

Mandated Benefits Review

**House Bill 854
Low Protein Modified
Food Products**

**The Pennsylvania Health Care
Cost Containment Council**

May 2000

The Pennsylvania Health Care Cost Containment Council (PHC4) was established as an independent state agency in 1986. Act 89 of 1986 (as reauthorized by Act 34 of 1993), provides that PHC4 review proposed mandated health benefits when requested by the Secretary of Health or appropriate committee chairmen in the Pennsylvania Senate or the House of Representatives. Act 34 provides for a preliminary PHC4 review of materials submitted by proponents and opponents of the proposed benefit to determine if documentation is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This report presents the results of PHC4's preliminary review.

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EXECUTIVE SUMMARY

After reviewing the analysis of House Bill 854 – amendments to the Medical Foods Insurance Coverage Act – the Pennsylvania Health Care Cost Containment Council does not find that there is sufficient evidence to support this legislation in its present form, although we do not oppose this bill based solely upon costs. The Council is sympathetic to those who have conditions such as PKU and appreciates the need for low protein modified food products. We suggest, however, that other, possibly more efficient, alternatives to this mandate should be fully explored. The Council is particularly concerned that House Bill 854 would not be of equal benefit to all families affected by metabolic conditions such as PKU because only those covered by private insurance would benefit. We strongly encourage the General Assembly to look at all possible alternatives to an insurance mandate as a means to provide financial assistance to people with metabolic diseases.

We note the following points:

- An insurance mandate may not be the most efficient means of providing financial assistance to people with these metabolic conditions. Only 300 to 400 people in Pennsylvania have one of these four metabolic diseases. Fewer people yet – approximately 125 to 170 – would actually benefit from this legislation since it would not cover people who have health insurance that is exempt from state mandates due to ERISA or people without health insurance. This is of particular concern with this bill since one of the conditions (i.e., maple syrup urine disease) occurs in the Mennonite population, a population which has a lower rate of privately insured individuals, 800 times more frequently than in the general population. We also note, however, that due to the small number of people with these metabolic conditions, even if everyone with one of the metabolic conditions accessed the benefits in House Bill 854, the potential costs are relatively small, at approximately \$1 million annually.
- There is justifiable concern that House Bill 854 would require coverage for “non-prescription, non-medical” goods. By mandating coverage of food products, the boundaries of an insurance mandate become unclear. For example, opponents note that many other medical conditions including food allergies, high cholesterol, and heart disease also require dietary modifications. There is concern that House Bill 854 would set a precedent to mandate coverage of foods (e.g., Lactaid® or Benecol®) used by individuals with such conditions.
- Due to the rarity of these metabolic conditions, some health insurance companies do not have members with these conditions. Nevertheless, *all* health plans licensed in Pennsylvania would be required to rewrite their policies and establish procedures to include these benefits regardless of whether or not they would have members who would benefit from such changes. Even those plans with affected members would be required to change their policies and procedures for the benefit of a very small number of people. For example, if one assumes that the number of people who stand to benefit from this legislation are split equally among the top 40 health insurance plans in Pennsylvania, these top plans would each have approximately 4 members who would be affected by House Bill 854. This does not include the hundreds of plans who, although they may not have any members with PKU, would have to change their policies because they do business in Pennsylvania. In this case, money would be spent on *administrative* changes rather than on coverage for low protein modified foods.
- The information received by the Council agrees upon the medical importance of a low protein diet in the treatment of diseases such as PKU and the consequences if such a diet

is not strictly followed. The disagreement, rather, centers around the need for an insurance mandate. For example, no information was submitted to suggest that insurance coverage of low protein modified food products does not already exist. Further, while the cost of low protein modified food products may be a burden on a small number of families, the information did not suggest that a lack of coverage (if it does indeed exist) results in either inadequate health care or financial hardship for Pennsylvanians. Finally, the cost of food does not appear to be a deterrent to people staying on a low protein diet. The information submitted to the Council, suggests that the main reasons that people go "off" the low protein diet include frustration with the limited foods on the diet, desire to "mainstream" their diets, and the substantial time and energy required to prepare and measure foods.

- Finally, the Council's enabling legislation provides for a preliminary review of submitted materials to determine if documentation received is sufficient to proceed with the formal Mandated Benefits Review process outlined in Act 34 of 1993. We conclude that neither supporters nor opponents of the bill provided sufficient information to warrant a full review by a Mandated Benefits Review Panel; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the ones reached here.

While the cost of this particular mandate may have minimal impact, the Council suggests that caution must be used when considering health care mandates. In particular, attention must be given to the cumulative financial impact of enacting mandates. It should also be remembered that while mandates increase the cost of health insurance generally, a state mandate will cover, on average, only 42% of the state's population (only 33% of the state's population if the mandate applies only to group plans).

