A Study of Assembly Bill 1830

A Report to the New Jersey State Assembly by the

Mandated Health Benefits Advisory Commission

June 20, 2012

Chris Christie
Governor

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Acting Commissioner

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Introduction

On February 21, 2012 the Mandated Health Benefits Advisory Commission (Commission) was asked to issue a report on Assembly Bill 1830 (A-1830), a bill originating in the 2012-2013 Legislative Session. A-1830 requires carriers issuing coverage in the Individual Health Coverage Program (IHC) market and the Small Employer Health Benefits Plan (SEH) market, as well as the State Health Benefits Program (SHBP) and School Employees' Health Benefits Program (SEHBP), to cover medications approved by the U.S. Food and Drug Administration (FDA) and prescribed "off-label" on the same basis as if that medication were prescribed in accordance with the FDA specifications (or "label") when certain criteria are met. The bill amends the criteria to be met for health carriers subject to the existing mandate to cover off-label drugs, specifically by excluding a compendium that is no longer published.

Current law or regulation already requires this coverage for individual and group health insurance, HMO coverage, and coverage by a non-profit health service corporation.[1] As such, A-1830 is an extension of this requirement to other markets, and makes statutory that which is currently required by regulations in others.

The Commission prepared this report using its own resources, including the New Jersey Department of Banking and Insurance (DOBI) staff. Commission members contributed significant professional expertise in providing direct input, evaluating published research, and drafting and reviewing the report.

The Commission is mandated by statute to examine the "social, financial, and medical impact of proposed mandated health benefits."[2] Because off-label uses are currently covered due to existing law and regulation, the economic costs of this mandate in the commercial market are expected to be negligible. However, the medical effects associated with prescription and use of off-label medications are significant, both positive and negative. This report addresses those considerations.

The report comments on the need for this mandate in the commercial market. To that end, the report addresses the current requirements concerning off-label medications in the IHC and SEH markets.

The Commission posts bills referred to it for study on its web site and invites the public to submit comments. The Commission received no public comments or any submissions of testimonies or statements on A-1830.

[1] See Appendix VI – New Jersey "Off-Label" Mandate Chart.
[2] P.L.2003, c.193.

Summary

If enacted, A-1830 would apply to the State-regulated commercial health insurance market[3] and the State-operated State Health Benefits Plan[4] (A-1830 specifically does not apply to the entire commercial insurance market, only to the IHC and SEH programs). There are slightly fewer than two million people covered by the State-regulated commercial market of 8.7 million residents of New Jersey. This market has annual premiums of approximately $9 billion. In addition, the State Health Benefits Plan covers approximately 850,000 employees, retirees and dependents at an annual cost of approximately $4.8 billion. This bill does not apply to the benefits provided by private employer or labor union self-funded plans due to federal preemption pursuant to the Employee Retirement Income Security Act of 1974 ("ERISA"; Pub. L. 93-406; 29 U.S.C. § 1002 et seq.).

The IHC program was established by law in 1992 and governs the issuance of individual health benefits plans issued after August 1, 1993 in New Jersey.[5] The IHC Board governs the program. Licensed health carriers offer coverage through rules that the Board promulgates. Approximately 140,000 people are currently covered by the IHC Program.

The SEH Program was established by law in 1992 and oversees the issuance of SEH benefits plans issued after January 1, 1994 in New Jersey.[6] The SEH Board governs the program. Licensed health carriers offer coverage through rules the Board promulgates. Approximately 700,000 people are currently covered by the SEH Benefits Program.

The SHBP and the SEHBP were also established by state law to provide benefits to certain public employees.[7] The Division of Pensions and Benefits in the Department of the Treasury operate both programs which are governed by their respective Commissions. The programs provide coverage to state employees, retirees and their dependents and (at the option of the employer) employees of local governments and agencies and public school systems. The programs collectively cover approximately 800,000 people.

[3] The regulated health market consists of individual and group coverage sold in New Jersey by insurers, Health Maintenance Organizations, and Horizon Blue Cross Blue Shield of New Jersey. It includes coverage in the Individual Health Coverage Program (IHC), Small Employer Health Benefits Plan (SEH) and large group market.
[4] This also includes the separate School Employees' Health Benefits Program (SEHBP) which was established by P.L.2007, c.103.
[5] N.J.S.A. 17B:27A-2 et seq.
[6] N.J.S.A. 17B:27A-17 et seq.
[7] N.J.S.A. 52:14-17.25 et seq. (SHBP); N.J.S.A. 52:14-17.46 et seq. (SEHBP)

Elements of Assembly Bill 1830

A-1830 would require carriers offering coverage in the IHC, SEH, SHBP and SEHBP programs, to cover off-label prescription drugs, when prescribed by a provider, to the same extent as use explicitly approved by the FDA ("on label use") in accordance with the following qualifying conditions:

1) The use is included in one of several approved lists (compendia) of allowed use of off-label drugs including:

a) the American Hospital Formulary Service (AHFS) Drug Information;[8] and

b) the United States Pharmacopoeia Drug Information (USP DI);[9] and

2) The use is recommended or supported by study in a peer-reviewed article.

New Jersey law currently requires that off-label drugs be covered subject to almost precisely the same conditions for groups that are not part of the SEH market ("large group") and individuals who were covered prior to August 1993 that are not part of the IHC market (pre-reform).[10]

Furthermore, although the laws governing the IHC and SEH Programs do not explicitly require similar coverage in these markets, such coverage is currently mandated by regulation to non-HMO carriers because the standard benefit plans established by regulation require coverage of off-label drugs using the same language as in the existing mandate.[11]

However, the benefit designs for the Public Employees' Plans do not currently include coverage of off-label drugs.[12]

Analysis

Medical Effectiveness

Before a medication can be (routinely) prescribed in the United States, it must be approved for use by the U.S. Food and Drug Administration (FDA). The FDA approval process evaluates whether drugs are safe and effective on an indication specific basis.

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[8] http://www.ahfsdruginformation.com/
[9] http://www.usp.org/
[10] See N.J.S.A. 17:48-6h, 17:48A-7g, 17:48E-35.5, 17B:26-2.1g, 17B:27-46.1g and 26:2J-4.5.
[11] See N.J.A.C. 11:20 Appendices and 11:21 Appendices.
[12] Pension and Health Benefits Review Commission: A-3868 Vote Results, July 8, 2011 http://www.state.nj.us/treasury/pensions/pension_hb_review_commission11.shtml#julv.

Once a drug is FDA approved for a specific indication and population, providers may choose to use "off-label" for other indications or populations.

