



Senate

General Assembly

File No. 48

February Session, 2004

Senate Bill No. 107

Senate, March 15, 2004

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT CONCERNING INSURANCE COVERAGE FOR MEDICAL NUTRITION THERAPY SERVICES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 38a-492c of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2004*):

3 (a) For purposes of this section:

4 (1) "Inherited metabolic disease" means a disease for which
5 newborn screening is required under section 19a-55, as amended.

6 (2) "Low protein modified food product" means a product
7 formulated to have less than one gram of protein per serving and
8 intended for the dietary treatment of an inherited metabolic disease
9 under the direction of a physician.

10 (3) "Amino acid modified preparation" means a product intended
11 for the dietary treatment of an inherited metabolic disease under the

12 direction of a physician.

13 (4) "Specialized formula" means a nutritional formula for children
14 [up to age three] that is exempt from the general requirements for
15 nutritional labeling under the statutory and regulatory guidelines of
16 the federal Food and Drug Administration and is intended for use
17 solely under medical supervision in the dietary management of
18 specific diseases.

19 (b) Each individual health insurance policy providing coverage of
20 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
21 section 38a-469 delivered, issued for delivery or renewed in this state
22 on or after October 1, 1997, shall provide coverage for amino acid
23 modified preparations and low protein modified food products for the
24 treatment of inherited metabolic diseases if the amino acid modified
25 preparations or low protein modified food products are prescribed for
26 the therapeutic treatment of inherited metabolic diseases and are
27 administered under the direction of a physician.

28 (c) Each individual health insurance policy providing coverage of
29 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
30 section 38a-469 delivered, issued for delivery or renewed in this state
31 on or after October 1, 2001, shall provide coverage for specialized
32 formulas when such specialized formulas are medically necessary for
33 the treatment of a disease or condition and are administered under the
34 direction of a physician.

35 Sec. 2. Section 38a-518c of the general statutes is repealed and the
36 following is substituted in lieu thereof (*Effective October 1, 2004*):

37 (a) For purposes of this section:

38 (1) "Inherited metabolic disease" means a disease for which
39 newborn screening is required under section 19a-55, as amended.

40 (2) "Low protein modified food product" means a product
41 formulated to have less than one gram of protein per serving and
42 intended for the dietary treatment of an inherited metabolic disease

43 under the direction of a physician.

44 (3) "Amino acid modified preparation" means a product intended
 45 for the dietary treatment of an inherited metabolic disease under the
 46 direction of a physician.

47 (4) "Specialized formula" means a nutritional formula for children
 48 [up to age three] that is exempt from the general requirements for
 49 nutritional labeling under the statutory and regulatory guidelines of
 50 the federal Food and Drug Administration and is intended for use
 51 solely under medical supervision in the dietary management of
 52 specific diseases.

53 (b) Each group health insurance policy providing coverage of the
 54 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
 55 38a-469 delivered, issued for delivery or renewed in this state on or
 56 after October 1, 1997, shall provide coverage for amino acid modified
 57 preparations and low protein modified food products for the treatment
 58 of inherited metabolic diseases if the amino acid modified preparations
 59 or low protein modified food products are prescribed for the
 60 therapeutic treatment of inherited metabolic diseases and are
 61 administered under the direction of a physician.

62 (c) Each group health insurance policy providing coverage of the
 63 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
 64 38a-469 delivered, issued for delivery or renewed in this state on or
 65 after October 1, 2001, shall provide coverage for specialized formulas
 66 when such specialized formulas are medically necessary for the
 67 treatment of a disease or condition and are administered under the
 68 direction of a physician.

This act shall take effect as follows:	
Section 1	<i>October 1, 2004</i>
Sec. 2	<i>October 1, 2004</i>

INS *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 05 \$	FY 06 \$
State Comptroller - Fringe Benefits	Various - Cost	None	Indeterminate
Insurance Dept.	IF - None	None	None

Note: IF=Insurance Fund

Municipal Impact:

Municipalities	Effect	FY 05 \$	FY 06 \$
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

The coverage of medically necessary specialized formula for children over the age of three is not provided under the current state employee plans. The Office of the Comptroller has indicated that there would be an increased cost associated with this expansion of mandated coverage. It is anticipated that this cost would be incurred in FY 06 when the state is expected to enter into new health insurance contracts.

The bill's impact on municipal health insurance costs will vary by municipality depending on the current coverage. To the extent that medically necessary infant formula over age three is not covered under a municipality's employee health insurance policy, there would be increased municipal costs to provide it.

OLR Bill Analysis

SB 107

AN ACT CONCERNING INSURANCE COVERAGE FOR MEDICAL NUTRITION THERAPY SERVICES**SUMMARY:**

This bill requires health insurance policies to cover medically necessary specialized formula for children of any age, instead of only children up to age three. Specialized formula is a nutritional formula that is exempt from the federal Food and Drug Administration's (FDA) general nutritional labeling requirements and is intended for use solely under medical supervision in the dietary management of specific diseases.

The bill applies to individual and group health insurance policies that are delivered, issued for delivery, or renewed in this state after September 30, 2004 and cover (1) basic hospital expenses, (2) basic medical-surgical expenses, (3) major medical expenses, (4) accidents only, or (5) hospital or medical services.

EFFECTIVE DATE: October 1, 2004

BACKGROUND***FDA Regulation***

The FDA's regulations exempt infant formula from the general nutritional labeling requirements that apply, with exceptions, to products intended for human consumption (21 CFR § 101.9(j)(7)). FDA has separate regulations on infant formula exempting certain types of formula that are represented and labeled for use by infants who have inborn metabolic disorders, low birth weights, or unusual medical or dietary problems from labeling requirements (21 CFR § 107.3).

FDA distinguishes between two types of exempt formulas: those that are readily available to the general public at retail stores and those that are not. Formulas that are available at a retail store are typically labeled for dietary management of diseases or conditions that are not clinically serious or life-threatening, even though they may also be

labeled for use in clinically serious or life-threatening disorders. Formulas that are not available for general consumer purchase are typically prescribed by a physician and must be requested from a pharmacist. They are labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time (21 CFR § 107.50).

Related Bill

HB 5201, favorably report by the Insurance and Real Estate Committee, requires health insurance policies to cover specialized formula on the same basis as other outpatient prescription drugs, among other things.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Report

Yea 16 Nay 2