With regard to mandates in general, the rise in the number of uninsured Pennsylvanians is of particular concern. The Health Insurance Association of America (HIAA) has reported that the number of uninsured under age 65 in Pennsylvania has jumped 34% since 1991, more than double the national increase of 16%. The role of mandates in this trend is not clear. It can be noted, however, that the number of mandates in Pennsylvania (currently almost 30) has grown in concert with rising costs of health insurance and the growing number of uninsured.

While the costs associated with this bill would not be significant, the Council cautions that relatively few Pennsylvanians stand to benefit from the coverage proposed in House Bill 854. We also suggest that other alternatives may be more efficient in addressing the issue of financial assistance for low protein modified food products.

Review of House Bill 854

Amendments to the Medical Foods Insurance Coverage Act

Overview of House Bill 854

House Bill 854 would require health insurance policies to provide coverage for the costs of low protein modified food products as medically necessary for the therapeutic treatment of phenylketonuria (PKU), branched-chain ketonuria, galactosemia and homocystinuria.

Coverage for low protein modified food products would be limited to \$2,500 for an insured individual for any calendar year or for a continuous period of 12 months. House Bill 854 would also require the Insurance Department to adjust the \$2,500 cap every three years based upon the Consumer Price Index. Benefits for low protein modified food products would be subject to any copayment and coinsurance provisions of health insurance to the extent that other medical services are covered, but would be exempt from deductible provisions.

House Bill 854 would also amend the Medical Foods Insurance Coverage Act so that coverage for prescription drugs is not required to access the benefits for low protein modified food products or nutritional supplements (i.e., formulas) for the treatment of these metabolic diseases.

All four of the specific diseases mentioned in House Bill 854 – PKU, branched chain ketonuria (which is more commonly referred to as maple syrup urine disease), homocystinuria, and galactosemia – are considered rare diseases. It is estimated that fewer than 400 Pennsylvanians suffer from these diseases. PKU, maple syrup urine disease, and homocystinuria all result from the body's inability to properly process various amino acids. Without treatment, people with these conditions will develop mental retardation and chronic physical health problems. While there is no cure for these diseases, by carefully controlling the amount of protein, and in so doing the amount of amino acids, in one's diet, people with these conditions can live healthy, normal lives. In galactosemia, the body lacks an enzyme that processes galactose, a component of lactose. Without treatment, people with galactosemia will develop cirrhosis of the liver and most likely enter renal failure (and ovarian failure in the case of females). By eliminating products which contain lactose (including breast milk for infants) from the diet, people with galactosemia can also live healthy lives.

Pennsylvania mandates that all newborns be tested at birth for both PKU and maple syrup urine disease. While screening for galactosemia and homocystinuria is not currently mandated by the state, many hospitals choose to offer this supplemental screening to their newborns. Diagnosis for these diseases is often confirmed within the first week of birth and treatment starts immediately. Infants are given specially formulated low protein nutritional supplements referred to as "medical foods" or "formulas" (except in the case of galactosemia where a lactose-free formula is given). As the children age, the standard practice is to slowly supplement the formulas with low protein modified food products. Upon entering adulthood, people with such diseases may be able to go "off diet" (i.e., eliminate low protein modified food products from their diet and consume "normal" food), particularly if these metabolic diseases were diagnosed quickly. Recent studies, however, indicate that adults may benefit from the continuation of a diet containing low protein modified food products.¹ In particular, strict adherence to a diet of low protein modified food products is highly recommended for women of childbearing age.²

The low protein modified food products used to treat PKU, maple syrup urine disease, and homocystinuria are specially processed foods not generally available at the local grocery store,

but are typically ordered through the mail or on the Internet. While not technically prescription products (as regulated by the FDA), this food should be consumed under the care of a physician.

The Mandated Benefits Review Process

The Pennsylvania Health Care Cost Containment Council's enabling legislation, Act 89 of 1986 (as reauthorized by Act 34 of 1993), provides that the Council review proposed mandated health benefits when requested by the Secretary of Health or appropriate committee chairmen in the Pennsylvania Senate or the House of Representatives.

In November 1999, Senator Edwin G. Holl, Chairman of the Senate Banking and Insurance Committee, requested that the Council review the provisions of House Bill 854 (PN 2459 – Representative Micozzie).

Notification was published in the Pennsylvania Bulletin (December 11, 1999) requesting that interested parties submit documentation and information pertaining to the bill to the Council by February 11, 2000. Letters were also sent to potentially interested individuals and organizations informing them of the pending review and inviting them to submit documentation pursuant to the notice. Following the initial comment period, an opportunity was provided for interested individuals and organizations to examine the responses received and submit additional comments based on that review by March 27, 2000. The Pennsylvania Department of Health and the Pennsylvania Insurance Department were notified and received copies of the submissions.