FDA approval is for specific populations and conditions or diagnoses and is based on a series of trials or studies to determine the drug's safety and efficacy for the indications tested. The "label" is the FDA specification of these approved uses. When an approved medication is used in some other way (that is, for a population or diagnosis not mentioned in the FDA approval) the use is referred to as "off-label."

The FDA's approach in recent years has placed increased emphasis on controlling the marketing of "off-label" drugs usage, strengthening post-marketing surveillance, facilitating adverse drug event reporting, implementing mandatory registration of industry studies and with the 2009 guidance providing information on providing good reprint practices, vis-à-vis peer-reviewed journals, and ensuring any study cited has evidence of disclosure so that the study is free from commercial bias.[13]

Off-label use of medications is widespread and generally regarded as necessary in order to allow providers adequate flexibility in treatment. Off-label use is described as clinically common in pediatric, geriatric, and obstetric-gynecologic practice because of the lack of medications that can be approved for these specific specialties, due to a paucity of studies specific to these populations (Off-label use also appears to be common in treatment of cancer and in behavioral health). By far the most common prescriptions written for off-label in both the Canadian and the Agency for Healthcare Research and Quality (AHRQ) studies were for drugs affecting the central nervous system (CNS), including anticonvulsants, antipsychotics and antidepressants.[14]

Considerations affecting off-label prescription

A recent editorial in Archives of Internal Medicine begins:

"This issue of off-label prescribing is a loaded subject. When one scratches the surface, one realizes the myriad limitations of such a construct related to the process of labeling, the monitoring of appropriate prescribing, the inadequacy of evidence to match the complexities of care, and the missed opportunities of leveraging our information systems to better optimize medication use for the care of patients."[15]

This thoughtful paragraph raises many of the relevant considerations on this subject.

Potential positives of off-label prescribing include, but are not limited to:

1) Availability of medication to treat conditions that are too rare to study to meet FDA approval criteria;

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[13] Off-Label Prescribing: A Call for Heightened Professional and Government Oversight Reference: Dresser, Rebecca and Joel Frader, Legal Studies Research Paper Series, Paper No. 10-09-03, Fall 2009.

[14] Canada: Drug, Patient, and Physician Characteristics Associated With Off-label Prescribing in Primary Care, Equale, Tewodros et al., *Arch Intern Med*, April 16, 2012 DOI: 10.1001/archinternmed.2012.340; Table 4. Clinical indications associated with the largest number of uses for approved and off-label uses with inadequate evidence, United States, July 2005 through June 2007, IMS health national therapeutic and disease index.

[15] Arch Int. Med., 2012 v.1, 789.

2) Availability of medication to treat populations less likely to be studied (specifically pediatric and pregnant patients); and
3) Availability of medications to treat conditions for which manufacturers will not undergo the expensive process necessary to obtain FDA approval.

Potential negatives include, but are not limited to:
1. A greater number of people are exposed to adverse effects;
2. Previously unknown adverse effects may be discovered with the off-label prescription of the medication to populations not previously studied;
3. Adverse effects due to drug interactions are likely to increase;
4. Decreased effectiveness compared to other on-label or off-label alternatives;
5. Increased cost compared to other on-label or off-label alternatives; and
6. Third party reimbursement for off-label prescriptions of medication would increase the potential for clearly inappropriate therapy.

In the cases of particular off-label uses, instances of these negatives are well-documented, generating publicity or lawsuits, and probably casting a shadow over off-label use.

Responses to these problems are possible at both the institutional and the professional level. At the institutional level, published compendia, journals, and review boards can give guidance to individual providers on the appropriateness of a particular off-label use.

At the professional level, providers can be encouraged and trained to use evidence-based methods in choosing to prescribe off-label. In addition to consulting the institutional sources mentioned above, providers should appropriately evaluate journal articles and remain aware that information from drug manufacturers, journal articles, and colleagues may be influenced by economic or other considerations, such as academic or professional vanity. Providers can also help this process by actively participating in the reporting of adverse or positive outcomes.

Payors, such as insurance carriers, governments, and self-funded private plans also can also be responsible institutional contributors. Current carrier practice is not to review prescriptions systematically for off-label use. In fact, currently there is often insufficient information in the prescription to identify the intended use as off-label. However, when certain classes of drugs are chosen or eliminated from formularies, or are subject to pre-authorization because of cost, effectiveness, or side effects such as toxicity or addiction, whether or not the use is off-label could be a part of the evaluation even if, pursuant to state law, the carrier cannot deny coverage solely because the use is off-label.

Social Impact

The social impact of off-label prescription use is primarily discussed in the medical effectiveness section above. The general population benefits from the availability of off-label medications, but is also the target of the negative aspects including side effects.

Patients may not be aware that the medication prescribed by their provider is being done so off-label, or be aware of the implications of such a prescription, unless this information is provided by the provider or pharmacist. As noted, providers have a responsibility to prescribe appropriately, whether on-label or off-label. They may also consider whether they have a responsibility to inform the patient that the use is off-label if that would be relevant to the patient.[16]

There have been instances where off-label use, supported by an article in a peer-reviewed journal, was subsequently determined to be inappropriate.[17] The Commission observes that there are various levels of weight that might be given to a journal article supporting off-label use. For example, an article documenting use in a particular setting might be given less weight than a survey article analyzing all of the literature on a particular off-label use.

Financial Impact

The current cost of off-label prescriptions is difficult to estimate. Most prescriptions do not contain information such as diagnosis which would allow identification of off-label use (As an exception, the New Jersey Medicaid/Family Care program is moving towards capturing information allowing review of off-label use in its prescription drug program).

Some surveys suggest that 11 to 20 percent of prescriptions are off-label. This may not translate to a percentage of cost because off-label use is concentrated in particular medications or practice areas which may be more or less expensive than the average medication cost. The Canadian estimate of 11 percent may be low because the study on which it is based tracked only diagnosis and did not include factors such as age and dosage. An AHRQ study, on the other hand, states that more than twenty percent of prescriptions are off-label.[18]

We estimate the incremental cost of the mandate as negligible because all commercial market coverage is already effectively covered by the mandate. Coverage other than that provided through the SEH and IHC markets is explicitly covered by statute. SEH and IHC regulations currently require that standard plans in these markets cover off-label drugs on the same basis as in other commercial markets.

Technically, carriers could legally offer decreasing benefit riders to SEH standard plans that limit prescription drug coverage for off-label prescriptions. We are unaware of any such riders. However, this bill would make such riders impossible (although its applicability to Basic & Essential plans may need to be clarified).

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[16] Dresser, Id.

[17] An example is the use of Recombinant Activated Factor VII approved by the FDA in 1999 for treatment of bleeding in patients with hemophilia, but suggested (in 2005), then subsequently contraindicated (in 2006), for treatment of intracerebral hemorrhage, http://www.nejm.org/doi/full/10.1056/NEJMoa042991; http://jama.ama-assn.org/content/295/3/293.full.

