Bureau of Insurance

A Report to the Joint Standing Committee on Insurance and Financial Services of the 123rd Maine Legislature

Review and Evaluation of LD 658, An Act To Protect the Health of Infants

June 6, 2007

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I. Executive Summary

An estimated 277 infants born in Maine each year may suffer from a medical condition or allergy which requires a specialized infant formula. These children suffer from extreme vomiting, diarrhea, hives, and a very low body weight.

One example of a specialized formula is amino acid-based formulas, which are not available off the shelf at the grocery store, rather they are only found behind the counter at some pharmacies.[1]

The Joint Standing Committee on Insurance and Financial Services of the 123rd Maine Legislature directed the Bureau of Insurance to review LD 658, An Act to Protect the Health of Infants. The review was conducted using the requirements stipulated under 24-A M.R.S.A., §2752. This review was a collaborative effort of NovaRest, Inc. and the Maine Bureau of Insurance (the Bureau).

Current law requires coverage for metabolic formula that has been prescribed by a licensed physician for a person with an inborn error of metabolism. This proposed mandate would extend coverage to any infant formula determined to be medically necessary, such as amino acid-based elemental formulas not covered by the current mandate.[2]

This bill requires that all individual and group health insurance policies and all HMO policies offer or make available coverage for infant formula determined to be medically necessary. The requirements of this bill apply to all policies, issued or renewed on or after January 1, 2008. Although the bill as drafted is a mandated offer, the Committee asked the Bureau to prepare its review and evaluation based on the following amendments to the bill:

- Requiring that individual and group health insurance policies include coverage for medically necessary amino acid-based elemental formula recommended by a physician; and
- Prohibiting carriers from restricting coverage to infants with a feeding tube.

There is currently no estimate of how many children will have conditions requiring medically necessary infant formulas, but studies suggest that 2% to 3%[3] of infants will have severe enough symptoms to require the amino acid-based formulas. With 13,852[4] births in Maine annually, it's projected that between 277 and 416 children would need medically necessary infant formula per year.

[1] Hession, Kate Testimony, April 10, 2007

[2] Cioppa, Eric A. Testimony, April 10, 2007

[3] Dowshen, Steven MD. "Milk Allergies in Infants". 2007. 11 May 2007 http://kidshealth.org/parent/pregnancy_newborn/medical_problems/milk_allergy.html

Potential complications from not treating or from partial treatment of severe food allergies include: growth failure, iron deficiency associated with cognitive learning impairment and/or anemia, as well as persistence of the enterocolitis and the accompanying malabsorption and possible internal bleeding.

Six states currently mandate coverage of amino acid-based formulas: Arizona, Connecticut, Massachusetts, New Hampshire, New Jersey and New York. Other states with infant formula mandates typically only mandate coverage of metabolic disorders, similar to Maine's current mandate. Some of these states also have dollar coverage limits.

Currently no carrier in Maine covers specialized infant formula except as mandated for the treatment of metabolic conditions unless it is administered enterally (i.e., by feeding tube) or parenterally (i.e., by intravenous administration).Carriers in Maine do not have the data necessary to estimate the impact of this bill on premiums due to the broad definition used in the bill.

We used estimates of the prevalence of severe allergies in infants (2%-3%) that would require amino acid-based infant formula and the cost of the products currently on the market ($700 a month) to estimate the impact on premiums. If the coverage was mandated rather than required to be offered, we estimate that this bill could impact current premiums for family coverage by as much as 0.24%, but total premium by 0.10%. If the coverage is required to be offered rather than mandated, the total impact on premiums will be less since not many will select it, but the impact on those selecting it will be huge. We assume that the impact on single coverage would be negligible since single coverage is rarely provided to infants.

[4] "Maine". 2003. 22 May 2007 <http://www.city-data.com/us-cities/The-Northeast/Maine.html>

II. Background

Medically necessary infant formula is used by physicians as a treatment for newborn diseases and conditions including: severe food allegories, food protein intolerance, short bowel syndrome, eosiniphilic disorders, gastrointestinal disorders, such as Gastrointestinal Reflux Disease (GERD), Eosinophilic Esophagitis (EE), and other conditions in which an elemental diet is required. Maine currently requires coverage of formula for metabolic disorders, but not for other conditions.

The Joint Standing Committee on Insurance and Financial Services of the 123rd Maine Legislature directed the Bureau of Insurance to review LD 658, An Act To Protect the Health of Infants. The review was conducted using the requirements stipulated under 24-A M.R.S.A., §2752. This review was a collaborative effort of NovaRest, Inc. and the Maine Bureau of Insurance.

The bill would amend sections of Maine law pertaining to individual and group health insurance plans. Appendix A includes the proposed amendments to the applicable sections of Maine law. The bill requires that health insurers and HMOs offer coverage for medically necessary infant formula. The requirements of this bill apply to all policies, contracts and certificates executed, delivered, issued for delivery and continued or renewed in this State on or after January 1, 2008.

Any policy or contract that provides coverage for medically necessary infant formula may contain provisions for maximum benefits and coinsurance and reasonable limitations, deductibles and exclusions.

III. Social Impact

A. Social Impact of Mandating the Benefit

1. The extent to which the treatment or service is utilized by a significant portion of the population.

We don't know for certain how many children will have conditions which require medically necessary amino acid-based infant formulas, but some estimates suggest that 2% to 3%[5] of infants will have severe enough allergies to require the amino acid-based formulas. With 13,852[6] births in Maine annually, it's projected that between 277 and 416 children would need medically necessary amino acid-based infant formula per year.

2. The extent to which the service or treatment is available to the population.

Medically necessary infant formula is available to the population at this time. It may need to be ordered in advance from some pharmacies with a doctor's note or directly through the manufacturer.

