

Diet for Life Work Group Report: Proposed Strategies, 2013-2014

*A comprehensive approach to assuring nutritional treatment for
inborn errors of metabolism across the lifespan*



Prepared for submission to the
Michigan Department of Community Health
April 2014

“My life experiences have led me to believe that ready, consistent access to the resources to manage PKU makes sense from a fiscal standpoint and from a moral standpoint. I want everyone who needs these resources to have the opportunity to experience the blessings and happiness I have experienced.”

- A Michigan young adult with PKU

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Table of Contents

Executive Summary	iii
Acronyms and Definitions	v
Background	I
Relevance to public health	I
Changes in screening and management	I
Cost of nutritional treatment	2
Increasing number of Michigan residents with IEM	4
MDCH budget for metabolic formula	4
Overview of the Diet for Life Work Group	8
Rationale	8
Objectives	8
Process	8
Work Group Investigations and Key Findings	10
Definitions	10
Barriers: food vs. drug classification	11
Existing Michigan funding sources for nutritional treatment	12
Role of WIC	13
Billing/reimbursement mechanisms and the DME dilemma	13
Addressing the DME barrier	15
Other state mandates and metabolic food programs	15
Need for state legislation	17
Components and Strategies	18
A coordinated metabolic treatment program	18
Family education and advocacy	19
Maximum use of third party insurance benefits for medical foods and other nutritional treatments	19
Increased access to low protein modified foods	20
A safety net for people with no available coverage	21
Coordination with state and federal supplemental food programs	21
Possible legislation, if needed	22
Other strategies	23
Next Steps	24
Work Group Participants and Acknowledgements	25
Appendices	26
References	45

Executive Summary

Diet for Life Work Group Report, 2013-2014

Newborn screening identifies more than 30 inborn errors of metabolism requiring medical nutrition therapy. Through early diagnosis and “Diet for Life” nutritional treatment, affected individuals can lead healthy and productive lives.

Genetic inborn errors of metabolism (IEM) are rare, inherited disorders present at birth that affect how food is broken down in the body. If untreated, individuals with IEM develop severe medical problems such as failure to thrive, cognitive impairments, behavior problems, mental health issues, seizures, respiratory distress, coma or death. Untreated, those who survive to adulthood are usually not able to live independently and require assisted living care. Without treatment before and during pregnancy, women with phenylketonuria (PKU) are at significant risk of having a child with birth defects, developmental delay and even fetal/infant death. Since 1965, newborn screening has allowed detection of PKU in the first few days of life, preventing the most serious complications of the disease. Today, more than 50 different conditions are included on the screening panel with over 30 requiring nutritional treatment. Through early diagnosis and treatment, individuals with IEM can lead healthy and productive lives.

The treatment for IEM is a lifelong, medically prescribed diet. For most metabolic disorders, protein intake from food must be severely restricted. A combination of strategies are used to limit intake of protein while providing substitute nutrients, frequently in the form of medical food or formula, low protein modified food, or amino acids and vitamin cofactors. Medical monitoring, including regular blood level checks, by an American Board of Medical Genetics Board Certified Medical or Clinical Biochemical Geneticist and specially trained metabolic dietitian is needed to adjust the diet based on factors like growth, activity, pregnancy and illness. Recommendations for treatment of IEM have evolved considerably over the decades. *Diet for Life* is currently known to be crucial for all individuals with IEM – regardless of age, gender or diagnosis.

It has become apparent that the current funding model for medical formula in Michigan is no longer sustainable. A more comprehensive approach encompassing all forms of medical and low protein foods, and other sources of available coverage, must be identified.

Historically, the Newborn Screening Program (NBS) has funded a designated metabolic clinic to coordinate follow-up and provide confirmatory diagnostic testing for babies with positive screens. A subsidy to support clinic staffing is provided, in addition to medical formula (at no cost to families) for patients identified through screening. In the past, the Children’s Special Health Care Services Program (CSHCS) and WIC also contributed a portion of the funding for medical formula. As of fiscal year 2014, the budget for medical formula alone has reached \$825,000 with the majority of funding provided by NBS. With NBS program costs beginning to exceed annual revenue, and the number of people with IEM requiring nutritional treatment projected to double by 2030, it has become apparent that the current funding model for medical food/formula in Michigan is no longer sustainable. A more comprehensive approach encompassing all forms of medical and low protein foods, and other sources of available coverage, must now be identified. The challenge is to design an approach that does not create additional barriers, but instead sustains access to life-saving nutritional treatments that will optimize health outcomes for all patients with IEM.

The Diet for Life Work Group brought together Michigan public health programs, Medicaid policy

makers, clinical experts, adults with IEM, family members and others concerned about barriers to maintaining necessary lifelong nutritional treatment. The objectives of the group were to:

- ◆ Identify and understand existing clinical best practice guidelines for lifelong dietary treatment of individuals with IEM detected through newborn screening
- ◆ Describe facilitators and barriers to dietary compliance in order to assure the best possible outcomes for individuals with IEM
- ◆ Recommend feasible solutions that enable patients of all ages to receive appropriate metabolic formulas in light of Newborn Screening Program budgetary constraints
- ◆ Suggest long term strategies for assisting families in obtaining insurance coverage and reimbursement for metabolic foods

The Diet for Life Work Group identified best practices for treatment of metabolic disorders and agreed on 7 key components for a Michigan-specific approach, including more than 40 possible strategies. This summary report is being submitted to the Public Health and Medical Services Administrations and is meant to inform decisions on ways to help assure access to lifelong nutritional treatment for all residents with IEM.

A series of meetings was held between October 2013 and January 2014, with approximately 50 individuals participating in one or more meetings. By sharing diverse experiences and expertise, the group was successful in developing a common understanding of the complexities of treatment and reimbursement for IEM; the efforts of patients, families and clinical staff to use and maintain dietary therapies, and the tremendous impact of treatment on people's lives. The process also helped to build stronger connections between the Public Health and Medical Services Administrations as well as between the Michigan Department of Community Health (MDCH), clinicians and families. The need for a Michigan-specific approach was recognized, and work group members identified more than 40 possible strategies which were grouped into 7 overarching components to address dietary treatment for IEM over the lifespan. A majority of members agreed that all of the following components were very important to absolutely essential for assuring access to lifelong treatment:

- 1. A coordinated metabolic treatment program**
- 2. Family education and advocacy**
- 3. Maximum use of third party insurance benefits for medical foods and other nutritional treatments**
- 4. Increased access to low protein modified foods**
- 5. A safety net for people with no available coverage**
- 6. Coordination with state and federal supplemental food programs**
- 7. Possible legislation, if needed**

This synopsis of the work group's findings was prepared by the Lifecourse Epidemiology and Genomics Division. It provides background on the importance and challenges of lifelong nutritional treatment, evolution in screening and management of metabolic disorders, and budgetary issues; an overview of the Diet for Life Work Group process, investigations and key findings; proposed strategies, and next steps. Additional information regarding Diet for Life may be found at www.michigan.gov/genomics.

The summary report is being provided to the directors of the MDCH Public Health and Medical Services Administrations and is meant to inform decisions on the best ways to help assure that all Michigan residents with IEM have lifelong access to medical formula and other critical dietary therapies. Following their review and feedback, a timeline and implementation plan will be developed based on priorities identified by the Diet for Life Work Group.

Acronyms and Definitions Used in This Report

CHM	Children’s Hospital of Michigan (Detroit)	LEGD	Lifecourse Epidemiology and Genomics Division
CMS	Centers for Medicare and Medicaid Services	MCT	Medium chain triglycerides
CSHCS	Children’s Special Health Care Services	MDCH	Michigan Department of Community Health
DHS	Department of Human Services	MPHI	Michigan Public Health Institute
DME	Durable Medical Equipment supplier	MPRO	Michigan’s Health Care Quality Improvement Organization (provides Medicaid prior authorizations)
ERISA	Employee Retirement Income Security Act	MSA	MDCH, Medical Services Administration
FDA	US Food and Drug Administration	MSUD	Maple Syrup Urine Disease
FY	Fiscal Year (October 1– September 30)	NBS	Newborn Screening
GA I	Glutaric Acidemia Type I	PHA	MDCH, Public Health Administration
HCPCS	Healthcare Common Procedure Coding System	PKU	Phenylketonuria
HCY	Homocystinuria	SSI	Supplemental Security Income
ICD	International Classification of Diseases	TYR-I	Tyrosinemia Type I
IEM	Inborn Errors of Metabolism	UM	University of Michigan (Ann Arbor)
		WIC	Special supplemental nutrition program for Women, Infants, and Children

Amino acid

A biologically important organic compound that forms the building blocks of protein. Some amino acids are considered to be “essential” meaning they cannot be made by the body and must be supplied through the diet.

Inborn error of metabolism; metabolic disorder

A rare inherited condition present at birth, which if untreated results in cognitive impairment, system damage or death. The treatment for metabolic disorders includes special medical foods, low protein foods and vitamins or amino acid supplements to optimize health.

Low protein modified food

A low protein substitute product, used in conjunction with medical food, as an energy source that is designed to be similar to “normal” food counterparts but with minimal protein

Medical food

A substitute protein product in the form of a liquid formula, powder, bar, or gel that has been modified to eliminate specific amino acids or other components that cannot be metabolized by the person with IEM

Medically necessary supplements

Vitamins or amino acid preparations used to replace conditionally essential nutrients or enhance enzyme activity (when not adequately utilized or produced by the body)

Metabolism

The life-sustaining chemical transformations that occur within cells of the body; for instance, breaking down food into energy

Background

Relevance to public health

Genetic inborn errors of metabolism (IEM) are rare, inherited disorders present at birth that affect how food is broken down in the body. Together, they affect about 1 in 1,500 Michigan births. Depending on the specific diagnosis, IEM cause defects in protein, carbohydrate, or fatty acid metabolism. IEM may cause substances found in foods (which are otherwise essential for people unaffected by the disorder) to accumulate, rising to toxic levels. In other cases IEM may result in a deficiency of products vital for the body's energy, growth, and development. If untreated, individuals with IEM develop severe medical problems such as failure to thrive, cognitive impairments, behavior problems, mental health issues, seizures, respiratory distress, coma and even death. Those who survive to adulthood are usually not able to live independently and require assisted living care. Additionally, untreated pregnant women with phenylketonuria (PKU) are at significant risk of having children with abnormalities (i.e. microcephaly, congenital heart defects), developmental delay and fetal/infant death. Fortunately, most of these serious adverse outcomes can now be prevented. Through early diagnosis and lifelong nutritional treatment, individuals with IEM can lead healthy and productive lives.

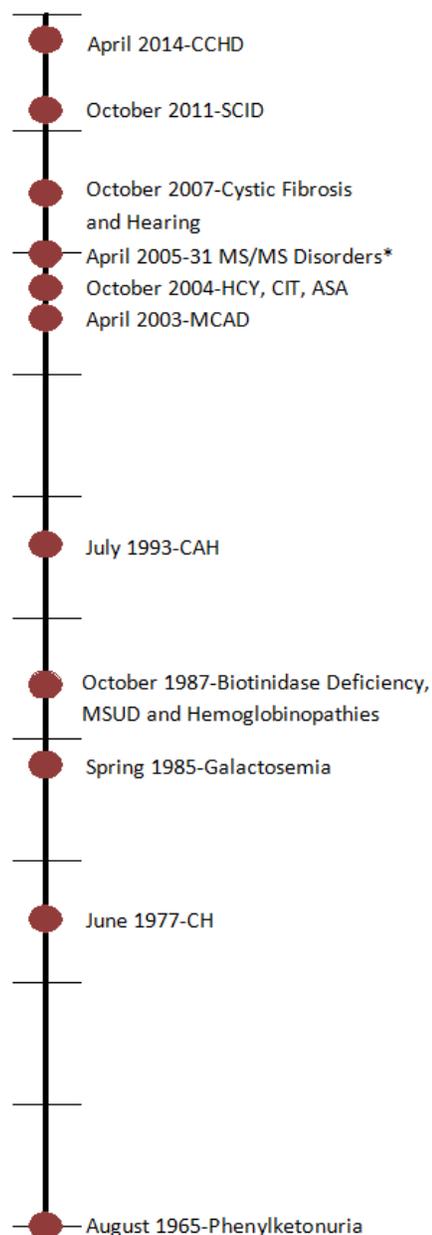
An important breakthrough in public health prevention occurred in 1963 when Dr. Robert Guthrie developed a laboratory blood filter paper assay for population screening and early detection of PKU. By then, it was known that restriction of dietary protein during early childhood could prevent the most serious complications of PKU. The state of Michigan adopted PKU bloodspot screening for all newborns beginning in 1965. Since then, additional metabolic disorders have been added to the mandated newborn screening panel as new technology allowed for accurate population-based screening and effective treatments became available even for IEM less common than PKU, such as maple syrup urine disease (MSUD) and homocystinuria (HCY). Screening every newborn is necessary because symptoms may not be apparent until after irreversible damage or death occurs. Between 1965 and 2012, 452 individuals with IEM requiring nutritional treatment have been identified by the MDCH Newborn Screening Program. The majority (346) of these individuals were found to have PKU. A complete list of the metabolic disorders currently detected through newborn screening in Michigan is included in Appendix A. There are also other metabolic conditions not yet detectable by screening that require lifelong treatment.

Changes in screening and management

The recommendations for treatment of IEM have evolved considerably over the decades, resulting in a greater need for medical food than ever before. The current accepted clinical practice for the majority of IEM includes a life-long medically prescribed, specialized diet. 'Diet for Life' is currently known to be crucial for all individuals with IEM— regardless of age, gender or IEM diagnosis. Depending on the disorder, individuals with IEM are treated through a combination of strategies including:

- 1) dietary restrictions to limit protein or other substances;

Timeline for Addition of Disorders to Michigan NBS Panel*



* See Appendix A for abbreviations and complete list of amino acid, fatty acid oxidation & organic acid disorders

- 2) medically necessary foods that provide essential nutrients inherently absent from the restrictive diet;
- 3) avoidance of fasting;
- 4) medications to bind or eliminate toxic products; and/or
- 5) treatment with supplemental cofactors/vitamins to enhance **essential** enzyme activity.