[18] United States: Walton SM, Schumock GT, Lee K-V, et al. Developing evidence-based research priorities for off-label drug use. Effective Health Care Research Report No. 12. (Prepared by the University of Illinois at Chicago DEcIDE Center Under Contract No. HHSA29020050038I T03.) Rockville, MD: Agency for Healthcare Research and Quality. May 2009. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

State Health Plans

We did not consider an analysis of the impact of this bill on the SHBP and SEHBP. We observe that the Pension and Health Benefits Review Commission (PHBRC)[19] voted on Assembly Bill 3868 (A-3868), a bill originating during the 2010 – 2011 Legislative Session, on July 8, 2011.[20] The PHBRC recommended against enactment. A-3868 was referred to the SHBP/SEHBP State Health Benefits Plan Design Committees in light of the enactment of, P.L.2011, c.78.[21] [22] Additionally, we observe that the SHBP staff commented on A-1830.[23] They suggested modifications to the bill noted that the financial impact to the SHBP/SEHBP "is anticipated to be minimal."

Other States and Medicare

Other states have addressed the issue of coverage for off-label medications.[24] Approximately 30 states mandate some form of coverage in a manner similar to A-1830. However, there are a number of differences. For example, some states limit the mandate to inclusion in compendia and do not mandate coverage based on support in journal articles. Other states that do mandate based on journal articles may require multiple articles or that the article is on a specific list.

The Center for Medicare and Medicaid Service's (CMS) benefit policy for the use of off-label drugs and biologicals in an Anti-Cancer Chemotherapeutic Regimen recognizes specifically listed authoritative compendia for use in the determination of a medically accepted indication.[25]

Conclusion: Balancing the Social Impact, Financial Impact and Medical Effectiveness

The charge of the Commission is to report on the social, medical, and financial impact of the bill on the state-regulated insurance markets of New Jersey. These markets include the IHC and SEH market, but do not include the public employees' benefits plans which are self-funded plans that the state operates and thus fall outside of the State's regulatory purview. (If the SHBP/SEHBP purchased coverage from commercial carriers, they would already be subject to the existing mandate.)

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[19] Established by P.L.1991, c.382 (N.J.S.A. 52:9HH-1)
[20] http://www.state.nj.us/treasury/pensions/boards_links.shtml
[21] Id.
[22] See Appendix IV – Pension and Health Benefits Review Commission: A-3868 Vote Results, July 8, 2011.
[23] See Appendix III – Division of Pensions and Benefits Bill Comments – Bill Number A-1830.
[24] See Appendix VII – State "Off-Label" Drug Use Mandate Chart.
[25] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R96BP.pdf

The initial observation of the Commission is that the impact of this bill on the state-regulated markets is almost non-existent because the envisioned requirements are already in place and operative for the IHC and SEH programs. It is important to note that these requirements are regulatory and are subject to change at the discretion of the Program Boards, which would not be true if this mandate were passed.

As we studied the potential impact of this bill, we noted that in many states the criteria for requiring a carrier to cover off-label use were slightly stricter than in New Jersey. In particular, the standard that the use be supported by a single article in a peer-reviewed journal may be inadequate. There are instances where medications were prescribed off-label and the use was later determined to be inappropriate. Furthermore, given the scope of this issue and the potential for both positive and negative results from off-label prescribing, we recommend that the Legislature consider establishing a board or committee that would review available evidence on off-label use and make recommendations on coverage based on this review. We note that New Jersey already has established the Drug Utilization Review Board which fulfills this review function to determine non-managed care Medicaid beneficiaries (fee-for service) coverage.[26]

[26] http://www.state.nj.us/humanservices/dmahs/boards/durb/

Appendix I

Assembly Bill 1830

ASSEMBLY, No. 1830

STATE OF NEW JERSEY

215th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2012 SESSION

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington)
Assemblywoman VALERIE VAINIERI HUTTLE
District 37 (Bergen)
Assemblyman RUBEN J. RAMOS, JR.
District 33 (Hudson)

Co-Sponsored by:
Assemblyman Fuentes and Assemblywoman Tucker

SYNOPSIS

Requires insurance coverage in the individual and small employer markets and SHBP and SEHBP for "off-label" uses of certain drugs.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel

(Sponsorship Updated As Of: 2/3/2012)

AN ACT concerning "off-label" uses of certain drugs, amending various parts of the statutory law and supplementing P.L.1992, c.161 (C.17B:27A-2 et seq.), P.L.1992, c.162 (C.17B:27A-17 et seq.), P.L.1961, c.49 (C.52:14-17.25 et seq.), and P.L.2007, c.103 (C.52:14-17.46.1 et seq.).

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

1. (New section) a. No individual health benefits plan 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 plan provides benefits to a covered person 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 in one of the following established reference compendia:

(1) the American Hospital Formulary Service Drug Information; or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 health benefits plan for drugs prescribed for a treatment approved by the Food and Drug Administration.

c. This section shall apply to all individual health benefits plans in which the carrier 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.

2. (New section) a. No small employer health benefits plan 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

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 <u>thus</u> is new matter.

act, unless the plan provides benefits to a covered person 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 in one of the following established reference compendia:

(1) the American Hospital Formulary Service Drug Information; or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 health benefits plan for drugs prescribed for a treatment approved by the Food and Drug Administration.

c. This section shall apply to all small employer health benefits plans in which the carrier 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. (New section) Notwithstanding any other provision of law to the contrary, the State Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of this act shall provide coverage pursuant to the provisions of this section.

a. The contract shall provide benefits 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 in one of the following established reference compendia:

(1) the American Hospital Formulary Service Drug Information; or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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. Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

4. (New section) Notwithstanding any other provision of law to the contrary, the School Employees' Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of this act shall provide coverage pursuant to the provisions of this section.

a. The contract shall provide benefits 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 in one of the following established reference compendia:

(1) the American Hospital Formulary Service Drug Information; or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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. Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

5. Section 2 of P.L.1993, c.321 (C.17:48-6h) is amended to read as follows:

2. a. **[**Except as provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** <u>No</u> 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 in one of the following established reference compendia:

(1) **[**the American Medical Association Drug Evaluations;

(2)**]** the American Hospital Formulary Service Drug Information;

[(3)**]** or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.2)

6. Section 3 of P.L.1993 c.321 (C.17:48A-7g) is amended to read as follows:

3. a. **[**Except as provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** 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 in one of the following established reference compendia:

(1) **[**the American Medical Association Drug Evaluations;

(2)**]** the American Hospital Formulary Service Drug Information;

[(3)**]** or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.3)

