**A** **BILL**

TO AMEND CHAPTER 39, TITLE 44, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO THE DIABETES INITIATIVE OF SOUTH CAROLINA BOARD, SO AS TO REQUIRE MANUFACTURERS OF DIABETES PRESCRIPTION DRUGS TO PROVIDE CERTAIN COST INFORMATION TO THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, TO REQUIRE CERTAIN NONPROFIT ORGANIZATIONS THAT RECEIVE FUNDING FROM THESE MANUFACTURERS TO COMPILE REPORTS ADDRESSING THE FUNDING RECEIVED AND MAKE THE INFORMATION PUBLICLY AVAILABLE, TO REQUIRE THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL TO POST REPORTED INFORMATION ON ITS PUBLICLY ACCESSIBLE WEBSITE, AND FOR OTHER PURPOSES; TO AMEND SECTION 38‑71‑46, RELATING TO MANDATED INSURANCE COVERAGE FOR THE TREATMENT OF DIABETES, SO AS TO REQUIRE CERTAIN HEALTH INSURANCE POLICIES TO PROVIDE NOTICE IN CERTIFICATES OF COVERAGE AND DURING OPEN ENROLLMENT PERIODS OF AVAILABLE PRESCRIPTION DRUGS TO TREAT DIABETES AND OF THE USE OF FORMULARIES; AND TO AMEND SECTION 39‑8‑20, RELATING IN PART TO THE DEFINITION OF A TRADE SECRET, SO AS NOT TO INCLUDE INFORMATION PROVIDED BY MANUFACTURERS OF DIABETES PRESCRIPTION DRUGS TO THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL PURSUANT TO CHAPTER 39, TITLE 44 AS A TRADE SECRET.

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

SECTION 1. Chapter 39, Title 44 of the 1976 Code is amended to read:

“CHAPTER 39

Diabetes

Article 1

Diabetes Initiative of South Carolina

Section 44‑39‑10. This ~~chapter~~ article may be cited as the ‘Diabetes Initiative of South Carolina Act’.

Section 44‑39‑20. (A) There is established within the Medical University of South Carolina the Diabetes Initiative of South Carolina Board. The purpose of this board is to establish a statewide program of education, surveillance, clinical research, and translation of new diabetes treatment methods to serve the needs of South Carolina residents with diabetes mellitus. The provisions of this ~~chapter~~ article and the initiatives undertaken by the board supplement and do not supplant existing programs and services provided to this population.

(B) The board consists of:

(1) the following officials or their designees:

(a) the President of the Medical University of South Carolina;

(b) the Dean of the University of South Carolina School of Medicine;

(c) the Director of the Department of Health and Environmental Control;

(d) the Director of the State Department of Health and Human Services;

(e) the President of the South Carolina Medical Association;

(f) the Vice President of the Southeastern Division of the American Diabetes Association;

(g) the President of the American Association of Diabetes Educators;

(h) the President of the South Carolina Academy of Family Physicians;

(i) the Head of the Office of Minority Health in the Department of Health and Environmental Control;

(j) the Governor of the South Carolina Chapter of the American College of Physicians;

(k) the Chair of the Division of Endocrinology at the Medical University of South Carolina;

(l) the President of the South Carolina Hospital Association;

(2) a representative of the Office of the Governor, to be appointed by the Governor; and

(3) six representatives appointed by the President of the Medical University of South Carolina, three of whom must be from the general public and one each from the Centers of Excellence Council, the Outreach Council, and the Surveillance Council, all of whom must be persons knowledgeable about diabetes and its complications.

(C) The board may elect nonvoting members and honorary members.

(D) A member of the board is elected for a three‑year term. A vacancy on the board must be filled for the remainder of the unexpired term in the manner of original appointment.

(E) The board shall elect from its members a chair for a term of three years.

(F) The board shall meet at least quarterly or more frequently upon the call of the chairman. A member of the board not employed by the State or a political subdivision of the State must receive per diem, subsistence, and mileage as provided by law for members of state boards, commissions, and committees while engaged in the work of the board.