A list of the submissions received and a copy of the bill are attached.

Act 34 provides for a preliminary Council review of submitted materials to determine if documentation submitted is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This report presents the results of the Council's preliminary review.

Analysis Of Documentation Submitted by Opponents and Proponents in Response To The Eight Categories Required By Act 34, Section 9

Act 34 of 1993 provides that the documentation submitted to the Council by supporters and opponents of a proposed mandated benefit should address eight specific areas. In reviewing these eight points, determination is made whether the information received is sufficient to warrant the formal Mandated Benefits Review process outlined in the Act. Following are Council findings pertaining to the documentation received for House Bill 854 addressing each of these eight points.

(i) *The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.*

While low protein modified foods are not needed or used by the general population, for the small number of people suffering from metabolic disorders such as PKU, these foods are a necessary part of the diet. A low protein diet, of which low protein modified food products are important components, is standard treatment for PKU, maple syrup urine disease and homocystinuria.

All of the submissions agreed on the need for inclusion of low protein modified food products in the diets of people who suffer from such conditions; the submissions, however, disagreed on the need for an insurance mandate to this end. The opponents questioned whether requiring health insurance policies to provide such coverage would be the most efficient way of assisting families of people who suffer from PKU.

PKU is recognized as the most common of the four specific diseases mentioned in House Bill 854, and is found in approximately 1 in every 13,000 births. According to the Pennsylvania Department of Health, of the 145,000 newborns screened for PKU in 1999, 24 cases of PKU were identified and referred for treatment. This suggests that the incidence for Pennsylvania in 1999 was closer to 1 case of PKU in every 6,000 births.

Galactosemia is the second most common of the metabolic diseases. Depending on the source, the incidence of galactosemia varies anywhere from 1 in every 20,000 births to 1 in every 80,000 births. Unlike the other metabolic diseases addressed in this bill, galactosemia does not require a low protein diet, but rather is treated by removing all products which contain galactose and lactose (e.g., dairy products) from the diet. People with galactosemia may eat foods containing protein, as long as such foods do not contain galactose or lactose. Therefore, the inclusion of galactosemia in this mandate is unusual.

Branched chain ketonuria, also known as maple syrup urine disease, appears in approximately 1 in every 200,000 births. According to the Insurance Federation, the incidence is higher within the Mennonite population with perhaps one child in 250 having the condition. According to the Pennsylvania Department of Health, there were 4 confirmed cases of maple syrup urine disease in 1999.

The final disease, homocystinuria, is found in 1 out of 250,000 babies. The Insurance Federation notes, however, that in conversation with a private laboratory which conducts newborn screening, no cases of homocystinuria have been detected in the 800,000 newborns screened to date.

The submission from the Hershey Medical Center stated that there are currently 294 Pennsylvanians with PKU who are on a special, low protein diet. Including patients with maple syrup urine disease, galactosemia, and homocystinuria, there are an estimated 300 to 400 Pennsylvanians who suffer from these metabolic diseases.

Availability of low protein modified foods is an important issue. While such foods should be consumed under the direction of a physician, they do not require a prescription. Because the demand for low protein modified foods is relatively small, such food is not readily available at the local supermarket or grocery store. Often, people requiring such food have to order it directly through the mail or on the Internet.

One of the main issues raised by opponents of House Bill 854 questions the need for an insurance mandate, not the need for low protein modified food products. Due to the rarity of the conditions, opponents suggest that the economic problems which low protein modified food products create for some families may be best alleviated by other means. For example, some states have programs in place which provide access to formulas free of charge or at a reduced rate. Since all families, not just families with health insurance, benefit from such programs, they may be more effective than an insurance mandate in assisting with the financial cost of low protein modified food products.

(ii) *The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.*

The extent of coverage for low protein modified foods is unclear. Neither proponents nor opponents submitted information to suggest that insurance coverage for such food items does not already exist, or that such benefits are already covered. Further, information did not suggest that lack of coverage resulted in either inadequate health care or financial hardship for the citizens of Pennsylvania. Only a general statement was put forth by proponents that said, "in regard to the cost of this food ... it presents a substantial burden to the individual families." Proponents did not, however, provide any data to support this statement.

There is no argument that low protein modified food products are more expensive than "normal" food. A study by the California Department of Health Services estimated that for ages 6 and up, the cost of feeding a person with one of these metabolic disorders is anywhere from three to four times more expensive than the cost of feeding someone without such a disorder.³ Examples of low protein food products and their costs include: \$4 per pound of flour, \$5 per loaf of bread, \$5 per one pound package of pasta, \$5 to \$15 per package of crackers or cookies, and \$4 per 4 oz. can of tomato sauce.⁴ In addition, since these products are typically ordered via the mail or the Internet, shipping charges are also included.

