~~Indicates Matter Stricken~~

Indicates New Matter

AMENDED

May 4, 2022

**S. 628**

Introduced by Senator Davis

S. Printed 5/4/22--H. [SEC 5/5/22 2:59 PM]

Read the first time April 27, 2021.

**A** **BILL**

TO ENACT THE “PHARMACY ACCESS ACT”; TO AMEND CHAPTER 43, TITLE 40 OF THE 1976 CODE, RELATING TO THE SOUTH CAROLINA PHARMACY PRACTICE ACT, BY ADDING SECTIONS 40-43-210 THROUGH 40-43-280, TO PROVIDE THAT THE SOUTH CAROLINA PHARMACY PRACTICE ACT DOES NOT CREATE A DUTY OF CARE FOR A PERSON WHO PRESCRIBES OR DISPENSES A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR ADMINISTERS AN INJECTABLE HORMONAL CONTRACEPTIVE, TO PROVIDE THAT CERTAIN PHARMACISTS MAY DISPENSE A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR ADMINISTER AN INJECTABLE HORMONAL CONTRACEPTIVE PURSUANT TO A STANDING PRESCRIPTION DRUG ORDER, TO PROVIDE A JOINT PROTOCOL FOR DISPENSING A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR ADMINISTERING AN INJECTABLE HORMONAL CONTRACEPTIVE WITHOUT A PATIENT‑SPECIFIC WRITTEN ORDER, TO REQUIRE CONTINUING EDUCATION FOR A PHARMACIST DISPENSING A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR ADMINISTERING AN INJECTABLE HORMONAL CONTRACEPTIVE, TO IMPOSE REQUIREMENTS ON A PHARMACIST WHO DISPENSES A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR ADMINISTERS AN INJECTABLE HORMONAL CONTRACEPTIVE, TO PROVIDE THAT A PRESCRIBER WHO ISSUES A STANDING PRESCRIPTION DRUG ORDER FOR A SELF‑ADMINISTERED HORMONAL CONTRACEPTIVE OR INJECTABLE HORMONAL CONTRACEPTIVE IS NOT LIABLE FOR ANY CIVIL DAMAGES FOR ACTS OR OMISSIONS RESULTING FROM THE DISPENSING OR ADMINISTERING OF THE CONTRACEPTIVE, AND TO PROVIDE THAT THE SOUTH CAROLINA PHARMACY PRACTICE ACT SHALL NOT BE CONSTRUED TO REQUIRE A PHARMACIST TO DISPENSE, ADMINISTER, INJECT, OR OTHERWISE PROVIDE HORMONAL CONTRACEPTIVES; AND TO AMEND ARTICLE 1, CHAPTER 6, TITLE 44 OF THE 1976 CODE, RELATING TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, BY ADDING SECTION 44-6-115, TO PROVIDE FOR PHARMACIST SERVICES COVERED UNDER MEDICAID; AND TO DEFINE NECESSARY TERMS.

Amend Title To Conform

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

SECTION 1. This act shall be referred to as the “Pharmacy Access Act”.

SECTION 2. Chapter 43, Title 40 of the 1976 Code is amended by adding:

“Section 40‑43‑210. As used in this chapter:

(1) ‘Administer’ has the same meaning as in Section 40‑43‑30.

(2) ‘Department’ means the Department of Labor, Licensing and Regulation.

(3) ‘Dispense’ has the same meaning as in Section 40‑43‑30.

(4) ‘Injectable hormonal contraceptive’ means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a practitioner administers to a patient by injection. ‘Injectable hormonal contraceptive’ does not include any drug intended to terminate a pregnancy.

(5) ‘Patient counseling’ has the same meaning as in Section 40‑43‑30.

(6) ‘Pharmacist’ has the same meaning as in Section 40‑43‑30.

(7) ‘Practitioner’ has the same meaning as in Section 40‑47‑20.

(8) ‘Prescriber’ means a physician licensed pursuant to Chapter 47, Title 40; an advanced practice registered nurse licensed pursuant to Chapter 33, Title 40 and prescribing in accordance with the requirements of that chapter; or a physician assistant licensed pursuant to Article 7, Chapter 47, Title 40 and prescribing in accordance with the requirements of that article.

(9) ‘Self‑administered hormonal contraceptive’ means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to himself. ‘Self‑administered hormonal contraceptive’ includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch. ‘Self‑administered hormonal contraceptive’ does not include any drug intended to terminate a pregnancy.

Section 40‑43‑230. (A) A person licensed under the South Carolina Pharmacy Practice Act who is acting in good faith and exercising reasonable care as a pharmacist and who is employed by a hospital or a pharmacy that is permitted by this State may dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive pursuant to a standing order by a prescriber to a patient who is:

(1) eighteen years of age or older; or

(2) under eighteen years of age if the person has evidence of a previous prescription from a practitioner for a self‑administered hormonal contraceptive or an injectable hormonal contraceptive.