The medically necessary foods may take the form of powdered formulas, premixed solutions, tablets or bars. Physicians can also prescribe manufactured low protein modified foods which are versions of common foods with a restricted protein content. Other nutritional treatment for IEM includes medically necessary single amino acids, amino acid mixtures and high doses of vitamins available only by prescription or from special pharmacies.

In order to assure appropriate dietary treatment, there is a need for medical monitoring by a team of experts that includes an American Board of Medical Genetics Board Certified Medical or Clinical Biochemical Geneticist and specially trained dietician. The suggested nutritional treatment for individuals with IEM is dynamic and changes frequently. Each patient's nutrition plan must be tailored to his or her individual needs. Based on regular checks of a patient's blood levels, recommended treatment may be adjusted frequently (as often as weekly or monthly). The nutritional treatment plan for IEM must be carefully calibrated to support an individual's optimal growth, development and health as nutritional needs change based on physical activity, weight change, illness or pregnancy. For example, a young child requires a diet that is distinct from that of a middle-aged adult— but individuals with IEM never outgrow the condition or need for a special diet.



Different forms of medical food



Amino acids and mixtures

Importantly, dietary treatment of individuals with IEM requires access to multiple types of medical foods, formulas, medications and supplements. Careful dietary monitoring and modifications are essential to determine appropriate nutritional treatment for the individual's physical and mental health, from infancy through adulthood.

Cost of nutritional treatment

The cost of medical food varies based on the type of product, patient's specific diagnosis, age, and taste preferences, but it is always significantly greater than the cost of normal counterpart foods. Table I compares the average annual wholesale costs of obtaining protein through medical food based on age and selected diagnoses. Adult males and pregnant females have the greatest protein requirements, and therefore highest cost to meet that requirement through special food and formula products. Average costs for PKU are somewhat lower than for more rare disorders such as homocystinuria (HCY), maple syrup urine disease (MSUD), glutaric acidemia (GA) and tyrosinemia (TYR).

For individuals with IEM, nutritional management based on a combination of strategies is usually preferred, and may be less costly when the patient's medical needs allow use of foods naturally low in

protein in combination with low protein modified foods and medical formula or food. Some examples of typical diets for individuals with PKU at different ages are included in Appendix B. Low protein modified foods are often recommended in conjunction with medical food because they provide an additional source of energy without additional protein. These products are made to simulate “normal” counterpart foods such as pasta, baking mixes, crackers, etc. that typically contain 10 to 40 times more protein than the special products. However, the low protein versions must be specially ordered from a manufacturer and the cost is much higher, typically 2 to 8 times more, than for the corresponding regular foods, as shown in Table 2.

Age (yrs)	Protein requirements per day	PKU	HCY	MSUD	GA 1	TYR-1
<1	10g	\$1,248	\$1,747	\$1,766	\$1,970	\$1,963
1-3	13g	\$1,806	\$2,524	\$2,551	\$2,845	\$2,836
4-8	19g	\$2,643	\$3,689	\$3,728	\$3,054	\$3,730
9-13	34g	\$4,829	\$5,816	\$6,185	\$6,488	\$7,111
Males 14-18	52g	\$7,386	\$8,895	\$9,459	\$9,922	\$10,876
Females 14+	46g	\$6,534	\$8,513	\$8,368	\$8,777	\$9,621
Males 19+	60g	\$8,522	\$10,264	\$10,915	\$11,449	\$12,549
Pregnant females	60g	\$8,522	\$10,264	\$10,915	\$11,449	\$12,549

Table 1. Estimated annual wholesale costs for medical foods in 2010 supplying Dietary Reference Intake age-based protein requirements for different metabolic disorders. Adapted from Camp et al (2012)

Even though low protein modified foods are less expensive than medical food or formula, they are also less likely to be reimbursed by insurance and are not covered by Medicaid. Appendix C provides a comparison of meeting a child’s nutritional requirements through medical food alone vs. a combination of medical food and low protein modified food. While there is variation from patient to patient depending on medical need and preferred diet, the overall cost is much higher than that of a typical diet. For example, in 2011 the average *wholesale* cost of a low protein special diet for a 9-year old child with PKU was estimated to be 2-4 times the usual cost of food provided at home based on



Examples of low protein modified foods

USDA food plans: \$560 per month vs. \$141.80 - \$280.10 per month. (Huntington, 2011) In summary, the use of medical foods, low protein modified foods, and medically necessary single amino acids, mixture and vitamins is not an optional, alternative food choice but rather a medical necessity (Berry et al, 2013). Despite this medical necessity, there are numerous barriers, including but not limited to cost, that are documented in the literature—and corroborated by Michigan families and providers—that interfere with access to nutritional treatment for IEM which are described later in this report.

Regular food option	Cost/100 g	Low protein version	Cost/100 g
Spaghetti	\$0.37	Aproten low protein pasta	\$2.20
Flour	\$0.17	Wel-plan baking mix	\$1.29
Bisquick	\$0.31	Taste connections low protein baking mix	\$0.58
Crackers	\$0.64	Loprofin crackers	\$1.98
Tortillas	\$0.40	Low-pro tortillas	\$2.04
Peanut butter	\$0.70	Low-pro peanut spread	\$1.94

Table 2. Costs of selected foods modified to be low in protein and their regular counterparts. Adapted from Camp et al (2012)

Increasing number of Michigan residents with IEM

The number of different metabolic disorders identified through NBS has increased dramatically in the past decade. In 1987, there were only 3 disorders detected through NBS that required medical formula as treatment. Today, the Michigan NBS Program screens for over 50 disorders with at least 30 disorders requiring nutritional treatment which is the focus of this document; thus, a greater number of individuals are identified who need some type of nutritional therapy. In addition, older individuals with IEM (who were born before NBS or taken off dietary treatment years ago) are returning to metabolic clinical care to be placed back on dietary treatment. For example, the number of CHM Metabolic Clinic visits by IEM patients has risen from 369 visits in 2005 to 687 in 2013 (Figure 1). Some patients with IEM are also treated at the University of Michigan Metabolic Clinic.

The number of people requiring medical foods in Michigan is projected to double by 2030 due to additional births with the disorders, improved health and life expectancy for those with IEM, and the lifelong treatment recommendation (Figure 2). It should also be noted that these numbers are an underestimate as adults with PKU who had discontinued treatment based on the former recommended guidelines, may not be included.

The use of medical foods, low protein modified foods, and medically necessary single amino acids, mixtures and vitamins is not merely an optional, alternative food choice but rather a medical necessity. (Berry et al, 2013)

MDCH contract for metabolic formula

In 1987, State Senators Ehlers and Sederburg introduced a bill to add three new disorders to the screening panel, permit the state public health department to require that screening be performed by the department, and allow collection of a fee for the test that could be adjusted for inflation annually based on the Detroit Consumer Price Index. The original fee was \$18 per infant. Subsequent amendments to the public health code specified additional disorders and the manner in which disorders were to be added along with necessary fee increases, through establishment of the NBS Quality Assurance Advisory Committee in 2006. Copies of the relevant NBS legislation are included in Appendix D.

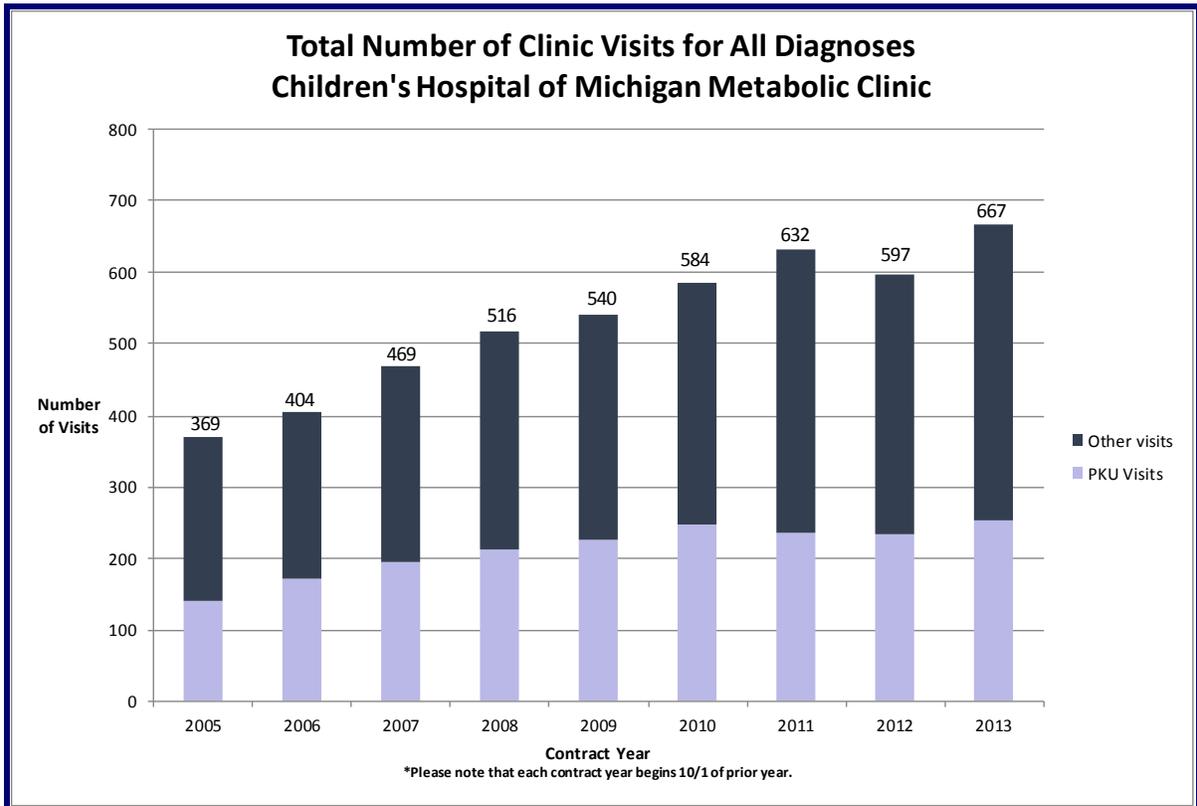


Figure 1. CHM Metabolic Clinic Volume, FY 2005 - 2013

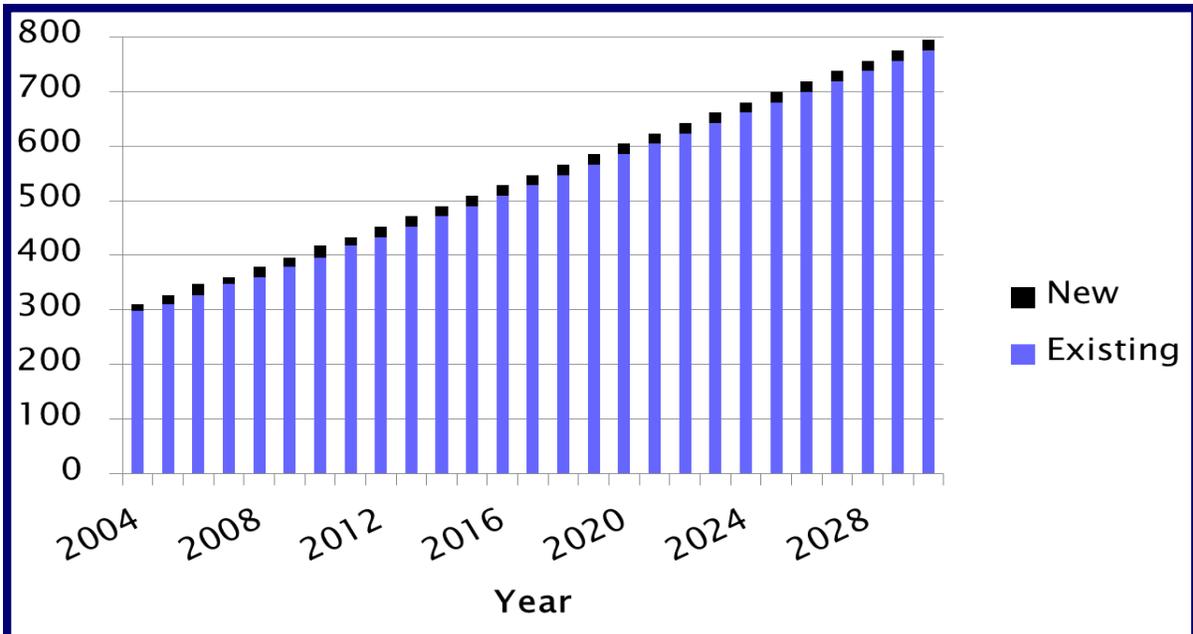
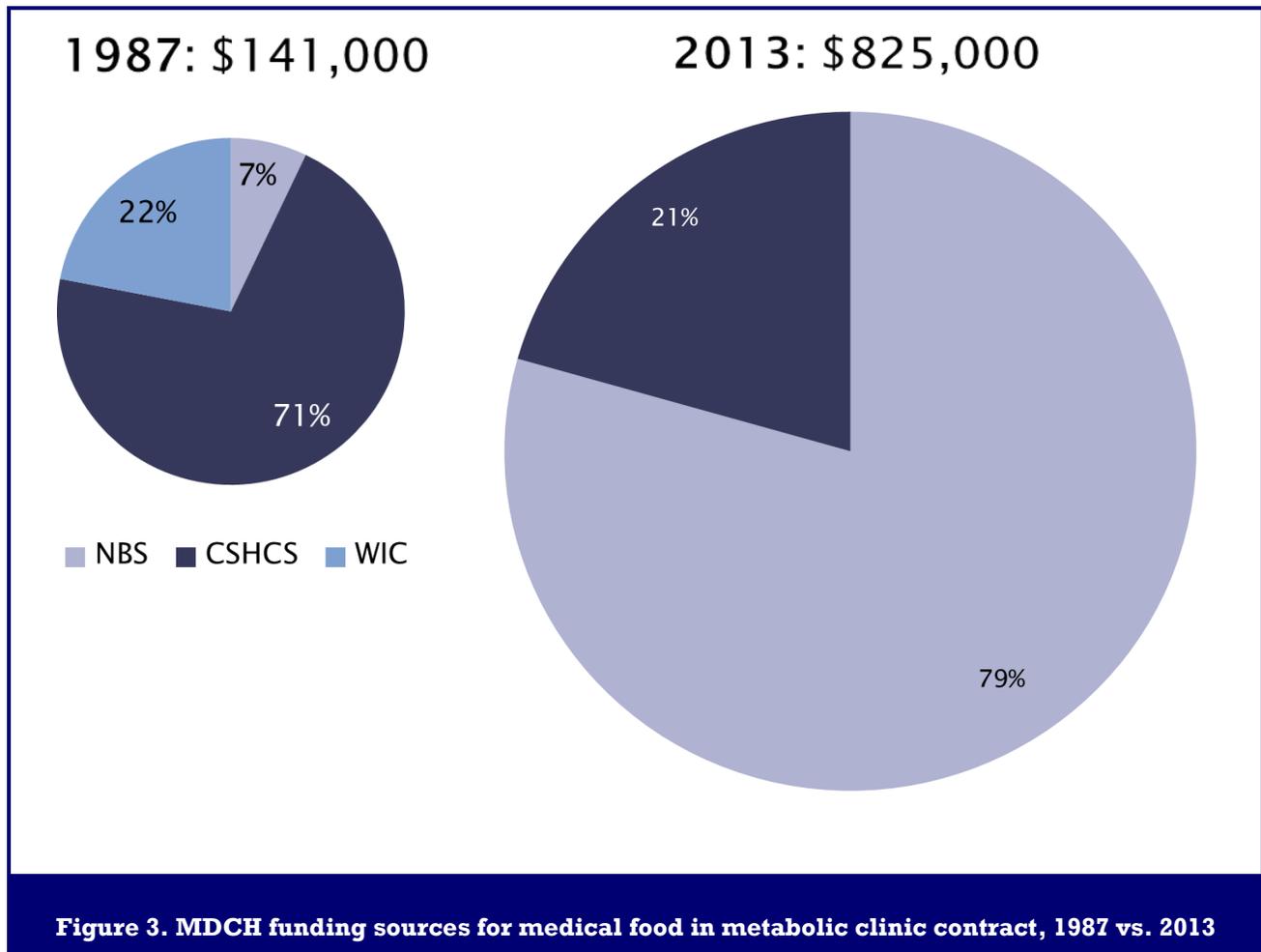


