

AN ACT relating to health benefit coverage of amino acid-based elemental formula.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 205.560 is amended to read as follows:

- (1) The scope of medical care for which the Cabinet for Health and Family Services undertakes to pay shall be designated and limited by regulations promulgated by the cabinet, pursuant to the provisions in this section. Within the limitations of any appropriation therefor, the provision of complete upper and lower dentures to recipients of Medical Assistance Program benefits who have their teeth removed by a dentist resulting in the total absence of teeth shall be a mandatory class in the scope of medical care. Payment to a dentist of any Medical Assistance Program benefits for complete upper and lower dentures shall only be provided on the condition of a preauthorized agreement between an authorized representative of the Medical Assistance Program and the dentist prior to the removal of the teeth. The selection of another class or other classes of medical care shall be recommended by the council to the secretary for health and family services after taking into consideration, among other things, the amount of federal and state funds available, the most essential needs of recipients, and the meeting of such need on a basis insuring the greatest amount of medical care as defined in KRS 205.510 consonant with the funds available, including but not limited to the following categories, except where the aid is for the purpose of obtaining an abortion:
 - (a) Hospital care, including drugs, and medical supplies and services during any period of actual hospitalization;
 - (b) Nursing-home care, including medical supplies and services, and drugs during confinement therein on prescription of a physician, dentist, or podiatrist;
 - (c) Drugs, nursing care, medical supplies, and services during the time when a recipient is not in a hospital but is under treatment and on the prescription of a physician, dentist, or podiatrist. For purposes of this paragraph, drugs shall

include products for the treatment of inborn errors of metabolism or genetic conditions, consisting of therapeutic food, formulas, supplements, *amino acid-based elemental formula*, or low-protein modified food products that are medically indicated for therapeutic treatment and are administered under the direction of a physician, and include but are not limited to the following conditions:

1. Phenylketonuria;
2. Hyperphenylalaninemia;
3. Tyrosinemia (types I, II, and III);
4. Maple syrup urine disease;
5. A-ketoacid dehydrogenase deficiency;
6. Isovaleryl-CoA dehydrogenase deficiency;
7. 3-methylcrotonyl-CoA carboxylase deficiency;
8. 3-methylglutaconyl-CoA hydratase deficiency;
9. 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG-CoA lyase deficiency);
10. B-ketothiolase deficiency;
11. Homocystinuria;
12. Glutaric aciduria (types I and II);
13. Lysinuric protein intolerance;
14. Non-ketotic hyperglycinemia;
15. Propionic acidemia;
16. Gyrate atrophy;
17. Hyperornithinemia/hyperammonemia/homocitrullinuria syndrome;
18. Carbamoyl phosphate synthetase deficiency;
19. Ornithine carbamoyl transferase deficiency;
20. Citrullinemia;

21. Arginosuccinic aciduria;
 22. Methylmalonic acidemia;~~[-and]~~
 23. Argininemia;
 - 24. Eosinophilic disorders; and**
 - 25. Short-bowel syndrome;**
- (d) Physician, podiatric, and dental services;
 - (e) Optometric services for all age groups shall be limited to prescription services, services to frames and lenses, and diagnostic services provided by an optometrist, to the extent the optometrist is licensed to perform the services and to the extent the services are covered in the ophthalmologist portion of the physician's program. Eyeglasses shall be provided only to children under age twenty-one (21);
 - (f) Drugs on the prescription of a physician used to prevent the rejection of transplanted organs if the patient is indigent;
 - (g) Nonprofit neighborhood health organizations or clinics where some or all of the medical services are provided by licensed registered nurses or by advanced medical students presently enrolled in a medical school accredited by the Association of American Medical Colleges and where the students or licensed registered nurses are under the direct supervision of a licensed physician who rotates his services in this supervisory capacity between two (2) or more of the nonprofit neighborhood health organizations or clinics specified in this paragraph;
 - (h) Services provided by health-care delivery networks as defined in KRS 216.900;
 - (i) Services provided by midlevel health-care practitioners as defined in KRS 216.900; and
 - (j) Smoking cessation treatment interventions or programs prescribed by a

physician, advanced practice registered nurse, physician assistant, or dentist, including but not limited to counseling, telephone counseling through a quitline, recommendations to the recipient that smoking should be discontinued, and prescription and over-the-counter medications and nicotine replacement therapy approved by the United States Food and Drug Administration for smoking cessation.

