

26:1A-36.9

LEGISLATIVE HISTORY CHECKLIST
Compiled by the NJ State Law Library

(Prescription--"off-labels")

NJSA: 26:1A-36.9 et al

LAWS OF: 1993 **CHAPTER:** 321

BILL NO: S1631

SPONSOR(S) Sinagra and others

DATE INTRODUCED: March 15, 1993

COMMITTEE: **ASSEMBLY:** Insurance
SENATE: Commerce

AMENDED DURING PASSAGE: Yes Amendments during passage
First reprint enacted denoted by superscript numbers

DATE OF PASSAGE: **ASSEMBLY:** December 13, 1993
SENATE: June 28, 1993

DATE OF APPROVAL: December 23, 1993

FOLLOWING STATEMENTS ARE ATTACHED IF AVAILABLE:

SPONSOR STATEMENT: Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes
SENATE: Yes

FISCAL NOTE: No

VETO MESSAGE: No

MESSAGE ON SIGNING: No

FOLLOWING WERE PRINTED:

REPORTS: No

HEARINGS: No

KBG:pp

[FIRST REPRINT]

SENATE, No. 1631

STATE OF NEW JERSEY

INTRODUCED MARCH 15, 1993

By Senators SINAGRA, BASSANO, Haines,
Ciesla and Cafiero

1 AN ACT requiring health insurance benefits for "off-label" uses
2 of certain drugs and supplementing P.L.1938, c.366 (C.17:48-1
3 et seq.), P.L.1940, c.74 (C.17:48A-1 et seq.), P.L.1985, c.236
4 (C.17:48E-1 et seq.), chapter 26 of Title 17B of the New Jersey
5 Statutes, chapter 27 of Title 17B of the New Jersey Statutes,
6 and P.L.1973, c.337 (C.26:2J-1 et seq.).
7

8 BE IT ENACTED *by the Senate and General Assembly of the*
9 *State of New Jersey:*

10 1. The Legislature finds and declares that:

11 a. Many citizens of this State rely upon health insurance to
12 cover the cost of obtaining health care.

13 b. It is essential that the citizens' expectation that their
14 health care costs will be paid by their insurance policies is not
15 disappointed and that they obtain the coverage necessary and
16 appropriate for their care within the terms of their insurance
17 policies.

18 c. Currently, some insurers deny payment for drugs that have
19 been approved by the Federal Food and Drug Administration
20 (FDA) when the drugs are prescribed for treatments other than
21 those stated in the labelling approved by the FDA ("off-label"
22 use) while other insurers providing similar coverage terms do pay
23 for "off-label" use.

24 d. Denial of payment for "off-label" use can interrupt or
25 effectively deny access to necessary and appropriate treatment
26 for a person being treated for a life-threatening illness.

27 e. "Off-label" use of an FDA-approved drug is legal when
28 prescribed in a medically appropriate way and is often necessary
29 to provide needed care. Approximately 50 percent of cancer
30 patients receive some type of "off label" drug in their
31 treatment. The FDA and the federal Department of Health and
32 Human Services recognize the wide variety of effective
33 "off-label" uses of FDA-approved drugs. Information on the
34 appropriate "off-label" use of FDA-approved drugs is obtained
35 from compendia published by the United States Pharmacopeial
36 Convention, the American Medical Association, and the American
37 Society of Hospital Pharmacists. In addition, scientific studies of
38 "off-label" use of drugs published in recognized peer-reviewed
39 professional journals provide information on appropriate uses of
40 "off-label" drugs.

41 f. The "Omnibus Budget Reconciliation Act of 1990," Pub. L.
42 101-508, requires Medicaid agencies to pay for "off-label" use of

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in the
above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹ Senate SCM committee amendments adopted June 14, 1993.

1 drugs prescribed for Medicaid patients if the use is stated in any
2 of the three compendia or peer-reviewed literature; thereby
3 providing recognition of the three compendia and peer-reviewed
4 literature as appropriate sources for reimbursement.

5 g. "Off-label" use of FDA-approved drugs provides efficacious
6 drugs at a lower cost. To require that all appropriate uses of a
7 drug undergo approval by the FDA may substantially increase the
8 cost of drugs and delay or even deny patients' ability to obtain
9 medically effective treatment. FDA approval for each use would
10 require substantial expenditure and time to undergo the clinical
11 trials necessary to obtain FDA approval.

