**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING SECTION 38‑71‑270 SO AS TO PROVIDE A HEALTH INSURANCE PLAN MAY NOT INCREASE A COPAYMENT OR REQUIRE AN INSURED TO PAY AN AMOUNT IN EXCESS OF THE COPAYMENT FOR A SPECIFIC ANTI‑EPILEPTIC DRUG PRESCRIBED TO TREAT EPILEPSY IN THE INSURED IF THE PRESCRIBING PRACTITIONER DETERMINES THAT USE OF THAT SPECIFIC DRUG IS NECESSARY FOR THE PATIENT TO MAINTAIN A CONSISTENT THERAPEUTIC LEVEL TO AVOID SEIZURE REOCCURRENCE, REGARDLESS OF WHETHER A PREFERRED OR GENERIC EQUIVALENT IS AVAILABLE AT A LOWER COST, AND TO PROVIDE AN EXPEDITED PROCESS FOR REVIEWING ALLEGED VIOLATIONS; TO AMEND SECTION 39‑24‑20, RELATING TO DEFINITIONS IN THE DRUG PRODUCT SELECTION ACT OF 1978, SO AS TO DEFINE NECESSARY TERMS; TO AMEND 39‑24‑30, RELATING TO THE AUTHORIZED SUBSTITUTION OF AN EQUIVALENT PRESCRIPTION DRUG BY A PHARMACIST UNDER THE DRUG PRODUCT SELECTION ACT OF 1978, SO AS TO PROVIDE A PHARMACIST MAY NOT INTERCHANGE AN ANTI‑EPILEPTIC DRUG OR FORMULATION OF AN ANTI‑EPILEPTIC DRUG, BRAND, OR GENERIC FOR THE TREATMENT OF SEIZURES OR EPILEPSY WITHOUT PRIOR NOTIFICATION OF, AND SIGNED, INFORMED CONSENT TO, THE INTERCHANGE FROM THE PRESCRIBING PRACTITIONER AND THE PATIENT OR THE PARENT, LEGAL GUARDIAN, OR SPOUSE OF THE PATIENT, TO PROVIDE BEFORE SUCH AN INTERCHANGE MAY OCCUR, THE PRESCRIBING PRACTITIONER MUST DETERMINE WHETHER THE INTERCHANGE CAN COMPROMISE THE ABILITY OF THE INSURED TO MAINTAIN A CONSISTENT THERAPEUTIC LEVEL TO AVOID SEIZURE REOCCURRENCE, AND TO PROVIDE THE PRESCRIBING PRACTITIONER MAY NOT CONSENT TO THE INTERCHANGE AND THE PHARMACIST MAY NOT PERFORM THE INTERCHANGE IF THE PRESCRIBING PHYSICIAN DETERMINES SUCH A COMPROMISE CAN OCCUR; AND TO AMEND SECTION 39‑24‑40, AS AMENDED, RELATING TO FORM, CONTENT, AND MISCELLANEOUS REQUIREMENTS CONCERNING PRESCRIPTIONS, SO AS TO MAKE CONFORMING CHANGES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Article 1, Chapter 71, Title 38 of the 1976 Code is amended by adding:

“Section 38‑71‑270. (A) A health insurance plan may not increase a copayment or require a patient to pay an amount in excess of the copayment for a specific anti‑epileptic drug prescribed to treat epilepsy in a particular insured if the prescribing practitioner determines that the use of that specific drug is necessary to maintain a consistent therapeutic level to avoid seizure reoccurrence, regardless of whether a preferred or generic equivalent is available at a lower cost. The provisions of this section also apply to the State Health Plan and Health Maintenance Organizations.

(B)(1) An aggrieved insured:

(a) who is not insured by the State Health Plan may request an expedited hearing on any alleged violation of this section from the Department of Insurance pursuant to the provisions of Article 1, Chapter 3 of this title, and the department shall conduct the hearing and render a decision within thirty days after the request is made; and

(b) who is insured by the State Health Plan may request an expedited hearing on any alleged violation of this section from the South Carolina Public Employee Benefits Authority pursuant to the procedures of the authority.

(2) An aggrieved insured may appeal from a decision of the department or authority, as appropriate, to the administrative law court pursuant to the provisions of Article 1, Chapter 3 of this title. The court must hold a hearing on the appeal and render a decision within fifteen days of receipt of the hearing request.

(C) The provisions of this section must liberally be construed in favor of the insured.”

