FIRST REGULAR SESSION

HOUSE BILL NO. 1589

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE VEIT.

3181H.01I JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal sections 191.300 and 208.152, RSMo, and to enact in lieu thereof four new sections relating to medical testing.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 191.300 and 208.152, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 191.300, 191.312, 208.152, and 376.1270, to read as follows:

191.300. As used in sections 191.300 to 191.380, the following terms mean:

(1) "Committee", the Missouri genetic disease advisory committee;

(2) "Cystic fibrosis", a serious lung problem of children; an inherited disorder which produces chronic involvement of the respiratory and digestive systems;

(3) "Department", the department of health and senior services;

(4) "Director", the director of the state department of health and senior services;

(5) "Genetic counseling", the provision and interpretation of medical information based on expanding knowledge of human genetics;

(6) "Genetic disorders", abnormalities of structure, function, or body metabolism which may be inherited or may result from damage to the fetus;

(7) "Genetic screening", the search through testing for persons with genetic disorders;

(8) "Health care professional", a physician or other health care practitioner licensed, accredited, or certified by the state of Missouri to perform specified health services;

(9) "Health care services", services for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease;

EXPLANATION — Matter enclosed in bold-faced brackets **[**~~thus~~**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(10) "Hemophilia", a bleeding tendency resulting from a genetically determined deficiency factor in the blood;

(11) "Outreach clinics", medical clinics which provide genetic diagnosis and counseling at sites away from the tertiary genetic centers;

(12) **"Pediatric rare diseases", any rare diseases with onset primarily in childhood and typically genetic in nature that affect fewer than two hundred thousand individuals in the United States;**

(13) "Program", the genetic program authorized by the provisions of sections 191.300 to 191.331, 191.340, and 191.365 to 191.380;

[~~(13)~~**] (14)** "Sickle cell anemia", a blood disease characterized by the presence of crescent shaped or sickle shaped erythrocytes in peripheral blood, excessive hemolysis, and active hematopoiesis, resulting from a genetic defect;

[~~(14)~~**] (15)** "Sickle cell trait", the healthy state wherein one carries the gene for sickle cell and could possibly pass that gene to his offspring;

[~~(15)~~**] (16)** "Tertiary genetic centers", permanent genetic divisions that provide comprehensive diagnostic treatment and counseling services.

191.312. 1. The department shall offer a comment period open to the public each year in which members of the public, such as patient advocacy organizations, research institutions, health care providers, and other stakeholders, may offer comments and information pertaining to best practices in genetically based newborn screening for pediatric rare diseases.

2. The department shall annually seek out information and research updates from prenatal and early childhood genetic screening research organizations including, but not limited to, SeqFirst, GUARDIAN Study, and Early Check.

3. The department shall prepare an annual report for the governor and general assembly no later than December thirty-first each year summarizing the department's findings under this section and recommendations for any updates to newborn screening for pediatric rare diseases.

208.152. 1. MO HealthNet payments shall be made on behalf of those eligible needy persons as described in section 208.151 who are unable to provide for it in whole or in part, with any payments to be made on the basis of the reasonable cost of the care or reasonable charge for the services as defined and determined by the MO HealthNet division, unless otherwise hereinafter provided, for the following:

(1) Inpatient hospital services, except to persons in an institution for mental diseases who are under the age of sixty-five years and over the age of twenty-one years; provided that the MO HealthNet division shall provide through rule and regulation an exception process for coverage of inpatient costs in those cases requiring treatment beyond the seventy-fifth

percentile professional activities study (PAS) or the MO HealthNet children's diagnosis length-of-stay schedule; and provided further that the MO HealthNet division shall take into account through its payment system for hospital services the situation of hospitals which serve a disproportionate number of low-income patients;

(2) All outpatient hospital services, payments therefor to be in amounts which represent no more than eighty percent of the lesser of reasonable costs or customary charges for such services, determined in accordance with the principles set forth in Title XVIII A and B, Public Law 89-97, 1965 amendments to the federal Social Security Act (42 U.S.C. Section 301, et seq.), but the MO HealthNet division may evaluate outpatient hospital services rendered under this section and deny payment for services which are determined by the MO HealthNet division not to be medically necessary, in accordance with federal law and regulations;