12 h. Reimbursement for "off-label" uses of FDA-approved drugs
13 is necessary to conform to the way in which appropriate medical
14 treatment is provided, to make needed drugs available to
15 patients, and may help to contain health care costs.

16 2. a. Except as provided in P.L.1992, c.161 (C.17B:27A-2 et
17 seq.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no group or
18 individual hospital service corporation contract which provides
19 benefits for expenses incurred in prescribing drugs approved by
20 the federal Food and Drug Administration shall be delivered,
21 issued, executed or renewed in this State, or approved for
22 issuance or renewal in this State on or after the effective date of
23 this act, unless the contract provides benefits to any subscriber
24 or other person covered thereunder for expenses incurred in
25 prescribing a drug for a treatment for which it has not been
26 approved by the Food and Drug Administration if the drug is
27 recognized as being medically appropriate for the specific
28 treatment for which it has been prescribed ¹[by the panel
29 established pursuant to section 8 of P.L. , c. (C.)
30 (pending before the Legislature as this bill), or if it is recognized
31 for that treatment]¹ in one of the following established reference
32 compendia:

33 (1) the American Medical Association Drug Evaluations;
34 (2) the American Hospital Formulary Service Drug Information;
35 (3) the United States Pharmacopeia Drug Information;
36 or, it is recommended by a ¹clinical study or¹ review article
37 ¹[or editorial comment]¹ in a major peer-reviewed professional
38 journal.

39 b. Notwithstanding the provisions of this section, coverage
40 shall not be required for any experimental or investigational drug
41 or any drug which the Food and Drug Administration has
42 determined to be contraindicated for the specific treatment for
43 which the drug has been prescribed. The benefits provided
44 pursuant to this section shall be provided to the same extent as
45 other benefits under the contract for drugs prescribed for a
46 treatment approved by the Food and Drug Administration.

47 c. This section shall apply to all hospital service corporation
48 contracts in which the hospital service corporation has reserved
49 the right to change the premium.

50 d. Any coverage of a drug required by this section shall also
51 include medically necessary services associated with the
52 administration of the drug.

53 3. a. Except as provided in P.L.1992, c.161 (C.17B:27A-2 et
54 seq.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no group or

1 individual medical service corporation contract which provides
2 benefits for expenses incurred in prescribing drugs approved by
3 the federal Food and Drug Administration shall be delivered,
4 issued, executed or renewed in this State, or approved for
5 issuance or renewal in this State on or after the effective date of
6 this act, unless the contract provides benefits to any subscriber
7 or other person covered thereunder for expenses incurred in
8 prescribing a drug for a treatment for which it has not been
9 approved by the Food and Drug Administration if the drug is
10 recognized as being medically appropriate for the specific
11 treatment for which it has been prescribed ¹[by the panel
12 established pursuant to section 8 of P.L. , c. (C.) (pending
13 before the Legislature as this bill), or if the drug is recognized
14 for that treatment]¹ in one of the following established reference
15 compendia:

16 (1) the American Medical Association Drug Evaluations;
17 (2) the American Hospital Formulary Service Drug Information;
18 (3) the United States Pharmacopeia Drug Information;
19 or, it is recommended by a ¹clinical study or¹ review article
20 ¹[or editorial comment]¹ in a major peer-reviewed professional
21 journal.

22 b. Notwithstanding the provisions of this section, coverage
23 shall not be required for any experimental or investigational drug
24 or any drug which the Food and Drug Administration has
25 determined to be contraindicated for the specific treatment for
26 which the drug has been prescribed. The benefits provided
27 pursuant to this section shall be provided to the same extent as
28 other benefits under the contract for drugs prescribed for a
29 treatment approved by the Food and Drug Administration.

30 c. This section shall apply to all medical service corporation
31 contracts in which the medical service corporation has reserved
32 the right to change the premium.

33 d. Any coverage of a drug required by this section shall also
34 include medically necessary services associated with the
35 administration of the drug.