Opponents noted that people with metabolic diseases such as PKU already receive certain health insurance benefits as mandated by law. The Medical Foods Insurance Coverage Act (Act 191 of 1996) mandates coverage for formulas necessary for the treatment of the metabolic disorders named in House Bill 854. Moreover, the Commonwealth also offers financial assistance through the Department of Health and the Department of Public Welfare. The Department of Public Welfare provides coverage for formulas for those people who are enrolled in the Medical Assistance program. The Department of Health funds a program which distributes formula through the Newborn Screening Program. Metabolic formula is paid for out of the Title V, Federal Maternal and Child Health Services Block Grant. Additionally, the Department of Health makes an effort to provide life-long services to PKU patients, especially women of childbearing age, which include education and counseling to encourage affected individuals to stay on their specialized diets.

The Insurance Federation writes that, "at present there are presumably some insurance products which cover the low protein modified food products without the need of the proposed bill under review here." In addition, the Federation writes that, "there is no widespread financial hardship, although one presumes that there are several cases in which the cost of the food products are

straining some families' ability to provide it." They did not, however, provide specific data to substantiate either of these statements.

No submission argued that people with PKU go "off diet" because of the lack of insurance coverage. To the contrary, the information submitted to the Council suggested the people who go "off diet" often do so because of the frustration with the limited foods on the diet, the time and energy required to prepare and measure foods, and the simple desire to eat foods which are not part of the PKU diet. Thus, while the cost of the food is substantial, it does not appear to be a major factor in people going off the PKU diet.

Ultimately, the submissions did not provide sufficient information to fully determine the extent of current insurance coverage for low protein modified food products or demonstrate that current levels of coverage result in either inadequate health care or financial hardship for those in Pennsylvania.

(iii) The demand for the proposed benefit from the public and the source and extent of the opposition to mandating the benefit.

Little information was received in support of House Bill 854. Supporters included the Pennsylvania Dietetic Association, the director and dietician of the PKU clinic at the Hershey Medical Center, and the family of a child with PKU. The submission from the Pennsylvania Dietetic Association also included a statement from the American Academy of Pediatrics supporting the reimbursement of medical foods used in the treatment of amino acid disorders such as PKU.⁵ It is unclear, however, whether this statement from the American Academy of Pediatrics applies only to the "medical foods" formula used to treat PKU or also supports the reimbursement for low protein modified foods as well.

Several groups submitted information to the Council in opposition to House Bill 854. These groups included the Pennsylvania Chamber of Business and Industry, the National Federation of Independent Business, the Pennsylvania Manufacturers' Association, the Insurance Federation of Pennsylvania, the Managed Care Association of Pennsylvania, and Highmark Blue Cross Blue Shield.

One of the opponents' main arguments is that public demand for such coverage is limited due to the rarity of these conditions. Because such a small number of people would stand to benefit from this legislation, opponents argue that it is not in the interest of the general public to include this coverage in commercial insurance packages.

In regard to this particular mandate, opponents are objecting more on principle than on the cost. Opponents note that while the cost of this particular mandate may be relatively small due to the rarity of the conditions and the reimbursement cap, the cost will be passed along to purchasers and consumers in the form of higher premiums. It is often the cumulative impact of mandates that concerns purchasers. For example, the Managed Care Association writes, "In comparison to other proposed coverage and regulatory mandates, House Bill 854 ... may have a minimal cost impact. Nonetheless, it is the combined impact of over 25 State-imposed mandate and numerous regulatory requirements that impose additional financial burdens on those who purchase insurance; namely, employers and individuals."

Most of the submissions opposing HB 854 expressed strong opposition to mandates in general. Typically, opponents of mandates include insurers and purchasers of health care coverage, who argue that employers and their employees are in the best position to determine health care coverage options that are suited to their needs from a cost and quality standpoint.

Opposition to mandates in general is based on both cost and policy issues. Among the arguments made were that mandates increase the cost of health insurance and the number of

uninsured, provide incentive for large employers to self insure, and have a disproportionate effect on small businesses. The point was made that any one mandate should be considered as contributing to the cumulative effect of mandates on businesses and on their ability to make affordable health insurance available to their employees. Workers end up paying for mandated benefits in the form of reduced wages or fewer benefits, as well as higher insurance premiums.