(3) Laboratory and X-ray services;

(4) Nursing home services for participants, except to persons with more than five hundred thousand dollars equity in their home or except for persons in an institution for mental diseases who are under the age of sixty-five years, when residing in a hospital licensed by the department of health and senior services or a nursing home licensed by the department of health and senior services or appropriate licensing authority of other states or government-owned and -operated institutions which are determined to conform to standards equivalent to licensing requirements in Title XIX of the federal Social Security Act (42 U.S.C. Section 301, et seq.), as amended, for nursing facilities. The MO HealthNet division may recognize through its payment methodology for nursing facilities those nursing facilities which serve a high volume of MO HealthNet patients. The MO HealthNet division when determining the amount of the benefit payments to be made on behalf of persons under the age of twenty-one in a nursing facility may consider nursing facilities furnishing care to persons under the age of twenty-one as a classification separate from other nursing facilities;

(5) Nursing home costs for participants receiving benefit payments under subdivision (4) of this subsection for those days, which shall not exceed twelve per any period of six consecutive months, during which the participant is on a temporary leave of absence from the hospital or nursing home, provided that no such participant shall be allowed a temporary leave of absence unless it is specifically provided for in his **or her** plan of care. As used in this subdivision, the term "temporary leave of absence" shall include all periods of time during which a participant is away from the hospital or nursing home overnight because he **or she** is visiting a friend or relative;

(6) Physicians' services, whether furnished in the office, home, hospital, nursing home, or elsewhere, provided, that no funds shall be expended to any abortion facility, as

defined in section 188.015, or to any affiliate, as defined in section 188.015, of such abortion facility;

(7) Subject to appropriation, up to twenty visits per year for services limited to examinations, diagnoses, adjustments, and manipulations and treatments of malpositioned articulations and structures of the body provided by licensed chiropractic physicians practicing within their scope of practice. Nothing in this subdivision shall be interpreted to otherwise expand MO HealthNet services;

(8) Drugs and medicines when prescribed by a licensed physician, dentist, podiatrist, or an advanced practice registered nurse; except that no payment for drugs and medicines prescribed on and after January 1, 2006, by a licensed physician, dentist, podiatrist, or an advanced practice registered nurse may be made on behalf of any person who qualifies for prescription drug coverage under the provisions of P.L. 108-173;

(9) Emergency ambulance services and, effective January 1, 1990, medically necessary transportation to scheduled, physician-prescribed nonelective treatments;

(10) Early and periodic screening and diagnosis of individuals who are under the age of twenty-one to ascertain their physical or mental defects, and health care, treatment, and other measures to correct or ameliorate defects and chronic conditions discovered thereby. Such services shall be provided in accordance with the provisions of Section 6403 of P.L. 101-239 and federal regulations promulgated thereunder;

(11) Home health care services;

(12) Family planning as defined by federal rules and regulations; provided, that no funds shall be expended to any abortion facility, as defined in section 188.015, or to any affiliate, as defined in section 188.015, of such abortion facility; and further provided, however, that such family planning services shall not include abortions or any abortifacient drug or device that is used for the purpose of inducing an abortion unless such abortions are certified in writing by a physician to the MO HealthNet agency that, in the physician's professional judgment, the life of the mother would be endangered if the fetus were carried to term;

(13) Inpatient psychiatric hospital services for individuals under age twenty-one as defined in Title XIX of the federal Social Security Act (42 U.S.C. Section 1396d, et seq.);

(14) Outpatient surgical procedures, including presurgical diagnostic services performed in ambulatory surgical facilities which are licensed by the department of health and senior services of the state of Missouri; except, that such outpatient surgical services shall not include persons who are eligible for coverage under Part B of Title XVIII, Public Law 89-97, 1965 amendments to the federal Social Security Act, as amended, if exclusion of such persons is permitted under Title XIX, Public Law 89-97, 1965 amendments to the federal Social Security Act, as amended;