Figure 2. Projected Number of Michigan Patients Requiring Diet for Life Treatment, Michigan, 2004-2030

Currently, revenue to operate all aspects of the NBS Program is based on fees charged to Michigan hospitals for purchase of filter paper kits that are used to obtain blood spot specimens for screening. As of October 1, 2013, the cost per newborn screening kit is \$106.77.

Although not specified in statute, state health department staff historically included funds collected through the fee as part of the financial support for a centralized metabolic clinic, originally located at the University of Michigan, in order to assure appropriate medical management for children with IEM. Medical formulas were ordered by the clinic and provided at no cost to families due to the difficulties in procuring appropriate formula products and obtaining insurance reimbursement. Three MDCH programs (NBS, CSHCS, WIC) historically provided partial funding support for metabolic clinic personnel and medical formula treatment for individuals with IEM through a contractual agreement with UM until 2004, and subsequently with the Children’s Hospital of Michigan (CHM). For eligible patients not detected through NBS, Medicaid has covered medical formula since the 1990’s through its standard payment processes.

As illustrated in Figure 3, the relative contribution to the formula funding within MDCH’s contract with the metabolic clinic has varied over the years; for instance, NBS fees accounted for just 7% (\$9,870) of the total budget for medical formula in 1987, whereas today they account for 79% (\$655,000). The WIC program is no longer able to supply formula through the metabolic clinic, but instead supports a small percentage of the metabolic dietitian’s time to serve as an expert resource for the WIC program. As of Fiscal Year 2013, the budget for CHM to purchase medical formula for patients with IEM is \$825,000, a substantial increase from the original budget of \$141,000 in 1987. The majority of current funding is provided by the NBS program with the balance provided by CSHCS. However, CSHCS will no longer be able to provide “lump sum” funding for medical care



and treatment through the metabolic clinic contract; instead, children with IEM up to age 21 years will need to be enrolled in the CSHCS program in order to receive benefits. CSHCS is a publically funded government program subject to rules, regulations and policies of MDCH. Over 2,700 different diagnoses are covered, and the policy for all other medically eligible conditions requires that families enroll in the program and share costs through a payment agreement based on income. Currently, the program is out of compliance in that CSHCS funds are being used for purchase and distribution of medical formula to individuals who are not enrolled in the program. Therefore, CSHCS is not able to properly monitor or provide detailed reporting of its expenditures in a way that is fiscally responsible and accountable. Families can choose not to participate in CSHCS if the cost of their payment agreement exceeds the cost of the benefits they need, but then they are not eligible for CSHCS services and products.

In FY2012, NBS program spending significantly exceeded its annual revenue of approximately 10.7 million dollars, and it became apparent that continuing increases in the medical formula budget are not sustainable. Multiple factors have contributed to the projected NBS budget deficit. These include:

- the state's declining birth rate (from 125,000 births in 2006 compared to only 112,000 in 2012) leading to fewer NBS kits sold;
- increased costs for laboratory assays and equipment;
- increased costs for public health and medical management coordinating center personnel; and
- increased need for metabolic formula including the relatively greater proportion of NBS funding being used to support the CHM clinic contract.

Therefore, due to changing birth patterns and increased costs for lifelong nutritional treatment of individuals with IEM, NBS funding alone is no longer sufficient to supply medical formula as in the past. As the discrepancy between available NBS resources and the cost of formula continues to increase, other sources of coverage must be identified and utilized in order to sustain access to nutritional treatments and optimize health outcomes for all patients with IEM.

It is also important to remember that the NBS fee covers state screening costs not only for IEM but also for numerous other disorders including congenital adrenal hyperplasia, congenital hypothyroidism, cystic fibrosis, hearing loss, sickle cell disease, and severe combined immunodeficiency. State NBS revenue is currently allocated to support the centralized metabolic clinic and coordinating center with about 42% of that budget used to purchase formula for patients. NBS revenue also supports laboratory screening; four medical management coordinating centers for all other NBS disorders; and public health follow-up and quality assurance. Unlike IEM where screening fees have been used to cover medical formula treatment for individual patients, medical treatment costs for other disorders are not covered by the NBS fee. However, it should be noted that treatment for these conditions generally consists of medications or procedures covered by third party insurance whereas historically there have been significant barriers to obtaining insurance reimbursement and accessing nutritional treatment unless it was funded through the metabolic clinic contract.

“...my formula is my medicine. I need it... It is the single most important thing to me...”

- A Central Michigan University Student with PKU

Overview of the Diet for Life Work Group

Rationale

In light of current medical recommendations, changing demographic patterns and budgetary constraints, Michigan needs a multi-part solution that provides feasible options to enable **patients of all ages** to obtain lifelong nutritional treatment for IEM. In order to address the potential barriers to accessing medically necessary nutrition for individuals with IEM, the Diet for Life Work Group was formed. The Diet for Life Work Group was identified by the Lifecourse Epidemiology and Genomics Division (LEGD) and Children's Special Health Care Services Division (CSHCS) as a way to bring together important stakeholders to examine the issues, learn from each other, and discuss possible solutions.

Objectives

The objectives of the Diet for Life Work Group were to:

- ◆ Identify and understand existing clinical best practice guidelines for lifelong dietary treatment of individuals with IEM detected through newborn screening
- ◆ Describe facilitators and barriers to dietary compliance in order to assure the best possible outcomes for individuals with IEM
- ◆ Recommend feasible solutions that enable patients of all ages to receive appropriate metabolic formulas in light of Newborn Screening Program budgetary constraints
- ◆ Suggest long term strategies for assisting families in obtaining insurance coverage and reimbursement for metabolic foods

Process

The four objectives were addressed during meetings held between October 2013 and January 2014. Facilitators and barriers to dietary compliance were described by families and other work group members throughout four meetings of the group. LEGD staff, with assistance from a student intern living with PKU, conducted additional background research and fact finding between meetings that included discussion with other states. The first meeting focused on existing clinical best practice guidelines, while the focus of subsequent meetings was on identification of barriers, feasible solutions and long-term strategies for Michigan. In addition to the information provided in this report, please visit www.michigan.gov/genomics to view meeting presentations and handouts.

In September 2013, all individuals and parents of children with IEM known by the MDCH NBS program, CHM and/or UM clinics were mailed an invitation to participate in the Diet for Life Work Group. Twenty individuals and family members representing different ages, genders, disorders, geographic regions and insurance types volunteered to participate. Additionally, over 40 health professionals from CHM, UM, MDCH and the Michigan Public Health Institute (MPHI) were invited to participate as work group members. MPHI staff from the HRSA-funded Region 4 Midwest Genetics Collaborative agreed to serve in-kind as neutral facilitators for the work group meeting process.

Meeting #1 (October 15, 2013; agenda in Appendix E). An introductory session was held with families and key MDCH and MPHI staff. The individuals with IEM and/or their family members provided invaluable insight regarding their experiences and the need for nutritional treatment. Background information including eligibility criteria was provided on key public programs: Women, Infants & Children (WIC), CSHCS, Medical Services Administration (Medicaid), and NBS. Personal examples

of barriers to accessing medically necessary food and other services through WIC, CSHCS and Medicaid were discussed by the families.

During the full work group meeting, CHM, UM and MDCH staff provided presentations. These included key MDCH administrators Melanie Brim, Senior Deputy Director, Public Health Administration and Sarah Lyon-Callo, Director, Lifecourse Epidemiology and Genomics Division; CHM Clinical Geneticist Gerald Feldman, MD, PhD; CHM Dietitian June Ventimiglia, RD; and UM Dietitian Sue Lipinski, MPH, RD. Through these expert presentations, work group participants were given information regarding existing clinical best practice guidelines for lifelong nutritional treatment of IEM.

Meeting #2 (Adults: November 18, 2013 and Children: November 22, 2013; agendas in Appendix E). The second set of meetings focused on possible solutions for adults with IEM and children with IEM, respectively. Examples of published definitions of medical food, formula and low protein modified special foods as well as strategies from selected other states were reviewed and discussed. Work group members identified the strategies of potential interest to Michigan. Michigan funding sources were also reviewed (Appendix F & G).



Participants were divided into small groups, each with representation from families with IEM, MDCH, MPHI, UM and CHM to brainstorm potential solutions for Diet for Life coverage for adults and children. Each small group presented their suggestions to the larger group. All of the suggested strategies were compiled by LEGD staff and shared electronically for review by work group members to solicit any additional ideas not already captured. MDCH staff were also assigned questions to answer prior to the final work group meeting.

Meeting #3 (January 13, 2014; agenda in Appendix E). The final meeting focused on a proposed model for Michigan consisting of 7 key components with 42 possible strategies that was prepared by LEGD staff and presented to the group. The model was based on the strategies and ideas previously collected through discussion and presentations by the clinical experts, patients and families. Three additional miscellaneous strategies were also identified.

Members in attendance were asked to rank for themselves the importance of each strategy on a scale of 1 to 5 using a paper worksheet, with 1=not necessary at all to 5=absolutely essential. Based on their worksheet notes, members were then asked to “vote” on the overall importance of each of the seven components using audience response clickers. The majority (75-94%, n=17) agreed that these 7 key components were very important to absolutely essential for Michigan, while the three other strategies were ranked as not very important or not necessary at all. Members unable to attend the third meeting were also invited to fill out and return a worksheet by email or fax.

Upon conclusion of the meeting, members were thanked for their participation and informed that a report would be prepared summarizing the strategies and information gathered throughout the process; and that the report would be made available for their review before formal transmittal to the MDCH Public Health and Medical Services Administrations. Following the full work group meeting, family members were invited to stay and participate in a wrap-up session facilitated by MPHI/Region 4 staff. The families agreed that the work group process had been very useful, and that it would be critical to maintain avenues for family involvement and input as any steps are taken to implement recommended strategies.

Work Group Investigations and Key Findings

Appropriate medical management for individuals with IEM, including necessary access and adherence to nutritional treatment, is exceedingly complex. In addition to concerns about individual compliance with recommended dietary therapies, numerous systems barriers were identified by work group members. Detailed below are results of work group fact finding to describe current obstacles, current practices in Michigan and other states, and potential solutions.

Definitions

Many different terms are used to describe products for treatment of IEM. This has led to confusion and misconceptions regarding the role of special food products in the treatment of metabolic disorders. Diet for Life Work Group members agreed on the following common definition to describe **medical nutrition therapy** or **nutritional treatment for IEM**:

“Nutritional products (in any form) labeled for use under medical supervision that are specially formulated or processed for patients who require them as a major treatment modality due to genetic inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism; and for which medical standard methods of diagnosis, treatment and monitoring exist.”

In addition, three main treatment sub-types were identified and descriptions of each provided: (1) medical food; (2) low protein modified special food; and (3) medically necessary single amino acids, amino acid mixtures, and vitamins.

The group further noted that the definition of nutritional treatment should be expanded to include greater detail as needed for use in policy language and/or possible legislation. Such detail might include stipulating that:

- Medical foods are to be consumed orally or administered internally;
- Medical foods are modified to eliminate the component(s) which are normally present in natural food and cannot be metabolized (and would therefore cause medical problems); and
- *Genetic inborn error* means a rare inherited disorder present at birth which if untreated results in cognitive impairment, system damage or death, and causes the necessity for consumption of special medical foods that are essential to optimize growth, health and metabolic homeostasis.

1. medical food

- ◆ Main alternative to natural protein
- ◆ Infant formula: substitute milk formula based on the composition of regular milk but lacking the toxic ingredients
- ◆ Alternative protein products: solid and powder forms of critical nutrients, amino acids and protein free beverages that are more acceptable to older children, adolescents and adults

2. low protein modified special food

- ◆ Energy source important for a balanced diet; used in conjunction with medical foods to prevent metabolic decompensation
- ◆ Low protein substitute products designed to be as similar as possible to the “normal” counterparts but with minimal protein (eg baking mixes, pasta, sauces, etc)
- ◆ Important dietary component to increase patient acceptance and compliance
- ◆ Does not include foods naturally low in protein

3. medically necessary single amino acids, amino acid mixtures, vitamins, and other compounds

- ◆ Used to replace conditionally essential nutrients or enhance enzyme activity (when not utilized or produced by the body of a person with IEM)
- ◆ Examples include tyrosine, arginine, citrulline, carnitine, biotin and MCT oil

Barriers: food vs. drug classification and billing codes

A confusing and complicated array of federal policies has had the effect of limiting insurance coverage and reimbursement, and therefore access, to some forms of nutritional treatment. Although professional organizations have called for insurance reimbursement as a medical expense, universal coverage remains elusive. (American Academy of Pediatrics 2003)

Despite the fact that medical oversight is required to assure proper use of medical nutrition therapy, the US Food and Drug Administration (FDA) no longer classifies medical food for IEM as a drug, but rather as “foods for special dietary uses.” Moreover, there are currently no federal laws requiring health plans to include medical food as a benefit. Federal legislation has been previously introduced but never passed; another attempt is currently underway. The Medical Foods Equity Act has been introduced into the 113th session of Congress as bill H.R. 3665. It would require federal health insurance programs including the Children’s Health Insurance Program, TRICARE, Medicaid, Medicare and Federal Employee Health Benefit Plans to cover the cost of medical foods for all IEM; however, it does not address coverage by other health plans.