Section 44‑39‑30. The powers and duties of the Diabetes Initiative of South Carolina Board are to:

(1) annually assess the effects of diabetes mellitus in South Carolina, and the status of education, clinical research, and translation of new diabetes treatment methods in South Carolina;

(2) oversee all operations of the Center of Excellence Advisory Committees, and the Diabetes Outreach Council including:

(a) reviewing annual reports;

(b) establishing annual budgets;

(c) setting annual priorities;

(3) make annual budget requests to the General Assembly to support the activities of the Diabetes Initiative of South Carolina Board;

(4) conduct diabetes surveillance activities including:

(a) obtaining data and maintaining a statewide data base

(b) analyzing data and reviewing trends on mortality and morbidity in diabetes;

(c) developing means to and disseminating important data to professionals and the public;

(d) developing proposals for grant funding.

(5) submit an annual report to the Governor and the General Assembly;

(6) other activities necessary to carry out the provisions of this ~~chapter~~ article.

Section 44‑39‑40. (A) A Diabetes Center of Excellence is established at the Medical University of South Carolina. The center shall develop and implement programs of professional education, specialized care, and clinical research in diabetes and its complications, in accordance with priorities established by the Diabetes Initiative of South Carolina Board. The Center of Excellence must submit an annual report to the Diabetes Initiative of South Carolina Board.

(B) The activities of the center must be overseen and directed by the Center of Excellence Advisory Committee. The council consists of members appointed by the president of the Medical University of South Carolina. The functions of the council include:

(1) reviewing programs in professional education, specialized care, and clinical research developed by the Center;

(2) assisting in the development of proposals for grant funding for the center’s activities;

(3) preparing an annual report and budget proposal for submission to the Diabetes Initiative of South Carolina Board.

Section 44‑39‑50. (A) There is created in the Medical University of South Carolina the Diabetes Outreach Council with three members appointed by the president of the university.

(B) The Diabetes Outreach Council shall oversee and direct efforts in patient education and primary care including:

(1) promoting adherence to national standards of education and care;

(2) ongoing assessment of patient care costs and reimbursement issues for persons with diabetes in South Carolina;

(3) preparing an annual report and budget proposal for submission to the Diabetes Initiative of South Carolina Board.

Article 3

Diabetes Treatment

Section 44‑39‑110. As used in this article:

(1) ‘Department’ means the Department of Health and Environmental Control.

(2) ‘Manufacturer’ means a person who derives, produces, prepares, cultivates, grows or processes a prescription drug.

(3) ‘Pharmacy’ means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in Section 44‑43‑30.

(4) ‘Usual and customary price’ means the usual and customary charges that a pharmacy charges to the general public for a drug, as described in 42 C.F.R. Section 447.512.

(5) ‘Wholesale acquisition cost’ means the manufacturer’s list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.

Section 44‑39‑120. On or before February first of each year, the Department of Health and Environmental Control shall compile a list of prescription drugs that the department determines to be essential for treating diabetes in this State and the wholesale acquisition cost of each such drug on the list. The list must include, but not be limited to, all forms of insulin and biguanides marketed for sale in this State.

Section 44‑39‑130. (A) On or before April first of each year, the manufacturer of a prescription drug that appears on the most current list compiled by the department pursuant to Section 44‑39‑120 shall prepare and submit to the department, in the form prescribed by the department, a report which must include:

(1) the total cost of research and development for the drug including, but not limited to, any cost for research and development incurred with respect to the drug by a predecessor entity of the manufacturer;

(2) any other costs of producing the drug;

(3) the total administrative expenditures relating to the drug, including marketing and advertising costs;

(4) the profit that the manufacturer has earned from the drug and the percentage of the manufacturer’s total profit attributable to the drug;

(5) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(6) the cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;

(7) the wholesale acquisition cost of the drug;

(8) a history of any increases in the wholesale acquisition cost of the drug over the five years immediately preceding the date on which the report is submitted, including the amount of each increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective, and any explanation for the increase; and

(9) any additional information prescribed by regulation of the department for the purpose of analyzing the cost of prescription drugs that appears on the list compiled pursuant to Section 44‑39‑120, trends in those costs, and rebates available for these drugs.

(B) On or before June first of each year, the department shall analyze the information submitted pursuant to subsection (A) and compile and post on the department’s publicly accessible website a report on the price of the prescription drugs that appear on the most current list compiled by the department pursuant to Section 44‑39‑120, the effect of those prices on overall spending on prescription drugs in this State, strategies and opportunities for lowering the cost of drugs for the treatment of diabetes while maintaining access to these drugs, and any other information the department determines appropriate for inclusion.

