F I S C A L I M P A C T R E P O R T

SPONSOR Garcia, R. **ORIGINAL DATE** 02/14/13 **LAST UPDATED** **HB** 480

SHORT TITLE Health Insurance for Metabolism Nutrition **SB**

ANALYST Geisler

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY13	FY14	FY15	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		NFI				

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
Public Regulation Commission (PRC)
Department of Health (DOH)
University of New Mexico Health Science Center (UNM/HSC)
Human Services Department (HSD)

SUMMARY

Synopsis of Bill

House Bill 480 (HB 480) would amend Section 59A-22-41.1 NMSA 1978, Coverage for Medical Diets for Genetic Inborn Errors of Metabolism. This Section, which has been in place since 2003, requires each individual and group health insurance policy, health care plan, certificate of health insurance, and managed health care plan to cover medical diets for genetic inborn errors of metabolism.

This bill would make the following changes to the Section:

- The prior limitation that the items would be covered only if "medically standard methods of diagnosis, treatment and monitoring exist" is being deleted and is replaced with broader language that extends coverage to an item "if a licensed physician issues a written order stating that the use of an amino-acid-based elemental formula is medically necessary."

- The prior requirement that "services" for this population will not be less than those available for physical illness generally under each insurance plan is being expanded to also include "medical supplies, prescription drugs, corrective lenses and special medical foods."

- A new provision is added to require that cost sharing provisions for medical foods will be equivalent to cost sharing for daily prescription medication for a 30 day supply and not based on a per meal or per day basis.

- The definition of "treatment" would be changed by removing the portion of the definition that says the provider must have "specific training in managing patients diagnosed with genetic inborn errors of metabolism" such that it now includes "licensed health care professionals, including physicians, dieticians and nutritionists" without reference to special training.

FISCAL IMPLICATIONS

No fiscal impact to state government noted.

SIGNIFICANT ISSUES

Genetic inborn errors of metabolism may result in profound illness in the affected patient that may be life-threatening in the first weeks of life. Fortunately, treatment in the form of special foods, prescription drugs, and other medical supplies can greatly improve outcomes. Prior to 2003, nutritional supplements and special diets and therapies related to these types of disorders were usually excluded from coverage under most insurance plans. Some insurance carriers viewed this as another mandated benefit that would raise premiums. Advocates argued that patients with these relatively rare metabolic disorders would ultimately cost insurance carriers far more with inpatient hospitalizations, and other complications rather than treatment provided on a preventive outpatient basis. Often the patient is a newborn or a young child and a relatively inexpensive medical diet can prevent a lifetime of medical problems and produce a contributing member of society. Please see additional information about these disorders and their treatment under "other substantive issues."

A few issues note by agencies include:

<u>Oversight over Prescriptions for Medical Foods, Supplies, Drugs</u>

The Human Services Department (HSD) notes that HB 480 would remove all possibility of any review of medical necessity for coverage as long as the prescriber states that the item is medically necessary. Since the bill also removes the requirements that the prescriber have "specific training in managing patients diagnosed with genetic inborn errors of metabolism" and that there be "medically standard methods of diagnosis, treatment and monitoring" for the condition, it is difficult to ensure that the covered items are appropriate, safe, or effective. Unlike prescription drug items on the market, the special food items do not always have national drug codes and federal Food and Drug Administration approval. A health care payer should be able to deny payment if there is no medical justification or no documented efficacy of the treatment.

The prescriber should be required to document the medical necessity of the treatment, not merely state that the item is medically necessary. This would bring the requirement more to generally accepted provisions for coverage of service and would likely be in the best interests of the patient also by assuring that only services and items known to be effective and safe are covered.

OTHER SUBSTANTIVE ISSUES

The UNM/HSC Provided Background on Genetic Inborn Errors of Metabolism

Inborn errors of metabolism are a large group of genetic disorders of biochemistry. The body is an extensive biochemical "machine" that processes the natural chemicals present in food to meet its needs for growth and development and energy production. Patients with inborn errors of metabolism have a genetic defect that precludes proper function of one of the many pathways involved in metabolism. Examples include phenylketonuria, maple syrup urine disease, propionic academia, methylmalonic academia and many others.

Treatment of many of these inborn errors is nutritional by restriction of an offending aspect of food, typically protein, to reduce the stress on the blocked metabolic pathway. For example, treatment with a low protein diet is needed in phenylketonuria to reduce the ingestion of phenylalanine and prevent its accumulation in the body. These nutritional manipulations are a standard of care and highly effective in the treatment of many of these disorders. The success has been such that New Mexico, and other states, has a newborn screening program to try and identify affected infants so that dietary therapy with medical foods can be instituted preventing the medical consequences of the untreated condition. As might be expected, these medical foods are highly processed and administered to a small number of patients. Hence, they are very expensive and represent a financial burden to the family. They do, however, represent the standard of medical care and are highly effective for the treatment of these conditions.

Additionally, cofactors such as vitamins are often used in inborn errors of metabolism. Vitamins are biochemicals that participate in biochemical reactions. Administration of pharmacologic amounts of vitamins may stimulate a defect pathway to proceed. And at times, there is a genetic defect in the normal processing of the vitamin that can be bypassed with pharmacologic amounts of a vitamin. It needs to be recognized by health coverage providers that these conditions have very specific medical reasons for administration of medical foods and cofactors and that there are not just give for "facilitation of health".

The major significant issue is that medical foods and cofactors are not necessarily FDA regulated. To stimulate the production of specific medical foods, approval has not typically been required. However, distribution of these foods still requires a prescription on the part of a medical provider and improper administration can result in nutritional deficiency. Pharmacies typically do not stock these medical foods but must order them on an as needed basis. Likewise, many vitamins are available over the counter. The purity and pharmacologic efficacy of these supplements is often not known. Many prescriptions for pharmacologic administration of vitamins are refused as they can be bought over-the-counter. This presents a financial burden to the family. It is also medical inappropriate as the vitamin is being prescribed for a very specific medical reason.

TECHNICAL ISSUES

The Department of Health (DOH) notes that the fairly broad coverage of treatment and medical food and supplies under 59A-22-41.1 Section B is contradicted to some extent by the new language in Section A, which appears to limit treatments only to disorders in "those instances where a physician issues a written order stating that the use of an amino-acid-based elemental formula is medically necessary." This leaves some ambiguity in relation to coverage for

treatments for children with inborn errors of metabolism related to carbohydrate and fat metabolism that might require special formulas other than those containing elemental amino acids. The previous law was not as specific and allowed for medical support for controlling inborn errors of metabolism that involved carbohydrate and fat metabolism for which standard methods of diagnosis, treatment, and monitoring exist. HB 480, as written, does not clarify what would be necessary for obtaining insurance coverage for treatment of all the other metabolic disorders. The DOH newborn screening program staff may be requested to help clients if issues arise with the health insurances ability to cover formula or foods for metabolic cases.

AMENDMENTS

The Public Regulation Commission (PRC) suggests that in order to mandate coverage for the treatment of genetic inborn errors of metabolism in group and blanket health insurance contracts, amend Subsection C of 59A-23-4 NMSA 1978 to include reference to Section 59A-22-41.1 NMSA 1978.

GG/svb