- (2) Payments for hospital care, nursing-home care, and drugs or other medical, ophthalmic, podiatric, and dental supplies shall be on bases which relate the amount of the payment to the cost of providing the services or supplies. It shall be one (1) of the functions of the council to make recommendations to the Cabinet for Health and Family Services with respect to the bases for payment. In determining the rates of reimbursement for long-term-care facilities participating in the Medical Assistance Program, the Cabinet for Health and Family Services shall, to the extent permitted by federal law, not allow the following items to be considered as a cost to the facility for purposes of reimbursement:
- (a) Motor vehicles that are not owned by the facility, including motor vehicles that are registered or owned by the facility but used primarily by the owner or family members thereof;
 - (b) The cost of motor vehicles, including vans or trucks, used for facility business shall be allowed up to fifteen thousand dollars (\$15,000) per facility, adjusted annually for inflation according to the increase in the consumer price index-u for the most recent twelve (12) month period, as determined by the United States Department of Labor. Medically equipped motor vehicles, vans, or trucks shall be exempt from the fifteen thousand dollar (\$15,000) limitation. Costs exceeding this limit shall not be reimbursable and shall be borne by the facility. Costs for additional motor vehicles, not to exceed a total of three (3) per facility, may be approved by the Cabinet for Health and Family Services if

- the facility demonstrates that each additional vehicle is necessary for the operation of the facility as required by regulations of the cabinet;
- (c) Salaries paid to immediate family members of the owner or administrator, or both, of a facility, to the extent that services are not actually performed and are not a necessary function as required by regulation of the cabinet for the operation of the facility. The facility shall keep a record of all work actually performed by family members;
 - (d) The cost of contracts, loans, or other payments made by the facility to owners, administrators, or both, unless the payments are for services which would otherwise be necessary to the operation of the facility and the services are required by regulations of the Cabinet for Health and Family Services. Any other payments shall be deemed part of the owner's compensation in accordance with maximum limits established by regulations of the Cabinet for Health and Family Services. Interest paid to the facility for loans made to a third party may be used to offset allowable interest claimed by the facility;
 - (e) Private club memberships for owners or administrators, travel expenses for trips outside the state for owners or administrators, and other indirect payments made to the owner, unless the payments are deemed part of the owner's compensation in accordance with maximum limits established by regulations of the Cabinet for Health and Family Services; and
 - (f) Payments made to related organizations supplying the facility with goods or services shall be limited to the actual cost of the goods or services to the related organization, unless it can be demonstrated that no relationship between the facility and the supplier exists. A relationship shall be considered to exist when an individual, including brothers, sisters, father, mother, aunts, uncles, and in-laws, possesses a total of five percent (5%) or more of ownership equity in the facility and the supplying business. An exception to

the relationship shall exist if fifty-one percent (51%) or more of the supplier's business activity of the type carried on with the facility is transacted with persons and organizations other than the facility and its related organizations.

- (3) No vendor payment shall be made unless the class and type of medical care rendered and the cost basis therefor has first been designated by regulation.
- (4) The rules and regulations of the Cabinet for Health and Family Services shall require that a written statement, including the required opinion of a physician, shall accompany any claim for reimbursement for induced premature births. This statement shall indicate the procedures used in providing the medical services.
- (5) The range of medical care benefit standards provided and the quality and quantity standards and the methods for determining cost formulae for vendor payments within each category of public assistance and other recipients shall be uniform for the entire state, and shall be designated by regulation promulgated within the limitations established by the Social Security Act and federal regulations. It shall not be necessary that the amount of payments for units of services be uniform for the entire state but amounts may vary from county to county and from city to city, as well as among hospitals, based on the prevailing cost of medical care in each locale and other local economic and geographic conditions, except that insofar as allowed by applicable federal law and regulation, the maximum amounts reimbursable for similar services rendered by physicians within the same specialty of medical practice shall not vary according to the physician's place of residence or place of practice, as long as the place of practice is within the boundaries of the state.
- (6) Nothing in this section shall be deemed to deprive a woman of all appropriate medical care necessary to prevent her physical death.
- (7) To the extent permitted by federal law, no medical assistance recipient shall be recertified as qualifying for a level of long-term care below the recipient's current level, unless the recertification includes a physical examination conducted by a

physician licensed pursuant to KRS Chapter 311 or by an advanced practice registered nurse licensed pursuant to KRS Chapter 314 and acting under the physician's supervision.

