American Hospital Formulary Service Drug
13 Information or information published by its successor
14 organization.

16 2. Required coverage for off-label use. All individual and
17 group nonprofit hospital and medical services plan contracts and
18 nonprofit health care plan contracts that provide coverage for
19 prescription drugs must provide coverage for off-label use in
20 accordance with the following.

22 A. Individual and group nonprofit hospital and medical
23 services plan contracts and nonprofit health care plan
24 contracts that provide coverage for prescription drugs may
25 not exclude coverage for any such drug used for the
26 treatment of cancer for a medically accepted indication on
27 the grounds that the drug has not been approved by the
28 federal Food and Drug Administration for that indication, as
29 long as that use of that drug is a medically accepted
30 indication for the treatment of cancer.

31 B. Coverage of a drug required by this subsection also
32 includes medically necessary services associated with the
33 administration of the drug.

34 C. This subsection may not be construed to require coverage
35 for a drug when the federal Food and Drug Administration has
36 determined its use to be contraindicated for treatment of
37 the current indication.

38 D. A drug use that is covered pursuant to paragraph A may
39 not be denied coverage based on a "medical necessity"
40 requirement except for a reason that is unrelated to the
41 legal status of the drug use.

42 E. A contract that provides coverage of a drug as required
43 by this subsection may contain provisions for maximum
44 benefits and coinsurance and reasonable limitations,
45 deductibles and exclusions to the same extent that these
46 benefits and exclusions are provided for in the contract.

2 provisions are applicable to coverage of all prescription
3 drugs and are not inconsistent with the requirements of this
4 subsection.

5 3. Application. The requirements of this section apply to
6 all policies, contracts and certificates executed, delivered,
7 issued for delivery, continued or renewed in this State on or
8 after January 1, 1999. For purposes of this section, all
9 contracts are deemed to be renewed no later than the next yearly
10 anniversary of the contract date.

11 §2320-G. Off-label use of prescription drugs for HIV or AIDS

12 1. Definitions. As used in this section, unless the
13 context otherwise indicates, the following terms have the
14 following meanings.

15 A. "Off-label use" means the prescription and use of drugs
16 for indications other than those stated in the labeling
17 approved by the federal Food and Drug Administration.

18 B. "Peer-reviewed medical literature" means scientific
19 studies published in at least 2 articles from major
20 peer-reviewed medical journals that present data that
21 supports the proposed off-label use as generally safe and
22 effective.

23 C. "Standard reference compendia" means:

24 (1) The United States Pharmacopeia Drug Information or
25 information published by its successor organization; or

26 (2) The American Hospital Formulary Service Drug
27 Information or information published by its successor
28 organization.

29 2. Required coverage for off-label use. All individual and
30 group nonprofit hospital and medical services plan contracts and
31 nonprofit health care plan contracts that provide coverage for
32 prescription drugs must provide coverage for off-label use in
33 accordance with the following.

34 A. Individual and group nonprofit hospital and medical
35 services plan contracts and nonprofit health care plan
36 contracts that provide coverage for prescription drugs may
37 not exclude coverage for any such drug used for the
38 treatment of HIV or AIDS on the grounds that the drug has
39 not been approved by the federal Food and Drug
40 Administration for that indication, as long as that drug is
41 recognized for the treatment of that indication in one of
42

2 the standard reference compendia or in peer-reviewed medical
3 literature.

4 B. Coverage of a drug required by this subsection also
5 includes medically necessary services associated with the
6 administration of the drug.

8 C. This subsection may not be construed to require coverage
9 for a drug when the federal Food and Drug Administration has
10 determined its use to be contraindicated for treatment of
11 the current indication.

12 D. A drug use that is covered pursuant to paragraph A may
13 not be denied coverage based on a "medical necessity"
14 requirement except for a reason that is unrelated to the
15 legal status of the drug use.

18 E. A contract that provides coverage of a drug as required
19 by this subsection may contain provisions for maximum
20 benefits and coinsurance and reasonable limitations,
21 deductibles and exclusions to the same extent that these
22 provisions are applicable to coverage of all prescription
23 drugs and are not inconsistent with the requirements of this
24 subsection.

26 3. Application. The requirements of this section apply to
27 all policies, contracts and certificates executed, delivered,
28 issued for delivery, continued or renewed in this State on or
29 after January 1, 1999. For purposes of this section, all
30 contracts are deemed to be renewed no later than the next yearly
31 anniversary of the contract date.