36 4. a. Except as otherwise provided in P.L.1992, c.161
37 (C.17B:27A-2 et seq.) and P.L.1992, c.162 (C.17B:27A-17 et seq.),
38 no group or individual health service corporation contract which
39 provides benefits for expenses incurred in prescribing drugs
40 approved by the federal Food and Drug Administration shall be
41 delivered, issued, executed or renewed in this State, or approved
42 for issuance or renewal in this State on or after the effective
43 date of this act, unless the contract provides benefits to any
44 subscriber or other person covered thereunder for expenses
45 incurred in prescribing a drug for a treatment for which it has not
46 been approved by the Food and Drug Administration if the drug is
47 recognized as being medically appropriate for the specific
48 treatment for which it has been prescribed ¹[by the panel
49 established pursuant to section 8 of P.L. , c. (C.) (pending
50 before the Legislature as this bill), or if the drug is recognized
51 for that treatment]¹ in one of the following established reference
52 compendia:

53 (1) the American Medical Association Drug Evaluations;
54 (2) the American Hospital Formulary Service Drug Information;

1 (3) the United States Pharmacopeia Drug Information;
2 or, it is recommended by a ¹clinical study or¹ review article
3 ¹[or editorial comment]¹ in a major-peer reviewed professional
4 journal.

5 b. Notwithstanding the provisions of this section, coverage
6 shall not be required for any experimental or investigational drug
7 or any drug which the Food and Drug Administration has
8 determined to be contraindicated for the specific treatment for
9 which the drug has been prescribed. The benefits provided
10 pursuant to this section shall be provided to the same extent as
11 other benefits under the contract for drugs prescribed for a
12 treatment approved by the Food and Drug Administration.

13 c. This section shall apply to all health service corporation
14 contracts in which the health service corporation has reserved
15 the right to change the premium.

16 d. Any coverage of a drug required by this section shall also
17 include medically necessary services associated with the
18 administration of the drug.

19 5. a. Except as otherwise provided in P.L.1992, c.161
20 (C.17B:27A-2 et seq.), no individual health insurance policy which
21 provides benefits for expenses incurred in prescribing drugs
22 approved by the federal Food and Drug Administration shall be
23 delivered, issued, executed or renewed in this State, or approved
24 for issuance or renewal in this State on or after the effective
25 date of this act, unless the policy provides benefits to any
26 policyholder or other person covered thereunder for expenses
27 incurred in prescribing a drug for a treatment for which it has not
28 been approved by the Food and Drug Administration if the drug is
29 recognized as being medically appropriate for the specific type of
30 treatment for which the drug has been prescribed ¹[by the panel
31 established pursuant to section 8 of P.L. , c. (C.) (pending
32 before the Legislature as this bill), or if the drug is recognized
33 for that treatment]¹ in one of the following established reference
34 compendia:

35 (1) the American Medical Association Drug Evaluations;

36 (2) the American Hospital Formulary Service Drug Information;

37 (3) the United States Pharmacopeia Drug Information;

38 or, it is recommended by a ¹clinical study or¹ review article
39 ¹[or editorial comment]¹ in a major-peer reviewed professional
40 journal.

41 b. Notwithstanding the provisions of this section, coverage
42 shall not be required for any experimental or investigational drug
43 or any drug which the Food and Drug Administration has
44 determined to be contraindicated for the specific treatment for
45 which the drug has been prescribed. The benefits provided
46 pursuant to this section shall be provided to the same extent as
47 other benefits under the policy for drugs prescribed for a
48 treatment approved by the Food and Drug Administration.

49 c. This section shall apply to all individual health insurance
50 policies in which the insurer has reserved the right to change the
51 premium.

52 d. Any coverage of a drug required by this section shall also
53 include medically necessary services associated with the
54 administration of the drug.

1 6. a. Except as otherwise provided in P.L.1992, c.162
2 (C.17B:27A-17 et seq.), no group health insurance policy which
3 provides benefits for expenses incurred in prescribing drugs
4 approved by the federal Food and Drug Administration shall be
5 delivered, issued, executed or renewed in this State, or approved
6 for issuance or renewal in this State, on or after the effective
7 date of this act unless the policy provides benefits to any
8 policyholder or other person covered thereunder for expenses
9 incurred in prescribing a drug for a treatment for which it has not
10 been approved by the Food and Drug Administration if the drug is
11 recognized as being medically appropriate for the specific
12 treatment for which the drug has been prescribed ¹[by the panel
13 established pursuant to section 8 of P.L. , c. (C.) (pending
14 before the Legislature as this bill), or if the drug is recognized
15 for that treatment]¹ in one of the following established reference
16 compendia:

17 (1) the American Medical Association Drug Evaluations;
18 (2) the American Hospital Formulary Service Drug Information;
19 (3) the United States Pharmacopeia Drug Information;
20 or, it is recommended by a ¹clinical study or¹ review article
21 ¹[or editorial comment]¹ in a major-peer reviewed professional
22 journal.