3. The extent to which insurance coverage for this treatment is already available.

No carrier in Maine reported covering orally administered amino acid-based infant formula unless it was for metabolic conditions. Aetna states that it will not cover any infant formulas that are taken by mouth, unless mandated by State law.[7] Maine currently only mandates coverage of infant formula for metabolic conditions.

Currently, the Women, Infants, and Children's Program (WIC) and MaineCare cover these medically necessary amino acid-based elemental formulas (regardless of the delivery method) for infants and children suffering from food allergies and gastrointestinal conditions.

4. If coverage is not generally available, the extent to which the lack of coverage results in a person being unable to obtain the necessary health care treatment.

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[5] Dowshen, Steven MD. "Milk Allergies in Infants". 2007. 11 May 2007 <http://kidshealth.org/parent/pregnancy_newborn/medical_problems/milk_allergy.html>

[6] "Maine". 2003. 22 May 2007 <http://www.city-data.com/us-cities/The-Northeast/Maine.html>

[7] "Clinical Policy Bulletin: Nutritional Support". 2007. 22 May 2007 <http://www.aetna.com/cpb/medical/data/1_99/0061.html>

If an individual's medical policy does not cover this service, they would be able to obtain the formula but would have to pay for it themselves. Currently, the Women, Infants, and Children's Program (WIC) and MaineCare cover these medically necessary infant formulas regardless of the delivery method.[8]

5. *If coverage is not generally available, the extent to which the lack of coverage involves unreasonable financial hardship.*

Assuming that an individual's health plan did not cover the cost of formula, the individual would have to pay the cost of the treatment.

The cost of the formula is based on the number of feedings and the severity of the ailment. Neocate is one of the leaders in providing amino acid-based formula to reduce the possibility of an allergic reaction. The Neocate product range has extensive clinical validation from infant through to childhood.[9] A typical one case (4 cans at 400g (14 oz)) costs $135. This can add up to estimates of $693 per month or $8,300 a year. The average family would find this to be a financial hardship.

6. *The level of public demand and the level of demand from providers for this treatment or service.*

The Academy of Pediatrics recommends breast milk as an optimal source of nutrition for infants. When either breast fed or formula fed infants, have food allergies they benefit from the use of hypoallergenic or a free amino acid-based formula. In its 2000 policy statement, the Academy states that,[10] "Those breastfeeding infants who develop symptoms of food allergies may benefit from:

a. maternal restriction of cows milk, egg, fish, peanuts and tree nuts and if this is unsuccessful,
b. use of a hypoallergenic (extensively hydrolyzed or if allergic symptoms persist, a free amino acid-based formula) as an alternative to breastfeeding. Those infants with IgE-associated symptoms of allergy may benefit from a soy formula, either as the initial treatment or instituted after 6 months of age following the use of a hypoallergenic formula. The prevalence of concomitant is not as great between soy and cows milk in these infants compared with those with nonIgE-associated syndromes such as enterocolitis, proctocolitis, malabsorption syndrome, or esophagitis. Benefits should be

[8] Hession, Kate Testimony, April 10, 2007

[9] "Products" 6 July 2006. 11 May 2007 <http://www.neocate.com/aaa_neocate/259-products.html>

[10] "Policy Statement". American Academy of Pediatrics. Pediatrics Vol 106, No. 2, August 2000. Pgs 346-349

seen within 2 to 4 weeks and the formula continued until the infant is 1 year of age or older.

c. Formula-fed infants with confirmed cows milk allergy may benefit from the use of a hypoallergenic or soy formula as described for the breastfed infant.

d. Infants at high risk for developing allergy, identified by a strong (biparental; parent, and sibling) family history of allergy may benefit from exclusive breastfeeding or a hypoallergenic formula or possibly a partial hydrolysate formula.

Conclusive studies are not yet available to permit definitive recommendations."

7. *The level of public demand and the level of demand from the providers for individual or group coverage of this treatment.*

Kate Hession has created a web site, ww.bbphi.com, for Maine residents that support insurance coverage for medically necessary infant formula.

Amy Carlisle is Chairperson of the Public Affairs Committee for the March of Dimes, which is a national voluntary health agency whose mission is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. Ms. Carlisle has provided testimony supporting insurance coverage of medically necessary infant formula. She testified that, "The March of Dimes' recommends the Insurance and Financial Services Committee protect the health of infants and children with health insurance in communities throughout the state by requiring insurance companies doing business in the State to cover amino acid-based elemental formula to treat medical diseases and allergies."[11]

8. *The level of interest in and the extent to which collective bargaining organizations are negotiating privately for the inclusion of this coverage by group plans.*

No information is available.

9. *The likelihood of meeting a consumer need as evidenced by the experience in other states.*

According to the Children's Milk Allergy and Gastrointestinal Coalition, six other states - New Hampshire, Massachusetts, Connecticut, New York, New Jersey, and Arizona - have passed legislation requiring insurance companies to cover amino acid-based elemental infant formulas, and legislation is pending in Minnesota, Washington, and Illinois.[12] Our interpretation of the requirements in other states is that most do not require coverage beyond the current mandate in Maine

[11] Carlusle, Amy, March of Dimes, Testimony April 10, 2007

for metabolic conditions and many include dollar limits on coverage (See Appendix C for a summary of requirements in other states). Note, Phenylalanine (PKU) is an example of an inherited metabolic condition.

Florida requires a mandated offer and reports that if the option is elected, special amino acid infant formula would be covered if it was prescribed by a physician for the treatment of inherited diseases of amino acids. Their law does not state whether the formula is to be administered by tube or mouth.

10. The relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

State agencies did not provide findings pertaining to the proposed legislation.