Except in states with specific mandates requiring medical food coverage by health plans, many families with private insurance may not receive any reimbursement for the high cost of medical food and/or low protein modified food products. Even in states with some form of medical food mandate for IEM, the Employee Retirement Income Security Act (ERISA), allowing health plans offered through self-insured employers an exemption from providing coverage, overrides state law. Additionally, military TRICARE insurance and other federal health plans currently have restrictions on portability and equal access to recognized standards of care. (Buist et al, 2009)

“All foods for special dietary use with accepted benefit for treatment of a medical condition should be reimbursed as a medical expense, provided the costs are over and above usual foods. Individual and family financial barriers to obtaining these foods should be removed.”

- American Academy of Pediatrics,
Committee on Nutrition 2003

Another barrier relates to federal billing codes for medical foods used by the Centers for Medicare and Medicaid Services (CMS). Billing codes available through the Healthcare Common Procedure Coding System (HCPCS) create problems for reimbursement because they do not adequately reflect products available for treatment of IEM or how they are used. For instance, “B codes” base reimbursement rates on calories provided, may specify that the product only be administered by tube-feeding or intravenous line. The “S codes” may be recognized by private payers but usually not Med-

A Michigan Case Study: the B code reimbursement paradox*

A 15-year old teenager requires treatment with medical formula. As a young child he used an older powdered formula with an unappealing taste and was required to try it again 5 years ago but would not drink it. He finds the new ready-to-drink formulas more acceptable. The powdered formula is more expensive per serving— \$9.39 compared to \$8.85 for the ready-to-drink. Both options provide the same amount of safe protein, 15 grams, for his disorder. However, the powdered formula supplies 205 calories while the ready-to-drink formula supplies 103 calories a day, so a DME receives better reimbursement for the powdered formula (because reimbursement rates are based on calories). The metabolic dietitian requested prior authorization from MPRO for her patient’s (ready-to-drink) medical formula and it was approved, but the dietitian still had trouble finding a DME willing to serve the patient due to the low reimbursement (even the higher-calorie powdered formula is only reimbursed about \$18 for a can that costs around \$68). Even though the ready-to-drink formulas preferred by the patient are a less expensive way of obtaining the safe protein he needs, the majority of DMEs are not willing to lose money every month while serving this patient.

* submitted by a work group member after the final meeting

icaid or Medicare, and are generally considered to be temporary. In addition to the lack of appropriate billing codes, clear diagnostic codes are not available to describe and document every specific diagnosis, leading to further barriers to reimbursement. (Buist et al, 2009)

Existing Michigan funding sources for nutritional treatment

Coverage for the various forms of nutritional treatment for Michigan residents with IEM is inconsistent and depends on individual circumstances. To date, the only constant provision of medical formula has been funded by MDCH and distributed through a single designated metabolic clinic in southeast Michigan. However, there are likely individuals, particularly adults who had discontinued treatment, who are not seen as patients at the clinic and therefore have not had access to that benefit.

Medical formula, as well as medically necessary amino acid mixtures and vitamins are a covered benefit for Michigan Medicaid and CSHCS beneficiaries, but low protein modified foods are not covered. Medical formula and food may or may not be covered by private insurance, and claims for reimbursement of vitamins and amino acids may or may not be approved. A review of possible funding sources for nutritional treatment of Michigan children and adults with IEM was prepared by LEGD staff and reviewed by members of the work group. (Appendix F and G)

- ◆ For **children under age 21**, current potential sources of coverage include:
 - CSHCS (with possible annual enrollment fee per family based on a sliding scale);
 - Medicaid/Medicaid Health Plan (based on income);
 - Commercial insurance (dependent on plan and may require co-pay); and
 - NBS program funding made available through contract with CHM (if IEM on NBS panel and patient is seen in clinic).

Many of the families in the work group were not previously familiar with CSHCS and had questions about benefits offered through the program. All Michigan resident children with IEM (with appropriate citizenship) under age 21 years are medically eligible for the program. CSHCS coverage is coordinated with any other existing health insurance benefits available to the child and includes medical formula, medically necessary single amino acids and mixtures, transportation for medical care, co-pays and deductibles from private insurance, and other specialty medical bills related to the child's qualifying diagnosis. Parents expressed concerns regarding the annual income review/payment agreement required to join the CSHCS program. The enrollment fee is waived for children on full Medicaid or MICHild, and for those living in a foster home/private placement agency. For others, the CSHCS annual payment agreement amount is based on family size and adjusted gross income. For example, a family of four people with an adjusted gross income of \$80,000 would have a yearly payment agreement amount of \$732 for CSHCS based on FY 2014 rates. The annual payment amount covers all eligible individuals within the family, regardless of the number of children with IEM. A detailed description of the payment agreement guide can be found at http://www.michigan.gov/mdch/0,4612,7-132-2942_4911_35698-15087--00.html. Families can choose not to participate in CSHCS, but then they are not eligible for CSHCS services and products.

- ◆ For **adults between 21 and 64** years of age, sources of funding for nutritional treatment might include Medicaid/Medicaid Health Plan (based on income, pregnancy status, or other medical disabilities), commercial insurance (dependent on plan and may require co-pay), or the NBS program (if IEM on NBS panel, seen at CHM at least annually, and born after screening began in 1965). However, each of these funding sources has eligibility restrictions and coverage limitations.

- ◆ *Healthy Michigan* is a new program starting April 1, 2014 that expands Medicaid eligibility for low-income adults between 19 and 64 years of age. This may be a good option for some adults with IEM who are working but previously did not qualify for Medicaid. *Healthy Michigan* coverage for medical formula is expected to be the same as that provided by Medicaid. For older or disabled adults eligible for Medicare, coverage is only provided for formula when received during a hospital stay or administered by tube feeding.
- ◆ **For adults 65 and older**, potential funding sources would include Medicare with the restrictions noted above, and any commercial insurance available to the individual. Currently, individuals with IEM over 65 were born before the availability of early detection and treatment through newborn screening and are therefore likely to qualify for Medicaid based on a medical disability.

The possibility of public insurance such as Medicaid or Supplemental Security Income (SSI) benefits covering all Michigan residents with IEM (regardless of income) via a disability-based designation was raised by some work group members. However, disability determinations are based on medical review by the Department of Human Services (DHS) using strict federal guidelines, so most individuals who are treated for IEM and functioning normally would not qualify. Changing the federal disability definitions to include individuals with IEM does not seem realistic at the present time.

Finally, some limited financial assistance programs for qualifying individuals with IEM are available through support groups and medical food/formula manufacturers. Currently no additional fundraising occurs in Michigan to support the nutritional treatment needs of patients with IEM, a model used successfully in Colorado.

Role of WIC

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is considered by the U.S. Department of Agriculture to be payer of last resort (after Medicaid and CSHCS) for exempt infant formulas and medical foods for eligible children under 5 years of age and pregnant/post-partum women. Michigan WIC does not authorize metabolic formula, because in 2009, Michigan WIC revised its formulary to better comply with federal regulations. Other WIC State Agencies are in various stages of compliance with USDA Regulations, which read “WIC State Agencies must coordinate with other Federal, State, or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC eligible nutritionals benefit mutual participants.” The Regulations further read, “The WIC State agency is responsible for providing up to the maximum benefit amount of exempt infant formulas and WIC eligible nutritionals under Food Package III in situations where reimbursement is not provided by another entity.” At this time, Michigan WIC is not aware of any situation where metabolic products are not covered by Medicaid, CSHCS, or the Metabolic Clinic at Children’s Hospital of Michigan. Other normal food products (not created or manufactured specifically for IEM) in the WIC food package that are naturally low in protein could be supplied to patients meeting age and income eligibility criteria for the WIC program. A list of these products is attached as Appendix H. Currently, Michigan WIC contributes financially to support the metabolic dietitian staffing at Children’s Hospital to facilitate coordination of services and consultation with WIC clinic personnel for joint WIC clients.



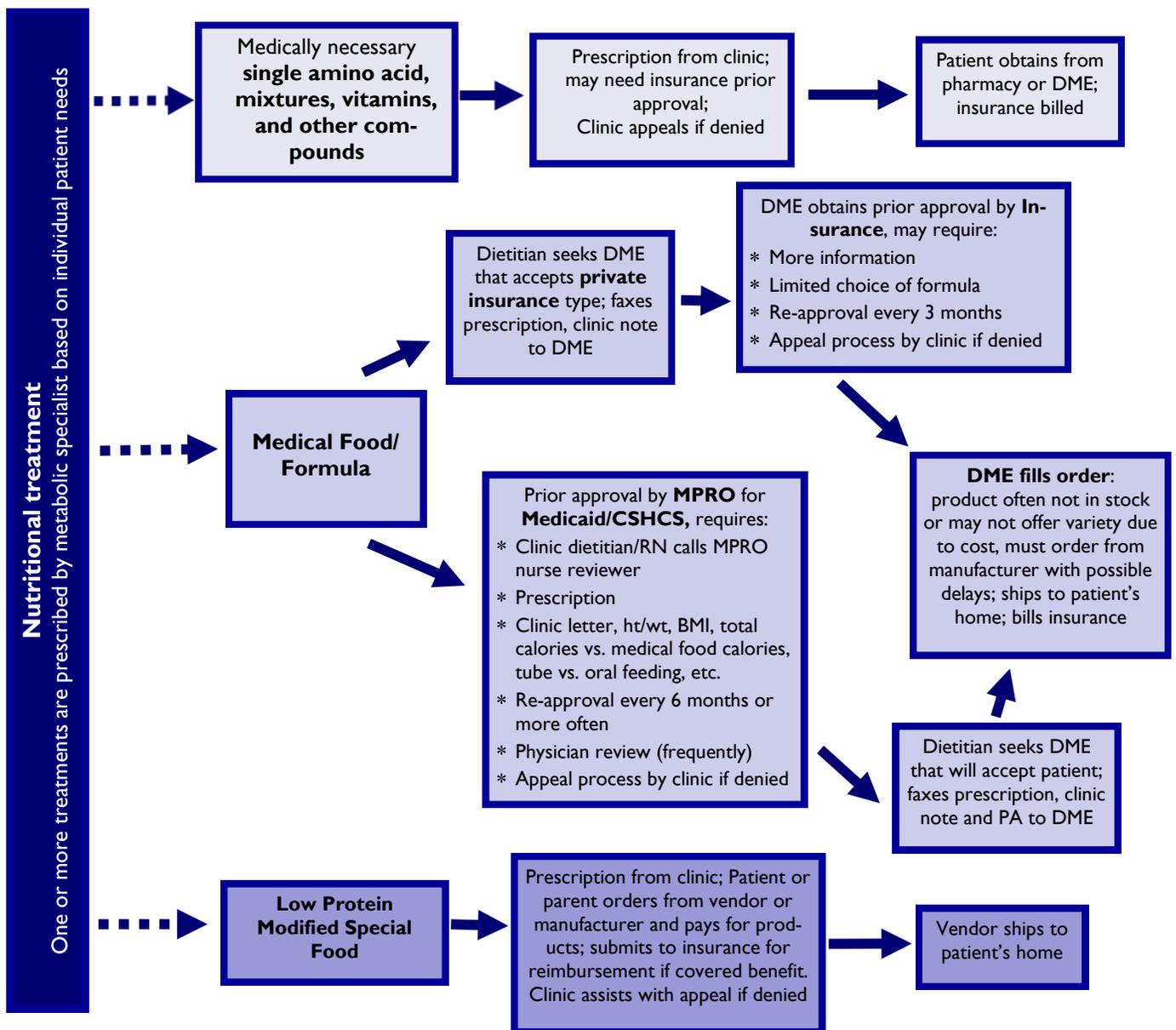
Fruits and vegetables are naturally low in protein

Billing/reimbursement mechanisms and the DME dilemma

Even when individuals with IEM have insurance coverage for nutritional treatment, the process of procuring dietary products is not straightforward. In Michigan, the points of access to the three treatment sub-types are not currently centralized and depend largely on type of insurance (or lack of) coverage and the decisions of insurers, durable medical equipment (DME) suppliers and pharmacies.

Because medical food/formula and low protein modified special foods are not currently recognized as medications by insurers, the process of ordering, billing, and reimbursement is complicated, as shown in Figure 4. LEGD staff investigated a number of questions related to the procurement process, and learned that Medicaid, CSHCS and some Michigan health plans require that any products eligible for coverage be ordered and billed through a DME following prior authorization by the insurer. However, many DMEs in Michigan do not choose to supply medical foods due to low volume, product cost and reimbursement levels, creating considerable barriers to access for patients in

Figure 4. Nutritional Treatment—Access & Billing Process



need of these products. This problem has historically been circumvented for the majority of patients with IEM receiving formula ordered directly by the CHM Metabolic Clinic and reimbursed through the MDCH contract. However, for all other patients with IEM, many of whom are disabled, it is a challenging and time-consuming process for dietitians who must first obtain prior approval from the patient's insurer and then locate a DME supplier. In fact, recent experiences of clinic staff at University of Michigan and Children's Hospital of Michigan suggest that the number of DMEs willing to supply medical food continues to dwindle, making it increasingly difficult for metabolic clinic staff to find a supplier willing to accommodate their patients' treatment needs.

Low protein modified foods are often not covered by Michigan insurers and therefore requirements for supply or billing through DMEs or pharmacies typically do not exist for these products. In the small number of cases where some coverage may exist, families must often pay up front for an order and wait to be reimbursed by their insurance company. For patients without any coverage for low protein products, families must pay 'out of pocket' for these expensive foods.