(15) Personal care services which are medically oriented tasks having to do with a person's physical requirements, as opposed to housekeeping requirements, which enable a person to be treated by his or her physician on an outpatient rather than on an inpatient or residential basis in a hospital, intermediate care facility, or skilled nursing facility. Personal care services shall be rendered by an individual not a member of the participant's family who is qualified to provide such services where the services are prescribed by a physician in accordance with a plan of treatment and are supervised by a licensed nurse. Persons eligible to receive personal care services shall be those persons who would otherwise require placement in a hospital, intermediate care facility, or skilled nursing facility. Benefits payable for personal care services shall not exceed for any one participant one hundred percent of the average statewide charge for care and treatment in an intermediate care facility for a comparable period of time. Such services, when delivered in a residential care facility or assisted living facility licensed under chapter 198**,** shall be authorized on a tier level based on the services the resident requires and the frequency of the services. A resident of such facility who qualifies for assistance under section 208.030 shall, at a minimum, if prescribed by a physician, qualify for the tier level with the fewest services. The rate paid to providers for each tier of service shall be set subject to appropriations. Subject to appropriations, each resident of such facility who qualifies for assistance under section 208.030 and meets the level of care required in this section shall, at a minimum, if prescribed by a physician, be authorized up to one hour of personal care services per day. Authorized units of personal care services shall not be reduced or tier level lowered unless an order approving such reduction or lowering is obtained from the resident's personal physician. Such authorized units of personal care services or tier level shall be transferred with such resident if he or she transfers to another such facility. Such provision shall terminate upon receipt of relevant waivers from the federal Department of Health and Human Services. If the Centers for Medicare and Medicaid Services determines that such provision does not comply with the state plan, this provision shall be null and void. The MO HealthNet division shall notify the revisor of statutes as to whether the relevant waivers are approved or a determination of noncompliance is made;

(16) Mental health services. The state plan for providing medical assistance under Title XIX of the Social Security Act, 42 U.S.C. Section 301, as amended, shall include the following mental health services when such services are provided by community mental health facilities operated by the department of mental health or designated by the department of mental health as a community mental health facility or as an alcohol and drug abuse facility or as a child-serving agency within the comprehensive children's mental health service system established in section 630.097. The department of mental health shall establish by administrative rule the definition and criteria for designation as a community mental health

facility and for designation as an alcohol and drug abuse facility. Such mental health services shall include:

(a) Outpatient mental health services including preventive, diagnostic, therapeutic, rehabilitative, and palliative interventions rendered to individuals in an individual or group setting by a mental health professional in accordance with a plan of treatment appropriately established, implemented, monitored, and revised under the auspices of a therapeutic team as a part of client services management;

(b) Clinic mental health services including preventive, diagnostic, therapeutic, rehabilitative, and palliative interventions rendered to individuals in an individual or group setting by a mental health professional in accordance with a plan of treatment appropriately established, implemented, monitored, and revised under the auspices of a therapeutic team as a part of client services management;

(c) Rehabilitative mental health and alcohol and drug abuse services including home and community-based preventive, diagnostic, therapeutic, rehabilitative, and palliative interventions rendered to individuals in an individual or group setting by a mental health or alcohol and drug abuse professional in accordance with a plan of treatment appropriately established, implemented, monitored, and revised under the auspices of a therapeutic team as a part of client services management. As used in this section, mental health professional and alcohol and drug abuse professional shall be defined by the department of mental health pursuant to duly promulgated rules. With respect to services established by this subdivision, the department of social services, MO HealthNet division, shall enter into an agreement with the department of mental health. Matching funds for outpatient mental health services, clinic mental health services, and rehabilitation services for mental health and alcohol and drug abuse shall be certified by the department of mental health to the MO HealthNet division. The agreement shall establish a mechanism for the joint implementation of the provisions of this subdivision. In addition, the agreement shall establish a mechanism by which rates for services may be jointly developed;

(17) Such additional services as defined by the MO HealthNet division to be furnished under waivers of federal statutory requirements as provided for and authorized by the federal Social Security Act (42 U.S.C. Section 301, et seq.) subject to appropriation by the general assembly;

(18) The services of an advanced practice registered nurse with a collaborative practice agreement to the extent that such services are provided in accordance with chapters 334 and 335, and regulations promulgated thereunder;