Section 44‑39‑140. At least ninety days before increasing the wholesale acquisition cost of a prescription drug included on the list compiled by the department pursuant to Section 44‑39‑120, the manufacturer of the drug shall notify the department of the planned price increase.

Section 44‑39‑150. On or before February first of each year, a nonprofit organization that advocates on behalf of patients or funds medical research in this State and has received a payment, donation, subsidy, or anything else of value from a manufacturer or a trade or advocacy group for manufacturers during the immediately preceding calendar year shall:

(1) compile a report which includes:

(a) for each such contribution, the amount of the contribution and the manufacturer or group that provided the payment, donation, subsidy, or other contribution; and

(b) the percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies, or other contributions from each manufacturer or group; and

(2) post the report required pursuant to item (1) on the nonprofit organization’s publicly accessible website. If the nonprofit organization does not maintain such a website, the nonprofit organization shall submit the report to the department.

Section 44‑39‑160. A person who manufactures, distributes, or dispenses any controlled substance or proposes to engage in the manufacture, distribution, or dispensing of a controlled substance and who is required to register with the department pursuant to Section 44‑53‑290 shall submit to the department with the annual application for registration a report, which must include, for the immediately preceding year:

(1) a list of health care providers whom the person, or an employee or agent of the person, contacted;

(2) the name and manufacturer of each prescription drug for which the person, or an employee or agent of the person, provided a free sample and the name of each health care provider to whom a free sample was provided; and

(3) the name of each health care provider to whom the person, or an employee or agent of the person, provided compensation including, but not limited to, gifts, food, or free supplies, and the value of the compensation.

Section 44‑39‑170. (A) Except as otherwise provided in subsection (B), the department shall:

(1) place or cause to be placed on the department’s publicly accessible website:

(a) the list of essential diabetes drugs compiled by the department pursuant to Section 44‑39‑120;

(b) the wholesale acquisition cost of each prescription drug reported pursuant to Section 44‑39‑130;

(c) the name of each drug for which the manufacturer has notified the department of a planned increase in the wholesale acquisition cost of the drug pursuant to Section 44‑39‑140; and

(d) the name of each nonprofit organization that is required to submit a report pursuant to Section 44‑39‑150 and the organization’s website address on which the report is publicly available or a link to a copy of the report on the department’s website;

(2) ensure that the information placed on the department’s publicly accessible website pursuant to subsection (A) is organized so that each individual pharmacy, manufacturer, and nonprofit organization has its own separate entry on that website;

(3) ensure that the information described in subsection (A) is placed on the department’s publicly accessible website as soon as practicable after the department receives the information; and

(4) ensure that the usual and customary price that each pharmacy charges for each prescription drug that is on the list and that is stocked by the pharmacy:

(a) is presented on the department’s publicly accessible website; and

(b) is updated not less frequently than once each calendar quarter.

Nothing in this subsection prohibits the department from determining the usual and customary price that a pharmacy charges for a prescription drug by extracting or otherwise obtaining such information from claims reported by pharmacies to the Medicaid program.

(B) If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the department may present the pricing information pertaining to such a pharmacy in a manner that the pricing information is combined with the pricing information relative to other pharmacies that are part of the same company, corporation, or chain, to the extent that the pricing information does not differ among those pharmacies.

(C) The department may establish additional or alternative procedures by which a consumer who is unable to access the Internet or is otherwise unable to receive the information described in subsection (A) in the manner in which it is presented by the department may obtain that information:

(1) in the form of paper records;

(2) through the use of a telephonic system; or

(3) using other methods or technologies designed specifically to assist consumers who are hearing impaired or visually impaired.

Section 44‑39‑180. If a manufacturer fails to provide the department the information required by Section 44‑39‑130 or 44‑39‑140 in a timely manner or a nonprofit organization fails to post or provide the department the information required by Section 44‑39‑150 in a timely manner, and the failure was not caused by excusable neglect, technical problems, or other extenuating circumstances, the department may impose against the manufacturer or nonprofit organization, an administrative penalty of not more than five thousand dollars for each day of such failure.”