23 b. Notwithstanding the provisions of this section, coverage
24 shall not be required for any experimental or investigational drug
25 or any drug which the Food and Drug Administration has
26 determined to be contraindicated for the specific treatment for
27 which the drug has been prescribed. The benefits provided
28 pursuant to this section shall be provided to the same extent as
29 other benefits under the policy for drugs prescribed for
30 treatments approved by the Food and Drug Administration.

31 c. This section shall apply to all group health insurance
32 policies in which the insurer has reserved the right to change the
33 premium.

34 d. Any coverage of a drug required by this section shall also
35 include medically necessary services associated with the
36 administration of the drug.

37 7. a. Notwithstanding any provision of law to the contrary,
38 and except as otherwise provided in P.L.1992, c.161 (C.17B:27A-2
39 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.), a certificate
40 of authority to establish and operate a health maintenance
41 organization in this State shall not be issued or continued on or
42 after the effective date of this act for a health maintenance
43 organization which provides health care services for prescribed
44 drugs approved by the federal Food and Drug Administration
45 unless the health maintenance organization provides health care
46 services to any enrollee for a drug prescribed for a treatment for
47 which it has not been approved by the Food and Drug
48 Administration if it is recognized to be medically appropriate for
49 the specific treatment for which the drug has been prescribed
50 ¹[by the panel established pursuant to section 8 of P.L. , c.
51 (C.) (pending before the Legislature as this bill), or if it is
52 recognized for that treatment]¹ in one of the following
53 established reference compendia:

54 (1) the American Medical Association Drug Evaluations;

1 (2) the American Hospital Formulary Service Drug Information;
2 (3) the United States Pharmacopeia Drug Information;
3 or, it is recommended by a ¹clinical study or¹ review article
4 ¹[or editorial comment]¹ in a major-peer reviewed professional
5 journal.

6 b. Notwithstanding the provisions of this section, coverage
7 shall not be required for any experimental or investigational drug
8 or any drug which the Food and Drug Administration has
9 determined to be contraindicated for the specific treatment for
10 which the drug has been prescribed. Health care services
11 provided pursuant to this section shall be ¹determined and¹
12 provided to the same extent as other services under the enrollee
13 plan for drugs prescribed for treatments which have been
14 approved by the Food and Drug Administration.

15 c. This section shall apply to health maintenance organization
16 plans in which the right to change the enrollee charge has been
17 reserved.

18 d. Any coverage of a drug required by this section shall also
19 include medically necessary services associated with the
20 administration of the drug.

21 ¹[8. a. Within 90 days of the effective date of this act, the
22 Commissioner of Health shall appoint a panel of seven medical
23 experts as follows: (1) three medical oncologists, upon the
24 recommendation of the Oncology Society of New Jersey; (2) two
25 specialists in the management of AIDS patients, upon the
26 recommendation of the Governor's Advisory Council on AIDS; (3)
27 one medical cardiologist, upon the recommendation the New
28 Jersey Chapter of the American College of Cardiology; and (4)
29 one physician, upon the recommendation of the State Medical
30 Society. The members of the panel shall serve for a term of
31 three years, and no member shall serve more than two
32 consecutive terms. The initial members of the panel shall serve
33 as follows: three members shall serve for a term of one year,
34 three members shall serve for a term of two years and one
35 member shall serve for a term of three years. Members of the
36 panel shall serve without compensation, except that they shall be
37 eligible for reimbursement for necessary and reasonable expenses
38 incurred in the performance of their official duties.
39 Reimbursement for those expenses shall be within the limits of
40 funds appropriated or otherwise made available for the panel's
41 purposes.

42 b. (1) When there is a dispute about payment by an insurer for
43 the "off-label" use of a drug, the panel, upon the request of the
44 Commissioner of Insurance, shall review the use in dispute, if it is
45 not recognized by the American Medical Association Drug
46 Evaluations, the American Hospital Formulary Service Drug
47 Information, the United States Pharmacopeia Drug Information,
48 or by peer-reviewed professional medical literature, and shall
49 advise the commissioner whether a particular "off-label" use is
50 medically appropriate for the purposes of sections 2 through 7 of
51 P.L. , c. (C.) (pending before the Legislature as this bill). A
52 majority vote of the panel shall be necessary to determine that
53 coverage is medically appropriate.