11. Alternatives to meeting the identified need.

This bill requires health insurers and health maintenance organizations to offer the coverage for medically necessary infant formula. Offering coverage for such a rare condition would be complicated. Questions arise such as:

- For individual coverage, will a person only be able to purchase the option when they first get coverage or can they add it later?
- If they have to select the coverage when they first get the policy, can they later drop it?
- Can they purchase the coverage later after they drop it?
- For group coverage, is the option offered to the employer or can an individual select the coverage?

Depending on the answers to these questions, the offer of coverage may have no impact at all. If the only individuals purchasing coverage are those that require the benefits, the cost may be as much or higher than if they purchased the infant formula themselves. This is true because insurers will add administrative cost to the cost of claims, resulting in a higher total cost to the family.

An alternative is to require the medically necessary infant formula to be covered by health insurers and HMOs. A copay could apply that would equate to the cost of typical baby formula, which a family would normally purchase and could afford.[13]

[12] Carlisle, Amy, March of Dimes, Testimony April 10, 2007

[13] Carlisle, Amy, March of Dimes, Testimony April 10, 2007: this is $2,175 a year

A second possibility is for one or more social agencies to provide funding for medically necessary infant formula that families cannot afford.

12. *Whether the benefit is a medical or a broader social need and whether it is inconsistent with the role of insurance and the concept of managed care.*

The requirements of LD 658 are not totally inconsistent with the role of insurance and the concept of managed care. Typically, insurance does not cover food, even specialized food needed due to health conditions. This bill raises the question of when does a specialized food being used for a unique health condition, become a medical treatment?

13. *The impact of any social stigma attached to the benefit upon the market.*

There is little or no social stigma attached to having coverage for the medically necessary infant formula.

14. *The impact of this benefit upon the other benefits currently offered.*

Children who have severe food allergies and do not receive amino acid-based formulas as a treatment for their condition will continue to incur doctor and hospital visits to address the symptoms of their conditions and have the potential for greater complications.[14] The coverage of medically necessary infant formula under this bill may reduce the need for these doctor and hospital visits, but we can not quantify the impact at this time.

15. *The impact of the benefit as it relates to employers shifting to self-insurance and the extent to which the benefit is currently being offered by employers with self-insured plans.*

State legislation that imposes benefit mandates will heighten an employer's concern with regard to future costs and make self-insurance a more attractive alternative. The 1998 Mercer/Foster Higgins National Survey of Employer-sponsored Health Plans indicates that 36% percent of the large employers (500 or more employees) in the Northeast self-insure health plans.

Given the high annual increases in medical care costs, large employers may be particularly sensitive to any legislation that places limits on managed care and increases the cost of health care.

No information is available as to the extent to which this benefit is currently being offered by employers with self-insured plans.

[14] Carlisle, Amy, March of Dimes, Testimony April 10, 2007

16. The impact of making the benefit applicable to the state employee health insurance program.

Due to the broad nature of the bill and the lack of specific data on specialized infant formula, Anthem Blue Cross Blue Shield of Maine could not estimate the impact on LD 658 on the Maine State Employees Health Insurance Program.

IV. Financial Impact

B. Financial Impact of Mandating Benefits.

1. The extent to which the proposed insurance coverage would increase or decrease the cost of the service or treatment over the next five years.

Since the manufacturers of specialized infant formulas serve a national market, it is unlikely that this bill would impact the cost of the formulas over the next five years.

2. The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.

LD 658 will increase the appropriate use of medically necessary infant formula treatments because the insurance coverage will allow those individuals that need specialized infant formula and cannot afford the cost to purchase the needed specialized formula.

It is possible that LD 658 would increase the inappropriate use of specialized infant formulas. Once a service is covered by insurance, there is a possibility of it being inappropriately used since the cost of its use becomes negligible to the patient. Specialized formulas could be used beyond the point that they are needed because it is less expensive to the family to continue the specialized formula than to return to formula from the grocery store.

This bill does not preclude applying a prior approval process or other utilization review procedures to minimize inappropriate usage. The bill does not preclude copays that would equate to the cost of normal infant formula, reducing the incentive to continue the specialized formula.

3. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

Carriers currently cover formula administered by feeding tube, which families will not choose, over oral feeding, if there is an option. Since coverage of orally administered formula is less expensive than the currently covered alternative of tube feeding, it theoretically may replace the more expensive alternative. We cannot estimate this impact of this substitution at this time.

The mandated formula options covered by this bill may replace less expensive formulas.

4. *The methods which will be instituted to manage the utilization and costs of the proposed mandate.*

LD 658 allows health plans to require prior authorization for the medically necessary infant formula the same manner that prior authorization is required for other covered diseases or conditions. The bill does not preclude copays that would equate to the cost of normal infant formula, reducing the incentive to substitute the specialized formula for normal formula.

5. *The extent to which insurance coverage may affect the number and types of providers over the next five years.*

It is unlikely that this LD 658 will affect the number or types of providers.

6. *The extent to which the insurance coverage of the health care service or providers may be reasonably expected to increase or decrease the insurance premium or administrative expenses of policyholders.*

In general, carriers could not provide estimates due to the broad nature of the requirement in the bill and the lack of data on the utilization of specialized infant formulas.

Aetna reported that it does not have claims data to be able to estimate the impact on premiums. Based on other studies, they estimate the premium cost impact to be between 0.5% and 1.0% for all coverage types and population segments.

Using estimates of the prevalence of severe allergies in infants (2%-3%) that would require medically necessary amino acid-based infant formula and the cost of the products currently on the market ($700 a month), we estimate that this bill could impact current premiums for family coverage by as much as 0.24%, but total premium by 0.10%.. We assume that the impact on single coverage would be negligible since single coverage is rarely provided to infants.

7. *The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the cost and benefits of coverage.*

There would not be any additional cost effect beyond benefit and administrative costs.

