2005 DRAFTING REQUEST

Bill

Received: **02/20/2006**

Received By: **pkahler**

Wanted: **As time permits**

Identical to LRB:

For: **Marlin Schneider (608) 266-0215**

By/Representing: **Mike Schoenfield**

This file may be shown to any legislator: **NO**

Drafter: **pkahler**

May Contact:

Addl. Drafters:

Subject: **Insurance - health**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Schneider@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Insurance coverage of orphan drugs

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	pkahler 02/24/2006	lkunkel 03/23/2006		_____ _____			S&L
/1			pgreensl 03/24/2006	_____ _____	lnorthro 03/24/2006	lnorthro 03/24/2006	

FE Sent For:

<END>

w/ intro

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/?	pkahler	1 lm c 3/23	3/23 ps	3/23 pg/lp			

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2-20 Mike S. Rep Schneider

coverage

Require insurance to ~~cover~~ "orphan drugs"

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

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◄ Previous Volume 354:445-447 February 2, 2006 Number 5 Next ►

Adopting Orphan Drugs — Two Dozen Years of Treating Rare Diseases

Marlene E. Haffner, M.D., M.P.H.

Since this article has no abstract, we have provided an extract of the first 100 words of the full text and any section headings.

In 1982, when the Orphan Drug Act was passed as an amendment to the Federal Food, Drug, and Cosmetic Act,[1] few suspected the extent to which this law would alleviate the plight of patients with rare diseases. The law defines an orphan drug as one with efficacy against a disease affecting fewer than 200,000 people in the United States or one that scientists and economists at the Food and Drug Administration (FDA) determine will not be profitable for seven years after FDA approval.[2] In the 24 years since this law was passed, 282 such drugs and biologic products, . . . *[Full Text of this Article]*

21 USC 360aa-360ee

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Orphan Drugs

The term "orphan drug" refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The Orphan Drug Act was signed into law on January 4, 1983. Since the Orphan Drug Act passed, over 100 orphan drugs and biological products have been brought to market.

The intent of the Orphan Drug Act is to stimulate the research, development, and approval of products that treat rare diseases. This mission is accomplished through several mechanisms:

- Sponsors are granted seven years of marketing exclusivity after approval of its orphan drug product.
- Sponsors also are granted tax incentives for clinical research they have undertaken.
- FDA's Office of Orphan Products Development coordinates research study design assistance for sponsors of drugs for rare diseases [Notice: This link will take you outside the CDER web site].
- The Office of Orphan Products Development also encourages sponsors to conduct open protocols, allowing patients to be added to ongoing studies.
- Grant funding is available to defray costs of qualified clinical testing expenses incurred in connection with the development of orphan products.

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Ask the Pediatric Cardiologist - What Is an Orphan Drug or Device?

In the United States, drugs and devices are approved for marketing by the U.S. Food and Drug Administration (FDA) based on data from studies. Results from studies are used to develop the specific "labeling claims" that companies are allowed to make about their products. The FDA usually requires fairly extensive data about the safety and efficacy of drugs or devices before they are approved.

Companies spend substantial sums of money to do studies to fulfill the FDA requirements, then reap profits from drug or device sales after their product is approved. Patent exclusivity (only the company that develops a drug is allowed to market it for a specified time) allows companies to get back their investment in drug or device development.

Companies recoup the cost of running clinical studies with profits from their approved drugs or devices being sold in the marketplace. Companies are often unwilling or unable to do studies for rare diseases or conditions — because they won't be able to generate enough money from sales to cover the study costs. Other barriers also prevent companies from performing studies in pediatric patients. Because pediatric diseases — even serious ones such as congenital heart disease — are rare, too few studies have been or will be performed. This has resulted in a lack of information about the safety and efficacy of drugs and devices in children.

The FDA has recognized this problem and provided an alternative pathway — and less expensive option for companies. Companies may seek to have a drug designated as an "orphan" drug for a specific problem, as long as they can show that it's likely to be used less than 200,000 times per year. Device companies can also seek to have a device designated as a "humanitarian use" device, as long as it will be used to treat fewer than 4,000 patients for a specific problem each year. After a product has received the orphan or humanitarian use designation, a company may be able to gain marketing approval for the product with a smaller amount of data than would usually be required. Companies may also be eligible to recoup some of the costs of drug development.

The orphan drug and humanitarian device legislation is one way the FDA has continued to provide incentives for companies to provide safe and effective products for infants and children. It has helped the pediatric community by providing more information on which to base treatment decisions. To learn more about the orphan drug and device legislation, visit the Office of Orphan Products Development at http://www.fda.gov/orphan/.

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2005 – 2006 LEGISLATURE

LRB–4689/2
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PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** requiring health insurance policies to cover orphan drugs and granting rule–making authority.

Analysis by the Legislative Reference Bureau

This bill requires health insurance policies and plans that cover prescription drugs to cover any drug that is prescribed for an insured by a physician for the treatment of a rare disease or condition. A rare disease or condition, which is defined in the bill by a cross–reference to federal law, is a disease or condition that: 1) affects fewer than 200,000 persons in the United States; or 2) affects 200,000 or more persons in the United States, but there is no reasonable expectation that the sale in the United States of a drug for the disease or condition will recover the cost of developing and making the drug available in the United States. The bill requires the commissioner of insurance to promulgate a rule that specifies the drugs to which the coverage requirement applies.