54 (2) If the dispute about payment by an insurer is over the

1 "off-label" use of a drug to treat a patient with a life
2 threatening disease or illness, the Commissioner of Insurance
3 shall refer the dispute to the panel within five days of
4 notification of the dispute, and the panel shall render its decision
5 within 15 days after its receipt of the referral.]¹

6 ¹[9.] 8.¹ The Commissioner of Insurance, after consultation
7 with the Commissioner of Health, shall, pursuant to the
8 provisions of the "Administrative Procedure Act," P.L.1968,
9 c.410 (C.52:14B-1 et seq.), promulgate rules and regulations to
10 effectuate the provisions of this act.

11 ¹[10.] 9.¹ This act shall take effect on the 180th day after
12 enactment.

13
14
15
16

17 Requires payment for certain "off-label" uses of certain drugs.

1 provisions of this act.

2 10. This act shall take effect on the 180th day after
3 enactment.

4

5

6

STATEMENT

7

8 This bill requires hospital service corporations (Blue Cross),
9 medical service corporations (Blue Shield), health service
10 corporations (Blue Cross/Blue Shield), commercial insurers and
11 health maintenance organizations which provide coverage for
12 drugs that are approved by the federal Food and Drug
13 Administration to also provide coverage for certain "off-label"
14 uses of those drugs. The bill requires coverage for any drug
15 prescribed for a treatment for which the drug has not been
16 approved by the Food and Drug Administration if the drug is
17 recognized for the specific treatment for which it has been
18 prescribed in one of three established reference compendia or is
19 recommended by a review article or editorial comment in a major
20 peer-reviewed professional journal.

21 When there is a dispute over coverage for "off-label" uses not
22 recognized by any of the reference compendia or peer-reviewed
23 professional literature, the bill requires that the Commissioner of
24 Insurance refer the dispute to a panel of seven medical experts.
25 Coverage for the "off-label" use shall be required if the use is
26 found to be medically appropriate by the panel. In a case where
27 the dispute is over the "off-label" use of a drug in the treatment
28 of a life threatening disease or illness, the bill requires the
29 Commissioner of Insurance to refer the dispute to the panel
30 within five days, and requires the panel to render its decision
31 within 15 days.

32 The bill also requires the Commissioner of Insurance, in
33 consultation with the Commissioner of Health, to promulgate
34 rules and regulations in order to effectuate the purposes of the
35 bill.

36

37

38

39

40 Requires payment for certain "off-label" uses of certain drugs.

ASSEMBLY INSURANCE COMMITTEE

STATEMENT TO

[FIRST REPRINT]

SENATE, No. 1631

STATE OF NEW JERSEY

DATED: NOVEMBER 22, 1993

The Assembly Insurance Committee reports favorably Senate Bill No. 1631 [1R].

This bill requires hospital service corporations, medical service corporations, health service corporations, commercial insurers and health maintenance organizations which provide coverage for drugs that are approved by the federal Food and Drug Administration to also provide coverage for certain "off-label" uses of those drugs. The bill requires coverage for any drug prescribed for a treatment for which the drug has not been approved by the Food and Drug Administration if the drug is recognized for the specific treatment for which it has been prescribed in one of three established reference compendia (the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia Drug Information) or is recommended by a clinical study or review article in a major peer-reviewed professional journal.

The bill does not require coverage for any experimental or investigational drug or any drug which the federal Food and Drug Administration has determined to be contraindicated for the specific treatment for which the drug has been prescribed.

The bill also requires the Commissioner of Insurance, in consultation with the Commissioner of Health, to promulgate rules and regulations in order to effectuate the purposes of the bill.

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 1631

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 14, 1993

The Senate Commerce Committee reports favorably and with committee amendments Senate, No. 1631.

This bill, as amended, requires hospital service corporations, medical service corporations, health service corporations, commercial insurers and health maintenance organizations which provide coverage for drugs that are approved by the federal Food and Drug Administration to also provide coverage for certain "off-label" uses of those drugs. The bill requires coverage for any drug prescribed for a treatment for which the drug has not been approved by the Food and Drug Administration if the drug is recognized for the specific treatment for which it has been prescribed in one of three established reference compendia (the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia Drug Information) or is recommended by a clinical study or review article in a major peer-reviewed professional journal.

The bill does not require coverage for any experimental or investigational drug or any drug which the federal Food and Drug Administration has determined to be contraindicated for the specific treatment for which the drug has been prescribed.

The bill also requires the Commissioner of Insurance, in consultation with the Commissioner of Health, to promulgate rules and regulations in order to effectuate the purposes of the bill.

"Off label" use of drugs is when drugs are prescribed for treatments other than those stated in the labelling approved by the federal Food and Drug Administration.