On the other hand, medically necessary single amino acids, mixtures and vitamins may be billable to insurance including Medicaid and CSHCS, and supplied through pharmacies that choose to carry such products. Unique patient needs may require provision of these products through a compounding pharmacy which further complicates access.

Addressing the DME barrier

In exploring other state models, LEGD staff discovered an example of a state public health agency's newborn screening program serving as its own DME to handle medical food orders. However, based on follow-up discussions with Medical Services Administration staff, it appears that such an arrangement would not be possible in Michigan since Medicaid is part of the same department as newborn screening (which may not be the case in other states with central DME such as Louisiana and Washington).

MDCH can explore other ways to support a single DME provider to serve all patients with IEM; however, it cannot require insurance plans to use that single DME for their members. Possible ways to streamline the prior authorization process for patients in Medicaid health plans will be explored, so that approvals can be obtained from a single point of contact (MPRO) used for patients with traditional Medicaid, in order to reduce the need for metabolic dietitians to work through multiple health plan approval processes. The CHM Metabolic Clinic will explore the possibility of using the hospital's DME to provide medical foods for the clinic's patients and other Michigan individuals with IEM, insofar as insurance allows. Because the clinic already receives discounts on pricing for medical food products that are comparable to discounts received through multi-state purchasing collaboratives, at this time it was not felt to be of any benefit to further investigate joining such a group.

Legislation may address who is responsible for providing coverage; the disorder(s) covered; benefit limits; whether a physician must order medical food; age limits; deductibles and co-payments; and/or income eligibility for public programs. (Weaver et al, 2010)

Other state mandates and metabolic food programs

Michigan is one of only 12 states in the US that have no mandated insurance coverage for children and/or adults with IEM. (Khamisi 2013; Berry, Brown et al 2013) In the Midwest region alone, 5 of 7 states have some form of mandated coverage as shown in Table 3. The nature of mandated coverage varies in the states that do have laws addressing the issue.

Some mandates address only medical food, while others include both medical food and low protein modified special foods. One state mandates coverage for low protein but not medical food. The legislation in some states may include age limits, restrictions on which IEM diagnoses are covered, or caps on the amount of coverage; others include tax credits for families with IEM for the out of pocket costs of nutritional treatment.

Even when legislation exists, it is not always logical given current standards for treatment. For instance, the state of Colorado has no age limit on insurance coverage for medical foods for IEM treatment EXCEPT for PKU. The maximum age for males with PKU to receive benefits is 21 years, while for females the maximum age is 35 years. Arizona requires insurance coverage for at least 50% of the cost of medical and low protein foods prescribed, but a plan may limit the maximum annual benefit for foods to \$5,000. Other states cap coverage for low protein foods at \$1,800– 2,500. In California, coverage is required only to the extent that the cost of necessary formulas and special food products exceeds the cost of a normal diet, while in Florida, formula is covered as medically

State	Medical food only	Medical food and low protein special foods	No mandated coverage
Illinois	■		
Indiana	■		
Kentucky		■	
Michigan			■
Minnesota		■	
Ohio			■
Wisconsin		■	

Table 3. Comparison of State Mandates for IEM Nutritional Treatment in the Midwest. (Berry, Brown et al and personal communications)

necessary but low protein food up to \$2,500 is covered only through the age of 24. Arkansas allows an income tax credit of up to \$2,400 per year per child with disorders of amino acid metabolism for the purchase of medically necessary medical foods and low protein modified food products, and all health plans in the state must provide modified food products if the cost for an individual or family exceeds the income tax credit.

Importantly, some national commercial health insurers (ie, Aetna) only provide coverage for nutritional treatment for IEM if there is a state mandate requiring coverage. Therefore, Michigan residents with these particular health plans would not have access to such coverage.

Some state mandates include a directive for the state public health agency to provide medical foods and formula for specific ages, genders and/or disorders, often on a sliding fee scale or as a last re-

sort if no other insurance coverage exists. For instance, the Indiana NBS program is the payer of last resort to assure access to medical formula, but only a single brand is available for each metabolic condition.

Numerous existing programs for distribution of medical food in other states were examined by LEGD staff through website reviews, email communications and telephone calls. A summary of the findings was shared with work group participants and is included in Appendix I. The strategies from the states of Kentucky, Louisiana, Oregon and Wisconsin were of greatest potential interest to Diet for Life Work Group members for consideration in Michigan.

Attractive features of these programs included:

- **Centralized ordering and distribution** (e.g. Oregon's medical food store);
- **Billing insurance for third party reimbursement;**
- **Provision of both medical and low protein foods;**
- **Sliding scale fees;** and
- **Maintaining patient choice** in the medical food products received.

Need for state legislation

The potential need for legislation in Michigan to address nutritional treatment for IEM was also explored. In contrast to Wisconsin, nutritional treatment for IEM is not specifically mentioned in Michigan's law mandating newborn screening. An attempt by parent advocates to have legislation passed in 2006 that would have mandated insurance coverage was not successful, despite considerable effort and a sympathetic legislative sponsor.

Several non-MDCH work group participants expressed interest in assisting with steps to explore future legislation. Some families were interested in pursuing state legislation; however, they have concerns regarding the feasibility and likelihood of success with any new state legislation at this time given past experience, and believe their work could be more productive by assisting with efforts at the national level to obtain federal legislation.

Components & Strategies

Based on compilation of all the information collected and feedback received from work group members, LEGD program staff identified 7 core components of a potential model for assuring a comprehensive approach to Diet for Life nutritional treatment for Michigan residents with IEM. Three miscellaneous ideas were suggested but did not fit within any of the 7 components and were labeled as “other strategies.” The 7 core components are:

- **A coordinated metabolic treatment program**
- **Family education and advocacy**
- **Maximum use of third party insurance benefits for medical foods and other nutritional treatments**
- **Increased access to low protein modified foods**
- **A safety net for people with no available coverage**
- **Coordination with state and federal supplemental food programs**
- **Possible legislation, if needed**

Possible strategies for implementing each component, as identified through the work group process, are detailed below. During the third meeting, members were asked to determine the relative importance of each component by voting on a 5-point scale whether it was (1) not necessary at all and therefore should not be included in a plan for Michigan; (2) not very important; (3) may or may not be helpful (neutral); (4) very important; or (5) absolutely essential and must be included. Overall, there was considerable support for all suggested components of the model, as detailed below. Specific strategies that received an average score of “4” or higher based on a tally of participant worksheets are denoted in **bold**. Strategies identified as particularly important by all of the small breakout discussion groups held during the “adult” and “child” work group meetings are denoted by *italics*.

I. A coordinated metabolic treatment program should be maintained in order to assure that qualified medical experts are available to provide appropriate services for all patients with IEM. Additional key strategies include policies that minimize disruption of the current system whereby med-

Strategies for Component #1: A Coordinated Metabolic Treatment Program	
A	Maintain a comprehensive metabolic disease treatment program supported by MDCH to assure qualified clinic personnel are available to provide appropriate diagnostic and follow-up services for all patients with inborn errors of metabolism
B	Develop policies that strive to minimize disruption of current system for providing medical formula/food shipped directly to the patient’s home based on metabolic dietitian and physician recommendations
C	<i>Establish a centralized Durable Medical Equipment Supplier (DME) as a single source supplier for medical foods*</i>
D	<i>Establish a centralized pharmacy as a single source supplier for medically necessary single amino acids, amino acid mixtures and vitamins*</i>

*Part of consensus recommendation to establish a centralized DME as a single source supplier for nutritional treatment products, as identified at November work group meetings

ical formula is ordered by the metabolic dietitian and shipped directly to a patient’s home. Ideally, a coordinated program would also involve centralization of a DME supplier and pharmacy to guarantee availability and access to all nutritional treatment products needed by patients with IEM.

Component #1 was deemed by 76% (n=17) of voting work group members to be absolutely essential, with an additional 18% of members feeling it was very important, while 6% were neutral. An additional written suggestion received during the third meeting included establishing a panel to review formulas annually that includes parents/patients.

“We need to address the very real issue that some families would have to contribute too much under a contract with CSHCS based upon income. It is in a very real way cost prohibitive.”

- A Parent Work Group Member

2. Family education and advocacy was felt to be an important part of any plan that might lead to changes in the way products for nutritional treatment are procured. Component #2 was deemed by 44% (n=18) of voting work group members to be absolutely essential, with an additional 44% of members feeling it was very important while 11% were neutral. Work group members, especially those who were parents of children with IEM, stressed the importance of clarifying the timeline for implementation of any changes with families as well as any out-of-pocket expenses they might be expected to contribute, including the additional financial burden of a yearly payment agreement required to join the CSHCS program. They also suggested continuing to maintain a work group with family representation as recommendations are implemented and to address ongoing needs related to nutritional treatment for IEM.

Strategies for Component #2: Family Education and Advocacy	
A	Clarify timeline for implementation of changes with families
B	Clarify out of pocket expenses for families- how much they should expect to contribute
C	Address concerns re: Children’s Special Health Care Services (CSHCS) from families of children with inborn errors of metabolism (IEM)
D	Develop metabolic clinic process to work with each family to assess insurance coverage and explain available options
E	Assist families with appeal process for denied claims, as needed <ul style="list-style-type: none"> • Educate individuals and families about calling helplines such as beneficiary line for Medicaid • Develop factsheet for parents and individuals with IEM regarding tips to approach payers; consider adapting National PKU recently developed factsheet on tips for families in dealing with payers; consider what is incentive for families to approach payers
F	Disseminate work group’s recommendations and solicit feedback from other MI families and individuals with IEM
G	Continue Diet for Life Work Group or similar group to implement recommendations and continue to address needs of MI individuals and families with IEM who require nutritional treatment

3. Maximum use of third party insurance benefits was considered to be absolutely essential by 56% of voting members (n=18), with an additional 28% believing it to be very important and 17% neutral on whether or not it would be helpful. It was recognized that each patient’s situation regarding potential existing coverage for any nutritional treatment is unique given the wide array of employer-based insurance plans and family income levels. In order to maximize use of insurance benefits as a funding source for nutritional treatment, some individuals with IEM who are currently uninsured may need assistance to apply and enroll in plans for which they are eligible, and CHM clinic

staff will need to establish additional procedures for obtaining prior authorizations from all public and private health insurance plans, as well as develop methods for tracking the results of attempted billing and appeals. Work group members recognized the considerable staff time required to systematically collect data relating to reimbursement for medical and low protein foods in Michigan. They agreed, however, that actual data are critical in order to identify gaps and deficiencies in health insurance coverage for all treatment sub-types.

Additional strategies for Component 3 suggested by work group members on the written worksheets included:

- modifying the CSHCS income and eligibility payment agreement formula to adjust for increased costs that families already pay for special foods and/or take into account whether medical formula is the only service being used;
- doing an actuarial study of lifetime costs, projected future incidence and comparing to costs of not providing coverage; and
- working toward prescribed food as a lifetime benefit covered by Medicaid.

Strategies for Component #3: Maximum Use of Third Party Insurance Benefits	
A	Develop and implement process for families of children under 21 to enroll in CSHCS
B	Develop and implement process for eligible individuals to apply for Medicaid and Healthy Michigan enrollment Assure income-eligible women of reproductive age are enrolled prior to pregnancy
C	Assess implications for Medicaid Health Plans; consider “carve out” for IEM nutritional treatments
D	<i>Bill all existing public or private insurance for all forms of nutritional treatment</i>
E	Assign MDCH staff to assist clinic and families with payer and billing issues regarding nutritional treatment for individuals with IEM
F	Assign metabolic clinic staff to become billing expert and liaison for families and payers (i.e. ‘insurance navigator’) regarding nutritional treatment for individuals with IEM
G	Attempt to find at least one contact at each health plan that is aware and knowledgeable about this issue
H	Develop methods for metabolic clinic to track results of all attempted billing- including rates of coverage, denials, reimbursement levels, health plan responses, problems with DME, etc.
I	Summarize current coverage and gaps in coverage for all three sub-types and various patient types and payer types

4. Increased access to low protein modified foods was considered a somewhat lower priority by the work group overall. While a majority (47%) of voting members (n=17) believed it was absolutely essential and 29% felt it was very important, a few people were neutral (12%) or felt it was not very important (12%). The centralized metabolic food store used in Oregon was identified as an attractive model for leveraging group purchasing power to reduce costs. Devising a strategy to provide families with a monthly low protein food package was another option that might help reduce overall costs by enabling easier access to food (to the extent it can safely replace formula in a person’s prescribed dietary regimen). Throughout the discussion, parents emphasized the importance of maintaining individual patient choice in the types of medical or low protein foods that might be made available through any public health program. The concept of fundraising to support a medical food store was also raised as a possible strategy. Another strategy suggested on one participant’s

worksheet was to investigate the possibility of providing a monthly stipend for low protein food based on patient's age and dietary needs.

Strategies for Component #4: Increased Access To Low Protein Modified Foods	
A	Develop centralized single source supplier for low protein modified foods (to leverage group purchasing power) <ul style="list-style-type: none"> • Use “metabolic food store” model or DME
B	Investigate possibility of providing a monthly low protein modified basic food package based on patient's age and dietary needs, with annual review of covered medical food products <ul style="list-style-type: none"> • Consider placing limits on quantities of food provided (rather than limits on types and/or sources of food)
C	Investigate if fundraising is possible to support a medical food store (like Colorado)

5. A safety net component for people with no available coverage met with strong support in that 65% of voting members (n=17) felt it was absolutely essential to have such a back-up system in place, with an additional 24% believing it to be very important while 2 individuals (12%) were neutral. Recognizing that individuals with IEM should never have to go without proper nutritional treatment for their disorder, a safety net program would be used to provide temporary coverage for provision of medical food in situations where prior authorization by insurance is delayed or denied, or when individuals do not qualify for any available programs, do not have or lose access to insurance benefits and are unable to afford the cost of required nutritional treatment. One important feature of a safety net program suggested was to explore the possibility of expanding CSHCS coverage for medical formula to adults over age 21.