(B) Nothing in this section requires a pharmacist to dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive. Nothing in this article shall be construed to amend a pharmacist’s duties to dispense or otherwise provide contraception prescribed by another provider.

Section 40‑43‑240. (A) The Board of Medical Examiners and the Board of Pharmacy must issue a written joint protocol to authorize a pharmacist to dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive without a patient‑specific written order.

(B) The written joint protocol must address, at a minimum, the following requirements:

(1) education or training requirements that the Board of Medical Examiners and the Board of Pharmacy determine to be necessary for a pharmacist to dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive;

(2) information that a pharmacist must provide to a patient prior to dispensing a self‑administered hormonal contraceptive or administering an injectable hormonal contraceptive and confirmation that the required information was provided to the patient;

(3) documentation regarding the dispensing of a self‑administered hormonal contraceptive or the administering of an injectable hormonal contraceptive;

(4) notification to a patient’s designated practitioner that a self‑administered hormonal contraceptive was dispensed to the patient or that an injectable hormonal contraceptive was administered to the patient;

(5) evaluation and review of the dispensing and administration practices used by pharmacists authorized to dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive; and

(6) any additional provisions that the Board of Medical Examiners and the Board of Pharmacy determine to be necessary or appropriate for inclusion in the protocol, including any reporting requirements.

(C) For each new patient requesting contraception and at least every twelve months for each returning patient, the written joint protocol must require a pharmacist dispensing or administering contraceptives pursuant to this chapter to:

(1) obtain a completed self‑screening risk assessment;

(2) utilize a standardized procedure as established by the Board of Medical Examiners and the Board of Pharmacy to perform a patient assessment;

(3) dispense, if clinically appropriate, a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive, or refer the patient to a practitioner;

(4) provide the patient with a visit summary;

(5) advise the patient to consult with a practitioner;

(6) refer any patient who may be subject to abuse to the appropriate social services agency; and

(7) ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality.

(D) The Board of Medical Examiners and the Board of Pharmacy may appoint an advisory committee of healthcare professionals licensed in this State to advise and assist in the development of the joint protocol for their consideration.

Section 40‑43‑250. (A) Prior to dispensing self‑administered hormonal contraceptives or administering injectable hormonal contraceptives pursuant to Section 40‑43‑240, a pharmacist must have completed a certificate program that has been accredited by the American Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners, as specified in the joint protocol, that is program‑specific to self‑administered hormonal contraceptives or injectable hormonal contraceptives, that includes the application of the United States Medical Eligibility Criteria for Contraceptive Use, and that includes other Centers for Disease Control and Prevention guidance on contraception. To maintain eligibility, a pharmacist must complete at least one hour of continuing education per year that is offered by an entity approved by the Board of Medical Examiners and the Board of Pharmacy.

(B) An equivalent, curriculum‑based training program completed on or after January 2021 in an accredited South Carolina pharmacy school satisfies the initial education requirement.

Section 40‑43‑260. (A) A pharmacist who dispenses a self‑administered hormonal contraceptive or administers an injectable hormonal contraceptive pursuant to this chapter shall:

(1) obtain a completed self‑screening risk assessment questionnaire that has been approved by the department, in collaboration with the Board of Pharmacy and the Board of Medical Examiners, from the patient before dispensing the self‑administered hormonal contraceptive or administering the injectable hormonal contraceptive. If the results of the assessment indicate that it is unsafe to dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive to a patient, then the pharmacist may not dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive to the patient, shall refer the patient to a practitioner, and may not continue to dispense a self‑administered hormonal contraceptive or administer an injectable hormonal contraceptive to the patient for more than twenty‑four months after the date of the initial prescription without evidence that the patient has consulted with a practitioner during the preceding twenty‑four months; and

(2) provide the patient with written information regarding:

(a) the importance of seeing the patient’s practitioner annually to obtain recommended tests and screening;

(b) the effectiveness and availability of long‑acting reversible contraceptives as an alternative to self‑administered hormonal contraceptives or injectable hormonal contraceptives;

(c) a copy of the record of the encounter with the patient that includes the patient’s completed assessment questionnaire pursuant to item (1);

(d) a description of the contraceptive dispensed or administered, or the basis for not dispensing or administering a contraceptive;

(e) the South Carolina Medicaid program and how to apply for Medicaid benefits; and

(f) the effectiveness of abstinence in preventing pregnancy and contracting a sexually transmitted infection or disease. The materials shall include the following: Abstinence is the choice not to have sex. This method is one hundred percent effective in preventing pregnancy and infection as long as all sexual contact is avoided, including vaginal, oral, and anal sex.