(19) Nursing home costs for participants receiving benefit payments under subdivision (4) of this subsection to reserve a bed for the participant in the nursing home

during the time that the participant is absent due to admission to a hospital for services which cannot be performed on an outpatient basis, subject to the provisions of this subdivision:

(a) The provisions of this subdivision shall apply only if:

a. The occupancy rate of the nursing home is at or above ninety-seven percent of MO HealthNet certified licensed beds, according to the most recent quarterly census provided to the department of health and senior services which was taken prior to when the participant is admitted to the hospital; and

b. The patient is admitted to a hospital for a medical condition with an anticipated stay of three days or less;

(b) The payment to be made under this subdivision shall be provided for a maximum of three days per hospital stay;

(c) For each day that nursing home costs are paid on behalf of a participant under this subdivision during any period of six consecutive months such participant shall, during the same period of six consecutive months, be ineligible for payment of nursing home costs of two otherwise available temporary leave of absence days provided under subdivision (5) of this subsection; and

(d) The provisions of this subdivision shall not apply unless the nursing home receives notice from the participant or the participant's responsible party that the participant intends to return to the nursing home following the hospital stay. If the nursing home receives such notification and all other provisions of this subsection have been satisfied, the nursing home shall provide notice to the participant or the participant's responsible party prior to release of the reserved bed;

(20) Prescribed medically necessary durable medical equipment. An electronic web-based prior authorization system using best medical evidence and care and treatment guidelines consistent with national standards shall be used to verify medical need;

(21) Hospice care. As used in this subdivision, the term "hospice care" means a coordinated program of active professional medical attention within a home, outpatient and inpatient care which treats the terminally ill patient and family as a unit, employing a medically directed interdisciplinary team. The program provides relief of severe pain or other physical symptoms and supportive care to meet the special needs arising out of physical, psychological, spiritual, social, and economic stresses which are experienced during the final stages of illness, and during dying and bereavement and meets the Medicare requirements for participation as a hospice as are provided in 42 CFR Part 418. The rate of reimbursement paid by the MO HealthNet division to the hospice provider for room and board furnished by a nursing home to an eligible hospice patient shall not be less than ninety-five percent of the rate of reimbursement which would have been paid for facility services in that nursing home

facility for that patient, in accordance with subsection (c) of Section 6408 of P.L. 101-239 (Omnibus Budget Reconciliation Act of 1989);

(22) Prescribed medically necessary dental services. Such services shall be subject to appropriations. An electronic web-based prior authorization system using best medical evidence and care and treatment guidelines consistent with national standards shall be used to verify medical need;

(23) Prescribed medically necessary optometric services. Such services shall be subject to appropriations. An electronic web-based prior authorization system using best medical evidence and care and treatment guidelines consistent with national standards shall be used to verify medical need;

(24) Blood clotting products-related services. For persons diagnosed with a bleeding disorder, as defined in section 338.400, reliant on blood clotting products, as defined in section 338.400, such services include:

(a) Home delivery of blood clotting products and ancillary infusion equipment and supplies, including the emergency deliveries of the product when medically necessary;

(b) Medically necessary ancillary infusion equipment and supplies required to administer the blood clotting products; and

(c) Assessments conducted in the participant's home by a pharmacist, nurse, or local home health care agency trained in bleeding disorders when deemed necessary by the participant's treating physician;

(25) **Subject to appropriations and necessary federal approval, genetic screening for pediatric rare diseases. Such screening shall include:**

(a) Rapid whole genome sequencing in inpatient settings for patients who are under twenty-two years of age; who have a complex or acute illness of unknown origin not attributed to environmental factors, toxic ingestion, infection with a normal response, or trauma; and for whom the treating health care provider determines that an immediate molecular diagnosis is necessary to provide clinical decision-making; and

(b) Biomarker testing in outpatient care settings for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a participant's disease or condition to guide treatment decisions if deemed medically necessary. Testing may be medically necessary if the testing is clinically appropriate as deemed by the treating health care provider to guide treatment, the findings of the test may directly impact the participant's treatment plan, and the patient presents complex or unexplained symptoms consistent with a potential genetic etiology. There shall be no age restriction on biomarker testing in outpatient settings.