SECTION 2. Section 39‑24‑20 of the 1976 Code is amended to read:

“Section 39‑24‑20. As used in this chapter:

(1) ‘Anti‑epileptic drug’ means a drug prescribed for the treatment of epilepsy or any drug used to treat or prevent seizures.

~~(1)~~(2) ‘Brand name’ means the proprietary or trade name placed upon a drug, its container, label or wrapping at the time of packaging~~;~~.

(3) ‘Epilepsy’ means a neurological condition characterized by recurrent seizures.

~~(2)~~(4) ‘Generic name’ means the United States Adopted Name (USAN) or the official title of a drug published in the latest edition of a nationally recognized pharmacopoeia or formulary~~;~~.

(5) ~~‘Practitioner’ means a physician, osteopath, dentist, podiatrist, veterinarian, or any other person authorized to prescribe drugs under the laws of this State.~~

‘Interchange’ means the substitution of one version of the same anti‑epileptic therapeutic product, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by a manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti‑epileptic drug, or a different anti‑epileptic therapeutic drug product for the anti‑epileptic product originally prescribed.

(6) ‘Seizure’ means an acute clinical change that is secondary to a brief disturbance in the electrical activity of the brain.

~~(3)~~(7) ‘Substitute’ means to dispense, with the practitioner’s authorization, a ‘therapeutically equivalent’ generic drug product of identical drug salt in place of the drug ordered or prescribed~~;~~.

~~(4)~~(8) ‘Therapeutically equivalent’ means the same efficacy and toxicity when administered to an individual in the same dosage form~~; and~~.

(9) ‘Practitioner’ means a physician, osteopath, dentist, podiatrist, veterinarian, or any other person authorized to prescribe drugs under the laws of this State.”

SECTION 3. Section 39‑24‑30 of the 1976 Code is amended to read:

“Section 39‑24‑30. As provided in Section ~~39‑4‑40~~ 39‑24‑40, upon receiving a prescription for a brand name product, except for an anti‑epileptic drug, a registered pharmacist may substitute a drug product of the same dosage form and strength which, in his professional judgment, is a therapeutically equivalent drug product.

However, a pharmacist may not interchange an anti‑epileptic drug or formulation of an anti‑epileptic drug, brand, or generic for the treatment of seizures or epilepsy without prior notification of, and signed, informed consent to, the interchange from the prescribing practitioner and the patient or the parent, legal guardian, or spouse of the patient. Before such an interchange may occur, the prescribing practitioner must determine whether the interchange can compromise the maintenance of a consistent therapeutic level to avoid seizure reoccurrence in the patient. If the prescribing practitioner determines such a compromise can occur, he may not consent to the interchange and the pharmacist may not perform the interchange.”

SECTION 4. Section 39‑24‑40 of the 1976 Code, as last amended by Act 314 of 2002, is further amended to read:

“Section 39‑24‑40. (A) An oral or written drug prescription must provide an authorization from the practitioner as to whether or not a therapeutically equivalent generic drug may be substituted or, with respect to an anti‑epileptic drug, whether an interchange may be made.

(B) A written prescription must have two signature lines at opposite ends on the bottom of the form. Under the line at the left side must be clearly printed the words ‘DISPENSE AS WRITTEN’. Under the line at the right side ~~shall~~ must be clearly printed the words ‘SUBSTITUTION PERMITTED’, unless the prescription is to be paid for with Medicaid funds. The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. A written prescription is not valid without the signature of the practitioner on one of these lines.

(C) An oral prescription from the practitioner must instruct the pharmacist as to whether or not a therapeutically equivalent generic drug product may be substituted, unless the prescription is to be paid for with Medicaid funds. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law.

(D) The pharmacist shall note the brand name or the manufacturer of the substituted drug dispensed on the file copy of a written or oral prescription or record this information electronically, or both.

(E) ~~Substitution~~ With respect to a drug other than an anti‑epileptic drug, substitution may not occur unless the pharmacist advises the patient that the practitioner has authorized substitution and the patient consents. Interchange of anti‑epileptic drugs must comply with the notice and consent requirements of Section 39‑24‑30.

(F) If a pharmacist substitutes a generic drug for a name brand prescribed drug when dispensing a prescribed medication, the brand name and the name of the generic drug and its manufacturer, with an explanation of “generic for” or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label.”

SECTION 5. This act takes effect upon approval by the Governor.

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