(B) If a pharmacist dispenses a self‑administered hormonal contraceptive or administers an injectable hormonal contraceptive to a patient, then the pharmacist shall, at a minimum, provide patient counseling to the patient regarding:

(1) the appropriate administration and storage of a self‑administered hormonal contraceptive, if appropriate;

(2) any potential side effects and risks of a self‑administered hormonal contraceptive or injectable hormonal contraceptive;

(3) the need for backup contraception;

(4) when to seek emergency medical attention; and

(5) the risk of contracting a sexually transmitted infection or disease, along with ways to reduce the risk of contraction.

Section 40‑43‑270. (A) A prescriber who issues a standing prescription drug order in accordance with Section 40‑43‑260 is not liable for any civil damages for acts or omissions resulting from the dispensing of a self‑administered hormonal contraceptive or the administering of an injectable hormonal contraceptive under this chapter.

(B) A pharmacist who dispenses a self-administered hormonal contraceptive or administers an injectable hormonal contraceptive in accordance with the provisions of this article is not as a result of an act or omission subject to civil or criminal liability or to professional disciplinary action.”

SECTION 3. Article 1, Chapter 6, Title 44 of the 1976 Code is amended by adding:

“Section 44‑6‑115. (A) Pharmacy services are a benefit under South Carolina Medicaid, subject to approval by the federal Centers for Medicare and Medicaid Services. The department shall establish a fee schedule for the list of pharmacy services.

(B)(1) The following services are covered pharmacy services that may be provided to a Medicaid beneficiary:

(a) dispensing self‑administered hormonal contraceptives, as outlined and authorized in Section 40‑43‑230; and

(b) administering injectable hormonal contraceptives, as outlined and authorized in Section 40‑43‑230.

(2) Covered pharmacy services shall be subject to department protocols and utilization controls.

(C) A pharmacist shall be enrolled as an ordering, referring, and dispensing provider under the Medicaid program prior to rendering a pharmacist service that is submitted by a Medicaid pharmacy provider for reimbursement pursuant to this section.

(D) The director of the department shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(E) This section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter or the Medicaid state plan.”

SECTION 4. The Board of Medical Examiners and the Board of Pharmacy must issue a written joint protocol pursuant to Section 40‑43‑240 not later than six months after the passage of this act.

SECTION 5. Section 44-53-362(B) of the 1976 Code is amended to read:

“(B) The Department of Health and Environmental Control shall develop guidance for pharmacies and other entities qualified to register as a collector to encourage participation. The department shall coordinate with law enforcement, health care providers, and the U.S. Drug Enforcement Administration to encourage registration as a collector and to promote public awareness of controlled substance take‑back events and mail‑back programs. A pharmacist who dispenses a self-administered hormonal contraceptive or administers an injectable hormonal contraceptive pursuant to Section 40-43-260 must provide the patient with written information regarding controlled substance take-back events and mail-back programs.”

SECTION 6. A. Chapter 43, Title 40 of the 1976 Code is amended by adding:

“Section 40‑43‑195. (A) For purposes of this section:

(1) ‘Central fill’ means the filling of a prescription drug order by one central fill pharmacy permitted by this State at the request of an originating pharmacy permitted by this State.

(2) ‘Central fill pharmacy’ means a permitted pharmacy facility that, upon the request of an originating pharmacy, fills a prescription drug order and returns the filled prescription to the originating pharmacy for delivery to the patient or patient’s agent. A central fill pharmacy that returns filled prescriptions to an originating pharmacy must not be required to obtain a wholesaler/distributor permit.

(3) ‘Originating pharmacy’ means a pharmacy permitted by and located in this State or another state if providing services on behalf of a patient located in South Carolina that, upon receipt of a prescription drug order from a patient, requests a central fill pharmacy to fill the order and upon receipt of the filled prescription drug order, delivers the prescription to the patient or patient’s agent.

(B)(1) An originating pharmacy permitted by this State may outsource a prescription drug order filling to a central fill pharmacy permitted by this State if the pharmacies:

(a) have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(b) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order;

(c) ensure all state and federal laws regarding patient confidentiality, network security, and use of shared databases are followed; and

(d) maintain the prescription information in a readily retrievable manner.

(2) The pharmacist‑in‑charge of a central fill pharmacy shall ensure that:

(a) the pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. These shipping processes must include the use of appropriate packaging material or devices, or both, to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and

(b) the filled prescriptions are shipped in containers that are sealed in a manner that would show evidence of having been opened or tampered with.

(3) To the extent that a central fill pharmacy dispenses controlled substances, the central fill pharmacy must obtain a registration from the Department of Health and Environmental Control, Bureau of Drug Control. Controlled substance prescriptions filled by a central fill pharmacy must comply with both state and federal statutes and regulations.