7. Section 4 of P.L.1993, c.321 (C.17:48E-35.5) is amended to read as follows:

4. a. **[**Except as otherwise provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** 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 in one of the following established reference compendia:

(1) **[**the American Medical Association Drug Evaluations;

(2)**]** the American Hospital Formulary Service Drug Information;

[(3)**]** or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.4)

8. Section 5 of P.L.1993, c.321 (C.17B:26-2.1g) is amended to read as follows:

5. a. **[**Except as otherwise provided in P.L.1992, c.161 (C.17B:27A-2 et al.), no**]** 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 in one of the following established reference compendia:

(1) **[**the American Medical Association Drug Evaluations;

(2)**]** the American Hospital Formulary Service Drug Information;

[(3)**]** or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(cf: P.L.1993, c.321, s.5)

9. Section 6 of P.L.1993, c.321 (C.17B:27-46.1g) is amended to read as follows:

6. a. [Except as otherwise provided in P.L.1992, c.162 (C.17B:27A-17 et seq.), no] 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 in one of the following established reference compendia:

(1) [the American Medical Association Drug Evaluations;

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

[(3)] or

(2) the United States Pharmacopoeia Drug Information;

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopoeia Drug Information; or, it is recommended by a clinical study or review article 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.

(cf: P.L.1993, c.321, s.6)

10. Section 7 of P.L.1993, c.321 (C.26:2J-4.5) is amended to read as follows:

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 al.) or P.L.1992, c.162 (C.17B:27A-17 et seq.), a] 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 in one of the following established reference compendia:

(1) **[**the American Medical Association Drug Evaluations;

(2)**]** the American Hospital Formulary Service Drug Information;

[(3)**]** or

(2) the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 determined and 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.

(cf: P.L.1993, c.321, s.7)

11. This act shall take effect on the 90th day following enactment.

STATEMENT

This bill requires health benefits plans offered in the individual and small employer markets in New Jersey, which provide benefits for drugs that are approved by the federal Food and Drug Administration (FDA), and the State Health Benefits Program (SHBP) and School Employees' Health Benefits Program (SEHBP), to provide coverage for certain "off-label" uses of those drugs for which they provide benefits.

Off-label use of a drug (that is, its use for a specific treatment for which the drug has not been approved by FDA) is legal when prescribed in a medically appropriate way.

The bill requires health insurance carriers that participate in the Individual Health Coverage Program and the Small Employer Health Benefits Program, and SHBP and SEHBP, to provide coverage for off-label use of a drug if the drug is recognized as being medically appropriate for the specific treatment for which it has been prescribed in one of the two established reference compendia (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 takes effect on the 90th day following enactment.

The purpose of this bill is to extend the medical benefits that may derive from the use of off-label drugs to persons who may not now be able to access these medications, in particular those individuals who are suffering from a terminal or chronically debilitating illness.

Appendix II

Assembly Bill 3868 (2010-2011 Legislative Session)

[Second Reprint]

ASSEMBLY, No. 3868

STATE OF NEW JERSEY

214th LEGISLATURE

INTRODUCED FEBRUARY 22, 2011

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington and Camden)
Assemblywoman VALERIE VAINIERI HUTTLE
District 37 (Bergen)
Assemblyman JACK CONNERS
District 7 (Burlington and Camden)
Assemblyman RUBEN J. RAMOS, JR.
District 33 (Hudson)

Co-Sponsored by:
Assemblyman Fuentes

SYNOPSIS

Requires insurance coverage in the individual and small employer markets and SHBP and SEHBP for "off-label" uses of certain drugs.

CURRENT VERSION OF TEXT

As reported by the Assembly Appropriations Committee on June 13, 2011, with amendments.

(Sponsorship Updated As Of: 6/24/2011)

AN ACT concerning "off-label" uses of certain drugs, amending various parts of the statutory law and supplementing P.L.1992, c.161 (C.17B:27A-2 et seq.), P.L.1992, c.162 (C.17B:27A-17 et seq.), [1]**[**and chapter 9 of Title 45 of the Revised Statutes**]** P.L.1961, c.49 (C.52:14-17.25 et seq.), and P.L.2007, c.103 (C.52:14-17.46.1 et seq.)[1].

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

1. (New section) a. No individual health benefits plan 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 plan provides benefits to a covered person 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information; [2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 health benefits plan for drugs prescribed for a treatment approved by the Food and Drug Administration.

c. This section shall apply to all individual health benefits plans in which the carrier 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.

2. (New section) a. No small employer health benefits plan

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]Assembly AHE committee amendments adopted March 7, 2011.
[2]Assembly AAP committee amendments adopted June 13, 2011.

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 plan provides benefits to a covered person 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 health benefits plan for drugs prescribed for a treatment approved by the Food and Drug Administration.

c. This section shall apply to all small employer health benefits plans in which the carrier 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.

[1]3. (New section) Notwithstanding any other provision of law to the contrary, the State Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of this act shall provide coverage pursuant to the provisions of this section.

a. The contract shall provide benefits 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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. Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.[1]

[1]4. (New section) Notwithstanding any other provision of law to the contrary, the School Employees' Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of this act shall provide coverage pursuant to the provisions of this section.

a. The contract shall provide benefits 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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. Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.[1]

[1]**[**3.**]** 5.[1] Section 2 of P.L.1993, c.321 (C.17:48-6h) is amended to read as follows:

2. a. **[**Except as provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.2)

[1]**[**4.**]** 6.[1] Section 3 of P.L.1993 c.321 (C.17:48A-7g) is amended to read as follows:

3. a. **[**Except as provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.3)

[1]**[**5.**]** 7.[1] Section 4 of P.L.1993, c.321 (C.17:48E-35.5) is amended to read as follows:

4. a. **[**Except as otherwise provided in P.L.1992, c.161 (C.17B:27A-2 et al.) and P.L.1992, c.162 (C.17B:27A-17 et seq.), no**]** 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(P.L.1993, c.321, s.4)

[1]**[**6.**]** 8.[1] Section 5 of P.L.1993, c.321 (C.17B:26-2.1g) is amended to read as follows:

5. a. **[**Except as otherwise provided in P.L.1992, c.161 (C.17B:27A-2 et al.), no**]** 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 in one of the following established reference compendia:

(1) [2]**[**the American Medical Association Drug Evaluations;

(2)**]**[2] the American Hospital Formulary Service Drug Information;

[2]**[**(3)**]** or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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.

