

SEP 19 2012

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58222
September 16, 2012

Dear Senator Lee,

This letter is to supplement my statement regarding the unique needs of children in an insurance policy. I understand that you questioned my statement regarding Medicaid's lack of coverage for specialty formula for metabolic disease. Attached are documents, including Medicaid's policy on enteral nutrition, which will hopefully clarify this issue.

These comments were provided for use at the Health Care Review Committee meeting held September 6, 2012, in which the consultative report comparing health insurance policies was discussed. Unfortunately, I was unable to attend that meeting due to a previously scheduled clinic. As noted in a copy of my written comments that I had provided for that meeting, Medicaid does not cover specialty formula for metabolic diseases. Also noted in my comments, North Dakota mandates coverage of specialty formula for maple syrup urine disease and phenylketonuria, with some specific age and gender requirements. North Dakota currently does not mandate insurance coverage of specialty formula for other types of metabolic disease. I have enclosed a copy of my comments, as well as the pertinent Medicaid policy and Century code, with the relevant areas highlighted for documentation of these statements.

I hope this information clarifies this for you. Specialty formula for metabolic diseases is one small piece of the giant pie of health care. As you tackle the wide variety of issues related to health care as a North Dakota Senator, I would be happy, and feel privileged, to be of service to you as a source. I appreciate your time in reading this letter.

Sincerely,

Joan M. Connell, MD

Pediatrician



UND Center for Family Medicine

Cc: Adam Hamm, North Dakota Insurance Commissioner

Representative George Keiser

Courtney Koebele, NDMA

Jennifer Clark-Legislative Council ✓

Sent: Monday, August 27, 2012 4:13 PM

To: afonkert@nd.gov; Gallup-Millner, Tammy L.; ckoebale@ndmed.com; Tiongson, Chris; Joan
Subject: North Dakota American Academy of Pediatrics response to consultative report

Dear Ms. Fonkert,

My name is Joan Connell. I am a pediatrician in Bismarck, ND. I currently serve as the vice president for the North Dakota Academy of Pediatrics. I appreciate you requesting feedback with regard to the consultative report that was provided regarding our state's options for choosing a health care benefit plan and what we value as essential health benefits. I appreciated the latter portion of this document which compared and contrasted the various options. I would like to reinforce some of the essential items relevant to children's health care benefits. Please note that the cost of the first 5 areas mentioned is really trivial in the grand scheme of the health care budget.

1. Provision for well child care using AAP endorsed Bright Futures criteria/recommendations for frequency of well checks. Essentially, this recommends well checks frequently in the first year of life, less frequently between ages 1 and 2 years, then annually thereafter. With well checks comes the necessity for coverage of

CDC recommended immunizations. This too needs to be a part of essential health benefits. It was not clear that the plans described will cover all recommended well checks, particularly those annual well checks occurring after age 2. These visits provide opportunities for a healthcare provider to monitor for signs of chronic disease, suboptimal development, discuss parenting and discipline issues, as well as establish a relationship with the child that will grow into an adolescent who may have needs related to risky behaviors and/or depression. Remember, the ND High School Activities Assn mandates a sports physical annually for all participants. This is one additional reason why annual well checks should be considered an essential health benefit in children >2 years of age. Also, given the broad scope of material that needs to be covered and the time required to do that in a comprehensive way, provision of these services must be associated with fair reimbursement.

2. Provision of habilitative and rehabilitative services. There are many studies that document the cost savings of early intervention services that can be utilized to optimize children's development. If we want to provide care in the most cost effective way, we need to take opportunities to intervene and fix small problems before they become large problems. Optimizing children's outcomes will optimize their future productivity as citizens. It appears that rehabilitative services will be included as part of essential health benefits. The particulars of these benefits must be customized for children and their needs as when it comes to meeting the healthcare needs of children, they cannot be considered "little adults". Children grow and develop, frequently with good responses to therapy. They therefore need to have items such as hearing aids and many pieces of durable medical equipment modified to account for their growing and changing bodies. Their therapy needs are also unique. This too may make their needs different from the adult population.