32 **Sec. 2. 24-A MRSA §§2745-E and 2745-F are enacted to read:**

34 **§2745-E. Off-label use of prescription drugs for cancer**

36 **1. Definitions. As used in this section, unless the**
37 **context otherwise indicates, the following terms have the**
38 **following meanings.**

40 **A. "Medically accepted indication" includes any use of a**
41 **drug that has been approved by the federal Food and Drug**
42 **Administration and includes another use of the drug if that**
43 **use is supported by one or more citations in the standard**
44 **reference compendia or if the insurer involved, based upon**
45 **guidance provided by the federal Department of Health and**
46 **Human Services Medicare program pursuant to 42 United States**
47 **Code, Section 1395x(t), determines that that use is**
48 **medically accepted based on supportive clinical evidence in**
49 **peer-reviewed medical literature.**
50

2 B. "Off-label use" means the prescription and use of drugs
4 for medically accepted indications other than those stated
 in the labeling approved by the federal Food and Drug
 Administration.

6
8 C. "Peer-reviewed medical literature" means scientific
 studies published in at least 2 articles from major
10 peer-reviewed medical journals that present data that
 supports the proposed off-label use as generally safe and
 effective.

12
14 D. "Standard reference compendia" means:

16 (1) The United States Pharmacopeia Drug Information or
 information published by its successor organization; or

18 (2) The American Hospital Formulary Service Drug
20 Information or information published by its successor
 organization.

22 2. Required coverage for off-label use. All individual
24 insurance policies and contracts that provide coverage for
 prescription drugs must provide coverage for off-label use in
 accordance with the following.

26
28 A. Individual insurance policies and contracts that provide
 coverage for prescription drugs may not exclude coverage for
30 any such drug used for the treatment of cancer for a
 medically accepted indication on the grounds that the drug
32 has not been approved by the federal Food and Drug
 Administration for that indication, as long as use of that
34 drug is a medically accepted indication for the treatment of
 cancer.

36 B. Coverage of a drug required by this subsection also
38 includes medically necessary services associated with the
 administration of the drug.

40 C. This subsection may not be construed to require coverage
42 for a drug when the federal Food and Drug Administration has
 determined its use to be contraindicated for treatment of
 the current indication.

44
46 D. A drug use that is covered pursuant to paragraph A may
 not be denied coverage based on a "medical necessity"
48 requirement except for a reason that is unrelated to the
 legal status of the drug use.

2 E. A contract that provides coverage of a drug as required
3 by this subsection may contain provisions for maximum
4 benefits and coinsurance and reasonable limitations,
5 deductibles and exclusions to the same extent that these
6 provisions are applicable to coverage of all prescription
7 drugs and are not inconsistent with the requirements of this
8 subsection.

9
10 3. Application. The requirements of this section apply to
11 all policies, contracts and certificates executed, delivered,
12 issued for delivery, continued or renewed in this State on or
13 after January 1, 1999. For purposes of this section, all
14 contracts are deemed to be renewed no later than the next yearly
15 anniversary of the contract date.

16 **§2745-F. Off-label use of prescription drugs for HIV or AIDS**

17 1. Definitions. As used in this section, unless the
18 context otherwise indicates, the following terms have the
19 following meanings.

20
21 A. "Off-label use" means the prescription and use of drugs
22 for indications other than those stated in the labeling
23 approved by the federal Food and Drug Administration.

24
25 B. "Peer-reviewed medical literature" means scientific
26 studies published in at least 2 articles from major
27 peer-reviewed medical journals that present data that
28 supports the proposed off-label use as generally safe and
29 effective.

30
31 C. "Standard reference compendia" means:

32
33 (1) The United States Pharmacopeia Drug Information or
34 information published by its successor organization; or

35
36 (2) The American Hospital Formulary Service Drug
37 Information or information published by its successor
38 organization.

39
40 2. Required coverage for off-label use. All individual
41 insurance policies and contracts that provide coverage for
42 prescription drugs must provide coverage for off-label use in
43 accordance with the following.

44
45 A. Individual insurance policies and contracts that provide
46 coverage for prescription drugs may not exclude coverage for
47 any such drug used for the treatment of HIV or AIDS on the
48 grounds that the drug has not been approved by the federal
49 Food and Drug Administration for that indication, as long as
50

2 that drug is recognized for the treatment of that indication
3 in one of the standard reference compendia or in
4 peer-reviewed medical literature.