- (8) If payments made to community mental health centers, established pursuant to KRS Chapter 210, for services provided to the intellectually disabled exceed the actual cost of providing the service, the balance of the payments shall be used solely for the provision of other services to the intellectually disabled through community mental health centers.
- (9) No long-term-care facility, as defined in KRS 216.510, providing inpatient care to recipients of medical assistance under Title XIX of the Social Security Act on July 15, 1986, shall deny admission of a person to a bed certified for reimbursement under the provisions of the Medical Assistance Program solely on the basis of the person's paying status as a Medicaid recipient. No person shall be removed or discharged from any facility solely because they became eligible for participation in the Medical Assistance Program, unless the facility can demonstrate the resident or the resident's responsible party was fully notified in writing that the resident was being admitted to a bed not certified for Medicaid reimbursement. No facility may decertify a bed occupied by a Medicaid recipient or may decertify a bed that is occupied by a resident who has made application for medical assistance.
- (10) Family-practice physicians practicing in geographic areas with no more than one (1) primary-care physician per five thousand (5,000) population, as reported by the United States Department of Health and Human Services, shall be reimbursed one hundred twenty-five percent (125%) of the standard reimbursement rate for physician services.
- (11) The Cabinet for Health and Family Services shall make payments under the Medical Assistance program for services which are within the lawful scope of practice of a chiropractor licensed pursuant to KRS Chapter 312, to the extent the Medical

Assistance Program pays for the same services provided by a physician.

- (12) (a) The Medical Assistance Program shall use the appropriate form and guidelines for enrolling those providers applying for participation in the Medical Assistance Program, including those licensed and regulated under KRS Chapters 311, 312, 314, 315, and 320, any facility required to be licensed pursuant to KRS Chapter 216B, and any other health care practitioner or facility as determined by the Department for Medicaid Services through an administrative regulation promulgated under KRS Chapter 13A. A Medicaid managed care organization shall use the forms and guidelines established under KRS 304.17A-545(5) to credential a provider. For any provider who contracts with and is credentialed by a Medicaid managed care organization prior to enrollment, the cabinet shall complete the enrollment process and deny, or approve and issue a Provider Identification Number (PID) within fifteen (15) business days from the time all necessary completed enrollment forms have been submitted and all outstanding accounts receivable have been satisfied.
- (b) Within forty-five (45) days of receiving a correct and complete provider application, the Department for Medicaid Services shall complete the enrollment process by either denying or approving and issuing a Provider Identification Number (PID) for a behavioral health provider who provides substance use disorder services, unless the department notifies the provider that additional time is needed to render a decision for resolution of an issue or dispute.
- (c) Within forty-five (45) days of receipt of a correct and complete application for credentialing by a behavioral health provider providing substance use disorder services, a Medicaid managed care organization shall complete its contracting and credentialing process, unless the Medicaid managed care organization

notifies the provider that additional time is needed to render a decision. If additional time is needed, the Medicaid managed care organization shall not take any longer than ninety (90) days from receipt of the credentialing application to deny or approve and contract with the provider.

- (d) A Medicaid managed care organization shall adjudicate any clean claims submitted for a substance use disorder service from an enrolled and credentialed behavioral health provider who provides substance use disorder services in accordance with KRS 304.17A-700 to 304.17A-730.
 - (e) The Department of Insurance may impose a civil penalty of one hundred dollars (\$100) per violation when a Medicaid managed care organization fails to comply with this section. Each day that a Medicaid managed care organization fails to pay a claim may count as a separate violation.
- (13) Dentists licensed under KRS Chapter 313 shall be excluded from the requirements of subsection (12) of this section. The Department for Medicaid Services shall develop a specific form and establish guidelines for assessing the credentials of dentists applying for participation in the Medical Assistance Program.