3. Provision for pharmaceuticals. I noticed that this was included in most/all of the plans. This provision should include medical food for patients with inborn errors of metabolism, including PKU. Our state currently mandates that formula be provided to all children and some adults with phenylketonuria and maple syrup urine disease, two diseases resulting from inborn errors of metabolism. Since the 1960s when this legislation was introduced, additional inborn errors of metabolism have been discovered. Those diseases often require specialty formula to optimize patient outcomes. Optimizing patient outcomes often times leads to overall less financial expenditure and superior patient outcomes, many times resulting in a more productive citizen. **Currently ND Medicaid does not provide for specialty formula for these other disease states. This is illogical and needs to be made a part of essential health benefits.**

4. Provision for treatment of mental illness. I noticed that not all plans included benefits for detoxification and residential treatment. I recently heard that North Dakota is currently the #1 binge drinking state in the nation. The experimental and risk taking behaviors typical of adolescence requires that detoxification be a component of health plans. I also believe that significant interventions, including residential treatment programs, may be most beneficial in the adolescent who is still somewhat capable of change and modification of bad behaviors. Furthermore, relocation of these particular children away from their dysfunctional environments to a setting that role models a healthier lifestyle may be imperative for successful long lasting changes in behavior to occur. We must stop thinking about short term costs and start thinking about investing in optimizing long term outcomes that will be overall financially efficient and result in a more productive citizen.

5. Vision and dental care. I understand that this is a new frontier. Children must be able to see the chalk/smart board, their books, etc to learn. Eyeglasses may be necessary. They must have good dentition to eat a standard healthy diet. These provisions, again, allow them to grow into healthy productive adults. I must say that refusing to pay for a dilated eye exam in a diabetic pediatric patient seems illogical. I would defer to the Children's Diabetes specialists/optometrists/ophthalmologists for recommendations on what is necessary for an appropriate annual eye exam in a child with diabetes.

6. Children with special health care needs. These children do account for the majority of pediatric health care expense. Determining health care benefits that will optimize their outcomes in a cost effective way is important. This applies to children with physical disabilities as well as mental/behavioral/developmental disabilities, including autism. Helping the families of these children avoid personal financial ruin due to holes in their children's health care coverage is also important and needs to be considered when determining a benefit plan. Keep in mind that one of the main goals of the Affordability Care Act is to prevent patients from "falling through the cracks". This is clearly an underinsured population.

Again, thank you for considering my comments. I would like to participate in the meeting September 6. However, I am in clinic that morning, which cannot be rescheduled. If it is possible to discuss issues relevant to the pediatric population later in the afternoon or if I may be of service to you at some other time, I would love to participate in this process. Thanks again for your time and consideration. Joan Connell, MD/Professor of

ENTERAL NUTRITION:

Prior authorization required
CMN REQUIRED (SFN 782)

Nutritional supplementation coverage through Medicaid is considered optional by CMS. The following outlines ND Medicaid's defined coverage of these products:

Approval Criteria:

1. Nasogastric or gastrostomy tube feeding
2. Malabsorption diagnoses including:
 - a. Short Bowel (Gut) Syndrome
 - b. Crohn's Disease
 - c. Pancreatic Insufficiency
3. Limited volumetric tolerance requiring a concentrated source of nutrition (i.e., athetoid cerebral palsy with high metabolic rate)
4. Severe swallowing and eating disorders where consistency and nutritional requirements can be met only using commercial nutritional supplements, including (refer below to non-covered swallowing and eating disorders):
 - a. Dysphagia due to excoriation of oral-pharyngeal mucosa
 - b. Mechanical swallowing dysfunction secondary to a disease process such as:
 - i. Cancer or herpetic stomatitis
 - ii. Other oral-pharyngeal tissue injury
5. Weight loss, with documentation providing the following information:
 - a. Normal weight, percentile weight, and number of pounds lost in a specified time period
 - b. A specific medical problem, which has caused the weight loss
 - c. Specific reasons why a diet of normal or pureed food cannot suffice
6. **Effective 1/1/2012 coverage added for HCPC code B4154 (Nutritionally complete formula, for special metabolic needs, excludes inherited disease of metabolism).** Examples include: Glucerna, Pulmocare, Renalcal, etc., Covered under the following criteria:
 - a. Patient must have a nasogastric or gastrostomy tube
 - b. The enteral nutrition formula must be the patients sole source (90%+) of nutrition