8. *The impact on the total cost of health care.*

NovaRest estimates that LD 658 could increase premiums by 0.10%. Since in many cases specialized infant formula is used even if it is not covered by insurance due to the cost, total health care cost will increase by an amount less than 0.10%.

9. *The effects of mandating the benefit on the cost of health care particularly the premium and administrative expenses and indirect costs, to employers and employees, including the financial impact on small employers, medium-sized employers and large employers.*

LD 658 would, on average, increase premiums for health plans that do not currently comply with LD 658, by an estimated 0.10%. Employers will pay this additional premium, as will employees to the extent the cost is passed on through the employee's contribution to the premiums. There is no reason that the estimated percentage premium increase will vary for small employers, medium-sized employers and large employers. This increase will contribute slightly to rising premiums that may cause employers who are too small to self-insure to discontinue offering health insurance to employees. Fewer employees may elect health insurance when confronted with rising premiums.

10. *The effect of the proposed mandates on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in this State.*

The infant formula covered by this mandate is currently covered by MaineCare. Some individuals may have insurance and still qualify for MaineCare. These individuals may apply for MaineCare, if their insurance does not cover the needed specialized infant formula, but if the formula is covered by their insurance, the tendency may be to submit the claims to the insurer. This will shift some cost from the public to the private sector.

V. Medical Efficacy

C. The Medical Efficacy of Mandating the Benefit.

1. *The contribution of the benefit to the quality of patient care and the health status of the population, including any research demonstrating the medical efficacy of the treatment or service compared to the alternative of not providing the treatment or service.*

If a child with severe food allergies is not treated with an appropriate infant formula, like Neocate, there is little else that will help the child. Most likely, the child will continue to have diarrhea, hives, and a very low body weight. Solid food in most cases would not be helpful either.

Potential complications from not treating or from partial treatment include growth failure, iron deficiency associated with cognitive learning impairment and/or anemia, as well as persistence of the enterocolitis and the accompanying malabsorption and possible bleeding.[15]

2. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

a. *The results of any professionally acceptable research demonstrating medical results achieved by the additional practitioners relative to those already covered.*

LD 658 will not require an additional class of practitioners.

b. *The methods of the appropriate professional organization that assure clinical proficiency.*

LD 658 will not require an additional class of practitioners.

[15] Lombard, Kenneth A., MD. Maine Medical Partners. Letter dated April 6, 2007

VI. Balancing the Effects

D. The Effects of Balancing the Social, Economic, and Medical Efficacy Considerations.

1. *The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders.*

The population covered by LD 658 is relatively small. The cost of providing medically necessary infant formula is estimated to be 0.10% of the total premium for medical plans that do not currently cover this mandate. This premium increase by itself would not seem likely to move health insurance purchasers to discontinue coverage. However, average annual premium increases for health insurance have been high for employer groups. Premiums for individual medical plans have seen even higher increases. The premium increase estimated for LD 658 when combined with large renewal increases could intensify the consumer's sensitivity to health insurance costs.

2. *The extent to which the problem of coverage can be resolved by mandating the availability of coverage as an option for policyholders.*

This bill as written does require offering the coverage of medically necessary infant formula as an option. It is not practical to offer this coverage as an option for individual policyholders. It is only applicable to a relatively small segment of the population. Therefore, only this small segment would be likely to request the option, all of whom would use it, resulting in a premium that may be as much or more than paying on an out-of-pocket basis.

3. *The cumulative impact of mandating this benefit in combination with existing mandates on costs and availability of coverage.*

The Bureau's estimates of the maximum premium increases due to existing mandates and the proposed mandate are displayed in Table B.

TABLE B MAXIMUM PREMIUM INCREASES			
	Group (more than 20 employees)	Group (20 or fewer employees)	Individuals
CURRENT MANDATES			
▪ Indemnity Plans	8.64%	4.27%	3.55%
▪ Managed Care Plans	7.51%	5.70%	3.58%
LD 658			
▪ Indemnity Plans	0.10%	0.10%	0.10%
▪ Managed Care Plans	0.10%	0.10%	0.10%
CUMULATIVE IMPACT			
▪ Fee-for-Service Plans	8.74%	4.37%	3.65%
▪ Managed Care Plans	7.61%	5.80%	3.68%

These increases are based on the estimated portion of claim costs that the mandated benefits represent, as detailed in Appendix B. The true cost impact is less than this for two reasons:

1. Some of these services would likely be provided even in the absence of a mandate.
2. It has been asserted (and some studies confirm) that covering certain services or providers will reduce claims in other areas. For instance, covering surgical treatments will reduce the use of currently covered less expensive therapies.

While both of these factors reduce the cost impact of the mandates, we are not able to estimate the extent of the reduction at this time.

III. Appendices

Appendix A: Letter from the Committee on Insurance and Financial Services with Proposed Legislative Amendments

STATE OF MAINE

ONE HUNDRED AND TWENTY-THIRD LEGISLATURE

COMMITTEE ON INSURANCE AND FINANCIAL SERVICES

April 17, 2007

Marti Hooper
Senior Insurance Analyst
Life and Health Division
Bureau of Insurance 34
State House Station
Augusta, Maine 04333

Dear Ms. Hooper:

Title 24-A Maine Revised Statutes Annotated, Section 2752 requires the Joint Standing Committee on Insurance and Financial Services to submit legislation proposing health insurance mandates to the Bureau of Insurance for review and evaluation if there is substantial support for the mandate among the committee after a public hearing on the proposed legislation. Pursuant to that statute, we request the Bureau of Insurance prepare a review and evaluation of **LD 658, An Act to Protect the Health of Infants.**

A copy of the bill is enclosed. Although the bill as drafted is a mandated offer, we ask that the Bureau prepare its review and evaluation based on the following amendments to the bill:

- Requiring that individual and group health insurance policies include coverage for medically necessary amino acid-based elemental formula recommended by a physician; and
- Prohibiting carriers from restricting coverage to infants with a feeding tube.