In support of these points, Highmark includes a study from Milliman and Robertson which emphasizes the cumulative effect of mandates on the cost of health insurance, though it does not specifically mention coverage for low protein modified food products. Milliman and Robertson estimated that the cost of 12 of the most common mandates can increase the cost of health insurance by as much as 30%.⁶ Pennsylvania has already enacted over 25 mandates, including 6 of the 12 most common discussed by Milliman and Robertson.

A 1999 study by Jensen and Morissey, *The Price of State Mandated Benefits*, supports the contention that mandates cost money. Jensen and Morissey report that in Virginia, mandates accounted for 21% of claims; in Maryland they accounted for 11 to 22% of claims; and in Massachusetts 13% of claims.⁷

Opponents claim that the growing number of mandates hurts Pennsylvania's business climate. In general, the submissions from the business community point out that an increase in the cost of health care could encourage businesses to drop coverage for their employees, resulting in a rise in the number of uninsured.

Along these lines, the Kaiser Family Foundation reports that the number of small businesses (under 199 employees) providing health insurance for their workers has declined over the past several years. The study, conducted by KPMG Peat Marwick, found that the percentage of U.S. small business workers receiving employer sponsored health coverage declined from 52% in 1996 to 47% in 1998.⁸ When employers who canceled their employees' health insurance policies have been polled on why they did so, the majority claimed that it was because the price was too high. Lower income employees are most likely to lose coverage. Insufficient information was submitted to determine whether these percentages are consistent with the experience in Pennsylvania.

The rise in the number of uninsured Pennsylvanians is an immediate and serious concern. The Health Insurance Association of America (HIAA) has reported that the number of uninsured under age 65 in Pennsylvania has jumped 34% since 1991, more than double the national increase of 16%.⁹

Jensen and Morrissey's report claims that between 20-25% of uninsured Americans lack coverage because of the cost of benefit mandates.¹⁰ Consumers may be forced into purchasing very expensive benefits or joining the ranks of the uninsured.

Another point noted by opponents is that though increasing the cost of health insurance generally, mandates only benefit a limited percentage of Pennsylvania citizens. Because ERISA preempts self-insured firms from state mandates, a state mandate that applies to private group plans, will cover, on average only 33% of the state's population. One that applies to private group plans *and* individual policies will cover about 42% of a state's population.¹¹ As the number of mandates increases, studies have indicated that more firms seek to self-insure to avoid being subject to mandates.

In summary, opposition to the proposed legislation is based primarily upon the impact of mandates on the number of Pennsylvanians without any health insurance, as well as having concerns about the cumulative effects of mandates on Pennsylvania's business climate. Thus, while the source of the opposition to House Bill 854 appears clear, insufficient information was submitted to the Council to determine the extent of the opposition to this particular mandate.

Likewise, the submissions did not provide sufficient information to determine the extent of *support* for this mandate.

(iv) *All relevant findings bearing on the social impact of the lack of the proposed benefit.*

Left untreated, PKU interferes with brain development, thereby leading to developmental disabilities and mental retardation. Adults with PKU who were not appropriately diagnosed and treated as infants often reside in group homes or institutions which specialize in mental retardation, both of which entail considerable costs. As previously stated, with early diagnosis and treatment, people with PKU can lead normal, healthy lives. In this regard, the lack of appropriate treatment for PKU and associated disorders has a significant impact.

Because the medical consequences of not maintaining a low protein diet are so severe, it is necessary for people with PKU to abide by a strict diet. While there are foods which are naturally low in protein (e.g., some fruits and vegetables), it is necessary to consume low protein modified food products to provide the bulk nutrients lacking in the restricted diet. Because controlling protein intake is necessary, one can assume that people with PKU will consume low protein modified foods, whether such foods are covered by insurance or not. Therefore, the social impact of the lack of the proposed benefit appears to be, in large part, based on the financial cost of the low protein modified food products to the people with such disorders.

(v) *Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies, and no therapy.*

The proposed benefit does not mandate coverage of a particular therapy.

(vi) *Where the proposed benefit would mandate coverage of an additional class of practitioners, the result of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.*

The proposed benefit does not mandate coverage of an additional class of practitioners.

(vii) *The results of any other relevant research.*

All research and analysis relevant to this issue is included elsewhere in this report.

(viii) *Evidence of the financial impact of the proposed legislation, including at least:*

(A) *The extent to which the proposed benefit would increase or decrease cost for treatment or service.*

None of the submissions received by the Council directly addressed this issue. It may be conjectured that if insurance coverage for low protein modified food products were mandated, insurance companies may be able to negotiate lower prices for such food products. This argument appears weak in this case, however, since the suppliers of these products are typically not recognized as eligible suppliers by insurance companies because they supply food products

rather than medical care, services or pharmaceutical products. Since no information related to this issue was submitted, no projections can be made.

