26:1A-36.9

LEGISLATIVE HISTORY CHECKLIST
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(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 denoted by superscript numbers
First reprint enacted

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

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

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

1. The Legislature finds and declares that:

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

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

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

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

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

f. The "Omnibus Budget Reconciliation Act of 1990," Pub. L. 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.

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopeia Drug Information;

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

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

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

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

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

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

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

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

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

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

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

provisions of this act.

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

STATEMENT

This bill requires hospital service corporations (Blue Cross), medical service corporations (Blue Shield), health service corporations (Blue Cross/Blue Shield), 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 or is recommended by a review article or editorial comment in a major peer-reviewed professional journal.

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

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.

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.