The department of social services shall seek any necessary waivers or state plan amendments from the Centers for Medicare and Medicaid Services to implement the provisions of this subdivision;

(26) The MO HealthNet division shall, by January 1, 2008, and annually thereafter, report the status of MO HealthNet provider reimbursement rates as compared to one hundred percent of the Medicare reimbursement rates and compared to the average dental reimbursement rates paid by third-party payors licensed by the state. The MO HealthNet division shall, by July 1, 2008, provide to the general assembly a four-year plan to achieve parity with Medicare reimbursement rates and for third-party payor average dental reimbursement rates. Such plan shall be subject to appropriation and the division shall include in its annual budget request to the governor the necessary funding needed to complete the four-year plan developed under this subdivision.

2. Additional benefit payments for medical assistance shall be made on behalf of those eligible needy children, pregnant women and blind persons with any payments to be made on the basis of the reasonable cost of the care or reasonable charge for the services as defined and determined by the MO HealthNet division, unless otherwise hereinafter provided, for the following:

(1) Dental services;

(2) Services of podiatrists as defined in section 330.010;

(3) Optometric services as described in section 336.010;

(4) Orthopedic devices or other prosthetics, including eye glasses, dentures, hearing aids, and wheelchairs;

(5) Hospice care. As used in this subdivision, the term "hospice care" means a coordinated program of active professional medical attention within a home, outpatient and inpatient care which treats the terminally ill patient and family as a unit, employing a medically directed interdisciplinary team. The program provides relief of severe pain or other physical symptoms and supportive care to meet the special needs arising out of physical, psychological, spiritual, social, and economic stresses which are experienced during the final stages of illness, and during dying and bereavement and meets the Medicare requirements for participation as a hospice as are provided in 42 CFR Part 418. The rate of reimbursement paid by the MO HealthNet division to the hospice provider for room and board furnished by a nursing home to an eligible hospice patient shall not be less than ninety-five percent of the rate of reimbursement which would have been paid for facility services in that nursing home facility for that patient, in accordance with subsection (c) of Section 6408 of P.L. 101-239 (Omnibus Budget Reconciliation Act of 1989);

(6) Comprehensive day rehabilitation services beginning early posttrauma as part of a coordinated system of care for individuals with disabling impairments. Rehabilitation

services must be based on an individualized, goal-oriented, comprehensive and coordinated treatment plan developed, implemented, and monitored through an interdisciplinary assessment designed to restore an individual to **an** optimal level of physical, cognitive, and behavioral function. The MO HealthNet division shall establish by administrative rule the definition and criteria for designation of a comprehensive day rehabilitation service facility, benefit limitations and payment mechanism. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this subdivision shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2005, shall be invalid and void.

3. The MO HealthNet division may require any participant receiving MO HealthNet benefits to pay part of the charge or cost until July 1, 2008, and an additional payment after July 1, 2008, as defined by rule duly promulgated by the MO HealthNet division, for all covered services except for those services covered under subdivisions (15) and (16) of subsection 1 of this section and sections 208.631 to 208.657 to the extent and in the manner authorized by Title XIX of the federal Social Security Act (42 U.S.C. Section 1396, et seq.) and regulations thereunder. When substitution of a generic drug is permitted by the prescriber according to section 338.056, and a generic drug is substituted for a name-brand drug, the MO HealthNet division may not lower or delete the requirement to make a co-payment pursuant to regulations of Title XIX of the federal Social Security Act. A provider of goods or services described under this section must collect from all participants the additional payment that may be required by the MO HealthNet division under authority granted herein, if the division exercises that authority, to remain eligible as a provider. Any payments made by participants under this section shall be in addition to and not in lieu of payments made by the state for goods or services described herein except the participant portion of the pharmacy professional dispensing fee shall be in addition to and not in lieu of payments to pharmacists. A provider may collect the co-payment at the time a service is provided or at a later date. A provider shall not refuse to provide a service if a participant is unable to pay a required payment. If it is the routine business practice of a provider to terminate future services to an individual with an unclaimed debt, the provider may include uncollected co-payments under this practice. Providers who elect not to undertake the provision of services based on a history of bad debt shall give participants advance notice and a reasonable opportunity for payment. A provider, representative, employee, independent contractor, or agent of a pharmaceutical manufacturer shall not make co-payment for a participant. This subsection

