House _____ **Amendment NO.**____

Offered By

_____ _____

AMEND House Committee Substitute for Senate Substitute for Senate Committee Substitute for Senate Bill No. 826, Page 11, Section 195.070, Lines 24-31, by deleting all of said lines and inserting in lieu thereof the following:

"patient, for any reason, if such practitioner did not originally dispense the drug, except as provided in section 195.265."; and

Further amend said bill, Page 12, Section 195.265, Line 1, by inserting immediately after the number "195.265." the following:

"1. Unused controlled substances may be accepted from ultimate users, from hospice or home health care providers on behalf of ultimate users to the extent federal law allows, or any person lawfully entitled to dispose of a decedent's property if the decedent was an ultimate user who died while in lawful possession of a controlled substance, through:

(1) Collection receptacles, drug disposal boxes, mail back packages, and other means by a Drug Enforcement Agency-authorized collector in accordance with federal regulations even if the authorized collector did not originally dispense the drug; or

(2) Drug take back programs conducted by federal, state, tribal, or local law enforcement agencies in partnership with any person or entity.

This subsection shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state, regarding the disposal of unused controlled substances. For the purposes of this section, the term "ultimate user" shall mean a person who has lawfully obtained and possesses a controlled substance for his or her own use or for the use of a member of his or her household or for an animal owned by him or her or a member of his or her household.

2."; and

Further amend said bill and section, Page 13, Line 7, by deleting the word "mailers" and inserting in lieu thereof the words "mail back packages"; and

Further amend said bill, page, and section, Line 12, by inserting immediately after the word "location" the phrase "and is updated every six months by the department"; and

Further amend said bill, page, and section, Line 13, by inserting immediately after the word "events" the words "and mail back events"; and

Action Taken_____ Date _____

Further amend said bill, page, and section, Line 14, by inserting immediately after the word "event" the phrase "and is updated every six months by the department"; and

Further amend said bill, page, and section, Line 16, by deleting the words "4 of section 195.070" and inserting in lieu thereof the words "1 of this section"; and

Further amend said bill, page, and section, Line 18, by inserting after all of said section and line the following:

"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."; and

Further amend said bill and page, Section 338.010, Line 9, by inserting immediately after the word "[~~twelve~~]" the words "at least"; and

Further amend said bill, page, and section, Line 10, by inserting after the word "the" the phrase "age recommended by the"; and

Further amend said bill, page, section, and line, by deleting the word "recommendations"; and

Further amend said bill and section, Page 14, Lines 47-48 and 53, by deleting each instance of the phrase "[~~and administration of viral influenza vaccines~~]" and inserting in lieu thereof "and administration of viral influenza vaccines"; and

Further amend said bill, Pages 16-17, Section 338.056, Lines 14-31, by deleting all of said lines and inserting in lieu thereof the following:

"2. A pharmacist who receives a prescription for a brand name drug or biological product may**[**~~, unless requested otherwise by the purchaser,~~**]** select a less expensive generically equivalent or interchangeable biological product **[**~~under the following circumstances:~~

~~(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line~~**]** unless:

(1) the patient requests a brand name drug or biological product; or

(2) the prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.

3. No prescription shall be valid without the signature of the prescriber **[**~~on one of these lines;~~

~~(2)~~**]** .

4. If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription."; and

Further amend said bill, Page 17, Section B, Lines 2 and 5, by deleting each instance of the phrase "section 195.070" and inserting in lieu thereof the phrase "sections 195.070 and 195.265"; and

Further amend said bill by amending the title, enacting clause, and intersectional references accordingly.