Strategies for Component #5: A Safety Net	
A	Develop and implement process for coverage when other means exhausted <ul style="list-style-type: none"> • Consider developing process of payment and receipt for nutritional treatments when ineligible for coverage by payers or state programs (similar to Kentucky) • Determine what NBS (or other state) funds can be used for nutritional treatment
B	Provide nutritional treatment based on diagnosis without means testing
C	Investigate sliding scale for costs related to nutritional treatment for families
D	Explore whether CSHCS would be able to cover adults with IEM (like adults with cystic fibrosis and hemophilia)
E	Investigate hardship programs offered by pharmaceutical companies, product manufacturers and others

6. Coordination with state and federal food programs is another component that may be worth pursuing in order to augment funding sources to support nutritional treatment for IEM. One-quarter of members (n=16) who voted on Component #6 believed it to be absolutely essential, while an additional 50% thought it was very important. 19% of individuals were neutral, and 6% felt it was not a very important part of the overall approach to nutritional treatment. This may reflect pessimism about the degree to which coordination with other food programs could be achieved, given that public food programs are not designed to deal with the special dietary needs of individuals with IEM.

Strategies for Component #6: Coordination with State and Federal Supplemental Food Programs	
A	Determine supplemental foods (i.e. naturally occurring low protein foods) available to eligible recipients of WIC, food stamps, school lunch programs, etc.
B	Develop and implement process for eligible families of children 0-5 and pregnant/post-partum women to enroll in WIC
C	Approach other state departments (i.e. Dept. of Human Services) about possible food coverage (i.e. food stamps/MI Bridges and MI school breakfast/lunch programs)

7. Possible legislation is the final overarching component to be considered in a comprehensive plan for addressing Diet for Life needs. Thirteen of 16 voting members (81%) felt that considering possible legislation is absolutely essential and must be included; one person (6%) believed it was very important, while two people thought it was not very important or not necessary at all. There are several different strategies for pursuing possible legislation that include mandates requiring insurance to cover medical and low protein food products regardless of age or gender; creation of a specific state metabolic food program to provide nutritional treatment for all patients; changing the NBS statute to specify coverage for nutritional treatment; and/or creating a tax credit for families who bear the cost of medical foods to treat IEM.

Strategies for Component #7: Possible Legislation, if needed	
A	<p><i>Consider state mandate for third-party/private insurers to cover medical foods, regardless of age or gender</i></p> <ul style="list-style-type: none"> • Include possibility of covering those without insurance coverage as ‘protected class’ (similar to Kentucky)
B	<p>Introduce legislation to create a state metabolic food program that provides coverage for all patients with genetic inborn errors of metabolism for all three sub-types of treatment</p> <ul style="list-style-type: none"> • Include all patients regardless of age or gender, whether or not detected by NBS • Include coverage for shipping or distribution costs, protein reimbursement and family costs
C	<p>Explore feasibility of amending NBS law to include coverage for nutritional treatments (similar to Wisconsin)</p> <ul style="list-style-type: none"> • Could this be added to the Michigan law and still remain budget neutral? • Leverage funds from other state programs and/or raise NBS fee?
D	Investigate introduction of legislation for state tax credit for costs of medical food for families and individuals with IEM
E	<p>If state legislation is pursued, ensure we can demonstrate need, is budget neutral and will be effective</p> <ul style="list-style-type: none"> • Investigate if health economic studies have been done and results available regarding nutritional treatment for inborn errors of metabolism • Investigate if other states have budget information available to show that their programs are budget neutral or that ultimate savings are beyond actual cost
F	Monitor federal bills regarding medical food legislation
G	Determine impact of ACA on nutritional treatment for inborn errors of metabolism and potential impact on current payers if new state legislation introduced
H	Identify patient advocates to work on nutritional treatment issue and lobby for legislation if needed

Although the vast majority of Diet for Life Work Group members believe legislation is the most effective way of making the needed sustainable changes to secure funding for all types of lifelong nutritional treatment, they also recognize that achieving new legislation is extremely difficult and may not be realistic in the near future. Given the current political climate with respect to any new mandates in addition to other public health budget issues under negotiation with the legislature, MDCH cannot initiate a request for any new legislation or fee increase in the foreseeable future. However, this would not preclude the possibility of the department reaching out to health insurance plans to educate their policy makers regarding the importance of comprehensive Diet for Life coverage.

Other strategies

The three suggestions that were classified in the ‘Other Strategies’ category were ranked by work group members as not very important to not necessary at all for Michigan’s model, perhaps due to the practicality of trying to effect such wide-sweeping changes related to making restaurants more IEM friendly, changing federal coding methods for medical food products or trying to improve the flavor of medical foods.

Other Strategies	
A	Investigate if restaurants can be more ‘IEM-friendly’
B	Attempt to change reimbursement based on calories amount
C	Attempt to determine if flavor of medical food can be improved

Next Steps

The rationale and success of over 50 years of NBS in the United States is based on the overwhelming evidence showing that initiation of prompt and effective treatment of children with IEM significantly improved outcomes. Unfortunately, numerous barriers to assuring ready access to lifesaving therapies still exist, as described in this report. In fact, a recent national survey of children with IEM found that insurance or other resources do not consistently cover the costs of treatment, potentially leading to health inequities in access to essential nutritional treatment products. (Berry, Kenney et al, 2013)

For Michigan, this report is intended as a first step to increase awareness and highlight the facilitators, barriers and changes needed to ensure Diet for Life for all individuals with IEM, regardless of age. The necessary components of a comprehensive model have been described, and numerous specific strategies suggested. Following review by work group members to identify additional ideas or suggestions that may not have been captured by the Diet for Life Work Group process, this summary report will be submitted to the Michigan Department of Community Health, Public Health Administration and Medical Services Administration and posted on the website for public comment. Based on feedback and guidance from MDCH administration and relevant programs, an implementation plan and timeline will be created, incorporating the strategies most likely to achieve our long term goal of ensuring Diet for Life in Michigan. Throughout these next steps, program staff will also continue to communicate with interested families and provide opportunities for continued involvement to help make health outcomes for children and adults with IEM the best they can be.

“Let’s make sure these Michigan children have coverage for their life essential medical formula and dietary products so that they thrive to become productive, healthy Michigan adults.”

- Mother of a Daughter with Homocystinuria, Traverse City

Work Group Participants and Acknowledgements

We wish to acknowledge and thank all of the work group members who contributed their valuable time and thoughtful input. Neutral facilitation for The Diet for Life Work Group was provided by the Region 4 Midwest Genetics Collaborative, a project of the Michigan Public Health Institute funded by the Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau (MCHB) H46MC24092.

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Appendix A. Michigan NBS Panel, highlighting inborn errors of metabolism that require Diet for Life nutritional treatment (as of April 1, 2014)

Amino Acid Disorders

Argininemia (ARG)
Argininosuccinic acidemia (ASA)
Citrullinemia Type I (CIT-I)
Citrullinemia Type II (CIT-II)
Homocystinuria (HCY)
Hypermethioninemia (MET)
Maple syrup urine disease (MSUD)
Phenylketonuria (PKU)
Benign hyperphenylalaninemia defect (H-PHE)
Biotpterin cofactor biosynthesis defect (BIOPT-BS)
Biotpterin cofactor regeneration defect (BIOPT-REG)
Tyrosinemia Type I (TYR-I)
Tyrosinemia Type II (TYR-II)
Tyrosinemia Type III (TYR-III)

Fatty Acid Oxidation Disorders

Carnitine acylcarnitine translocase deficiency (CACT)
Carnitine palmitoyltransferase I deficiency (CPT-1A)
Carnitine palmitoyltransferase II deficiency (CPT-II)
Carnitine uptake defect (CUD)
Dienoyl-CoA reductase deficiency (DERED)
Glutaric acidemia type II (GA-2)
Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (LCHAD)
Medium/short-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (M/SCHAD)
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
Medium-chain ketoacyl-CoA thiolase deficiency (MCKAT)
Short-chain acyl-CoA dehydrogenase deficiency (SCAD)
Trifunctional protein deficiency (TFP)
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)

Organic Acid Disorders

2-Methyl-3-hydroxy butyric aciduria (2M3HBA)
2-Methylbutyryl-CoA dehydrogenase deficiency (2MBG)
3-hydroxy 3-methylglutaric glutaric aciduria (HMG)
3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)
3-Methylglutaconic aciduria (3MGA)
Beta-ketothiolase deficiency (BKT)
Glutaric acidemia type I (GA1)
Isobutyryl-CoA dehydrogenase deficiency (IBG)
Isovaleric acidemia (IVA)
Methylmalonic acidemia cobalamin disorders (Cbl A,B)
Methylmalonic aciduria with homocystinuria (Cbl C,D)
Methylmalonic acidemia methylmalonyl-CoA mutase (MUT)
Multiple carboxylase deficiency (MCD)
Propionic acidemia (PROP)

Hemoglobinopathies

S/Beta thalassemia
S/C disease
Sickle cell anemia
Variant hemoglobinopathies
Hemoglobin H disease

Endocrine Disorders

Congenital adrenal hyperplasia (CAH)
Congenital hypothyroidism (CH)

Other Disorders

Biotinidase deficiency (BIOT)
Galactosemia (GALT)

Cystic fibrosis (CF)
Severe combined immunodeficiency (SCID)
T-cell related lymphocyte deficiencies

Hearing

Critical Congenital Heart Disease

Appendix B. Sample PKU daily diets at different ages

(from presentation by June Ventimiglia, RD to Diet for Life Work Group on October 15, 2013)

In general, medical food/formula provides 85-90% of protein. The diet consists of fruits, vegetables, fats, sugars and low protein foods, with total avoidance of higher protein foods such as meats, dairy, peanut butter and eggs.

9-month old infant

- Phe goal from food and formula - 250 mg
- Formula mix of Similac and Periflex -18.9 ounces = 127.7 mg phe (6.74 mg phe/oz)
- Food— average was 125 mg phe— rice cereal, strained carrots and strained fruit.

4-year old child

- Food and formula provide: 274 mg phe, 37 gm protein and 1250 calories
- 1 slice toast -100 mg phenylalanine
- 2 tbsp margarine -12 mg
- 1 medium banana - 43 mg
- 1 lemon pudding - free
- ½ cup blueberries -18 mg
- ½ cup baked potato (no skin) -56 mg
- 10 strawberries -14 mg
- 12 cherry tomatoes -31 mg phe

TOTAL 274 mg phe and 650 calories
29 ounces of phenyl free 2 -31.6 mg protein and 589 calories

11-year old child

- 1 cup froot loops - 88 mg phenylalanine
- ¼ cup coffee rich - 8 mg
- 8 ounces apple juice - 2 mg
- 1/3 medium banana - 14 mg
- 10 french fries - 76 mg
- 1 tbsp ketchup - 7 mg
- 1 cup lettuce - 28 mg
- 1/2 cup tomato - 22 mg
- 2 tbsp mushrooms - 7 mg
- 2 tbsp Italian dressing - 0 mg
- 1 gel snack cup - free
- 10 jelly beans - free
- 1 cup low protein spaghetti, dry - 14 mg
- ¼ cup spaghetti sauce - 24 mg
- ¼ cup green beans - 21 mg
- 1 slice low protein bread - 15 mg
- 1 tbsp margarine - 6 mg
- ½ cup strawberries - 13 mg

TOTAL 345 mg phe and 1242 calories
5 scoops phenylade essential -50 gm protein and 785 calories
Food and formula provide 345 mg phe, 56.9 gm protein with 2027 calories

Typical Adult

- 2 low protein pancakes - 4 mg phenylalanine
- 1 tbsp margarine - 6 mg
- Syrup - 0 mg
- 1 cup chunky veg. soup RTS - 160 mg phe
- 3 saltine crackers - 43 mg

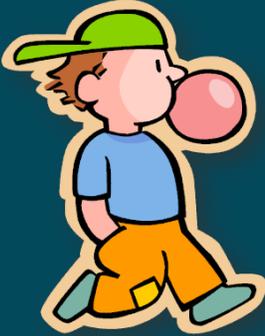
TOTAL 475 mg phe, 9.5 gm protein, 1043 calories
3 PKU 20 coolers = 60 gm protein, 372 calories

- 1 medium banana - 43 mg
- 1 cup baked potato -118 mg
- ¼ cup cooked broccoli - 35 mg
- 2 tbsp margarine - 12 mg
- 1/3 cup low protein shredded cheese - 42 mg
- ½ cup watermelon - 12 mg

Food and formula provide 475 mg phe, 69.5 gm protein, 1415 calories

Appendix C. Cost comparison of medical food vs. combination treatment that includes low protein food

Case Example

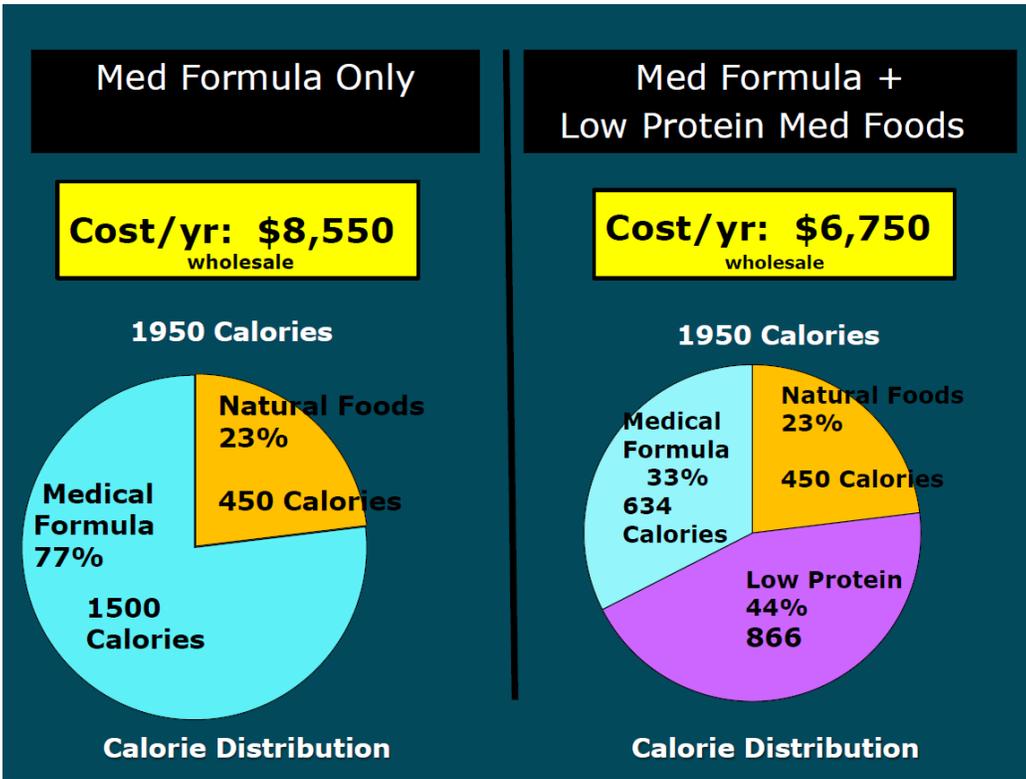


9 Yrs old
Diagnosis: PKU

- RDA: 34 Grams Protein**
- 1950 Calories**

•**Tolerates 300 mg of Phenylalanine Per Day (= 6 grams protein)**

Provides ~ 450 calories



From a presentation by Kathleen Huntington, MS, RD, LD: **Resolving The Paradox Known As Medical Food Reimbursement for Treatment of Inborn Errors of Metabolism**, given February 10, 2011 at the NORD Medical Foods Conference. Downloaded from <https://www.rarediseases.org/docs/medical-foods/huntington-2011> on March 25, 2014.