shall not apply to other qualified children, pregnant women, or blind persons. If the Centers for Medicare and Medicaid Services does not approve the MO HealthNet state plan amendment submitted by the department of social services that would allow a provider to deny future services to an individual with uncollected co-payments, the denial of services shall not be allowed. The department of social services shall inform providers regarding the acceptability of denying services as the result of unpaid co-payments.

4. The MO HealthNet division shall have the right to collect medication samples from participants in order to maintain program integrity.

5. Reimbursement for obstetrical and pediatric services under subdivision (6) of subsection 1 of this section shall be timely and sufficient to enlist enough health care providers so that care and services are available under the state plan for MO HealthNet benefits at least to the extent that such care and services are available to the general population in the geographic area, as required under subparagraph (a)(30)(A) of 42 U.S.C. Section 1396a and federal regulations promulgated thereunder.

6. Beginning July 1, 1990, reimbursement for services rendered in federally funded health centers shall be in accordance with the provisions of subsection 6402(c) and Section 6404 of P.L. 101-239 (Omnibus Budget Reconciliation Act of 1989) and federal regulations promulgated thereunder.

7. Beginning July 1, 1990, the department of social services shall provide notification and referral of children below age five, and pregnant, breast-feeding, or postpartum women who are determined to be eligible for MO HealthNet benefits under section 208.151 to the special supplemental food programs for women, infants and children administered by the department of health and senior services. Such notification and referral shall conform to the requirements of Section 6406 of P.L. 101-239 and regulations promulgated thereunder.

8. Providers of long-term care services shall be reimbursed for their costs in accordance with the provisions of Section 1902 (a)(13)(A) of the Social Security Act, 42 U.S.C. Section 1396a, as amended, and regulations promulgated thereunder.

9. Reimbursement rates to long-term care providers with respect to a total change in ownership, at arm's length, for any facility previously licensed and certified for participation in the MO HealthNet program shall not increase payments in excess of the increase that would result from the application of Section 1902 (a)(13)(C) of the Social Security Act, 42 U.S.C. Section 1396a (a)(13)(C).

10. The MO HealthNet division may enroll qualified residential care facilities and assisted living facilities, as defined in chapter 198, as MO HealthNet personal care providers.

11. Any income earned by individuals eligible for certified extended employment at a sheltered workshop under chapter 178 shall not be considered as income for purposes of determining eligibility under this section.

12. If the Missouri Medicaid audit and compliance unit changes any interpretation or application of the requirements for reimbursement for MO HealthNet services from the interpretation or application that has been applied previously by the state in any audit of a MO HealthNet provider, the Missouri Medicaid audit and compliance unit shall notify all affected MO HealthNet providers five business days before such change shall take effect. Failure of the Missouri Medicaid audit and compliance unit to notify a provider of such change shall entitle the provider to continue to receive and retain reimbursement until such notification is provided and shall waive any liability of such provider for recoupment or other loss of any payments previously made prior to the five business days after such notice has been sent. Each provider shall provide the Missouri Medicaid audit and compliance unit a valid email address and shall agree to receive communications electronically. The notification required under this section shall be delivered in writing by the United States Postal Service or electronic mail to each provider.

13. Nothing in this section shall be construed to abrogate or limit the department's statutory requirement to promulgate rules under chapter 536.

14. Beginning July 1, 2016, and subject to appropriations, providers of behavioral, social, and psychophysiological services for the prevention, treatment, or management of physical health problems shall be reimbursed utilizing the behavior assessment and intervention reimbursement codes 96150 to 96154 or their successor codes under the Current Procedural Terminology (CPT) coding system. Providers eligible for such reimbursement shall include psychologists.

15. There shall be no payments made under this section for gender transition surgeries, cross-sex hormones, or puberty-blocking drugs, as such terms are defined in section 191.1720, for the purpose of a gender transition.