Non-Covered Diagnoses:

1. Swallowing disorders, which may lead to aspiration
2. Swallowing disorders, which are psychosomatic in nature, as in anorexia or dementia
3. Reduced appetite due to side effects of drug products, as with methylphenidate, amphetamines, appetite suppressants, etc.
4. Mastication problems due to dentition problems

Products considered for coverage:

ND Medicaid will only offer coverage for the following:

1. Products classified by First Data Bank (FDB) as Therapeutic Class Code, Specific C5F (e.g. Ensure, Pediasure, Boost, Resource)
2. B4154 (Nutritionally complete formula , for special metabolic needs, excludes inherited disease of metabolism)
 - a. Coverage for these B4154 products is effective for dates of service 1/1/2012 and after
 - b. Coverage for these B4154 products will only be allowed for patients
 - i. With nasogastric or gastrostomy tubes
 - ii. When the product is their sole source (90% +) of nutrition
3. Food thickeners

Products excluded from coverage:

ND Medicaid will not offer coverage for the following:

1. Infant formulas, nucleic acid/ nucleotide supplements, protein replacement, diet foods, geriatric supplements, sport shakes
2. Any product when used in amounts less than 51% of daily intake (must essentially be majority source of nutrition)
3. Nutritional products for persons living in TLC facilities (enteral products are included in the per diem).

Additional covered supplies:

1. Some enteral patients may experience complications associated with syringe or gravity method of administration and require a more controlled administration method. The pump may be covered if medically necessary and ordered by the physician. Documentation will be required to accompany the prior authorization to support pump therapy. (Example: gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not medically necessary.
2. Supply kits (B4034-B4036): Must correspond to the method of administration. Allowed one supply kit per day or maximum of 31 per month. Supply kits include all supplies, other than the feeding tube itself, required for the administration of enteral nutrients to the patient for one day.

- More than one gastrostomy/jejunostomy tube, or three nasogastric tubes every 3 months are rarely medically necessary.
- Dressings/anchoring devices are included in the supply kit and will not be paid separately.
- A revised CMN is necessary if the number of units per month, method of administration, route of administration or type of nutrition has changed.
- Recertification yearly unless required earlier due to change in orders/quantity.



MEDICAL SERVICES DIVISION

- No more than one month's supply of enteral nutrients, equipment or supplies are allowed for one month's prospective billing.
- B4087 and B4088 are the only codes allowed for gastrostomy/jejunostomy tubes. Must not use B9998.
- Pump & pump supplies are allowed if enteral nutrition is ordered for an infant. The nutrition is non-covered / no exception as infant formulas are non-covered regardless of age of recipient.

Policy Effective 1/1/2012

CHAPTER 23-41
CHILDREN WITH SPECIAL HEALTH CARE NEEDS

23-41-01. Definitions.

In this chapter unless the context or subject matter otherwise requires:

1. "County agency" means the county social service boards in this state.
2. "Department" means the state department of health.

23-41-02. Administration of services for children with special health care needs.

Services for children with special health care needs must be administered by the department in conformity with title 5, part 2, of the federal Social Security Act, as amended through July 1, 2007 [Pub. L. 74-271; 49 Stat. 620; 42 U.S.C. 701 et seq.].

23-41-03. Duties of the department.