5 B. Coverage of a drug required by this subsection also
6 includes medically necessary services associated with the
7 administration of the drug.

8 C. This subsection may not be construed to require coverage
9 for a drug when the federal Food and Drug Administration has
10 determined its use to be contraindicated for treatment of
11 the current indication.

12 D. A drug use that is covered pursuant to paragraph A may
13 not be denied coverage based on a "medical necessity"
14 requirement except for a reason that is unrelated to the
15 legal status of the drug use.

16 E. A contract that provides coverage of a drug as required
17 by this subsection may contain provisions for maximum
18 benefits and coinsurance and reasonable limitations,
19 deductibles and exclusions to the same extent that these
20 provisions are applicable to coverage of all prescription
21 drugs and are not inconsistent with the requirements of this
22 subsection.

23 3. Application. The requirements of this section apply to
24 all policies, contracts and certificates executed, delivered,
25 issued for delivery, continued or renewed in this State on or
26 after January 1, 1999. For purposes of this section, all
27 contracts are deemed to be renewed no later than the next yearly
28 anniversary of the contract date.

29 **Sec. 3. 24-A MRSA §§2837-F and 2837-G are enacted to read:**

30 **§2837-F. Off-label use of prescription drugs for cancer**

31 **1. Definitions. As used in this section, unless the**
32 **context otherwise indicates, the following terms have the**
33 **following meanings.**

34 A. "Medically accepted indication" includes any use of a
35 drug that has been approved by the federal Food and Drug
36 Administration and includes another use of the drug if that
37 use is supported by one or more citations in the standard
38 reference compendia or if the insurer involved, based upon
39 guidance provided by the federal Department of Health and
40 Human Services Medicare program pursuant to 42 United States
41 Code, Section 1395x(t), determines that that use is

2 medically accepted based on supportive clinical evidence in
3 peer-reviewed medical literature.

4 B. "Off-label use" means the prescription and use of drugs
5 for medically accepted indications other than those stated
6 in the labeling approved by the federal Food and Drug
7 Administration.

8 C. "Peer-reviewed medical literature" means scientific
9 studies published in at least 2 articles from major
10 peer-reviewed medical journals that present data that
11 supports the proposed off-label use as generally safe and
12 effective.

13 D. "Standard reference compendia" means:

14 (1) The United States Pharmacopeia Drug Information or
15 information published by its successor organization; or

16 (2) The American Hospital Formulary Service Drug
17 Information or information published by its successor
18 organization.

19 2. Required coverage for off-label use. All group
20 insurance policies and contracts that provide coverage for
21 prescription drugs must provide coverage for off-label use in
22 accordance with the following.

23 A. Group insurance policies and contracts that provide
24 coverage for prescription drugs may not exclude coverage of
25 any such drug used for the treatment of cancer for a
26 medically accepted indication on the grounds that the drug
27 has not been approved by the federal Food and Drug
28 Administration for that indication, as long as that use of
29 that drug is a medically accepted indication for the
30 treatment of cancer.

31 B. Coverage of a drug required by this subsection also
32 includes medically necessary services associated with the
33 administration of the drug.

34 C. This subsection may not be construed to require coverage
35 for a drug when the federal Food and Drug Administration has
36 determined its use to be contraindicated for treatment of
37 the current indication.

38 D. A drug use that is covered pursuant to paragraph A may
39 not be denied coverage based on a "medical necessity"
40 requirement except for a reason that is unrelated to the
41 legal status of the drug use.

2 E. A contract that provides coverage of a drug as required
4 by this subsection may contain provisions for maximum
6 benefits and coinsurance and reasonable limitations,
8 deductibles and exclusions to the same extent that these
provisions are applicable to coverage of all prescription
drugs and are not inconsistent with the requirements of this
subsection.

10 3. Application. The requirements of this section apply to
12 all policies, contracts and certificates executed, delivered,
14 issued for delivery, continued or renewed in this State on or
16 after January 1, 1999. For purposes of this section, all
18 contracts are deemed to be renewed no later than the next yearly
20 anniversary of the contract date.

22 **§2837-G. Off-label use of prescription drugs for HIV or AIDS**

24 1. Definitions. As used in this section, unless the
26 context otherwise indicates, the following terms have the
28 following meanings.

30 A. "Off-label use" means the prescription and use of drugs
32 for indications other than those stated in the labeling
34 approved by the federal Food and Drug Administration.

