FIRST REGULAR SESSION

SENATE COMMITTEE SUBSTITUTE FOR

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 552

96TH GENERAL ASSEMBLY

Reported from the Committee on Financial and Governmental Organizations and Elections, May 10, 2011, with recommendation that the Senate Committee Substitute do pass.

TERRY L. SPIELER, Secretary.

1601S.06C

AN ACT

To repeal section 208.152, RSMo, and to enact in lieu thereof two new sections relating to the standard of care for the treatment of persons with bleeding disorders.

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

Section A. Section 208.152, RSMo, is repealed and two new sections enacted in lieu thereof, to be known as sections 208.152 and 338.400, to read as follows:

208.152. 1. MO HealthNet payments shall be made on behalf of those eligible needy persons as defined 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;

EXPLANATION–Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

(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. 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. 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 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 is visiting a friend or relative;

(6) Physicians' services, whether furnished in the office, home, hospital, nursing home, or elsewhere;

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

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

(9) 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;

(10) Home health care services;

(11) Family planning as defined by federal rules and regulations; provided, however, that such family planning services shall not include abortions unless such abortions are certified in writing by a physician to the MO HealthNet agency that, in his professional judgment, the life of the mother would be endangered if the fetus were carried to term;

(12) 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. 1396d, et seq.);

(13) 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;

(14) 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 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 her 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;

(15) Mental health services. The state plan for providing medical assistance under Title XIX of the Social Security Act, 42 U.S.C. 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;

(16) 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. 301, et seq.) subject to appropriation by the general assembly;

(17) Beginning July 1, 1990, the services of a certified pediatric or family nursing practitioner with a collaborative practice agreement to the extent that such services are provided in accordance with chapters 334 and 335, and regulations promulgated thereunder;

(18) 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;

(19) 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;

(20) Hospice care. As used in this **[**subsection**]** **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);

(21) 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;

(22) 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;

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

(24) 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 division of medical services, unless otherwise hereinafter provided, for the following:

(1) Dental services;

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

(3) Optometric services as defined 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 subsection, 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 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 (14) and (15) 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. 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 Missouri 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. 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. 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. 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.

338.400. 1. As used in this section, the following terms shall mean:

(1) "Ancillary infusion equipment and supplies", the equipment and supplies required to infuse a blood clotting therapy product into a human vein, including syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs;

(2) "Assay", the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug;

(3) "Bleeding disorder", a medical condition characterized by a deficiency or absence of one or more essential blood-clotting components in the human blood, including all forms of hemophilia, von Willebrand's disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting;

(4) "Blood clotting product", a medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;

(5) "Home nursing services", specialized nursing care provided in the home setting to assist a patient in the reconstitution and

administration of blood clotting products;

(6) "Home use", infusion or other use of a blood clotting product in a place other than a hemophilia treatment center, hospital, emergency room, physician's office, outpatient facility, or clinic;

(7) "Pharmacy", an entity engaged in practice of pharmacy as defined in section 338.010 that provides patients with blood clotting products and ancillary infusion equipment and supplies.

2. The Missouri state board of pharmacy shall promulgate rules governing the standard of care for pharmacies dispensing blood clotting therapies. Such rules shall include, when feasible, the standards established by the medical advisory committees of the patient groups representing the hemophilia and von Willebrand diseases, including but not limited to Recommendation 188 of the National Hemophilia Foundation's Medical and Scientific Advisory Council. Such rules shall include safeguards to ensure the pharmacy:

(1) Has the ability to obtain and fill a physician prescription as written of all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges of low, medium, and high, as applicable, and vial sizes, including products manufactured from human plasma and those manufactured from recombinant technology techniques, provided manufacturer supply exists and payer authorization is obtained;

(2) Provides for the shipment of prescribed blood clotting products to the patient within two business days or less for established patients and three business days or less for new patients in nonemergency situations;

(3) Provides established patients with access to blood clotting products within twelve hours of notification by the physician of the patient's emergent need for blood clotting products;

(4) Provides all ancillary infusion equipment and supplies necessary for established patients for administration of blood clotting products;

(5) Has a pharmacist available twenty-four hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products;

(6) Provides patients who have received blood clotting products with a designated contact telephone number for reporting problems

with a delivery or product;

(7) Provides patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within twenty-four hours of receipt of the notification; and

(8) Provides containers for the disposal of hazardous waste, and provide patients with instructions on the proper collection, removal, and disposal of hazardous waste under state and federal law.

3. Notwithstanding the provisions of subsection 2 of this section, pharmacies and pharmacists shall exercise that degree of skill and learning ordinarily exercised by members of their profession in the dispensing and distributing of blood clotting products.

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