SECTION 2. Section 38‑71‑46 of the 1976 Code is amended to read:

“Section 38‑71‑46. (A) On or after January 1, 2000, every health maintenance organization, individual and group health insurance policy, or contract issued or renewed in this State must provide coverage for the equipment, supplies, Food and Drug Administration‑approved medication indicated for the treatment of diabetes, and outpatient self‑management training and education for the treatment of people with diabetes mellitus, if medically necessary, and prescribed by a health care professional who is legally authorized to prescribe such items and who demonstrates adherence to minimum standards of care for diabetes mellitus as adopted and published by the Diabetes Initiative of South Carolina. ~~This subsection does not prohibit a health maintenance organization or an individual or a group health insurance policy from providing coverage for medication according to formulary or using network providers.~~ Coverage must not be denied unless the health care professional demonstrates a persistent pattern of failure to adhere to the minimal standards of care and unless the health maintenance organization or insurer has first provided written notice to the health care professional that coverage will be denied if the health care professional fails to adhere to the minimal standards of care.

(B)(1) Subsection (A) does not prohibit a health maintenance organization or an individual or a group health insurance policy from providing coverage for medication according to a formulary or using network providers. Every health maintenance organization or individual or a group health insurance policy shall include with the summary, certificate, or evidence or coverage required for the treatment of diabetes, notice of whether a formulary is used and, if so, of the opportunity to secure information regarding the formulary from the insurer pursuant to item (2). The notice required by this subsection must:

(a) be in a language that is easily understood and in a format that is easy to understand; and

(b) if a formulary is used, include an explanation of what a formulary is, how often the contents of the formulary are reviewed, the procedure and criteria for determining which prescription drugs for the treatment of diabetes are included in and excluded from the formulary, and the telephone number of the insurer for making a request for information regarding the formulary.

(2) A health maintenance organization or an individual or group health insurance policy which provides coverage for prescription drugs to treat diabetes according to a formulary shall:

(a) provide to any insured or participating health care provider, upon request:

(i) information regarding whether a specific drug is included in the formulary; and

(ii) access to the most current list of prescription drugs in the formulary for the treatment of diabetes with an indication of whether any listed drugs are preferred over other listed drugs and, if more than one formulary is maintained, notice that a choice of formulary lists are available;

(b) notify each person who requests information regarding the formulary that the inclusion of a drug in the formulary does not guarantee that a health care provider will prescribe that drug for the treatment of diabetes;

(c) during each period for open enrollment, publish on the insurer’s publicly accessible website, or include in any enrollment materials distributed by the insurer, a notice of all prescription drugs that:

(i) are included on the most recent list of drugs that are essential for treating diabetes in this State compiled by the Department of Health and Human Services; and

(ii) have been removed or will be removed from the formulary for the treatment of diabetes during the current plan year or the next plan year.

The notice required by this subitem must be updated throughout the period for open enrollment as necessary to provide accurate and complete lists.

(C) Services and payment for diabetes education programs shall conform to regulations of the Health Care Financing Administration, US Department of Health and Human Services, pursuant to Section 4105 of the Balanced Budget Act of 1997. Diabetes outpatient self‑management training and education shall be provided by a registered or licensed health care professional with certification in diabetes by the National Certification Board of Diabetes Educators, or other accredited program approved by the Diabetes Initiative of South Carolina, or by the Diabetes Control Program of the SC Department of Health and Environmental Control in order to meet the needs of rural communities wherein certified health care professionals providing this service are not available.

~~(C)~~(D) Nothing contained in this section may be construed to affect in any way the ability of a managed care plan to credential or recredential a provider.

~~(D)~~(E) For purposes of this section: ‘health insurance policy’ means a health benefit plan, contract, or evidence of coverage providing health insurance coverage as defined in Section 38‑71‑670(6) and Section 38‑71‑840(14).”

SECTION 3. Section 39‑8‑20(5) of the 1976 Code, as added by Act 38 of 1997, is amended by adding an appropriately lettered subitem to read:

“( ) Notwithstanding subitems (a) and (b), a trade secret does not consist of information that a manufacturer is required to report pursuant to Section 44‑39‑130 to the extent that the information is required to be disclosed by that section.”

SECTION 4. This act takes effect upon approval by the Governor.

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