The department, in administering this chapter, shall:

1. Cooperate with the federal government in the development of plans and policies for services for children with special health care needs.
2. Adopt rules and take any necessary action to entitle the state to receive aid from the federal government for services for children with special health care needs in conformity with title 5, part 2, of the federal Social Security Act and its amendments.
3. Take action, give directions, and adopt rules to carry out the provisions of this chapter, including the adoption and application of suitable standards and procedures to ensure uniform and equitable treatment of all applicants for services for children with special health care needs.
4. Cooperate with the federal government in matters of mutual concern pertaining to services to children with special health care needs, including the adoption of methods of administration found necessary by the federal government for the efficient operation of the plan for assistance.
5. Provide necessary qualified employees and representatives.
6. Establish and enforce a merit system as may be required under the federal Social Security Act, as amended through July 1, 2007 [Pub. L. 74-271; 49 Stat. 620; 42 U.S.C. 701 et seq.].
7. Make reports in the form and containing the information the federal government requires and comply with the provisions, rules, and regulations the federal government makes to assure the correctness and verification of a report.
8. Publish a biennial report and any interim reports necessary.
9. Provide medical food and low-protein modified food products to individuals with phenylketonuria or maple syrup urine disease under chapter 25-17.
10. Establish eligibility criteria for services under this chapter at one hundred eighty-five percent of the poverty line, except for criteria relating to Russell-Silver syndrome, phenylketonuria, or maple syrup urine disease treatment services for which income is not to be considered when determining eligibility. For purposes of this chapter, "poverty line" has the same meaning as defined in section 50-29-01.

23-41-04. Birth report of child with special health care needs made to department.

Within three days after the birth in this state of a child born with a visible congenital deformity, the licensed maternity hospital or home in which the child was born, or the legally qualified physician or other person in attendance at the birth of the child outside of a maternity hospital, shall furnish the department a report concerning the child with the information required by the department.

23-41-05. Birth report of child with special health care needs - Use - Confidential.

The information contained in the report furnished to the department under section 23-39-04 concerning a child with a visible congenital deformity may be used by the department for the care and treatment of the child pursuant to this chapter. The report is confidential and is solely

for the use of the department in the performance of its duties. The report is not open to public inspection nor considered a public record.

23-41-06. Duties of county agencies.

A county agency shall:

1. Cooperate with the department in administering this chapter in its county subject to rules adopted by the department.
2. Make surveys and reports regarding children with special health care needs in the various counties to the department when the department directs and in the way the department directs.
3. Provide for the transportation of a child with special health care needs to a clinic for medical examination and to a hospital or a clinic for treatment.

23-41-07. Russell-Silver syndrome - Services - Definitions.

1. The department shall provide payment of a maximum of fifty thousand dollars per child per biennium for medical food and growth hormone treatment at no cost to individuals through age eighteen who have been diagnosed with Russell-Silver syndrome, regardless of income. If the department provides an individual with services under this section, the department may seek reimbursement from any governmental program that provides coverage to that individual for the services provided. The parent of an individual receiving services under this section shall obtain any health insurance available to the parent on a group basis or through an employer or union, and that insurance must be the primary payer before payment under this program.
2. For purposes of this section:
 - a. "Growth hormone treatment" means a drug prescribed by a physician or other licensed practitioner for the long-term treatment of growth failure, the supplies necessary to administer the drug, one out-of-state physician visit per year to obtain expert consultation for the management of Russell-Silver syndrome, appropriate in-state physician visits, and the travel expenses associated with physician visits for the child and one parent.
 - b. "Medical food" means a formula that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered under the direction of a physician as well as any medical procedure and supplies necessary for assimilation of the formula.

CHAPTER 25-17
TESTING AND TREATMENT OF NEWBORNS

25-17-00.1. Definitions.

As used in this chapter, unless the context otherwise requires:

1. "Low-protein modified food product" means a food product that is specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of a metabolic disease. The term does not include a natural food that is naturally low in protein.
2. "Medical food" means a food that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered under the direction of a physician.
3. "Metabolic disease" and "genetic disease" mean a disease as designated by rule of the state health council for which early identification and timely intervention will lead to a significant reduction in mortality, morbidity, and associated disabilities.

