5656S.02F

SENATE SUBSTITUTE

FOR

HOUSE BILL NO. 1953

AN ACT

To amend chapters 192 and 208, RSMo, by adding thereto two new sections relating to the dissemination of information on the treatment of certain diseases.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Chapters 192 and 208, RSMo, are amended by adding thereto two new sections, to be known as sections 192.1120 and 208.183, to read as follows:

192.1120. 1. Each primary care provider and urgent care physician may inquire of new patients who are eighteen years of age or older and under forty-five years of age on their new patient intake form as to whether the patient is registered with the bone marrow registry. If the patient states that he or she is not registered with the bone marrow registry, the provider or physician shall provide information developed and disseminated by the department of health and senior services regarding the bone marrow registry to the patient.

2. The department of health and senior services shall develop and disseminate information regarding the bone marrow registry, which shall include, but not be limited to, the following:

(1) The need for bone marrow donations;

(2) Patient populations that would benefit from bone marrow

donations;

(3) How to join the bone marrow registry; and

(4) How to acquire a free buccal swab kit from the bone marrow registry.

3. The department of health and senior services may promulgate rules and regulations to implement the provisions of this section. 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 section 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, 2018, shall be invalid and void.

4. Dissemination of the information under this section may be by oral, print, or electronic notification or any other method, provided that the department of health and senior services determines that the dissemination of information is cost-effective for the department and for primary care providers and urgent care physicians.

208.183. 1. There shall be established an "Advisory Council on Rare Diseases and Personalized Medicine" within the MO HealthNet division. The advisory council shall serve as an expert advisory committee to the drug utilization review board, providing necessary consultation to the board when the board

makes recommendations or determinations regarding beneficiary access to drugs or biological products for rare diseases, or when the board itself determines that it lacks the specific scientific, medical, or technical expertise necessary for the proper performance of its responsibilities and such necessary expertise can be provided by experts outside the board. "Beneficiary access", as used in this section, shall mean developing prior authorization and reauthorization criteria for a rare disease drug, including placement on a preferred drug list or a formulary, as well as payment, cost-sharing, drug utilization review, or medication therapy management.

2. The advisory council on rare diseases and personalized medicine shall be composed of the following health care professionals, who shall be appointed by the director of the department of social services:

(1) Two physicians affiliated with a public school of medicine who are licensed and practicing in this state with experience researching, diagnosing, or treating rare diseases;

(2) Two physicians affiliated with private schools of medicine headquartered in this state who are licensed and practicing in this state with experience researching, diagnosing, or treating rare diseases;

(3) A physician who holds a doctor of osteopathy degree, who is active in medical practice, and who is affiliated with a school of medicine in this state with experience researching, diagnosing, or treating rare diseases;

(4) Two medical researchers from either academic research institutions or medical research organizations in this state who

have received federal or foundation grant funding for rare disease research;

(5) A registered nurse or advanced practice registered nurse licensed and practicing in this state with experience treating rare diseases;

(6) A pharmacist practicing in a hospital in this state which has a designated orphan disease center;

(7) A professor employed by a pharmacy program in this state that is fully accredited by the Accreditation Council for Pharmacy Education and who has advanced scientific or medical training in orphan and rare disease treatments;

(8) One individual representing the rare disease community or who is living with a rare disease;

(9) One member who represents a rare disease foundation;

(10) A representative from a rare disease center located within one of the state's comprehensive pediatric hospitals;

(11) The chair of the joint committee on the life sciences or the chair's designee; and

(12) The chairperson of the drug utilization review board, or the chairperson's designee, who shall serve as an ex officio, nonvoting member of the advisory council.

3. The director shall convene the first meeting of the advisory council on rare diseases and personalized medicine no later than February 28, 2019. Following the first meeting, the advisory council shall meet upon the call of the chairperson of the drug utilization review board or upon the request of a majority of the council members.

4. The drug utilization review board, when making

recommendations or determinations regarding beneficiary access to drugs and biological products for rare diseases, as defined in the federal Orphan Drug Act of 1983, P.L. 97-414, and drugs and biological products that are approved by the U.S. Food and Drug Administration and within the emerging fields of personalized medicine and noninheritable gene editing therapeutics, shall request and consider information from the advisory council on rare diseases and personalized medicine.

5. The drug utilization review board shall seek the input of the advisory council on rare diseases and personalized medicine to address topics for consultation under this section including, but not limited to:

(1) Rare diseases;

(2) The severity of rare diseases;

(3) The unmet medical need associated with rare diseases;

(4) The impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other Medicaid policies on access to rare disease therapies;

(5) An assessment of the benefits and risks of therapies to treat rare diseases;

(6) The impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other policies on patients' adherence to the treatment regimen prescribed or otherwise recommended by their physicians;

(7) Whether beneficiaries who need treatment from or a consultation with a rare disease specialist have adequate access

and, if not, what factors are causing the limited access; and

(8) The demographics and the clinical description of patient populations.

6. Nothing in this section shall be construed to create a legal right for a consultation on any matter or to require the drug utilization review board to meet with any particular expert or stakeholder.

7. Recommendations of the advisory council on rare diseases and personalized medicine on an applicable treatment of a rare disease shall be explained in writing to members of the drug utilization review board during public hearings.

8. For purposes of this section, a "rare disease drug" shall mean a drug used to treat a rare medical condition, defined as any disease or condition that affects fewer than two hundred thousand persons in the United States, such as cystic fibrosis, hemophilia, and multiple myeloma.

9. All members of the advisory council on rare diseases and personalized medicine shall annually sign a conflict of interest statement revealing economic or other relationships with entities that could influence a member's decisions, and at least twenty percent of the advisory council members shall not have a conflict of interest with respect to any insurer, pharmaceutical benefits manager, or pharmaceutical manufacturer.