(B) *The extent to which similar mandated benefits in other states have affected charges, costs and payments for services.*

Eighteen states have enacted some form of a mandate for coverage of low protein modified food products. These states include: Connecticut, Florida (optional rider only), Kansas, Louisiana, Maine, Maryland (for employers with 50 or more employees only), Massachusetts, Minnesota, Nebraska, Nevada, New Jersey, New Hampshire, New York, North Dakota, Oregon, Rhode Island, Tennessee and Utah.¹² Half of these states include a benefits limit similar to the one proposed in House Bill 854, ranging anywhere from \$1,500 in Kansas to \$3,000 in North Dakota and Maine.

No information was submitted to the Council regarding how such legislation in other states has affected charges, costs, or payments for low protein modified food products, nor could the Council locate such information. Officials from surrounding states were also contacted, but were unable to provide information regarding how many people benefited from such legislation or the cost of the legislation to insurers. Some states, however, indicated that due to the rarity of these metabolic conditions, they chose to expand assistance programs and subsidize the cost of formulas and/or low protein modified food products instead of enacting an insurance mandate.

(C) *The extent to which the proposed benefit would increase the appropriate use of treatment or service.*

As previously discussed, a diet of low protein modified foods is essential in the treatment of these metabolic disorders. Therefore, one would assume such food products are already used appropriately since the consequences of not consuming these products are so severe.

One submission directly addressed this point, however, and said that in Utah, "where coverage of medical foods was mandated in 1999, use of the treatment has significantly increased as a result of the mandate. Prior to the enactment of the Utah medical foods mandate, the number of individuals in the state that were expected to use the medical foods coverage benefit was approximately 65. However, once the bill took effect, one plan determined that 280 of its members were utilizing the benefit. This corresponds to a 1,650 percent increase above anticipated utilization."

(D) *The impact of the proposed benefit on administrative expenses of health care insurers.*

Only one submission directly addressed the administrative costs this legislation would have on insurers. Highmark wrote that their, "actuaries estimate that [Highmark] will realize a cost of approximately \$18,000 annually in administrative costs associated with House Bill 854." Based on the submissions, it was not possible to judge the impact on administrative expenses for other insurers in Pennsylvania.

Opponents point out that, from an administrative standpoint, this mandate would be particularly difficult to manage. While House Bill 854 specifies a \$2,500 yearly cap on reimbursement for low protein modified foods, it does not define the scope or frequency of foods to be covered. For example, would insurers be required to provide coverage for "luxuries" such as cakes, cookies, brownies, and ice cream cones, or would coverage be limited to items such as flour, egg substitute, pasta? In addition, since suppliers of low protein modified food products are often not recognized as eligible providers by health insurers, insurers may need to negotiate contracts with such suppliers, thereby limiting the choice of suppliers to which people with PKU have access.

(E) *The impact of the proposed benefits on benefits costs of purchasers.*

Submissions noted that any increase in the cost of health insurance is passed along to purchasers of health insurance in the form of higher premiums. For example, "Highmark actuarial projections indicate the cost of mandating the coverage outlined in House Bill 854 will exceed \$381,000 annually. This includes claims and administrative expenses for Highmark and its subsidiaries." Submissions, however, did not provide information about the impact that this specific mandate would have on the benefits costs of purchasers. Therefore, no specific projections can be made.

(F) *The impact of the proposed benefits on the total cost of health care within the Commonwealth.*

Submissions did not fully address the total cost of this mandate. Since reimbursement for low protein modified food products is capped at \$2,500 annually for any individual, the approximate cost of the mandate can be estimated by multiplying the per person cap by the number of Pennsylvanians who would benefit from this bill. Because there are estimated to be between 300 and 400 people in Pennsylvania who suffer from these conditions, the cost for this mandate would be approximately \$1 million per year, including administrative costs. The actual cost of this bill would likely be less, however, since it is unknown how many of these people already have coverage for low protein modified foods or would be unaffected by this bill because they are either uninsured or insured by an employer which is exempt from state benefit mandates due to ERISA.

Proponents, however, raise the possibility of potential cost savings if people with disorders such as PKU maintain control of their diet. A mother of one child with PKU said that by maintaining a proper diet, children with PKU are less likely to require costly special education services and receive public assistance. This woman also suggested that children who maintain the PKU diet are less likely to require prescription drugs for conditions such as anxiety attacks than children who go "off diet." She argues that provision of low protein modified food products is a form of preventive medicine which can control the future cost of treating someone with PKU.

