



House of Representatives

General Assembly

File No. 45

February Session, 2004

House Bill No. 5201

House of Representatives, March 15, 2004

The Committee on Insurance and Real Estate reported through REP. OREFICE of the 37th Dist., Chairperson of the Committee on the part of the House, that the bill ought to pass.

AN ACT CONCERNING NEWBORN SCREENING AND MEDICALLY NECESSARY NUTRITIONAL FORMULA FOR CYSTIC FIBROSIS.

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 Section 38a-492c of the general statutes is repealed and the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 by
6 this act.

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

11 (3) "Amino acid modified preparation" means a product intended

12 for the dietary treatment of an inherited metabolic disease under the
13 direction of a physician.

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

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

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

36 (d) Such policy shall provide coverage for such food products and
37 formulas on the same basis as outpatient prescription drugs.

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

40 (a) For purposes of this section:

41 (1) "Inherited metabolic disease" means a disease for which
42 newborn screening is required under section 19a-55, as amended by

43 this act.

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

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

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

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

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

73 (d) Such policy shall provide coverage for such food products and

74 formulas on the same basis as outpatient prescription drugs.

75 Sec. 3. Section 19a-55 of the general statutes, as amended by section
76 5 of public act 03-3 of the June 30 special session, is repealed and the
77 following is substituted in lieu thereof (*Effective October 1, 2004*):

78 (a) The administrative officer or other person in charge of each
79 institution caring for newborn infants shall cause to have administered
80 to every such infant in its care an HIV-related test, as defined in section
81 19a-581, a test for phenylketonuria and other metabolic diseases, cystic
82 fibrosis, hypothyroidism, galactosemia, sickle cell disease, maple syrup
83 urine disease, homocystinuria, biotinidase deficiency, congenital
84 adrenal hyperplasia and such other tests for inborn errors of
85 metabolism as shall be prescribed by the Department of Public Health.
86 The tests shall be administered as soon after birth as is medically
87 appropriate. If the mother has had an HIV-related test pursuant to
88 section 19a-90 or 19a-593, the person responsible for testing under this
89 section may omit an HIV-related test. The Commissioner of Public
90 Health shall (1) administer the newborn screening program, (2) direct
91 persons identified through the screening program to appropriate
92 specialty centers for treatments, consistent with any applicable
93 confidentiality requirements, and (3) set the fees to be charged to
94 institutions to cover all expenses of the comprehensive screening
95 program including testing, tracking and treatment. The fees to be
96 charged pursuant to subdivision (3) of this section shall be set at a
97 minimum of twenty-eight dollars. The commissioner shall adopt
98 regulations, in accordance with chapter 54, specifying the abnormal
99 conditions to be tested for and the manner of recording and reporting
100 results. On or before January 1, 2004, such regulations shall include
101 requirements for testing for amino acid disorders, organic acid
102 disorders and fatty acid oxidation disorders, including, but not limited
103 to, long-chain 3-hydroxyacyl CoA dehydrogenase (L-CHAD) and
104 medium-chain acyl-CoA dehydrogenase (MCAD).

105 (b) The provisions of this section shall not apply to any infant whose
106 parents object to the test or treatment as being in conflict with their

107 religious tenets and practice.

This act shall take effect as follows:	
Section 1	<i>October 1, 2004</i>
Sec. 2	<i>October 1, 2004</i>
Sec. 3	<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 \$
Public Health, Dept.	GF - Cost	224,760	233,015
Public Health, Dept.	GF - Revenue Gain	Potential	Potential
UConn Health Ctr.	SF - Savings	Potential Significant	Potential Significant
UConn Health Ctr.	SF - Revenue Loss	Potential Significant	Potential Significant
Social Services, Dept.	GF - Savings	Potential	Potential
Comptroller Misc. Accounts (Fringe Benefits)	GF - Cost	18,365	49,035
Comptroller Misc. Accounts (Fringe Benefits)	Various - Cost	None	Minimal

Note: GF=General Fund; SF=Special Fund (Non-appropriated)

Municipal Impact:

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

Explanation

Passage of this bill will result in a significant cost and a potential revenue gain to the Department of Public Health (DPH), and a potential significant savings and revenue loss to the University of Connecticut Health Center (UCHC). It could also affect state and municipally funded health insurance and other programs. Specific impacts are as follows:

Addition of Cystic Fibrosis to Newborn Screening:

The state will incur an FY 05 cost of approximately \$243,125 to initiate DPH screening of 43,000 newborns for cystic fibrosis annually

and perform tracking and follow-up services for families with infants identified with this inherited disorder. An estimated 860 newborns each year will have presumptive positive screens, requiring notification and follow-up.¹

In order to process tests for cystic fibrosis, the Connecticut State Laboratory will have to purchase equipment costing approximately \$24,000. Other laboratory costs will include \$42,000 to support the salary of one Chemist, \$105,000 in related laboratory supplies (chemical reagents, testing kits) and \$8,500 for associated fringe benefits.²

Additional FY 05 costs of \$48,760 will be incurred to support the three-quarter year salary of one Nurse Consultant (at an annual salary of \$65,015) required to engage in follow-up activities involving families of newborns with positive screens. \$9,865 in additional fringe benefits costs will result. Finally, \$5,000 in one-time data processing charges will also be incurred to modify the agency's computer tracking system.