Please prepare the evaluation using the guidelines set out in Title 24-A § 2752 and submit the report to the committee within 8 weeks so the committee can take final action on LD 658 before adjournment of the First Regular Session. If you have any questions, please do not hesitate to contact us or our legislative analyst, Colleen McCarthy Reid.

Sincerely,

Nancy B. Sullivan (CM)
Senate Chair

John R. Brautigam (CM)
House Chair

cc: Members, Insurance and Financial Services Committee

123rd MAINE LEGISLATURE

FIRST REGULAR SESSION-2007

Legislative Document **No. 658**

H.P. 507 House of Representatives, February 8, 2007

An Act To Protect the Health of Infants

Reference to the Committee on Insurance and Financial Services suggested and ordered printed.

Millicent M. MacFarland

MILLICENT M. MacFARLAND
Clerk

Presented by Representative CURTIS of Madison.
Cosponsored by Senator SHERMAN of Aroostook and
Representatives: GIFFORD of Lincoln, JOY of Crystal.

Be it enacted by **the People of the State of Maine as follows:**

Sec. 1. 24 MRSA §2332-0 is enacted to read:

2332-0. Offer of coverage for medically necessary infant formula

All individual and group nonprofit hospital and medical services plan policies, contracts and certificates and all nonprofit health care plan policies, contracts and certificates must make available coverage for infant formula determined to be medically necessary health care as defined in Title 24-A, section 4301-A. subsection 10-A.

See. 2. 24-A MRSA §2762 is enacted to read:

2762. Offer of coverage for medically necessary infant formula

All individual health insurance policies, contracts and certificates must make available coverage for infant formula determined to be medically necessary health care as defined in section 4301-A, subsection 10-A.

Sec. 3. 24-A MRSA §2847-M is enacted to read:

2847-M. Offer of coverage for medically necessary infant formula

All group health insurance policies, contracts and certificates must make available coverage for infant formula determined to be medically necessary health care as defined in section 4301-A, subsection 10-A.

Sec. 4. 24-A MRSA §4253 is enacted to read:

4253. Offer of coverage for medically necessary infant formula

All health maintenance organization individual and group health insurance policies, contracts and certificates must make available coverage for infant formula determined to be medically necessary health care as defined in section 4301-A, subsection 10-A.

Sec. 5. Application. This Act applies to health insurance policies, contracts and certificates executed, delivered, issued for delivery, continued or renewed in this State on or after January 1, 2008. For purposes of this Act, all contracts are deemed to be renewed no later than the next yearly anniversary of the contract date.

SUMMARY

This bill requires health insurance carriers doing business in the State to provide coverage for medically necessary infant formula in individual and group policies, contracts and certificates.

Appendix B: Cumulative Impact of Mandates

Cumulative Impact of Mandates in Maine

Following are the estimated claim costs for the existing mandates:

- ***Mental Health*** (Enacted 1983) – The mandate applies only to group plans. It applies to all group HMO plans but does not apply to employee group indemnity plans covering 20 or fewer employees. Mental health parity for listed conditions was effective 7/1/96 but does not apply to any employer with 20 or fewer employees, whether under HMO or indemnity coverage. The list of conditions for which parity is required was expanded effective 10/1/03. The amount of claims paid has been tracked since 1984 and has historically been in the range of 3% to 4% of total group health claims. The percentage had remained in the 3.27% to 3.47% range from 1998 to 2002 but has decreased since then, reaching 2.90% in 2005. For 2005, this broke down as 2.62% for HMOs and 3.49% for indemnity plans. This decrease occurred despite the fact that an expansion of the list of conditions for which parity is required was fully implemented in 2005. Either the expansion has had no impact or the impact was offset by other factors such as the continuing shift from inpatient care to outpatient care. We estimate a continuation of 2005 levels going forward. For HMO plans covering employers with 20 or fewer employees, we use half the value for larger groups to reflect the fact that parity does not apply. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent. However, this overstatement is offset by the fact that the data is an aggregate of all groups, while groups of 20 or fewer are exempt from the parity requirement in the case of HMO coverage and from the entire mandate in the case of indemnity coverage.

- ***Substance Abuse*** (Enacted 1983) – The mandate applies only to groups of more than 20 and originally did not apply to HMOs. Effective 10/1/03, substance abuse was added to the list of mental health conditions for which parity is required. This applies to HMOs as well as indemnity carriers. The amount of claims paid has been tracked since 1984. Until 1991, it was in the range of 1% to 2% of total group health claims. This percentage showed a downward trend from 1989 to 2000 when it reached 0.31%. It then increased and leveled off at a range of 0.59% to 0.67% for 2002 through 2005 despite implementation of the parity requirement. The long-term decrease was probably due to utilization review, which sharply reduced the incidence of inpatient care. Inpatient claims decreased from about 93% of the total in 1985 and leveled off at about 55% for 1999-2005. The 0.67% for 2005 broke down as 0.55% for HMOs and 0.93% for indemnity plans. We estimate substance abuse benefits to remain at the current levels going forward. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how

much. We have included the entire amount, thereby overstating the impact of the mandate to some extent. However, this overstatement is offset by the fact that the data is an aggregate of all groups, while the mandate applies only to groups larger than 20.