As previously stated, opposition to this mandate stems more from concern about mandates in general than from the actual costs involved. As the Managed Care Association writes, "the mandate requirements of House Bill 854 may have a minimal impact on costs when compared to other proposed mandates. However, it is the cumulative cost of all existing mandates and regulations that impact the affordability of quality health care. At a time when the State's uninsured rate stands at 12 percent and rising, it would seem more prudent to look at ways to stem the growth of the uninsured population rather than impose yet another disease-specific mandate that impacts a relatively small segment of the population."

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Submissions for House Bill 854

AFLAC – The American Family Life Assurance Company of Columbus (Richard J. Gmerek)

1. Cover letter regarding House Bill 854 dated February 11, 2000.
2. "Statement of AFLAC Regarding Health Care Cost Containment Council's Review of House Bill 854."
3. Excerpt from the Health Insurance Portability and Accountability Act of 1996 at Section 2791(5); Individuals Health Coverage, under Subsection (c): Excepted Benefits. Public Law 104-191. August 21, 1996.
4. National Association of Insurance Commissioners Health Carrier External Review Model Act.
5. Omnibus language found in NAIC External Review Model Act.

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1. Letter regarding House Bill 854 dated March 12, 2000.
2. "What is PKU? – A Guide for Parents." Children's Hospital of Pittsburgh.
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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 854

Session of
1999

INTRODUCED BY MI COZZIE, KENNEY, STERN, MELIO, SCHRODER, FLEAGLE, DeLUCA, BELARDI, BAKER, BARRAR, L. I. COHEN, DAILEY, DALEY, GEIST, HENNESSEY, JOSEPHS, KAISER, MANDERINO, McILHATTAN, MUNDY, PESCI, PETRARCA, PIPPY, PRESTON, ROHRER, SCRIMENTI, B. SMITH, E. Z. TAYLOR, TRELLA, WILLIAMS, ADOLPH, CURRY, STEELMAN, CIVERA, J. TAYLOR, RAMOS, YOUNGBLOOD, HARHAI, MAHER, MASLAND, COLAFELLA AND SEYFERT, MARCH 10, 1999

AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES,
OCTOBER 18, 1999

AN ACT

1 Amending the act of December 20, 1996 (P. L. 1492, No. 191),
2 entitled "An act providing for certain health insurance
3 policies to cover the cost of formulas necessary for the
4 treatment of phenylketonuria and related disorders," further
5 defining "health insurance policy"; and providing for low
6 protein modified food products.

7 The General Assembly of the Commonwealth of Pennsylvania
8 hereby enacts as follows:

9 Section 1. Sections 2, 3, 4, 6 and 7 of the act of December
10 20, 1996 (P. L. 1492, No. 191), known as the Medical Foods
11 Insurance Coverage Act, are amended to read:

12 Section 2. Declaration of policy.

13 The General Assembly finds and declares as follows:

14 (1) Phenylketonuria (PKU), branched-chain ketonuria,
15 galactosemia and homocystinuria are aminoacidopathies that
16 are rare hereditary genetic metabolic disorders.

17 (2) Lacki ng in these aminoacidopathies is the body's

1 ability to process or metabolize amino acids, and, if left
2 untreated or without proper therapeutic management, these
3 disorders cause severe mental retardation and chronic
4 physical disabilities.

5 (3) The only form of treatment is by restricting food
6 intake in order to remove the problem amino acids, which are
7 necessary in the diet, and then replenishing them in
8 carefully controlled measured amounts of a nutritional food
9 substitute.

10 (4) In an attempt to encourage the development of new
11 products, increase availability and reduce cost, formulas
12 were removed from the Federal prescription list and
13 reclassified as medical foods. An unfortunate side effect has
14 been the reluctance of many insurance companies to cover the
15 cost of these formulas. In instances where coverage is
16 provided, it is random and subject to inconsistent
17 interpretation.

18 (5) The intent of this legislation is not to require
19 insurance coverage for [normal food products] natural food
20 products that are naturally low in protein which are used in
21 dietary management of these disorders, but to provide for
22 such coverage of formulas that are equivalent to a
23 prescription drug and low protein modified food products
24 medically necessary for the therapeutic treatment of such
25 rare hereditary genetic metabolic disorders and administered
26 under the direction of a physician.

27 (6) In recognition by the General Assembly that such
28 formulas and low protein modified food products are medically
29 necessary and critical to the well-being of individuals
30 afflicted with rare hereditary genetic metabolic disorders,

1 it shall be required that health insurance policies issued in
2 this Commonwealth shall include such coverage.