In FY 06 and subsequent fiscal years, an ongoing cost of approximately \$282,050 will be incurred to support the continuing costs of the two employees as well as recurring laboratory supply needs.

¹ Confirmation testing and final diagnosis of these disorders, as well as ensuing family counseling and treatment, will likely occur at one of two genetic disease treatment centers in Connecticut (Yale-New Haven Hospital, Connecticut Children's Medical Center).

² The fringe benefit costs for state employees are budgeted centrally in the Miscellaneous Accounts administered by the Comptroller. The total fringe benefit reimbursement rate as a percentage of payroll is 45.82%, effective July 1, 2003. However, first year fringe benefit costs for new positions do not include pension costs - lowering the rate to 20.23% in FY 05. The state's pension contribution is based upon the prior year's certification by the actuary for the State Employees Retirement System.

Presently cystic fibrosis testing is performed at the UCHC and Yale University's School of Medicine on a voluntary basis. The UCHC performs in excess of 20,000 screens annually. This testing would be assumed in whole by the DPH's State Laboratory, thus resulting in potentially significant savings for the Health Center. A corresponding revenue loss to the UCHC Clinical Services Fund would be expected to the extent that it would cease to bill patients for this service.

It is uncertain at this time whether any offsetting revenue will be generated due to passage of this bill. The DPH is currently authorized to collect a fee of at least \$28 per child from hospitals submitting samples for newborn testing. The exact fee is set at the discretion of the commissioner. If the agency elects to increase the fee to cover the costs of cystic fibrosis testing, a corresponding General Fund revenue gain will occur. It should be noted that the number of births at Dempsey Hospital is relatively low (approximately 600 annually). Consequently, it is not anticipated that the UCHC will experience a significant fiscal impact from any resulting increase in the State Laboratory fee - any additional costs would likely be partially recouped via patient billings.

The expanded testing program may enhance the early identification and treatment of certain children, and thus reduce the frequency of some medical complications. To the extent that any resulting health care savings are passed on to the state through future contracts negotiated for Medicaid managed care services, a future indeterminate savings to the Department of Social Services will result. Any such savings would be partially offset by reduced federal financial participation. A potential savings may result for municipal employee health insurance plans should health care costs be reduced due to enhanced early identification and treatment.

Health Insurance Mandates:

The state employee health plans currently cover the formula with the same co-payments as prescription drugs, so there is no fiscal impact from the co-payment requirement in the bill. The Office of the

State Comptroller has indicated that there would be a minimal cost from the cystic fibrosis screening. 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 cystic fibrosis screening is not covered under a municipality's employee health insurance policy, there would be increased municipal costs to provide it that are anticipated to be minimal.

OLR Bill Analysis

HB 5201

AN ACT CONCERNING NEWBORN SCREENING AND MEDICALLY NECESSARY NUTRITIONAL FORMULA FOR CYSTIC FIBROSIS**SUMMARY:**

This bill:

1. adds cystic fibrosis to the list of diseases for which newborns must be screened,
2. requires health insurance policies to cover amino acid modified preparations and low protein modified food products prescribed for the treatment of cystic fibrosis, and
3. requires health insurance policies to cover food products prescribed to treat cystic fibrosis and other inherited metabolic diseases and specialized formulas prescribed for the dietary management of such diseases on the same basis as other outpatient prescription drugs.

This bill applies to individual and group health insurance policies that are delivered, issued for delivery, or renewed in this state on or after October 1, 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***Cystic Fibrosis***

Cystic fibrosis (CF) is a genetic disorder. It is a chronic and progressive disease usually diagnosed in childhood that causes mucus to build up and clog passages in many of the body's organs, but primarily the lungs and pancreas. In the lungs, the mucus can lead to serious breathing problems and lung disease. In the pancreas, it can lead to malnutrition and problems with growth and development.

Sometimes the first sign of CF is a blocked small intestine at birth, which prevents a baby from passing his first stool. Some babies have

very salty sweat or skin. If CF is suspected, the health professional will order a sweat test, which measures the amount of salt in the sweat on the skin's surface. Two sweat tests usually are done to confirm a diagnosis. Other tests may also be done.

There is no cure for CF. Management of the disease varies widely from person to person and generally focuses on treating respiratory and digestive problems to prevent complications, especially infections. Treatment usually involves a combination of medications, home treatment methods (including respiratory and nutritional therapies), and specialized care by health professionals.

Newborn Screening

The Public Health Commissioner administers the newborn screening program; directs those diagnosed with disease to the appropriate specialty center for treatment, consistent with applicable confidentiality requirements; and sets the screening program fees, including testing, tracking, and treatment. The fees must be at least \$28. The testing and treatment requirements do not apply to any newborn whose parents object based on their religious beliefs.

Food Products and Inherited Metabolic Disease

Amino acid modified preparations and low-protein modified food products are intended for the dietary treatment of an inherited metabolic disease under the direction of a physician. Under Connecticut's nutritional formula law, an inherited metabolic disease is a disease for which newborn screening is required.

RELATED BILL

SB 107

SB 107, favorably reported by the Insurance and Real Estate Committee, requires health insurance policies to cover medically necessary specialized formulas used under medical supervision for the dietary management of specific diseases in children of any age, instead of children up to age three.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Report
Yea 16 Nay 2