Appendix D. Michigan Newborn Screening Legislation

Act 14 of 1987

STATE OF MICHIGAN 84TH LEGISLATURE REGULAR SESSION OF 1987

Introduced by Senators Ehlers and Sederburg

ENROLLED SENATE BILL No. 162

AN ACT to amend section 5431 of Act No. 368 of the Public Acts of 1978, entitled as amended "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to provide for penalties and remedies; and to repeal certain acts and parts of acts," as amended by Act No. 300 of the Public Acts of 1986, being section 333.5431 of the Michigan Compiled Laws.

The People of the State of Michigan enact:

Section 1. Section 5431 of Act No. 368 of the Public Acts of 1978, as amended by Act No. 300 of the Public Acts of 1986, being section 333.5431 of the Michigan Compiled Laws, is amended to read as follows:

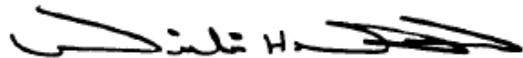
Sec. 5431. (1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for phenylketonuria and, beginning July 1, 1987, shall administer or cause to be administered to the infant a test for galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, and other treatable but otherwise handicapping conditions as designated by the department. The results of a positive test shall be reported to the infant's parents, guardian, or person in loco parentis. The test shall be administered within a time and under conditions prescribed by the department. In addition, the department may require that the test be performed by the department.

(2) If the department performs a test required under subsection (1), the department may charge a fee for the test of not more than \$18.00. The amount stated in this subsection shall be adjusted annually by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index. As used in this subsection, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics of the United States department of labor.

(3) A person who violates this section or a rule promulgated under this part is guilty of a misdemeanor.

(4) The department shall provide for a hardship waiver of the fee authorized under subsection (2) under circumstances found appropriate by the department.

This act is ordered to take immediate effect.



Secretary of the Senate.



Clerk of the House of Representatives.

PUBLIC HEALTH CODE (EXCERPT)

Act 368 of 1978

333.5431 Testing newborn infant for certain conditions; reporting positive test results to parents, guardian, or person in loco parentis; compliance; fee; "Detroit consumer price index" defined; violation as misdemeanor; hardship waiver; conduct of department regarding blood specimens; pamphlet; additional blood specimen for future identification.

Sec. 5431. (1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following:

- (a) Phenylketonuria.
- (b) Galactosemia.
- (c) Hypothyroidism.
- (d) Maple syrup urine disease.
- (e) Biotinidase deficiency.
- (f) Sickle cell anemia.
- (g) Congenital adrenal hyperplasia.
- (h) Medium-chain acyl-coenzyme A dehydrogenase deficiency.
- (i) Other treatable but otherwise disabling conditions as designated by the department.

(2) The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.

(3) If the results of a test administered under subsection (1) are positive, the results shall be reported to the infant's parents, guardian, or person in loco parentis. A person is in compliance with this subsection if the person makes a good faith effort to report the positive test results to the infant's parents, guardian, or person in loco parentis.

(4) Subject to the annual adjustment required under this subsection and subject to subsection (6), if the department performs 1 or more of the tests required under subsection (1), the department may charge a fee for the tests of not more than \$53.71. The department shall adjust the amount prescribed by this subsection annually by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index. As used in this subsection, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics of the United States department of labor.

(5) A person who violates this section or a rule promulgated under this part is guilty of a misdemeanor.

(6) The department shall provide for a hardship waiver of the fee authorized under subsection (4) under circumstances found appropriate by the department.

(7) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1):

(a) By April 1, 2000, develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet at least all of the following requirements:

- (i) Be consistent with nationally recognized standards for laboratory accreditation and federal law.
- (ii) Require that the disposal be conducted in compliance with section 13811.
- (iii) Require that the disposal be conducted in the presence of a witness. For purposes of this subparagraph, the witness may be an individual involved in the disposal or any other individual.
- (iv) Require that a written record of the disposal be made and kept, and that the witness required under subparagraph (iii) signs the record.

(b) Allow the blood specimens to be used for medical research during the retention period established under subdivision (a), as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal regulations.

(8) The department shall rewrite its pamphlet explaining the requirements of this section when the supply of pamphlets in existence on March 15, 2000 is exhausted. When the department rewrites the explanatory pamphlet, it shall include at least all of the following information in the pamphlet:

(a) The nature and purpose of the testing program required under this section, including, but not limited to, a brief description of each condition or disorder listed in subsection (1).

(b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (9) in a safe place.

(c) The department's schedule for retaining and disposing of blood specimens developed under subsection (7)(a).

(d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) may be used for medical research pursuant to subsection (7)(b).

(9) In addition to the requirements of subsection (1), the health professional described in subsection (1) or the hospital or other facility in which the birth of an infant takes place, or both, may offer to draw an additional blood specimen from the infant. If such an offer is made, it shall be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of subsection (1). If the infant's parent, guardian, or person in loco parentis accepts the offer of an additional blood specimen, the blood specimen shall be preserved in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination. The health professional or hospital or other facility employee making the offer shall explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. The health professional or hospital or other facility making the offer may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 300, Eff. Mar. 31, 1987;—Am. 1987, Act 14, Imd. Eff. Apr. 14, 1987;—Am. 1988, Act 264, Imd. Eff. July 15, 1988;—Am. 1992, Act 81, Imd. Eff. June 2, 1992;—Am. 1998, Act 88, Imd. Eff. May 13, 1998;—Am. 1999, Act 138, Imd. Eff. Oct. 5, 1999;—Am. 2000, Act 33, Imd. Eff. Mar. 15, 2000;—Am. 2002, Act 691, Eff. Apr. 1, 2003.

Popular name: Act 368

Administrative rules: R 325.1471 et seq. of the Michigan Administrative Code.

PUBLIC HEALTH CODE (EXCERPT)

Act 368 of 1978

333.5430 Newborn screening quality assurance advisory committee; membership; appointment; screening tests; annual review of list; report; recommendations; approval or rejection by legislature.

Sec. 5430. (1) The newborn screening quality assurance advisory committee is created in the department. The newborn screening quality assurance advisory committee shall consist of 10 members and be appointed by the department as follows:

- (a) One individual representing a Michigan nonprofit health care corporation.
- (b) One individual representing the Michigan health and hospital association.
- (c) One individual representing the Michigan state medical society.
- (d) One individual representing the Michigan osteopathic association.
- (e) One individual representing the department's medical services administration.
- (f) One individual representing the department's public health administration.
- (g) One individual who is a neonatologist with experience and background in newborn screening.
- (h) One individual representing health maintenance organizations.
- (i) Two individuals representing the general public.

(2) The newborn screening quality assurance advisory committee shall meet annually to review the list of newborn screening tests required under section 5431 and under department rules, regulations, and guidelines. The newborn screening quality assurance advisory committee shall, on an annual basis, submit a written report to the department regarding the appropriateness of the existing list of required newborn screening tests. The newborn screening quality assurance advisory committee shall also include in the report recommendations to revise the list to include additional newborn screening tests that are nationally recognized in the scientific literature or national standards for conditions that can be ameliorated or treated if identified by a newborn screening test and to remove certain tests that are no longer supported in the scientific literature or national standard as being effective for ameliorating or treating conditions that can be identified by newborn screening.

(3) The newborn screening quality assurance advisory committee shall conduct a financial review of any recommended changes to the list of newborn screening tests and shall include in the written report required under subsection (2) a recommendation for the increase or decrease in the amount charged pursuant to section 5431 for newborn screening tests. The recommended change shall not exceed any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up.

(4) Within 30 days after the department has received the report required under subsection (2), the department may approve or reject the recommendations of the newborn screening quality assurance advisory committee. If the department does not reject the recommendations or fails to act within the 30 days, then the recommendations shall be forwarded to the standing committees in the senate and house of representatives that consider issues pertaining to public health for approval.

(5) Within 45 days after the recommendations are forwarded and received, the legislature shall approve or reject those recommendations without amendment by concurrent resolution adopted by both standing committees of the senate and house of representatives that consider issues pertaining to public health and both houses of the legislature by recorded vote. If the proposed recommendations are not submitted on a legislative session day, the 45 days commence on the first legislative session day after the recommendations are submitted. The 45 days shall include not less than 9 legislative session days. If the recommendations are not rejected within the 45-day period, the recommendations shall be considered approved, shall be adopted by the department, and shall take effect 6 months after the recommendations are adopted by both houses of the legislature or considered approved as provided under this subsection.

History: Add. 2006, Act 31, Imd. Eff. Feb. 23, 2006.

Popular name: Act 368

Appendix E. Work Group Agendas

Michigan Department of Community Health

Diet for Life Workgroup

October 15, 2013

Michigan Public Health Institute

Interactive Learning Center

INTRODUCTION FOR FAMILIES

11:00-11:10 pm	Introduction by Facilitators
11:10-11:30 pm	Family/Consumer Introductions
11:30-12:00 pm	Lunch
12:00-12:45pm	Panel Discussion
12:00-12:05	Newborn Screening
12:05-12:10	5 Minute Q&A
12:10-12:15	Women, Infants & Children (WIC)
12:15-12:20	5 Minute Q&A
12:20-12:25	Children's Special Health Care Services (CSHCS)
12:25-12:30	5 Minute Q&A
12:30-12:35	Medical Services Administration-Medicaid
12:35-12:40	5 Minute Q&A
12:40-12:45	Wrap up
12:45-1:00 pm	Break

DIET FOR LIFE WORK GROUP

Meeting #1

October 15, 2013

1 – 4 pm

Michigan Public Health Institute: Interactive Learning Center
2436 Woodlake Circle, Suite 380, Okemos, MI 48864

AGENDA

- | | |
|--------------|---|
| 1:00-1:15 pm | Welcome and Introductions
Melanie Brim, Senior Deputy Director, MDCH Public Health Administration
Lisa Gorman, Director, Region 4 Midwest Genetics Collaborative |
| 1:15-1:35 pm | Work Group Rationale, Objectives and Process
Sarah Lyon-Callo, Director
MDCH Lifecourse Epidemiology and Genomics Division |
| 1:35-1:55 pm | Overview of Metabolic Disorders
Gerald Feldman, MD, PhD
Wayne State University/Children’s Hospital of Michigan |
| 1:55-2:15 pm | Current Recommendations and Guidelines for Diet for Life
Gerald Feldman, MD, PhD |
| 2:15-2:30 pm | Diets for Individuals with PKU
June Ventimiglia, RD
Children’s Hospital of Michigan |
| 2:30-2:45 pm | Break |
| 2:45-3:00 pm | Diets for Individuals with Other Metabolic Disorders
Sue Lipinski, MPH, RD
University of Michigan |
| 3:00-3:30 pm | Family Perspectives
Patient and family work group members living with inborn errors of metabolism |
| 3:30-3:45 pm | Consensus on Common Definitions for Work Group
Lisa Gorman and work group members |
| 3:45-4:00 pm | Wrap-up and planning for next meeting
Additional information needed?
Other stakeholders needed at the table? |

DIET FOR LIFE WORK GROUP

Meeting #2- Focus on Adults

November 18, 2013

1 – 4 pm

**State of Michigan Library
702 West Kalamazoo Street
Forum, First Floor
Lansing, Michigan 48915**

AGENDA

- | | |
|--------------|--|
| 1:00-1:15 pm | Introductions & Overview of Meeting |
| 1:15-1:30 pm | Family Member Presentations:
Experience Obtaining Medical Food for Adult Patients |
| 1:30-1:45 pm | Review of Common Definitions:
Medical food, Low protein modified food |
| 1:45-2:10 pm | Review of Funding Source Grid and Selected State Models |
| 2:10-2:20 pm | Break |
| 2:20-2:25 pm | Overview of Group Discussion Process |
| 2:20-3:50 pm | Brainstorm Possible Solutions & Identify Facilitators and Barriers |
| 3:50-4:00 pm | Next Steps |

DIET FOR LIFE WORK GROUP

Meeting #2- Focus on Children

November 22, 2013

9 am – Noon

Michigan Department of Community Health

Capitol View Building

201 Townsend

First Floor, Conference Rooms A-C

Lansing, Michigan 48913

AGENDA

9:00-9:15 am	Introductions & Overview of Meeting
9:15-9:25 am	Family Member Presentations: Experience Obtaining Medical Food for Children
9:25-9:30 am	Review of Common Definitions: Medical food, Low protein modified food
9:30- 10:00 am	Review of Funding Source Grid and Selected State Models
10:00-10:05 am	Break
10:05-10:10 am	Overview of Group Discussion Process
10:10-11:50 am	Brainstorm Possible Solutions & Identify Facilitators and Barriers
11:50 am- noon	Next Steps

DIET FOR LIFE WORK GROUP

Meeting #3

January 13, 2014

1 – 4 pm

Capitol View Building- 1st Floor Conference Center
201 Townsend Street, Lansing, MI 48913