(cf: P.L.1993, c.321, s.5)

[1][7.] 9.[1] Section 6 of P.L.1993, c.321 (C.17B:27-46.1g) is amended to read as follows:

6. a. [Except as otherwise provided in P.L.1992, c.162 (C.17B:27A-17 et seq.), no] 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 in one of the following established reference compendia:

(1) [2]the American Medical Association Drug Evaluations;

(2)][2] the American Hospital Formulary Service Drug Information;

[2](3)] or

(2)[2] the United States Pharmacopoeia Drug Information;

(1) the American Medical Association Drug Evaluations;

(2) the American Hospital Formulary Service Drug Information;

(3) the United States Pharmacopoeia Drug Information; or,

it is recommended by a clinical study or review article 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.

(cf: P.L.1993, c.321, s.6)

[1][8.] 10.[1] Section 7 of P.L.1993, c.321 (C.26:2J-4.5) is amended to read as follows:

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 al.) or P.L.1992, c.162 (C.17B:27A-17 et seq.), a] 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 in one of the following established reference compendia:

(1) [2]the American Medical Association Drug Evaluations;

(2)[2] the American Hospital Formulary Service Drug Information;

[2](3)] or

(2)[2] the United States Pharmacopoeia Drug Information;

or, it is recommended by a clinical study or review article 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 determined and 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.

(cf: P.L.1993, c.321, s.7)

[1][9.] (New section) A physician who prescribes a drug for which insurance coverage is required pursuant to sections 1 and 2 of P.L. , c. (pending before the Legislature as this bill), section 2 of P.L.1993, c.321 (C.17:48-6h), section 3 of P.L.1993, c.321 (C.17:48A-7g), section 4 of P.L.1993, c.321 (C.17:48E-35.5), section 5 of P.L.1993, c.321 (C.17B:26-2.1g), section 6 of P.L.1993, c.321 (C.17B:27-46.1g), and section 7 of P.L.1993, c.321 (C.26:2J-4.5), in cases in which the drug is the subject of a clinical trial to evaluate the use of that drug for the specific treatment for

which the physician prescribes the drug, shall report the treatment results that are attributed to the drug to the manufacturer of the drug, on a form and in a manner to be prescribed by the State Board of Medical Examiners.**]**[1]

[1]**[**10.**]** 11.[1] This act shall take effect on the 90th day following enactment.

Appendix III

Division of Pensions and Benefits Bill Comments – Bill Number A-1830

Division of Pensions and Benefits

Bill Comments

Bill Number: A-1830
Last Session's Number: A-3868 (2R)

Sponsors: Conaway/ Huttle/Ramos + 1

Recommendation: Conditional Support.

Executive Summary:	• Requires insurance coverage in the individual and small employer markets and SHBP and SEHBP for "off-label" uses of certain drugs; • Provides benefits for expenses incurred in prescribing a drug which has not been approved by the FDA if the drug is recognized as medically appropriate; • The Division's support is conditional upon the adoption of suggested amendments; • Continues the questionable practice of legislatively mandating health benefit coverage; • **Relative priority – Medium**.

Bill Description:

This bill requires the State Health Benefits Commission, the School Employees' Health Benefits Commission and health benefit plans offered in the individual and small employer markets to provide benefits to a covered person 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 in one of the following established reference compendia: 1) the American Hospital Formulary Service Drug Information; 2) the United States Pharmacopoeia Drug Information; or, it is recommended by a clinical study or review article in a major peer-reviewed professional journal.

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 shall be to the same extent as other benefits under the

health benefits plan for drugs prescribed for a treatment approved by the Food and Drug Administration.

The State Health Benefits Commission and the School Employees' Health Benefits Commission shall ensure that every contract purchased by the Commission on or after the effective date of this act shall provide benefits 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 by the reference compendia mentioned above.

This bill would take effect on the 90th day after enactment and apply to all contracts and policies issued on or after the effective date.

Policy Considerations:

The Division would lend its support to this bill on condition it is amended to provide the plan the ability to implement a drug utilization review that includes criteria that verifies whether or not the drug is for an "off label" use that is supported by required literature, and require supporting documentation from two studies in major professional journals instead of just one as suggested in the bill.

The SHBP and SEHBP administer the Employee Prescription Drug Plan and utilize the services of Medco Health Solutions, Inc., the pharmacy benefit manager for all eligible members. The Employee Prescription Drug Plan includes various procedural and administrative rules and requirements designed to ensure appropriate prescription drug usage and to encourage the use of cost-effective drugs. The plan does not cover any prescription drugs which lack U.S. Food and Drug Administration (FDA) approval, or which are approved but prescribed for other than a FDA approved use, or in a dosage other than that approved by the FDA. In addition, the plan has drug utilization reviews, which are performed by Medco to determine a prescription's suitability in light of the patient's health, drug history, drug-to-drug interactions, and drug contraindications.

The Employee Prescription Drug Plan also relies on the medical necessity and appropriateness criteria and guidelines that are established and approved by the Pharmacy and Therapeutics Committee, which consists of practicing physicians and pharmacists. Eligible prescription drugs must meet the FDA approved indications and be safe and effective for their intended use. A prescription drug is medically necessary and appropriate if, as recommended by the treating practitioner and as determined by Medco's medical director or designee(s) it is all of the following:

- A health intervention for the purpose of treating a medical condition;
- The most appropriate intervention, considering potential benefits and harm to the patient;
- Known to be effective in improving health outcomes (For new interventions, effectiveness is determined by scientific evidence. For existing interventions, effectiveness is determined first by scientific evidence; then if necessary, by professional standards; then if necessary, by expert opinion);
- Cost effective for the applicable condition, compared to alternative interventions, including no intervention, “Cost effective” does not mean lowest price.

The fact that an attending practitioner prescribes, orders, recommends, or approves the intervention, or length of treatment time does not make the intervention “medically necessary and appropriate.”

The Division recommends that the bill be amended to provide the plan the ability to implement a coverage review process that includes criteria that verifies whether or not the drug is for an off label use that is supported by compendia or peer reviewed literature. Without the ability to conduct a coverage review, the plan is left with a loop hole that may allow inappropriate coverage. Further the criteria should require supporting documentation from two studies in major journals vs. one. Today cases like this are typically supported by an off-label use study validated in a second study before the use is accepted, unless the treatment effect is profoundly positive in the first one.

The financial impact to the SHBP/SEHBP if the bill were enacted is anticipated to be minimal. The plan usually manages these types of requests to cover the prescription once denied by the plan via appeal to the Commission.

Finally, aside from the SHBP, this bill would mandate the coverage for all health insurance policies issued in the State, other than self-insured contracts. Such mandates generally tend to continue to place the health insurance industry outside of the "free enterprise" system and drive up the cost of health insurance for both employer provided coverage and individual policies. The continued enactment of health benefit mandate legislation could soon make coverage unaffordable for both.

Impact on Pensions' Operations:

Minimal.