The coverage requirement applies to both individual and group health insurance policies and plans, including defined network plans and cooperative sickness care associations; to health care plans offered by the state to its employees, including a self–insured plan; and to self–insured health plans of counties, cities, towns, villages, and school districts. The requirement specifically does not apply to limited service health organizations or preferred provider plans that provide only limited–scope dental or vision benefits, medicare replacement or supplement policies, or policies covering only certain specified diseases. The requirement may be subject to any limitations, exclusions, or cost–sharing provisions that apply generally under the policy or plan.

For further information see the ***state and local*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 40.51 (8) of the statutes is amended to read:

40.51 **(8)** Every health care coverage plan offered by the state under sub. (6) shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8) and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to (5), 632.895 (5m) and (8) to ~~(14)~~ (15), and 632.896.

SECTION 2. 40.51 (8m) of the statutes is amended to read:

40.51 **(8m)** Every health care coverage plan offered by the group insurance board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15).

SECTION 3. 66.0137 (4) of the statutes is amended to read:

66.0137 **(4)** SELF–INSURED HEALTH PLANS. If a city, including a 1st class city, or a village provides health care benefits under its home rule power, or if a town provides health care benefits, to its officers and employees on a self–insured basis, the self–insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and 767.25 (4m) (d).

SECTION 4. 111.91 (2) (n) of the statutes is amended to read:

111.91 **(2)** (n) The provision to employees of the health insurance coverage required under s. 632.895 (11) to ~~(14)~~ (15).

SECTION 5. 120.13 (2) (g) of the statutes is amended to read:

120.13 **(2)** (g) Every self–insured plan under par. (b) shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and 767.25 (4m) (d).

SECTION 6. 185.981 (4t) of the statutes is amended to read:

185.981 **(4t)** A sickness care plan operated by a cooperative association is subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85, 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to ~~(14)~~ (15), and 632.897 (10) and chs. 149 and 155.

SECTION 7. 185.983 (1) (intro.) of the statutes is amended to read:

185.983 **(1)** (intro.) Every such voluntary nonprofit sickness care plan shall be exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41, 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93, 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to ~~(14)~~ (15), 632.896, and 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association shall:

SECTION 8. 632.895 (15) of the statutes is created to read:

632.895 **(15)** DRUGS FOR THE TREATMENT OF RARE DISEASES. (a) In this subsection, "rare disease or condition" has the meaning given in 21 USC 360bb (a) (2).

(b) Except as provided in par. (e), every disability insurance policy, and every self–insured health plan of the state or a county, city, village, town, or school district, that provides coverage of prescription medication shall provide coverage for any drug that is prescribed for an individual covered under the policy or plan by a physician for the treatment of a rare disease or condition.

(c) The coverage required under par. (b) may be subject to any limitations, exclusions, or cost–sharing provisions that apply generally to other prescription medication under the disability insurance policy or self–insured health plan.

(d) The commissioner shall by rule specify the prescription drugs to which the requirement under par. (b) applies.

(e) This subsection does not apply to any of the following:

1. A disability insurance policy that covers only certain specified diseases.

2. A health care plan offered by a preferred provider plan, as defined in s. 609.01 (4), that provides only limited–scope dental or vision benefits, or by a limited service health organization, as defined in s. 609.01 (3).

3. A medicare replacement policy or a medicare supplement policy.

SECTION 9. Initial applicability.

(1) This act first applies to all of the following:

(a) Except as provided in paragraphs (b) and (c), disability insurance policies that are issued or renewed, and self–insured health plans that are established, extended, modified, or renewed, on the effective date of this paragraph.

(b) Disability insurance policies covering employees who are affected by a collective bargaining agreement containing provisions inconsistent with this act that are issued or renewed on the earlier of the following:

1. The day on which the collective bargaining agreement expires.

2. The day on which the collective bargaining agreement is extended, modified, or renewed.

(c) Self–insured health plans covering employees who are affected by a collective bargaining agreement containing provisions inconsistent with this act that are established, extended, modified, or renewed on the earlier of the following:

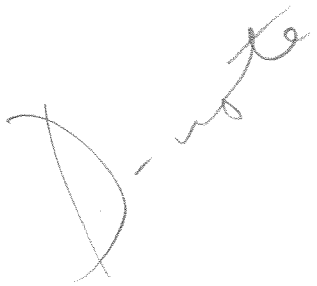
1. The day on which the collective bargaining agreement expires.

2. The day on which the collective bargaining agreement is extended, modified, or renewed.

SECTION 10. Effective date.

(1) This act takes effect on the first day of the 13th month beginning after publication.

(END)



DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

(date)

LRB-4689/2dn
PJK:...:...
lmk

Because the definition under federal law is quite vague, I thought it best to have the commissioner of insurance promulgate a rule that would list the drugs to which the requirement applies. Because rules take some time to promulgate and be adopted by the legislature, I delayed the effective date for one year.

Pamela J. Kahler
Senior Legislative Attorney
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DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4689/1dn
PJK:lmk:pg

March 23, 2006

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Basford, Sarah

From: Schneider, Marlin
Sent: Friday, March 24, 2006 10:07 AM
To: LRB.Legal
Subject: Draft Review: LRB 05-4689/1 Topic: Insurance coverage of orphan drugs

Please Jacket LRB 05-4689/1 for the ASSEMBLY.