- ***Chiropractic*** (Enacted 1986) – The amount of claims paid has been tracked since 1986 and has been approximately 1% of total health claims each year. However, the percentage increased from 0.84% in 1994 to a high of 1.51% in 2000. Since then, it has decreased slightly to between 1.32% and 1.46% during 2001 to 2005. The level varies significantly between group and individual. The variation between HMOs and indemnity plans has decreased to an insignificant level. For 2005, the percentages for group plans were 1.46% for HMO plans and 1.30% for indemnity plans with an aggregate of 1.41%. For individual plans, it was 0.33% for HMO plans, and 0.71% for indemnity plans with an aggregate of 0.70%. We estimate the aggregate levels going forward. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Screening Mammography*** (Enacted 1990) – The amount of claims paid has been tracked since 1992. It increased from 0.11% of total claims in 1992 to 0.7% in 2002, decreasing slightly to 0.69% in 2005, which may reflect increasing utilization of this service followed by a leveling off. This figure broke down as 0.70% for HMO plans, 0.67% for indemnity plans. We estimate 0.69% in all categories going forward. Although it is likely that some of these costs would be covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

- ***Dentists*** (Enacted 1975) – This mandate requires coverage to the extent that the same services would be covered if performed by a physician. It does not apply to HMOs. A 1992 study done by Milliman and Robertson for the Mandated Benefits Advisory Commission estimated that these claims represent 0.5% of total health claims and that the actual impact on premiums is "slight." It is unlikely that this coverage would be excluded in the absence of a mandate. We include 0.1% as an estimate.

- ***Breast Reconstruction*** (Enacted 1998) – At the time this mandate was being considered in 1995, Blue Cross and Blue Shield of Maine estimated the cost at $0.20 per month per individual. We have no more recent estimate. We include 0.02% in our estimate of the maximum cumulative impact of mandates.

- ***Errors of Metabolism*** (Enacted 1995) – At the time this mandate was being considered in

1995, Blue Cross estimated the cost at $0.10 per month per individual. We have no more recent estimate. We include 0.01% in our estimate.

- ***Diabetic Supplies*** (Enacted 1996) – Our report on this mandate indicated that most of the 15 carriers surveyed in 1996 said there would be no cost or an insignificant cost because they already provide coverage. One carrier said it would cost $.08 per month for an individual. Another said .5% of premium ($.50 per member per month) and a third said 2%. We include 0.2% in our estimate.

- ***Minimum Maternity Stay*** (Enacted 1996) – Our report stated that Blue Cross did not believe there would be any cost for them. No other carriers stated that they required shorter stays than required by the bill. We therefore estimate no impact.

- ***Pap Smear Tests*** (Enacted 1996) – No cost estimate is available. HMOs would typically cover these anyway. For indemnity plans, the relatively small cost of this test would not in itself satisfy the deductible, so there would be no cost unless other services were also received. We estimate a negligible impact of 0.01%.

- ***Annual GYN Exam Without Referral*** (managed care plans) (Enacted 1996) – This only affects HMO plans and similar plans. No cost estimate is available. To the extent the PCP would, in absence of this law, have performed the exam personally rather than referring to an OB/GYN, the cost may be somewhat higher. We include 0.1%.

- ***Breast Cancer Length of Stay*** (Enacted 1997) – Our report estimated a cost of 0.07% of premium.

- ***Off-label Use Prescription Drugs*** (Enacted 1998) – The HMOs claimed to already cover off-label drugs, in which case there would be no additional cost. However, providers testified that claims have been denied on this basis. Our 1998 report did not resolve this conflict but stated a "high-end cost estimate" of about $1 per member per month (0.6% of premium) if it is assumed there is currently no coverage for off-label drugs. We include half this amount, or 0.3%.

- ***Prostate Cancer*** (Enacted 1998) – No increase in premiums should be expected for the HMOs that provide the screening benefits currently as part of their routine physical exam benefits. Our report estimated additional claims cost for indemnity plans would approximate $0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately $0.11 per member per month, or about 0.07% of total

premiums.

- ***Nurse Practitioners and Certified Nurse Midwives*** (Enacted 1999) – This law mandates coverage for nurse practitioners and certified nurse midwives and allows nurse practitioners to serve as primary care providers. This mandate is estimated to increase premium by 0.16%.

- ***Coverage of Contraceptives*** (Enacted 1999) – Health plans that cover prescription drugs are required to cover contraceptives. This mandate is estimated to increase premium by 0.8%.

- ***Registered Nurse First Assistants*** (Enacted 1999) – Health plans that cover surgical first assisting are mandated to cover registered nurse first assistants if an assisting physician would be covered. No material increase in premium is expected.

- ***Access to Clinical Trials*** (Enacted 2000) – Our report estimated a cost of 0.46% of premium.

- ***Access to Prescription Drugs*** (Enacted 2000) – This mandate only affects plans with closed formularies. Our report concluded that enrollment in such plans is minimal in Maine and therefore the mandate will have no material impact on premiums.

- ***Hospice Care*** (Enacted 2001) – No cost estimate was made for this mandate because the Legislature waived the requirement for a study. Since carriers generally cover hospice care already, we assume no additional cost.

- ***Access to Eye Care*** (Enacted 2001) – This mandate affects plans that use participating eye care professionals. Our report estimated a cost of 0.04% of premium.

- ***Dental Anesthesia*** (Enacted 2001) – This mandate requires coverage for general anesthesia and associated facility charges for dental procedures in a hospital for certain enrollees for whom general anesthesia is medically necessary. Our report estimated a cost of 0.05% of premium.

- ***Prosthetics*** (Enacted 2003) – This mandate requires coverage for prosthetic devices to replace an arm or leg. Our report estimated a cost of 0.03% of premium for groups over 20 and 0.08% for small employer groups and individuals.

- ***LCPCs*** (Enacted 2003) – This mandate requires coverage of licensed clinical professional counselors. Our report on mental health parity indicated no measurable cost impact for coverage of LCPCs.

- Licensed Pastoral Counselors and Marriage & Family Therapists (Enacted 2005) – This

mandate requires coverage of **licensed pastoral counselors and marriage & family therapists**. Our report indicated no measurable cost impact for this coverage.

These costs are summarized in the following table.