36 B. "Peer-reviewed medical literature" means scientific
38 studies published in at least 2 articles from major
40 peer-reviewed medical journals that present data that
42 supports the proposed off-label use as generally safe and
44 effective.

46 C. "Standard reference compendia" means:

48 (1) The United States Pharmacopeia Drug Information or
50 information published by its successor organization; or

(2) The American Hospital Formulary Service Drug
Information or information published by its successor
organization.

2. Required coverage for off-label use. All group
insurance policies and contracts that provide coverage for
prescription drugs must provide coverage for off-label use in
accordance with the following.

A. Group insurance policies and contracts that provide
coverage for prescription drugs may not exclude coverage of
any such drug used for the treatment of HIV or AIDS on the
grounds that the drug has not been approved by the federal

2 Food and Drug Administration for that indication, as long as
3 that drug is recognized for the treatment of that indication
4 in one of the standard reference compendia or in
5 peer-reviewed medical literature.

6 B. Coverage of a drug required by this subsection also
7 includes medically necessary services associated with the
8 administration of the drug.

10 C. This subsection may not be construed to require coverage
11 for a drug when the federal Food and Drug Administration has
12 determined its use to be contraindicated for treatment of
13 the current indication.

14 D. A drug use that is covered pursuant to paragraph A may
15 not be denied coverage based on a "medical necessity"
16 requirement except for a reason that is unrelated to the
17 legal status of the drug use.

18 E. A contract that provides coverage of a drug as required
19 by this subsection may contain provisions for maximum
20 benefits and coinsurance and reasonable limitations,
21 deductibles and exclusions to the same extent that these
22 provisions are applicable to coverage of all prescription
23 drugs and are not inconsistent with the requirements of this
24 subsection.

25 3. Application. The requirements of this section apply to
26 all policies, contracts and certificates executed, delivered,
27 issued for delivery, continued or renewed in this State on or
28 after January 1, 1999. For purposes of this section, all
29 contracts are deemed to be renewed no later than the next yearly
30 anniversary of the contract date.

31 Sec. 4. 24-A MRSA §§4234-D and 4234-E are enacted to read:

32 §4234-D. Off-label use of prescription drugs for cancer

33 1. Definitions. As used in this section, unless the
34 context otherwise indicates, the following terms have the
35 following meanings.

36 A. "Medically accepted indication" includes any use of a
37 drug that has been approved by the federal Food and Drug
38 Administration and includes another use of the drug if that
39 use is supported by one or more citations in the standard
40 reference compendia or if the health maintenance
41 organization involved, based upon guidance provided by the
42 federal Department of Health and Human Services Medicare
43 program pursuant to 42 United States Code, Section 1395x(t).

2 determines that that use is medically accepted based on
3 supportive clinical evidence in peer-reviewed medical
4 literature.

5 B. "Off-label use" means the prescription and use of drugs
6 for medically accepted indications other than those stated
7 in the labeling approved by the federal Food and Drug
8 Administration.

9 C. "Peer-reviewed medical literature" means scientific
10 studies published in at least 2 articles from major
11 peer-reviewed medical journals that present data that
12 supports the proposed off-label use as generally safe and
13 effective.

14 D. "Standard reference compendia" means:

15 (1) The United States Pharmacopeia Drug Information or
16 information published by its successor organization; or

17 (2) The American Hospital Formulary Service Drug
18 Information or information published by its successor
19 organization.

20 2. Required coverage for off-label use. All health
21 maintenance organization individual and group contracts that
22 provide coverage for prescription drugs must provide coverage for
23 off-label use in accordance with the following.

24 A. Health maintenance organization individual and group
25 contracts that provide coverage for prescription drugs may
26 not exclude coverage of any such drug used for the treatment
27 of cancer for a medically accepted indication on the grounds
28 that the drug has not been approved by the federal Food and
29 Drug Administration for that indication, as long as that use
30 of that drug is a medically accepted indication for the
31 treatment of cancer.

32 B. Coverage of a drug required by this subsection also
33 includes medically necessary services associated with the
34 administration of the drug.

35 C. This subsection may not be construed to require coverage
36 for a drug when the federal Food and Drug Administration has
37 determined its use to be contraindicated for treatment of
38 the current indication.

39 D. A drug use that is covered pursuant to paragraph A may
40 not be denied coverage based on a "medical necessity"

2 requirement except for a reason that is unrelated to the
3 legal status of the drug use.