AGENDA

- 1:00-1:15 pm **Welcome and Introductions**
Mikelle Robinson, Public Health Administration
Lisa Gorman, Michigan Public Health Institute
- 1:15-1:30 pm **Family Member Presentations**
- 1:30-1:40 pm **Review of Background, Work Group Objectives and Process**
Lisa Gorman
- 1:40-2:50 pm **Presentation, discussion, and voting on components of a proposed model
for a Michigan nutritional treatment initiative**
Janice Bach, Genomics and Genetic Disorders Section,
Lisa Gorman and Work Group Members
- 2:50-3:00 pm **Conclusion and Next Steps**
Sarah Lyon-Callo, Lifecourse Epidemiology and Genomics Division
-

- 3:00-3:15 pm **Break**
- 3:15-4:00 pm **Wrap-up Meeting for Family Members**

Appendix F. Possible Funding Sources for Michigan Children and Young Adults for Nutritional Treatment of IEM

Funding Sources Available to Michigan Children & Young Adults for Dietary Treatment of Inborn Errors of Metabolism							
Population	CSHCS	Medicaid/Medicaid Health Plan	Medicare	WIC	Commercial insurance	Newborn Screening Contract	No Coverage
Children, 0-4 years	 Eligibility: Medical with annual fee to join based on income Covers: Formula & supplements based on medical need	 Eligibility: Based on income Covers: Formula & supplements based on medical need		 Eligibility: Based on income & other factors Covers: Limited authorization of special formulas for IEM	 Covers: Varies by plan; may have co-pays	 Eligibility: IEM detectable by NBS & seen at CHM clinic at least 1x/year Covers: Formula, occasional food & supplements	 Ability to purchase depends on income
Children, 5-17 years	 Eligibility: Medical with annual fee to join based on income Covers: Formula & supplements based on medical need	 Eligibility: Based on income Covers: Formula & supplements based on medical need			 Covers: Varies by plan; may have co-pays	 Eligibility: IEM detectable by NBS & seen at CHM clinic at least 1x/year Covers: Formula, occasional food & supplements	 Ability to purchase depends on income
Young Adults, 18-20 years	 Eligibility: Medical with annual fee to join based on income Covers: Formula & supplements based on medical need	 Eligibility: Based on income and under age 21 Covers: Formula & supplements based on medical need			 Covers: Varies by plan; may have co-pays	 Eligibility: IEM detectable by NBS & seen at CHM clinic at least 1x/year Covers: Formula, occasional food & supplements	 Ability to purchase depends on income

=Program eligibility with some level of coverage for low protein medical food products such as formula

= Program eligibility but currently limited coverage for low protein medical food products such as formula

IEM = Inborn Errors of Metabolism

Supplements = Medically necessary supplements, eg tyrosine

Note other possible sources: Food Assistance Programs; School lunch program, Medical food company hardship programs?

Appendix G. Possible Funding Sources for Michigan Adults for Nutritional Treatment of IEM

Funding Sources Available to Michigan Adults for Dietary Treatment of Inborn Errors of Metabolism							
Population	CSHCS	Medicaid/Medicaid Health Plan	Medicare	WIC	Commercial insurance	Newborn Screening Contract	No Coverage
Young Adults, 18-20 years	 Eligibility: Medical with annual fee to join based on income Covers: Formula & supplements based on medical need	 Eligibility: Based on income and under age 21 Covers: Formula & supplements based on medical need			 Covers: varies by plan; may have co-pays	 Eligibility: IEM detectable by NBS & seen at CHM clinic at least 1x/year Covers: Formula, occasional food & supplements	 Ability to purchase depends on income
Adults, 21-64 years		 Eligibility: Based on Social Security determination of medical disability OR based on income through Medicaid expansion Covers: Formula & supplements based on medical need	 Eligibility: Based on Social Security determination of medical disability Covers: Formula only in hospital or by tube feeding		 Covers: varies by plan; may have co-pays	 Eligibility: IEM detectable by NBS & seen at CHM clinic at least 1x/year; under 48 yrs Covers: Formula, occasional food & supplements	 Ability to purchase depends on income
Pregnant females		 Eligibility: Based on income; only while pregnant Covers: Formula & supplements based on medical need		 Eligibility: Based on income & other factors; only while pregnant or post-partum Covers: Limited authorization of special formulas for IEM			
Adults, over 65		 Eligibility: medically disabled based on Social Security determination Covers: Formula & supplements based on medical need	 Eligibility: Over age 65 Covers: Formula only in hospital or by tube feeding		 Covers: varies by plan; may have co-pays		

 =Program eligibility with some level of coverage for low protein medical food products such as formula

 = Program eligibility but currently limited coverage for low protein medical food products such as formula

IEM = Inborn Errors of Metabolism

Supplements = Medically necessary supplements, eg tyrosine

Note other possible sources: Food Assistance Programs; School lunch program, Medical food company hardship programs?

Appendix H. Michigan WIC Food Guide—Food Allowed on Metabolic Diets

Fresh Fruits & Vegetables

- Any variety fresh fruit or vegetable (except white potatoes) without added sweetener or fat
- May be whole, cut, bagged or packaged
- Sweet potatoes and yams

Whole Grains—Tortillas

- *Don Marcos* White Corn 18 count
- *Don Pancho* White Corn 18 count
- *Hacienda* Corn Maiz 18 count
- *La Burrita* Corn 12 count
- *Meijer* White Corn 18 count
- *Mission* Yellow Corn Extra Thin 24 count

Whole Grains – Bread

- *Meijer* Whole Grain White
- *Pepperidge Farm* Light Style Soft Wheat
- *Pepperidge Farm* Very Thin Sliced Soft 100% Whole Wheat

Cold Cereals—16 oz Package or larger

- *Cheerios* Plain
- *Dora the Explorer*
- *Kix* Plain.
- *Scooby-Doo!*
- *Mini-Wheats* Unfrosted
- *Mini-Wheats* Frosted
- *Mini-Wheats* Frosted Big Bite
- *Corn Flakes* Plain
- *Honey Bunches of Oats* Honey Roasted
- *Honey Bunches of Oats* Cinnamon Bunches
- *Honey Bunches of Oats* Fruit Blends Banana Blueberry
- *Honey Bunches of Oats* Fruit Blends Peach Raspberry
- *Honey Bunches of Oats* Tropical Blends Mango Coconut
- *Crispy Rice*

Cold Cereals—12 oz Package or larger

- *Chex* Rice
- *Store Brand* Corn Flakes
- *Crispy Rice* Corn Squares, Biscuits, Bitz

Juices for Women—48 oz plastic

- **Juicy Juice** Any flavor Added calcium allowed

Juice Concentrates for Women—Frozen—11.5 oz and 12 oz

- **Orange Juice** Any brand
- **Grapefruit Juice** Any brand or variety
- **Dole** Any flavor
- **Old Orchard** Any flavor with green peel strip
- **Welch's** Any flavor with yellow peel strip

Juice Concentrates for Women—Non Frozen—11.5 oz

- **Welch's** Any flavor with yellow band

Juices for Children—64 oz Plastic

- **Store Brand** Any store brand fruit juice
- **Everfresh** Apple, Kiwi Strawberry, Orange
- **Indian Summer** Apple Juice only
- **Juicy Juice** Any flavor
- **Old Orchard** Any flavor
- **Welch's Grape Juice** Grape, White Grape, Red Grape ONLY (*added calcium is **NOT** ALLOWED for Welch's*)

Infant Cereal—8 oz or 16 oz box/container

- Any brand dry infant cereal WITHOUT fruit, formula or DHA/ARA
- **CHOOSE ONLY:** barley, corn, oatmeal, mixed grain, multigrain, rice or whole wheat

Infant Fruits and Vegetables—4 oz glass jar or plastic tubs ONLY (multipacks allowed)

- Gerber
- Meijer Baby
- Meijer Naturals

Information courtesy of June Ventimiglia, RD, Children's Hospital of Michigan

Appendix I. Examples of State Metabolic Food Programs

Indiana

Mandate: Department's NBS program will ensure all Indiana residents with IEM diagnosed by NBS will have access to appropriate metabolic formula as follows:

- Single brand of metabolic formula for each metabolic condition on NBS will be designated by state contracted metabolic geneticist
- Appropriate metabolic formula will be made available regardless of individual's ability to pay or SES as follows:
 - Payment for formula will be on sliding scale as designated by department
 - All efforts will be made to collect payment for metabolic formula from private insurance companies or other third party payers
 - NBS program will serve as payer of last resort for patients without private insurance coverage or for whom reimbursement cannot be obtained by another third-party payer.

Iowa Metabolic Food and Formula Program

No insurance mandate

- **Mandate:** (641-4.3)(9) and (10) "Department shall include as part of this fee an amount determined by the committee and department to fund the provision of **special medical formula and foods** for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the [NBS] program..."
- Provided through the University of Iowa
 - Payments received from clients based on third-party payment, sliding fee scales and donations
 - Individuals with incomes at or above 185% of federal poverty level charged a fee
- "provision through this funding allocation shall be available only after individual has shown that all benefits from third-party payers including, but not limited to, health insurers, health maintenance organizations, Medicare, Medicaid, WIC and other government assistance programs have been exhausted."

Kentucky

- **Insurance mandate:** "Health plan that provides prescription drug coverage shall include in that coverage therapeutic food, formulas, supplements and low protein modified food products for the treatment of inborn errors of metabolism..."
 - Annual cap of \$25,000 for therapeutic food, formulas, and supplements
 - Separate annual cap of \$4,000 for low protein modified foods
- **Women, Infants and Children:** Cost of formula for eligible IC client, without other source of coverage, shall be covered by WIC
- **Mandate for Kentucky Metabolic Food and Formula Program:**
 - Verified Kentucky residents who do not qualify for another insurance program or whose insurance coverage is exhausted or denied
 - Medically necessary therapeutic foods, formulas, supplements and low protein modified food products
 - Products must be billed and denied before a person can seek coverage (including WIC, Medicaid, K-CHIP and private insurance)
 - Program works with DME providers, pharmacies and university metabolic centers
 - Provider shall submit prescription, authorization form and invoice from supplier to receive actual cost plus 20%
 - Source of funds is Vital Records fee of \$1 for certified copies of birth certificates

Louisiana

Insurance Mandate: requires coverage of low protein foods only up to \$200 per month; includes reimbursement by Medicaid. Medical food/formula not included in mandate but expect to amend this year.

- Dept. of Health And Hospitals, Genetic Diseases Program:
 - Serves as DME, bills Medicaid and insurance with 25% mark-up
 - Managed by Genetics Nutritionist Consultant; follows all children needing nutritional treatment, places food orders
 - Member of Minnesota Multistate Contracting Alliance for Pharmacy with distributor that delivers to every parish (county) by truck; patients pick up 3-month supply at a time
 - Covers all ages, most metabolic disorders
 - NBS fees used as safety net when insurance denies coverage

New Jersey

- **Mandate:** Individual, group or health service corporation medical health insurer, small employer health benefits, and HMO plans must cover therapeutic treatment of any inherited metabolic disease that is screened for in the state's NBS program
- Medical food and low protein modified food products covered
- Coverage mandated to be on *same basis as other conditions that are covered under the same plan.*
- Includes Medicare/Medicaid
- State Health Benefits Program also covers IEM
 - State employees and their families
 - 90% in-network; 70% out-of-network

Ohio

- **No mandates**
- Health Department provides metabolic formula to individuals with IEM
- Family will receive all required metabolic formula if:
 - Resident of Ohio
 - Receive care for specified IEM at an approved Ohio center
 - Apply annually to Bureau of Children with Medical Handicaps Treatment Program (if under 21)
 - Apply to Medicaid if financially eligible
 - Apply to WIC if <5 years and attend WIC appointments, if eligible
 - Consume formula as directed by metabolic dietician
- Formula shipped directly to patient's home
- Funds: portion of NBS fee, Bureau for Children with Medical Handicap Program, WIC

Oregon

- **Mandate:** Insurance coverage shall include expenses of diagnosing, monitoring and controlling the [inborn errors of metabolism] by nutritional and medical assessment, including but not limited to clinical visits, biochemical analysis and medical foods used in treatments of such disorders.
- **Oregon Medical Foods Program** provides all types of nutritional treatment:
 - Medical protein options
 - Low-protein medical foods labeled to be used under medical supervision
 - Conditional essential amino acids
 - Specific types of energy modules required by patients diagnosed with carbohydrate or fatty acid oxidation disorders
- Orders placed with Medical Food Inventory Administrator (MFIA), including updated insurance information
 - MFIA requests prior authorizations, obtains food from medical food inventory, packages order for shipment through UPS or family picks it up
 - Billing department issues claims to health plan providers (HCPC code S9435)
 - Patients billed if they are responsible for co-pay by their health plan
 - Oregon Medicaid patients are covered EXCEPT for non-disabled adults with PKU

Virginia

- **No Insurance Mandate**
- **Mandate:** Health department shall assist eligible persons in obtaining metabolic formula, low protein modified foods and metabolic supplements
- Expenditures shall be limited to available funding
- Applicants must demonstrate they are not eligible for other state/federal medical assistance program and that they do not have insurance coverage for products listed below
- **Formula Distribution and Purchase Plan**
 - Resident children <21 years with condition and meet financial eligibility for CSHCSN Program pool of funds may qualify to receive metabolic formula at no cost.
 - Resident adults ages 21+ with condition who have a gross family income at or below 300% of federal poverty level may qualify to receive metabolic formula at no cost
 - Resident adults age 21+ with condition who DO NOT meet financial criteria may qualify to purchase metabolic formula through the Virginia department of health.
- **Food/Supplement Reimbursement Plan**
 - Residents with condition who have a gross family income at or below 300% of federal poverty level may be eligible to receive reimbursement from the department of up to \$1,500 per year to purchase low protein modified foods and medical supplements.

Wisconsin

- **Mandate:** Department shall provide the special diet required upon recommendation of any physician who diagnoses a patient as having a medical disorder that requires a special dietary treatment.Shall impose a fee for tests performed... and shall include.... An amount the department determines is sufficient to fund the provision of special dietary treatment under this subsection.
- State NBS fee “surcharge” covers food and formula, no age limit
 - Clinicians in contracted clinics order food and formula off formulary; invoice the department
 - Projected operating deficit in 2010 led to fee increase and Task Force to address ways of reducing cost/increasing revenue
 - Currently \$50.50 per NBS screen for metabolic disease services: \$34 for medical foods, total ~\$2.38 million with ~\$1.6 million for low protein foods; remainder for clinical contracts.

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