COST OF EXISTING MANDATED HEALTH INSURANCE BENEFITS

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium	
			Indemnity	HMO
1975	**Maternity** benefits provided to married women must also be provided to unmarried women.	All Contracts	0[1]	0[1]
1975	Must include benefits for **dentists'** services to the extent that the same services would be covered if performed by a physician.	All Contracts except HMOs	0.10%	--
1975	Family Coverage must cover any **children** born while coverage is in force from the moment of birth, including treatment of congenital defects.	All Contracts except HMOs	0[1]	--
1983	Benefits must be included for treatment of **alcoholism and drug dependency**.	Groups of more than 20	0.93%	0.55%
1975 1983 1995 2003	Benefits must be included for **Mental Health Services**, including psychologists and social workers.	Groups of more than 20	3.49%	2.62%
		Groups of 20 or fewer	--	1.31%
1986 1994 1995 1997	Benefits must be included for the services of **chiropractors** to the extent that the same services would be covered by a physician. Benefits must be included for therapeutic, adjustive and manipulative services. HMOs must allow limited self referred for chiropractic benefits.	Group	1.41%	1.41%
		Individual	0.70%	0.70%
1990 1997	Benefits must be made available for screening **mammography**.	All Contracts	0.69%	0.69%
1995	Must provide coverage for **reconstruction of both breasts** to produce symmetrical appearance according to patient and physician wishes.	All Contracts	0.02%	0.02%
1995	Must provide coverage for **metabolic formula** and up to $3,000 per year for prescribed modified low-protein food products.	All Contracts	0.01%	0.01%
1996	Benefits must be provided for **maternity (length of stay)** and newborn care, in accordance with "Guidelines for Prenatal Care."	All Contracts	0	0
1996	Benefits must be provided for medically necessary equipment and supplies used to treat **diabetes** and approved self-management and education training.	All Contracts	0.20%	0.20%
1996	Benefits must be provided for **screening Pap tests**.	Group, HMOs	0.01%	0

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium	
			Indemnity	HMO
1996	Benefits must be provided for **annual gynecological exam** without prior approval of primary care physician.	Group managed care	--	0.10%
1997	Benefits provided for **breast cancer treatment** for a medically appropriate period of time determined by the physician in consultation with the patient.	All Contracts	0.07%	0.07%
1998	Coverage required for **off-label use of prescription drugs** for treatment of cancer, HIV, or AIDS.	All Contracts	0.30%	0.30%
1998	Coverage required for **prostrate cancer screening**.	All Contracts	0.07%	0
1999	Coverage of nurse **practitioners and nurse midwives** and allows nurse practitioners to serves as primary care providers.	All Managed Care Contracts	--	0.16%
1999	Prescription drug must include **contraceptives**.	All Contracts	0.80%	0.80%
1999	Coverage for **registered nurse first assistants**.	All Contracts	0	0
2000	Access to **clinical trials**.	All Contracts	0.46%	0.46%
2000	Access to **prescription drugs**.	All Managed Care Contracts	0	0
2001	Coverage of **hospice care services** for terminally ill.	All Contracts	0	0
2001	Access to **eye care**.	Plans with participating eye care professionals	0	0.04%
2001	Coverage of **anesthesia** and facility charges for certain **dental** procedures.	All Contracts	0.05%	0.05%
2003	Coverage for **prosthetic devices** to replace an arm or leg	Groups >20	0.03%	0.03%
		All other	0.08%	0.08%
2003	Coverage of licensed clinical professional counselors	All Contracts	0	0
2005	Coverage of licensed pastoral counselors and marriage & family therapists	All Contracts	0	0
	Total cost for groups larger than 20:		**8.64%**	**7.51%**
	Total cost for groups of 20 or fewer:		**4.27%**	**5.70%**
	Total cost for individual contracts:		**3.55%**	**3.58%**

Appendix C: Scope of Similar Laws in Other States

METABOLIC DISEASE FORMULAS

8/06

STATE	CITATION	SUMMARY
AK (8/06)	§ 21.42.380	Shall provide coverage for formulas for treatment of PKU, with same co-payment and deductible as for other illness.
AZ (8/06)	§§ 20-2327; 20-826; 20-1057; 20-1342; 20-1402; 20-1404	Coverage that contains a prescription drug benefit shall provide coverage for medical foods to treat inherited metabolic disorders. Cover at least 50% of the cost of medical foods. Also cover amino acid-based formula that is ordered by a physician
AR (8/06)	§§ 23-79-701 to 23-79-703 § 23-79-129	A tax credit up to $2400 per year per child for medical food, low protein food for persons afflicted with PKU and other listed metabolic diseases is allowed against the Ark. income tax. All health plans shall provide coverage for PKU, galactosemia, organic acidemias and disorders of amino acid metabolism, subject to same co-pay and deductible as required by health plan, for amounts paid exceeding the tax credit. Every accident and health insurance policy or health care plan shall cover newborn children and shall include tests for PKU.
CA (8/06)	Ins. § 10123.89; Health & Safety § 1374.56	Policies issued by a health care service plan or an insurer must cover testing and treatment of PKU, including special food products.
CO (8/06)	§ 10-16-104	Coverage for inherited enzymatic disorders, including PKU, etc. Maximum age for PKU treatment is 21; no limit for other metabolic diseases. Cover medical foods used to treat metabolic disease. May impose coinsurance and deductibles.
CT (8/06)	§§ 38a-492c; 38a-518c	Individual and group health insurance policies must cover low protein modified food products, amino acid modified preparations and specialized formulas intended for the dietary treatment if administered under the direction of a physician for children up to age 8. Covered same as prescriptions.
DC (8/06)	§ 31-3802.01	All group and individual health policies providing maternity and newborn care shall include metabolic newborn screening.
FL (8/06)	§ 627.42395	Any health insurance policy must offer prescription and nonprescription enteral formulas for treatment of inherited diseases as specified.