4 E. A contract that provides coverage of a drug as required
5 by this subsection may contain provisions for maximum
6 benefits and coinsurance and reasonable limitations,
7 deductibles and exclusions to the same extent that these
8 provisions are applicable to coverage of all prescription
9 drugs and are not inconsistent with the requirements of this
10 subsection.

11 3. Application. The requirements of this section apply to
12 all policies, contracts and certificates executed, delivered,
13 issued for delivery, continued or renewed in this State on or
14 after January 1, 1999. For purposes of this section, all
15 contracts are deemed to be renewed no later than the next yearly
16 anniversary of the contract date.

17 **§4234-E. Off-label use of prescription drugs for HIV or AIDS**

18 1. Definitions. As used in this section, unless the
19 context otherwise indicates, the following terms have the
20 following meanings.

21 A. "Off-label use" means the prescription and use of drugs
22 for indications other than those stated in the labeling
23 approved by the federal Food and Drug Administration.

24 B. "Peer-reviewed medical literature" means scientific
25 studies published in at least 2 articles from major
26 peer-reviewed medical journals that present data that
27 supports the proposed off-label use as generally safe and
28 effective.

29 C. "Standard reference compendia" means:

30 (1) The United States Pharmacopeia Drug Information or
31 information published by its successor organization; or

32 (2) The American Hospital Formulary Service Drug
33 Information or information published by its successor
34 organization.

35 2. Required coverage for off-label use. All health
36 maintenance organization individual and group contracts that
37 provide coverage for prescription drugs must provide coverage for
38 off-label use in accordance with the following.

39 A. Health maintenance organization individual and group
40 contracts that provide coverage for prescription drugs may
41 provide coverage for off-label use in accordance with the
42 following:

2 not exclude coverage of any such drug used for the treatment
4 of HIV or AIDS on the grounds that the drug has not been
6 approved by the federal Food and Drug Administration for
8 that indication, as long as that drug is recognized for the
10 treatment of that indication in one of the standard
12 reference compendia or in peer-reviewed medical literature.

14 B. Coverage of a drug required by this subsection also
16 includes medically necessary services associated with the
18 administration of the drug.

20 C. This subsection may not be construed to require coverage
22 for a drug when the federal Food and Drug Administration has
24 determined its use to be contraindicated for treatment of
26 the current indication.

28 D. A drug use that is covered pursuant to paragraph A may
30 not be denied coverage based on a "medical necessity"
32 requirement except for a reason that is unrelated to the
34 legal status of the drug use.

36 E. A contract that provides coverage of a drug as required
38 by this subsection may contain provisions for maximum
40 benefits and coinsurance and reasonable limitations,
42 deductibles and exclusions to the same extent that these
44 provisions are applicable to coverage of all prescription
46 drugs and are not inconsistent with the requirements of this
48 subsection.

3. Application. The requirements of this section apply to
all policies, contracts and certificates executed, delivered,
issued for delivery, continued or renewed in this State on or
after January 1, 1999. For purposes of this section, all
contracts are deemed to be renewed no later than the next yearly
anniversary of the contract date.'

Further amend the bill by inserting at the end before the
summary the following:

FISCAL NOTE

The state employees' health insurance program will incur
some minor additional costs related to the requirement that
health insurance policies include coverage for the use of certain
off-label prescriptions. These costs are not expected to affect
the amounts budgeted by state departments and agencies for state
employee health insurance.

2 The Bureau of Insurance within the Department of
3 Professional and Financial Regulation will incur some minor
4 additional costs to review new contract filings. These costs can
5 be absorbed within the bureau's existing budgeted resources.'

6
7
8 **SUMMARY**

9 This amendment replaces the bill. The amendment adds a
10 definition of "medically accepted indication" and requires that
11 carriers determine whether or not use of a drug for the treatment
12 of cancer is a medically accepted indication based on guidance
13 provided by the federal Department of Health and Human Services.
14 The amendment retains the language in the original bill regarding
15 coverage of off-label prescription drugs for the treatment of HIV
16 or AIDS.

17 This amendment amends the definition of "peer-reviewed
18 medical literature." The amendment clarifies that coverage
19 provisions for maximum benefits, coinsurance and deductibles
20 apply to coverage for off-label prescription drugs to the same
21 extent that the provisions are applicable to coverage of all
22 prescription drugs.

23 The amendment also adds a fiscal note to the bill.
24