3 Section 3. Definitions.

4 The following words and phrases when used in this act shall
5 have the meanings given to them in this section unless the
6 context clearly indicates otherwise:

7 "Health insurance policy." Except for specified disease and
8 accident-only policies, the term shall mean any group health
9 insurance policy, contract or plan or any individual policy,
10 contract or plan [with coverage for prescription drugs] which
11 provides medical coverage on an expense-incurred, service or
12 prepaid basis. The term includes the following:

13 (1) A health insurance policy or contract issued by a
14 nonprofit corporation subject to 40 Pa. C. S. Chs. 61 (relating
15 to hospital plan corporations) and 63 (relating to
16 professional health services plan corporations) and the act
17 of December 14, 1992 (P. L. 835, No. 134), known as the
18 Fraternal Benefit Societies Code.

19 (2) A health service plan operating under the act of
20 December 29, 1972 (P. L. 1701, No. 364), known as the Health
21 Maintenance Organization Act.

22 "Low protein modified food product." A food product that is
23 speci ally formulated to have less than one gram of protein per
24 serving, and intended to be administered by and used under the
25 direction of a physician for the therapeutic and dietary
26 treatment of phenylketonuria, branched-chain ketonuria,
27 galactosemia and homocystinuria. The term does not include a
28 natural food that is naturally low in protein.

29 Section 4. Medical foods insurance coverage.

30 (A) GENERAL RULE. --Except as provided in section 7, any

<—

1 health insurance policy which is delivered, issued for delivery,
2 renewed, extended or modified in this Commonwealth by any health
3 care insurer shall provide that the health insurance benefits
4 applicable under the policy include coverage for the cost of
5 nutritional supplements (formulas) and low protein modified food
6 products as medically necessary for the therapeutic treatment of
7 phenylketonuria, branched-chain ketonuria, galactosemia and
8 homocystinuria as administered under the direction of a
9 physician. Coverage for low protein modified food products for
10 the treatment of phenylketonuria, branched-chain ketonuria,
11 galactosemia and homocystinuria for any calendar year or for any
12 continuous period of 12 months shall not exceed \$2,500 for an
13 insured individual SUBJECT TO ADJUSTMENT AS PROVIDED IN <—
14 SUBSECTION (B).

15 (B) ADJUSTMENT OF CAP. --

16 (1) THE INSURANCE DEPARTMENT, AT LEAST ONCE EVERY THREE
17 YEARS, SHALL ADJUST THE \$2,500 CAP OR LIMIT RELATIVE SET
18 FORTH IN SUBSECTION (A) TO CHANGES IN THE COMPONENTS OF THE
19 CONSUMER PRICE INDEX (URBAN) TO MEASURE SEASONALLY ADJUSTED
20 CHANGES IN LOW PROTEIN MODIFIED FOOD PRODUCT COSTS AND SHALL
21 MAKE SUCH ADJUSTMENTS TO THE CAP OR LIMIT AS SHALL BE
22 NECESSARY TO MAINTAIN THE SAME RATE OF CHANGE IN THE CAP OR
23 LIMIT AS HAS OCCURRED IN THE CONSUMER PRICE INDEX (URBAN).
24 SUCH ADJUSTMENTS MAY BE ROUNDED OFF TO THE NEAREST \$50
25 FIGURE.

26 (2) THE INSURANCE DEPARTMENT SHALL PUBLISH THE
27 ADJUSTMENT AS A NOTICE IN THE PENNSYLVANIA BULLETIN.

28 Section 6. Cost-sharing provisions.

29 (a) Applicability. --Benefits for nutritional supplements
30 (formulas) and low protein modified food products as medically

1 necessary for the therapeutic treatment of phenylketonuria,
2 branched-chain ketonuria, galactosemia and homocystinuria as
3 administered under the direction of a physician shall be subject
4 to copayment and coinsurance provisions of a health insurance
5 policy to the extent that other medical services covered by the
6 policy are subject to those provisions.

7 (b) Exemption. --Benefits for nutritional supplements
8 (formulas) and low protein modified food products as medically
9 necessary for the therapeutic treatment of phenylketonuria,
10 branched-chain ketonuria, galactosemia and homocystinuria as
11 administered under the direction of a physician shall be exempt
12 from deductible provisions in a health insurance policy. This
13 exemption must be explicitly provided for in the policy.

14 Section 7. Exemption.

15 Notwithstanding sections 4 and 5, this act shall not be
16 construed to require a health insurance policy to include
17 coverage for nutritional supplements (formulas) and low protein
18 modified food products as medically necessary for the
19 therapeutic treatment of phenylketonuria, branched-chain
20 ketonuria, galactosemia and homocystinuria as administered under
21 the direction of a physician for an individual who is a resident
22 of this Commonwealth if all of the following apply:

23 (1) The individual is employed outside this
24 Commonwealth.

25 (2) The individual's employer maintains a health
26 insurance policy for the individual as an employment benefit.

27 Section 2. This act shall take effect in 180 days.