

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)



118th MAINE LEGISLATURE

SECOND REGULAR SESSION-1998

Legislative Document

No. 2068

S.P. 761

In Senate, January 15, 1998

An Act to Permit Off-label Use of Prescription Drugs for Cancer, HIV or AIDS.

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 203.

Reference to the Committee on Banking and Insurance suggested and ordered printed.

A handwritten signature in cursive script, reading "Joy J. O'Brien".

JOY J. O'BRIEN
Secretary of the Senate

Presented by President LAWRENCE of York.

Cosponsored by Senators: ABROMSON of Cumberland, LaFOUNTAIN of York, LONGLEY of Waldo, RAND of Cumberland, Representative: SAXL of Bangor.

Be it enacted by the People of the State of Maine as follows:

2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50

Sec. 1. 24 MRSA §2320-F is enacted to read:

§2320-F. Off-label use of prescription drugs for cancer, HIV or AIDS

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

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

B. "Peer-reviewed medical literature" means scientific studies published in at least 2 articles from major peer-reviewed medical journals that present data that supports the proposed off-label use as generally safe and effective, unless there is clear and convincing contradictory evidence presented in another major peer-reviewed medical journal.

C. "Standard reference compendia" means:

(1) The United States Pharmacopeia Drug Information, or 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 individual and group nonprofit hospital and medical services plan contracts and nonprofit health care plan contracts that provide coverage for prescription drugs must provide coverage for off-label use in accordance with the following.

A. Individual and group nonprofit hospital and medical services plan contracts and nonprofit health care plan contracts that provide coverage for prescription drugs may not exclude coverage for any such drug used for the treatment of cancer, HIV or AIDS on the grounds that the drug has not been approved by the federal Food and Drug Administration for that indication, as long as that drug is recognized for the treatment of that indication in one of the standard reference compendia, or in peer-reviewed medical literature.

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

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

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

16 3. Application. The requirements of this section apply to
18 all policies, contracts and certificates executed, delivered,
20 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.

22 Sec. 2. 24-A MRSA §2745-E is enacted to read:

24 §2745-E. Off-label use of prescription drugs for cancer, HIV or
26 AIDS

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

32 A. "Off-label use" means the prescription and use of drugs
34 for indications other than those stated in the labeling
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
effective, unless there is clear and convincing
contradictory evidence presented in another major
peer-reviewed medical journal.

44 C. "Standard reference compendia" means:

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

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

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

8 A. Individual insurance policies and contracts that provide
coverage for prescription drugs may not exclude coverage for
10 any such drug used for the treatment of cancer, HIV or AIDS
on the grounds that the drug has not been approved by the
12 federal Food and Drug Administration for that indication, as
long as that drug is recognized for the treatment of that
14 indication in one of the standard reference compendia, or in
peer-reviewed medical literature.

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

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

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

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

36 Sec. 3. 24-A MRS §2837-F is enacted to read:

38 §2837-F. Off-label use of prescription drugs for cancer, HIV or
40 AIDS

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

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

50 B. "Peer-reviewed medical literature" means scientific
studies published in at least 2 articles from major

2 peer-reviewed medical journals that present data that
3 supports the proposed off-label use as generally safe and
4 effective, unless there is clear and convincing
5 contradictory evidence presented in another major
6 peer-reviewed medical journal.

7 C. "Standard reference compendia" means:

8
9 (1) The United States Pharmacopeia Drug Information,
10 or information published by its successor organization;
11 or

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

16
17 2. Required coverage for off-label use. All group
18 insurance policies and contracts that provide coverage for
19 prescription drugs must provide coverage for off-label use in
20 accordance with the following.

21
22 A. Group insurance policies and contracts that provide
23 coverage for prescription drugs may not exclude coverage of
24 any such drug used for the treatment of cancer, HIV or AIDS
25 on the grounds that the drug has not been approved by the
26 federal Food and Drug Administration for that indication, as
27 long as that drug is recognized for the treatment of that
28 indication in one of the standard reference compendia, or in
29 peer-reviewed medical literature.

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

44
45 3. Application. The requirements of this section apply to
46 all policies, contracts and certificates executed, delivered,
47 issued for delivery, continued or renewed in this State on or
48 after January 1, 1999. For purposes of this section, all
49 contracts are deemed to be renewed no later than the next yearly
50 anniversary of the contract date.

2
3 Sec. 4. 24-A MRSA §4234-C is enacted to read:

4 §4234-C. Off-label use of prescription drugs for cancer, HIV or
5 AIDS

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

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

14 B. "Peer-reviewed medical literature" means scientific
15 studies published in at least 2 articles from major
16 peer-reviewed medical journals that present data that
17 supports the proposed off-label use as generally safe and
18 effective, unless there is clear and convincing
19 contradictory evidence presented in another major
20 peer-reviewed medical journal.

22 C. "Standard reference compendia" means:

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

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

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

36 A. Health maintenance organization individual and group
37 contracts that provide coverage for prescription drugs may
38 not exclude coverage of any such drug used for the treatment
39 of cancer, HIV or AIDS on the grounds that the drug has not
40 been approved by the federal Food and Drug Administration
41 for that indication, as long as that drug is recognized for
42 the treatment of that indication in one of the standard
43 reference compendia, or in peer-reviewed medical literature.

44 B. Coverage of a drug required by this subsection also
45 includes medically necessary services associated with the
46 administration of the drug.

47 C. This subsection may not be construed to require coverage
48 for a drug when the federal Food and Drug Administration has
49 approved the drug for that indication.

2 determined its use to be contraindicated for treatment of
3 the current indication.

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

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

16

18

SUMMARY

20

21 This bill provides that health insurance policies must
22 include coverage for off-label use of prescriptions for the
23 treatment of cancer, HIV or AIDS when such use is recognized in
24 standard medical compendia or peer-reviewed professional journals.

26

27 This bill applies to all policies and contracts in effect on
28 or after January 1, 1999 that provide coverage for prescription
 drugs.

28