25-17-01. Newborn screening education programs and tests.

The state department of health shall:

1. Develop and implement a metabolic and genetic disease educational program among physicians, hospital staffs, public health nurses, and the citizens of this state. This educational program must include information about the nature of the diseases and about screening for the early detection of these diseases so that proper measures may be taken to reduce mortality, morbidity, and associated disabilities.
2. Provide, on a statewide basis, a newborn screening system and short-term followup services for metabolic and genetic diseases.
3. Coordinate with or refer individuals to public and private health care service providers for long-term followup services for metabolic diseases or genetic diseases, or both.

25-17-02. Rulemaking requirement.

The state health council shall adopt rules necessary to implement this chapter.

25-17-03. Treatment for positive diagnosis - Registry of cases.

The state department of health shall:

1. Follow up with attending physicians cases with positive tests for metabolic diseases or genetic diseases, or both, in order to determine the exact diagnosis.
2. Refer every diagnosed case of a metabolic disease or genetic disease, or both, to a qualified health care provider for necessary treatment.
3. Maintain a registry of cases of metabolic and genetic diseases.
4. Provide medical food at no cost to males under age twenty-two and females under age forty-five who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income. If treatment services under this subsection are provided to an individual by the department, the department may seek reimbursement from any government program that provides coverage to that individual for the treatment services provided by the department.
5. Offer for sale at cost medical food to females age forty-five and over and to males age twenty-two and over who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income. These individuals are responsible for payment to the department for the cost of medical food.
6. Provide low-protein modified food products, if medically necessary as determined by a qualified health care provider, to females under age forty-five and males under age twenty-two who are receiving medical assistance and are diagnosed with phenylketonuria or maple syrup urine disease.

25-17-04. Testing and reporting requirements.

The physician attending a newborn child, or the birth attendant in the case of an out-of-hospital birth, shall provide the parents with written information regarding the nature of the proposed testing and then cause that newborn child to be subjected to testing for metabolic and genetic diseases, in the manner prescribed by the state department of health. A physician attending a patient with a metabolic disease or genetic disease, or both, shall report the case to the state department of health. The testing requirements of this section do not apply if the parents of a newborn child object to the testing.

25-17-05. Testing charges.

The state health council may adopt rules that establish reasonable fees and may impose those fees to cover the costs of administering tests under this chapter. All test fees collected by the state department of health must be deposited in the state department of health operating account.

CHAPTER 26.1-36
ACCIDENT AND HEALTH INSURANCE

26.1-36-01. Scope.

No section of this chapter applies to or affects any policy of workforce safety and insurance or any policy of liability insurance with or without supplementary expense coverage therein; or any policy or contract of reinsurance; or any blanket or group insurance policy, except when the section refers to a blanket or group insurance policy; or life insurance, endowment or annuity contracts, or contracts supplemental thereto which contain only such provisions relating to accident and sickness insurance as provide additional benefits in case of death or dismemberment or loss of sight by accident, or as operate to safeguard such contracts against lapse, or to give a special surrender value or special benefit or an annuity in the event that the insured or annuitant shall become totally and permanently disabled, as defined by the contract or supplemental contract.

26.1-36-02. Accident and health insurance policy defined.

"Accident and health insurance policy" includes any contract policy insuring against loss resulting from sickness or bodily injury, or death by accident, or both.

26.1-36-02.1. Accident and health policies and certificates - Notice of free examination.

Accident and health policies and certificates must have a notice prominently printed on or attached to the first page of the policy or certificate stating in substance that the applicant may return the policy or certificate within ten days of its delivery and have the premium refunded if, after examination of the policy or certificate, the applicant is not satisfied for any reason.

26.1-36-03. Form of policy.