Impact on General Fund:

Limiting the Division's estimate to the SHBP/SEHBP, the Division estimates that the enactment of this bill will have an immaterial financial impact on employer costs associated with the State-administered Employee Prescription Drug Plan since the plan already manages coverage for "off-label" prescription drugs via the appeal process.

ANNUAL ADDITIONAL SHBP/SEHBP COSTS:					
	FY2012	**FY2013**	**FY2014**	**FY2015**	**FY2016**
STATE	$ -	$ -	$ -	$ -	$ -
LOCAL	$ -	$ -	$ -	$ -	$ -
EST. FIRST YEAR'S IMPLEMENTATION COST:					
MATERIALS	$ -				
DATA PROCESSING	$ -				
TOTAL	$ -				

Appendix IV

Pension and Health Benefits Review Commission:
A-3868 Vote Results, July 8, 2011

Pension and Health Benefits Review Commission
Vote Results
July 8, 2011

A-3868 (Conaway/Vainieri Huttle/Conners)
Requires insurance coverage in the individual and small employer markets and SHBP and SEHBP for "off-label" uses of certain drugs.

Motion: Recommend against enactment. In light of the enactment of Chapter 78, P.L. 2011, the subject of "off-label" uses of certain drugs is a plan design issue and should be referred to the SHBP/SEHBP State Health Benefits Plan Design Committees.

Discussion: The bill requires insurance coverage in the individual and small employer markets and SHBP/SEHBP for "off-label" uses of certain drugs. It provides benefits for expenses incurred in prescribing a drug which has not been approved by the FDA if the drug is recognized as medically appropriate. The concern with the bill is that it relies solely on the recommendation that the drug is recognized as being medically appropriate for the specific treatment for which it has been prescribed by the referenced compendia. The fact that an attending practitioner prescribes and approves the drug intervention, or length of treatment does not make the intervention "medically necessary and appropriate." Therefore, the Commission recommends that the subject of "off label" uses of certain drugs be referred to the new SHBP/SEHBP State Health Benefits Plan Design Committee as established by the enactment of Chapter 78.

Appendix V

CMS Manual System Pub 100-02 Medicare Benefit Policy

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 96	Date: October 24, 2008
	Change Request 6191

SUBJECT: Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen

I. SUMMARY OF CHANGES: CMS is recognizing four authoritative compendia and listing them in chapter 15, section 50.4.5 of the Medicare Benefit Policy Manual for use in the determination of a medically accepted indication of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen.

New / Revised Material
Effective Date: June 5, 2008 - NCCN Drugs and Biologics Compendium
June 10, 2008 - Thomson Micromedex DrugDex
July 2, 2008 - Clinical Pharmacology
Implementation Date: November 25, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED.

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/Table of Contents
R	15/50.4.5/Off-Label Use of Anti-Cancer Drugs and Biologicals
R	15/50.4.5.1/Process for Amending the List of Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-02	Transmittal: 96	Date: October 24, 2008	Change Request: 6191

SUBJECT: Compendia as Authoritative Sources for Use in the Determination of a "Medically-Accepted Indication" of Drugs and Biologicals Used Off-label in an Anti-Cancer Chemotherapeutic Regimen

Effective Dates: **Existing American Hospital Formulary Service-Drug Information**
June 5, 2008-National Comprehensive Cancer Network Drugs and Biologics Compendium
June 10, 2008 -Thomson Micromedex DrugDex
July 2, 2008-Clinical Pharmacology

Implementation Date: November 25, 2008

I. GENERAL INFORMATION

A. Background: Section 1861(t)(2)(B)(ii)(I) of the Social Security Act (the Act), as amended by section 6001(f)(1) of the Deficit Reduction Act of 2005, Pub. Law 109-171, recognizes three compendia-- American Medical Association Drug Evaluations (AMA-DE), United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication, and American Hospital Formulary Service-Drug Information (AHFS-DI)-- as authoritative sources for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia.

Due to changes in the pharmaceutical reference industry, AHFS-DI was the only remaining statutorily-named compendia available for our reference; the AMA-DE and the USP-DI are no longer published. Consequently, the Centers for Medicare & Medicaid Services (CMS) received requests from the stakeholder community for a process to revise the list of compendia. In the Physician Fee Schedule final rule for calendar year 2008, CMS established a process for revising the list of compendia, as authorized under section 1861(t)(2) of the Act, and also established a definition for "compendium." See 72 FR 66222, 66303-66306, 66404. Under 42 CFR 414.930(a), a compendium is defined "as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment." A compendium: (1) includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; and, (2) is indexed by drug or biological. See 42 CFR 414.930(a); 72 FR 66222, 66404.

In addition, CMS increased the transparency of the process by incorporating a list of desirable compendium characteristics outlined by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) as criteria for decision-making. The list of desirable compendium characteristics was developed by the MedCAC during a public session on March 30, 2006. The goal of this session was to review the evidence and advise CMS on the desirable characteristics of compendia for use in the determination of medically-accepted indications of drugs and biologicals in anti-cancer therapy. As a result of this meeting, the MedCAC generated a list of desirable characteristics to use when reviewing a compendium.

CMS generated one internal request to delete AMA-DE which is no longer published, and received four external requests from stakeholders for additions to the authoritative list: NCCN, Micromedex DrugDex, Micromedex DrugPoints, and Clinical Pharmacology. CMS staff conducted a review of specific compendia comparing the qualities with the MedCAC desirable characteristics.

B. Policy: CMS is recognizing the following as authoritative compendia and listing them in Pub. 100-02 of the Medicare Benefit Policy Manual, chapter 15, section 50.4.5 for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- NCCN Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical Pharmacology

Contractors shall recognize medically accepted indications as those that:

- are favorably listed in one or more of the compendia listed above, or,
- the contractor determines from a review of the peer-reviewed literature as described above that it is a medically accepted indication,

unless CMS has determined that the use is not medically accepted, or any of the listed compendia list the use as not medically accepted, or words to that effect.

CMS is aware that the listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:

1. indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,
2. narrative text in AHFS or Clinical Pharmacology is supportive.

A use is not medically accepted by a compendium if the:

1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,
2. narrative text in AHFS or Clinical Pharmacology is "not supportive."

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

NOTE: Referencing compendia for off-label anti-cancer chemotherapeutic drug use is an ongoing contractor instruction. The Secretary has the authority under section 1861(t)(2) of the Act to revise the compendia list as is appropriate for identifying medically acceptable off-label drug use. This instruction constitutes an update to the existing compendia list found at Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.4.5.