(4) To the extent a pharmacy is acting as a central fill pharmacy, it may not:

(a) fill prescriptions for controlled substances listed in Schedule II;

(b) fill prescriptions provided directly by a patient or an individual practitioner;

(c) mail or otherwise deliver a prescription directly to a patient or an individual practitioner; or

(d) provide or dispense cannabis products not approved by the Federal Drug Administration.

(C)(1) An originating pharmacy that outsources prescription filling to a central fill pharmacy must, prior to outsourcing the prescription:

(a) notify patients that their prescription may be filled by another pharmacy; and

(b) provide the name of that pharmacy or notify the patient if the pharmacy is part of a network of pharmacies under common ownership and that any of the network pharmacies may fill the prescription.

(2) Patient notification may be provided through a one‑time written notice to the patient or through use of a sign in the pharmacy.

(D)(1) A central fill pharmacy must provide written information regarding the prescription with the filled prescription and a toll‑free phone number for patient questions. The following statement must be provided with the prescription before delivery to the patient:

‘Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions’.

(2) A pharmacist at the originating pharmacy shall offer the patient or the patient’s agent information about the prescription drug or device in accordance with Section 40‑43‑86(L).

(3) This subsection does not apply to patients in facilities including, but not limited to, hospitals or nursing homes, where drugs are administered to patients by a person authorized to do so by law.

(E) The central fill pharmacy must:

(1) place on the prescription label:

(a) the name and address or name and pharmacy license number of the pharmacy filling the prescription;

(b) the name and address of the originating pharmacy which receives the filled prescription for delivery to the patient or the patient’s agent; and

(c) in some manner indicate which pharmacy filled the prescription (e.g., ‘Filled by ABC Pharmacy for XYZ Pharmacy’); and

(2) comply with all other labeling requirements of federal and state law including, but not limited to, Section 40‑43‑86.

(F) A central fill policy and procedure manual must be maintained at both pharmacies and must be available for inspection. The originating and central fill pharmacies are required to maintain only those portions of the policy and procedure manual that relate to that pharmacy’s operations. The manual must at minimum contain:

(1) An outline of the responsibilities of the central fill pharmacy and the originating pharmacy including, but not limited to:

(a) patient notification of central fill processing;

(b) confidentiality and integrity of patient information procedures;

(c) drug utilization review;

(d) record keeping and logs, including a list of the names, addresses, phone numbers, and license or registration numbers of the pharmacies, pharmacists, and pharmacy technicians at the central fill pharmacy and at the originating pharmacy;

(e) counseling responsibilities;

(f) procedures for return of prescriptions not delivered to a patient and procedures for invoicing medication transfers;

(g) policies for operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(h) safe delivery of prescriptions to patients;

(i) processes to ensure stability and potency of medication;

(j) requirements for storage and shipment of prescription medication; and

(k) procedures for conducting an annual review of written policies and procedures and for documentation of this review.

(2) Other responsibilities regarding proper handling of a prescription and delivery to a patient or a patient’s agent pursuant to this chapter and the Department of Health and Environmental Control, controlled substances laws and regulations.

(G)(1) Records may be maintained in an alternative data retention system including, but not limited to, a data processing system or direct imaging system, if:

(a) the records maintained in the alternative system contain all of the information required on the manual record; and

(b) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agency.

(2) Each pharmacy must maintain records in accordance with the provisions of Section 40‑43‑86 and must be able to produce records as requested by the board.

(3) The originating pharmacy records must include the date the request for filling was transmitted to the central fill pharmacy.

(4) The central fill pharmacy records must include:

(a) the date the filled prescription was mailed by the central fill pharmacy; and

(b) the name and address to which the filled prescription was shipped.

(H)(1) A central fill pharmacy must complete a central fill pharmacy permit application provided by the board, following the procedures as specified in Section 40‑43‑83, and also provide the following information:

(a) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(b) the name of the owner, permit holder, and pharmacist‑in‑charge of the pharmacy for service of process;

(c) evidence of the applicant’s ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this State not later than seventy‑two hours after the time the board requests the record;

(d) an affidavit by the pharmacist‑in‑charge which states that the pharmacist has read and understands the laws and regulations relating to a central fill pharmacy in this State; and

(e) pay the required fee as set by the board through regulation.

(2) A central fill pharmacy must comply with all provisions of this chapter.

(I) Nothing in this section may be construed to circumvent any requirement of Section 40‑43‑86 of the South Carolina Pharmacy Practice Act.

(J) A central fill pharmacy may not contact a patient for whom it has provided central fill services on behalf of an originating pharmacy for the purpose of soliciting or requesting to refill a prescription, or to fill a new prescription, for a period of five years after the originating pharmacy has stopping using the services of the central fill pharmacy.”

B. This SECTION takes effect upon approval by the Governor.

SECTION 7. Except as otherwise specifically provided, this act takes effect upon the issuance of a written joint protocol pursuant to SECTION 4 of this act.

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