➔Section 2. KRS 213.141 is amended to read as follows:

- (1) Except as provided in subsection (2) of this section, the cabinet shall prescribe by regulation a fee not to exceed five dollars (\$5), to be paid for certified copies of certificates or records, or for a search of the files or records when no copy is made, or for copies or information provided for research, statistical, or administrative purposes.
- (2) The cabinet shall prescribe by administrative regulation pursuant to KRS Chapter 13A a fee not to exceed ten dollars (\$10) to be paid for a certified copy of a record of a birth:
 - (a) Three dollars (\$3) of which shall be used by the Cabinet for Health and Family Services for the sole purpose of contracting for the operation of

private, not-for-profit, self-help, education, and support groups for parents who want to prevent or cease physical, sexual, or mental abuse of children; and

- (b) One dollar (\$1) of which shall be used by the Division of Maternal and Child Health to pay for therapeutic food, formulas, supplements, *amino acid-based elemental formula*, or low-protein modified foods for all inborn errors of metabolism and genetic conditions if:
 1. The therapeutic food, formulas, supplements, *amino acid-based elemental formula*, or low-protein modified food products are medically indicated for the therapeutic treatment of inborn errors of metabolism or genetic conditions and are administered under the direction of a physician; and
 2. The affected person's therapeutic food, formulas, supplements, *amino acid-based elemental formula*, or low-protein foods are not covered under any public or private health benefit plan.
- (3) Fees collected under this section by the state registrar shall be used to help defray the cost of administering the system of vital statistics.
- (4) (a) No fee or compensation shall be allowed or paid for furnishing certificates of birth or death required in support of any claim against the government for compensation, insurance, back pay, or other allowances or benefits for any person who has at any time served as a member of the Army, Navy, Marine Corps, or Air Force of the United States.
 - (b) No fee or compensation shall be allowed or paid for furnishing a certificate of birth to a member of the Kentucky National Guard who has received deployment orders during the sixty (60) days prior to the furnishing of the certificate.
- (5) The cabinet shall notify the State Board of Elections monthly of the name, address,

birthdate, sex, race, and Social Security number of residents of the Commonwealth who died during the previous month. This data shall include only those persons who were over the age of eighteen (18) years at the date of death. No fee or compensation shall be allowed for furnishing these lists.

➔Section 3. KRS 304.17A-258 is amended to read as follows:

(1) For purposes of this section:

(a) "Therapeutic food, formulas, and supplements" means products intended for the dietary treatment of inborn errors of metabolism or genetic conditions under the direction of a physician;~~and~~

(b) "Low-protein modified food" means a product formulated to have less than one (1) gram of protein per serving and intended for the dietary treatment of inborn errors of metabolism or genetic conditions under the direction of a physician; and

(c) "Amino acid-based elemental formula" means a product intended for the diagnosis and dietary treatment of eosinophilic disorders and short-bowel syndrome under the direction of a physician.

(2) A health benefit plan that provides prescription drug coverage shall include in that coverage therapeutic food, formulas, supplements, amino acid-based elemental formula, and low-protein modified food products for the treatment of inborn errors of metabolism or genetic conditions if the therapeutic food, formulas, supplements, amino acid-based elemental formula, and low-protein modified food products are obtained for the therapeutic treatment of inborn errors of metabolism or genetic conditions under the direction of a physician. Coverage under this subsection may be subject, for each plan year, to a cap of twenty-five thousand dollars (\$25,000) for therapeutic food, formulas, amino acid-based elemental formula, and supplements and a separate cap for each plan year of four thousand dollars (\$4,000) on low-protein modified foods. Each cap shall be subject to annual inflation adjustments

based on the consumer price index.

- (3) The requirements of this section shall apply to all health benefit plans issued or renewed on and after *the effective date of this Act*~~[July 15, 2008]~~.
- (4) Nothing in this section or KRS 205.560, 213.141, or 214.155 shall be construed to require a health benefit plan to provide coverage for therapeutic foods, formulas, supplements, *amino acid-based elemental formula*, or low-protein modified food for the treatment of lactose intolerance, protein intolerance, food allergy, food sensitivity, or any other condition or disease that is not an inborn error of metabolism or genetic condition.

➔Section 4. This Act may be cited as Noah's Law.