NOTE: The contractor may maintain its own subscriptions to the listed compendia updates or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6191.1	Effective with the dates noted above in processing claims, contractors shall be aware of the additions and deletions to the list of compendia as authoritative sources for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia as described in Pub. 100-02, chapter 15, section 50.4.5.	X	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6191.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Kate Tillman, coverage, 410-786-9252, Katherine.tillman@cms.hhs.gov, Brijet Burton, coverage, 410-786-7364, Brijet.burton@cms.hhs.gov

Post-Implementation Contact(s): Appropriate CMS RO

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*, use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

Table of Contents
(Rev.96, 10-24-08)

50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

(Rev.96, Issued: 10-24-08, Effective: 06-05-08 NCCN/06-10-08 Thomson Micromedex/07-02-08 Clinical Pharmacology, Implementation: 11-25-08)

A. *Overview*

Effective January 1, 1994, *off-label, medically accepted indications* of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are *identified* under the conditions described *below*. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. *Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.*

B. *Recent Revisions to the Compendia List*

Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by *any* of the following *compendia* and the use is **not** listed as *unsupported,* not indicated, *not recommended, or equivalent terms,* in any of the *following* compendia:

Existing - American Hospital Formulary Service Drug Information *(AHFS-DI)*

Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Effective June 10, 2008 - Thomson Micromedex DrugDex

Effective July 2, 2008 - Clinical Pharmacology

*The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as **medically accepted** if the:*

1. *indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,*

2. *narrative text in AHFS-DI or Clinical Pharmacology is supportive.*

*A use is **not medically accepted** by a compendium if the:*

1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,

2. narrative text in AHFS or Clinical Pharmacology is "not supportive."

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

C. Use Supported by Clinical Research That Appears in Peer-Reviewed Medical Literature

Contractors may also identify off-label uses that are supported by clinical research under the conditions identified in this section. Peer-reviewed medical literature may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical products are excluded from consideration. Abstracts (including meeting abstracts) are excluded from consideration.

In determining whether an off-label use is supported, the contractors will evaluate the evidence in published, peer-reviewed medical literature listed below. When evaluating this literature, they will consider (among other things) the following:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The contractor will consider:

1. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);

2. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,

3. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

The *contractor* will use peer-reviewed medical literature appearing in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors.

American Journal of Medicine;
Annals of Internal Medicine;
Annals of Oncology;
Annals of Surgical Oncology;
Biology of Blood and Marrow Transplantation;
Blood;
Bone Marrow Transplantation;
British Journal of Cancer;
British Journal of Hematology;
British Medical Journal;
Cancer;
Clinical Cancer Research;
Drugs;
European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
Gynecologic Oncology;
International Journal of Radiation, Oncology, Biology, and Physics;
The Journal of the American Medical Association;
Journal of Clinical Oncology;
Journal of the National Cancer Institute;
Journal of the National Comprehensive Cancer Network (NCCN);
Journal of Urology;
Lancet;
Lancet Oncology;
Leukemia;
The New England Journal of Medicine; or
Radiation Oncology

D. Generally

FDA-approved drugs and biologicals may also be considered for use in the determination of medically accepted indications for off-label use if determined by the contractor to be reasonable and necessary.

If a use is identified as not indicated by *the Centers for Medicare and Medicaid Services (CMS)* or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia *listed*, or if the *contractor* determines, based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the *off-label* usage is not supported and, therefore, the drug is not covered.

50.4.5.1 - Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

(Rev.96, Issued: 10-24-08, Effective: 06-05-08 NCCN/06-10-08 Thomson Micromedex/07-02-08 Clinical Pharmacology, Implementation: 11-25-08)

A. Background

In the Physician Fee Schedule final rule for calendar year 2008, the CMS established a process for revising the list of compendia, as authorized under section 1861(t)(2) of the Social Security Act, and also established a definition for "compendium." See 72 FR 66222, 66303-66306, 66404. At 42 CFR 414.930(a), a compendium is defined "as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment." *A compendium: (1)* includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; and, *(2)* is indexed by drug or biological. *See 42 CFR 414.930(a); 72 FR 66222, 66404.*

B. Desirable Characteristics of Compendia

In addition, CMS increased the transparency of the process by incorporating a list of desirable compendium characteristics outlined by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) as criteria for decision-making. The list of desirable compendium characteristics was developed by the MedCAC during a public session on March 30, 2006. The goal of this session was to review the evidence and advise CMS on the desirable characteristics of compendia *for use in the determination of* medically accepted indications of drugs and biologicals in anti-cancer therapy. *As a result of this meeting, the MedCAC generated the following list of desirable characteristics:*

- Extensive breadth of listings,
- Quick processing from application for inclusion to listing,
- Detailed description of the evidence reviewed for every individual listing,
- Use of pre-specified published criteria for weighing evidence,
- Use of prescribed published process for making recommendations,
- Publicly transparent process for evaluating therapies,
- Explicit "Not Recommended" listing when validated evidence is appropriate,
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies,
- Explicit "Equivocal" listing when validated evidence is equivocal, and,
- Process for public identification and notification of potential conflicts of interest of the compendias' parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

C. Process for Changing List of Compendia

CMS will provide an annual 30-day open request period starting January 15 for the public to submit requests for additions or deletions to the compendia list contained on the CMS Web site at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp.

Complete requests as defined in section 50.4.5.1.D will be posted to the Web site by March 15 for public notice and comment. The request will identify the requestor and the requested action to the list. Public comments will be accepted for a 30-day period beginning on the day the request is posted on the Web site. In addition to the annual process, CMS may generate a request for changes to the list at any time an urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

D. Content of Requests

For a request to be considered complete and therefore accepted for review, it must include the following information:

- The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- Full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

- A complete written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide CMS with electronic access by furnishing at no cost to the Federal Government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.

- The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.

- Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, non-specific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.

A request may have only a single compendium as its subject. This will provide greater clarity to the scope of the Agency's review of a given request. A requestor may submit multiple requests, each requesting a different action.

E. Submission of Requests

Requests must be in writing and submitted in one of the following two ways (no duplicates please):

1. Electronic requests are encouraged to facilitate administrative efficiency. Each solicitation will include the electronic address for submissions.

2. Hard copy requests can be sent to:

Centers for Medicare & Medicaid Services
Coverage and Analysis Group
Mailstop C1–09–06
7500 Security Boulevard
Baltimore, MD 21244

Allow sufficient time for hard copies to be received prior to the close of the open request period.

F. Review of Requests

CMS will consider a compendium's attainment of the desirable characteristics specified in 50.4.5.1.B when reviewing requests. CMS may consider additional, reasonable factors in making a determination. For example, CMS may consider factors that are likely to impact the compendium's suitability for this use, such as a change in ownership or affiliation, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. CMS may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians, or both, in choosing among treatment options. CMS will also consider a compendiums' grading of evidence used in making recommendations regarding off-label uses, and the process by which the compendium grades the evidence. CMS may, at its discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in the review of requests.