376.1270. 1. As used in this section, terms shall have the meanings ascribed to them in section 376.1350, and the following terms mean:

(1) "Biomarker", a measurable molecular characteristic that may be evidence of rare genetic disorders or abnormal biological processes;

(2) "Biomarker testing", testing specifically designed to detect genetic markers for rare diseases including, but not limited to, exome sequencing and genome sequencing;

(3) "Genetic counseling", the provision and interpretation of medical information based on expanding knowledge of human genetics;

(4) "Pediatric rare disease", a rare disease with onset primarily in childhood and typically genetic in nature, affecting fewer than two hundred thousand individuals in the United States;

(5) "Rapid whole genome sequencing" or "rWGS", an analysis of a person's entire human genome, including coding and noncoding regions and mitochondrial DNA, to detect disease-causing genetic changes, providing preliminary test results within seven days of receiving a sample and final results within fifteen days of receiving a sample.

2. For enrollees receiving high-acuity inpatient care, including, but not limited to, intensive care or care in neonatal units, who meet criteria for a pediatric rare disease suspected to be genetic in nature:

(1) Health benefit plans shall cover rWGS if coverage for biomarker testing would otherwise be required under subsection 3 of this section and:

(a) The enrollee is under twenty-two years of age;

(b) The enrollee has a complex or acute illness of unknown origin not attributed to environmental factors, toxic ingestion, infection with a normal response, or trauma; and

(c) The treating provider determines an immediate molecular diagnosis is necessary to guide clinical decision-making;

(2) Reimbursement for rWGS under this subsection shall be made separately from the inpatient stay, allowing the performing laboratory to bill separately as if the test were provided in an outpatient setting; and

(3) Health benefit plans shall not require prior authorization for coverage required under this subsection but may perform retrospective review.

3. For enrollees meeting criteria for a pediatric rare disease suspected to be genetic in nature:

(1) Health benefit plans shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, management, or ongoing monitoring of an enrollee's disease or condition in order to guide treatment decisions if medical and scientific evidence indicates the biomarker testing may provide clinical utility to the enrollee. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the United States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare administrative contractor; or

(d) A nationally recognized clinical practice guideline;

(2) No health benefit plan shall impose an age restriction on coverage under this subsection;

(3) Coverage under this section may be deemed medically necessary if any of the following circumstances, but not limited thereto, apply:

(a) The test is indicated for a rare disease diagnosis based on clinical guidelines or the test is recommended as medically necessary by the treating provider to guide treatment or management decisions;

(b) The test may uncover actionable findings that will directly impact the patient's treatment plan or help clarify a broad differential diagnosis that would require multiple tests if biomarker testing were unavailable; or

(c) The patient presents complex or unexplained symptoms that are consistent with a potential genetic etiology including, but not limited to:

a. Unexplained congenital abnormalities or multi-system organ involvement;

b. Abnormal laboratory findings or chemistry profiles consistent with a genetic or metabolic disorder;

c. Refractory or treatment-resistant symptoms such as seizures, muscle weakness, severe endocrine disturbances, global developmental delay, or failure to thrive;

d. Documented familial history of a genetically suspected condition or rare disease; or

e. A diagnosis of autism, cancer, or Alzheimer's disease or a related dementia; and

(4) Coverage under this subsection shall not require prior authorization if the test is ordered by a clinical specialist with a relevant specialty. No utilization review entity shall revoke, limit, condition, or otherwise restrict a prior authorization for coverage under this subsection, provided the patient is an enrollee of the health benefit plan.

4. Coverage under this section shall not be denied on the basis of the test being experimental or investigational if the test meets established clinical guidelines or is recommended by a recognized medical society.

5. Coverage under this section shall include genetic counseling, including both pretest and posttest genetic counseling.

6. Health carriers shall maintain, accessible on their public websites, up-to-date policies on covered genomic and biomarker tests, including the criteria for medical necessity.

7. Testing covered under this section shall be performed by a laboratory certified by the Centers for Medicare and Medicaid Services as meeting the standards of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

8. This section shall apply to health benefit plans delivered, issued for delivery, continued, or renewed on or after January 1, 2026.

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