(continued)

METABOLIC DISEASE FORMULAS

8/06

STATE	CITATION	SUMMARY
IN (8/06)	§§ 27-8-24.1; 27-13-7-18	Must cover medical food intended for the dietary treatment of an inherited metabolic disease or condition. Same deductibles, coinsurance amounts as apply to other coverages.
HI (8/06)	§§ 431:10A-120; 432:1-609	Must cover medical foods and low-protein modified food products for the treatment of an inborn error of metabolism.
KY (8/06)	§ 304.17A-139	Provide coverage for amino acid modified preparations and low-protein modified food products for the treatment of inherited metabolic diseases. May be subject to a cap of $4000 per year for low-protein foods and a separate cap of $25,000 for medical formulas.
LA (8/06)	§§ 22:215.22; 22:2004.2; 22:3018.1	Must provide coverage for low protein foods for treatment of inherited metabolic disorders. Benefit limited to $200 a month.
ME (8/06)	tit 24 § 2320-D; tit. 24-A §§ 2745-d; 2837-d; 4238	Must include coverage for metabolic formula and special modified low-protein foods for inborn error of metabolism. Benefit limited to $3,000 per year.
MD (8/06)	Ins. § 15-807; 19-705.5 Ins. § 15-817	Group policy shall cover medical foods prescribed by doctor for therapeutic treatment of inherited metabolic disease. Child wellness services shall include a visit for the collection of adequate samples for hereditary and metabolic newborn screening.
MA (8/06)	§ 175:47C §§176A:8B; 176B:4c; 175:47I; 176A:8L; 176B:4k; 176G:4D	Coverage of newborns shall include special medical formulas necessary for treatment of PKU. Shall provide coverage for nonprescription enteral formulas for home use. Coverage for inherited diseases of amino acids and organic acids shall include food products modified to be low protein. Benefit limit not to exceed $2,500 annually.
MN (8/06)	§§ 62A.26; 62E.06	Must provide dietary treatment for PKU.

(continued)

METABOLIC DISEASE FORMULAS

8/06

STATE	CITATION	SUMMARY
MO (8/06)	§ 376.1219	Shall provide coverage for formula and low protein modified food products for PKU or any inherited disease of amino and organic acids. Insured must be less than six years of age.
MT (8/06)	§§ 33-22-131; 33-31-102	Mandated coverage for dietary formulas for PKU sufferers. Covers treatment of inborn errors of metabolism. Coverage must include expenses of diagnosing, monitoring and controlling the disorder.
NV (8/06)	§§ 689A.0423; 689B.0353; 695B.1923; 695C.1723	Mandated coverage for enteral formulas medically necessary for treatment of inherited metabolic diseases and up to at least $2500 per year for special food products prescribed by physician.
NH (8/06)	§§ 415:6-c; 415:18-e; 420-A:17; 420-B:8-ff	Provide nonprescription enteral formula for treatment of impaired absorption of nutrients.
NJ (8/06)	§§ 17:48-6s; 17:48A-7q; 17:48E-35.16; 17B:26-2.1*o*; 17B:27-46.1r; 17B:27A-7.4; 17B:27A-19.6; 26:2J-4.17 §§ 17:48-62; 17:48A-7y; 17:48E-35.24; 17B:27-46.1Z; 17B:26-2.1v; 17B:27A-7; 17B:27A-19; 26:2J-4.25	Cover expense of treatment of metabolic disease, including purchase of medical foods. Specialized non-standard infant formulas for babies with multiple food protein intolerance.
NM (8/06)	§§ 59A-22-41.1; 59A-46-43.2; 59A-47-38	Every individual and group policy must provide coverage for genetic inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism and for which medically standard treatments exist.
NY (8/06)	Ins. Law § 3216(i)(21); 3221; 4303; 4322	Every policy which provides coverage for prescription drugs, must include cost of enteral formulas when prescribed as medically necessary for disorders that will cause the individual to become malnourished. Includes modified solid food products that are medically necessary. Benefit limit is $2500 per 12-month period.
ND (8/06)	§ 26.1-36-09.7; 54-52.1-04.11	Cover medical foods and low protein modified food products for therapeutic treatment of inherited metabolic disease.
OR (8/06)	§ 743.726 (Repealed effective 7/3/2009)	Must include coverage for inborn errors of metabolism. Coverage includes diagnosis, monitoring and controlling disorders, including medical foods.
PA (8/06)	§ 40-39-342	Shall provide coverage for formulas for treatment of hereditary genetic metabolic disorders.

(continued)

METABOLIC DISEASE FORMULAS

8/06

STATE	CITATION	SUMMARY
RI (8/06)	§ 27-50-10	Standard health benefit plans shall include newborn metabolic screening.
SD (8/06)	§§ 58-17-62; 58-18-41; 58-38-23; 58-40-21; 58-41-98	Mandated offer of coverage for testing and treatment, including dietary management and formulas.
TN (8/06)	§ 56-7-2505	Mandated coverage for dietary formulas for treatment of PKU.
TX (8/06)	I.C. Sec. 1359.003	Mandated coverage for formulas necessary for treatment of PKU, same as prescription drugs.
UT (8/06)	§ 31A-22-623; R590-76-4; R590-194	Must include coverage for special dietary products for those suffering from hereditary metabolic disease.
VT (8/06)	tit. 8 § 4089d	Must include coverage for medical foods prescribed for medically necessary treatment for an inherited metabolic disease. Coverage for low protein modified food products must be at least $2,500 per 12-month period.
WA (8/06)	§§ 48.21.300; 48.46.510; 48.44.440; 48.20.520	Shall provide coverage for formulas for treatment of PKU.

Appendix D: References

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