G. Publishing Review Results

CMS will publish decisions on the CMS Web site within 90 days after the close of the public comment period.

(This instruction was last reviewed by CMS in September 2008.)

Appendix VI

New Jersey “Off-Label” Mandate Chart

"Markets"	Legal Requirement for off label	A1830 requirement for off-label
Pre 8/1/93 individual	P.L.1993, c.321, s.5	
IHC (i.e. post 8/1/93)	N.J.A.C. 11:20 Appendices	A1830
SEH	N.J.A.C. 11:21 Appendices	A1830
Non-SEH Group	P.L.1993, c.321, s.6	
SHBP	No requirement	A1830
SEHBP	No requirement	A1830
Medicaid/NJFC (Managed Care)	By contract	
“Carriers”		
Insurance Companies	Varies with the market, see above	
Service Corporations	P.L.1993, c.321, s.2, 3, and 4	
HMOs	P.L.1993, c.321, s.7	

Appendix VII

State “Off-Label” Drug Use Mandate Chart

State	Standard Reference Compendia	Medical/Peer-Reviewed Literature	Definition
Alabama 27-1-10.1	X	X	Published scientific studies published in any peer-reviewed national professional journal
Arizona A.R.S. 20-2326	X	X	At least two articles from major peer reviewed professional medical journals
Arkansas A.C.A. 23-79-147	X	X	Two articles from major peer-reviewed medical journals specified by the UD DOHHS
California Cal Health & Saf Code 1367.21	X	X	Two articles from major peer reviewed medical journals
Colorado C.R.S. 10-16-104.6	X		Reference compendia identified by USDHHS
Connecticut Conn. Gen. Stat. 38a-518B	X		
Florida Fla. Stat. 627.4239	X	X	Scientific studies published in a US peer-reviewed national professional journal
Georgia O.C.G.A. 33-24-59.11	X	X	Two articles from major peer reviewed medical journals
Illinois 215 ILCS 5/365z.7	X	X	Formal clinical studies, the results of which have been published in at least two peer reviewed professional medical

			journals published in the US and Great Britain
Indiana Burns Ind. Code Ann. 27-8-20-7	X	X	Formal clinical studies, the results of which have been published in a peer reviewed professional medical journal published in the US or Great Britain
Kansas K.S.A. 40-2,168	X	X	Substantially accepted peer-reviewed medical literature
Louisiana LA. R. S. 22:999	X	X	Scientific studies published in a journal specified by the USDHSS
Maine 24 M.R.S. 2320-F	X	X	Scientific studies published in at least two articles from major peer-reviewed medical journals
Maryland Md. Ins. Code Ann. 15-1804	X	X	Scientific studies published in a peer-reviewed national professional medical journal
Massachusetts ALM GL ch 175, 47K	X	X	Scientific studies appearing any peer-reviewed national professional journal
Michigan MCL 500.3506q	X	X	Two articles from major peer-reviewed medical journals
Minnesota Minn. Stat. 62Q.525	X	X	Articles from major peer-reviewed medical journals

Mississippi Miss. Code Ann. 83-9-8	X	X	Two articles from major peer-reviewed professional medical journals
Nebraska R.R.S. Neb 44-478	X	X	Two articles from major peer-reviewed professional medical journals
Nevada Nev. Rev. Stat. Ann. 689A.0404	X	X	Two articles reporting the results of scientific studies that are published in scientific or medical journals
New Hampshire RSA 415:6-g	X	X	Medical literature as recommended by current AMA policies
New Jersey L. 1993, c. 321	X	X	A clinical study or review article in a major peer-reviewed professional journal
North Carolina N.C. Gen. Stat. 58-51-59	X		
North Dakota N.D. Cent. Code 26.1-36-06.1	X	X	Scientific studies published in a peer reviewed national medical journal
Ohio ORC Ann. 1751.66	X	X	Two articles from major peer-reviewed professional journals
Oklahoma 63 Okl. St. 1-1401	X		

Oregon ORS 743A.062	X	X	Majority of relevant peer-reviewed medical literature
Rhode Island R.I. Gen. Laws 27-55-1	X	X	Published scientific studies in at least two articles from major peer reviewed medical journals
South Carolina S.C. Code Ann. 38-71-275	X	X	Two articles from major peer-reviewed medical journals
South Dakota S.D. Codified Laws 58-17-100	X	X	A published scientific study in a journal or other publication
Tennessee Tenn. Code Ann. 56-6-2352	X	X	Published scientific studies published in any peer-reviewed national professional journal
Texas Tex. Ins. Code 1369.004	X	X	Substantially accepted peer-reviewed medical literature
Vermont 8 V.S.A. 4100e	X	X	Peer-reviewed scientific studies published in medical journals, medical literature that meets criteria of EMBASE and HSTAR, medical journals recognized by HHS, studies by federal government agencies/grantees and nationally recognized federal research

			institutes, peer-reviewed abstracts accepted for presentation at major medical association meetings
Virginia Va. Code Ann. 38.2-34-7.5	X	X	Scientific study published only after having been critically reviewed for scientific accuracy, validity and reliability by unbiased experts
Washington WAC 284-30-450	X	X	Majority of scientific studies printed in journals or other publications where clinically reviewed for scientific accuracy, validity and reliability by unbiased independent experts

Appendix VIII

Review Request for A-1830

NEW JERSEY GENERAL ASSEMBLY

HERB CONAWAY, MD
ASSEMBLYMAN
7TH LEGISLATIVE DISTRICT
DELRAN PROFESSIONAL CENTER
8008 ROUTE 130 NORTH, BLDG. C, SUITE 450
DELRAN, NJ 08075
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COMMITTEES
CHAIRMAN, HEALTH AND SENIOR SERVICES
VICE CHAIR, STATE GOVERNMENT
APPROPRIATIONS

February 21, 2012

New Jersey Mandated Health Benefits Advisory Commission
P.O. Box 325
Trenton, NJ 08625

Dear Members of the Commission:

As the chair of the Assembly Health and Senior Services Committee, I respectfully request the Commission review and prepare a written report of A-1830. This bill, sponsored by me, Assemblywoman Vainieri Huttle and Assemblyman Ramos, would require insurance coverage in the individual and small employer markets and SHBP and SEHBP for "off-label" uses of certain drugs.

If you have any questions, please do not hesitate to contact Nicole Brown, aide to the Assembly Health and Senior Services Committee, at (609) 292-7065 or by email at nbrown@njleg.org.

Thank you for your attention to this matter.

Very truly yours,

Herb Conaway MD

Honorable Herb Conaway, M.D., Chair
Assembly Health and Senior Services Committee