1. No accident and health insurance policy may be delivered or issued for delivery to any person in this state unless:
 - a. The entire money and other considerations for the policy are expressed in the policy.
 - b. The time at which the insurance takes effect and terminates is expressed in the policy.
 - c. The policy purports to insure only one person, except that a policy may insure, originally or by subsequent amendment, upon the application of an adult member of a family who is deemed the policyholder, any two or more eligible members of that family, including spouse, dependent children or any children under a specified age which may not exceed twenty-two years, and any other person dependent upon the policyholder.
 - d. The style, arrangement, and overall appearance of the policy give no undue prominence to any portion of the text, and unless every printed portion of the text of the policy and of any endorsements or attached papers is plainly printed in lightfaced type of a style in general use, the size of which is uniform and not less than ten point with a lowercase unspaced alphabet length not less than one hundred twenty point. The "text" must include all printed matter except the name and address of the insurer, name or title of the policy, the brief description, if any, and captions and subcaptions.
 - e. The exceptions and reductions of indemnity are set forth in the policy and, except those which are set forth in section 26.1-36-04, are printed at the insurer's option, either included with the benefit provisions to which they apply, or under an appropriate caption such as "EXCEPTIONS" or "EXCEPTIONS AND REDUCTIONS". If an exception or reduction specifically applies only to a particular benefit of the policy, a statement of the exception or reduction must be included with the benefit provision to which it applies.

26.1-36-09.6. Health insurance policy and health service contract - Prostate-specific antigen test coverage.

An insurance company, nonprofit health service corporation, or health maintenance organization may not deliver, issue, execute, or renew any health insurance policy, health service contract, or evidence of coverage on an individual, group, blanket, franchise, or association basis unless the policy, contract, or evidence of coverage provides an annual digital rectal examination and a prostate-specific antigen test for an asymptomatic male aged fifty and over, a black male aged forty and over, and a male aged forty or over with a family history of prostate cancer.

26.1-36-09.7. Foods and food products for inherited metabolic diseases.

1. As used in this section:

- a. "Inherited metabolic disease" means maple syrup urine disease or phenylketonuria.
 - b. "Low-protein modified food product" means a food product that is specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease. The term does not include a natural food that is naturally low in protein.
 - c. "Medical food" means a food that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered under the direction of a physician.
2. An insurance company, nonprofit health service corporation, or health maintenance organization may not deliver, issue, execute, or renew any health insurance policy, health service contract, or evidence of coverage that provides prescription coverage on an individual, group, blanket, franchise, or association basis, unless the policy or contract provides, for any person covered under the policy or contract, coverage for medical foods and low-protein modified food products determined by a physician to be medically necessary for the therapeutic treatment of an inherited metabolic disease.
 3. This section applies to any covered individual born after December 31, 1962. This section does not require coverage in excess of three thousand dollars per year total for low-protein modified food products or medical food for an individual with an inherited metabolic disease of amino acid or organic acid.
 4. This section does not require medical benefits coverage for low-protein modified food products or medical food for an individual to the extent those benefits are available to that individual under a state department of health or department of human services program.

26.1-36-09.8. Health insurance policy and health service contract - Postdelivery coverage for mothers and newborns.

1. An insurance company, nonprofit health service corporation, or health maintenance organization may not deliver, issue, execute, or renew any health insurance policy, health service contract, or evidence of coverage that provides maternity benefits on an individual, group, blanket, franchise, or association basis unless the policy, contract, or evidence of coverage provides benefits, of the same type offered under the policy or contract for illnesses, for health services to any person covered under the policy or contract for:
 - a. Inpatient care for at least forty-eight hours for a mother and her newborn child following a normal vaginal delivery, and inpatient care for at least ninety-six hours following a caesarean section, without requiring the attending physician or health care provider to obtain authorization to care for a mother and her newborn child in the inpatient setting for this period of time.
 - b. Inpatient care in excess of forty-eight hours following a vaginal delivery and ninety-six hours following a caesarean section if the stay is determined to be reasonable and medically necessary.