COMMITTEE REPORT

March 3, 2022

**S. 1034**

Introduced by Senator Gambrell

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Read the first time February 1, 2022.

**THE COMMITTEE ON MEDICAL AFFAIRS**

To whom was referred a Bill (S. 1034) to amend the Code of Laws of South Carolina, 1976, by adding Section 40‑43‑195 so as to authorize central fill pharmacies to be established in this State, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass:

DANIEL B. VERDIN III for Committee.

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING SECTION 40‑43‑195 SO AS TO AUTHORIZE CENTRAL FILL PHARMACIES TO BE ESTABLISHED IN THIS STATE FOR THE PURPOSE OF FILLING PRESCRIPTIONS FOR, AND AT THE REQUEST OF, AN ORIGINATING PHARMACY; TO ESTABLISH CERTAIN OPERATING PROCEDURES AND REQUIREMENTS FOR CENTRAL FILL PHARMACIES INCLUDING, AMONG OTHER THINGS, OBTAINING A CENTRAL FILL PHARMACY PERMIT AND A CONTROLLED SUBSTANCES REGISTRATION, IF APPROPRIATE, NOTIFYING PATIENTS OF CENTRAL FILL PROCESSING PROCEDURES, REQUIRING WRITTEN PRESCRIPTION DRUG INFORMATION AND A TOLL‑FREE NUMBER, PROVIDING PRESCRIPTION LABELING AND RECORD KEEPING REQUIREMENTS, AND REQUIRING POLICIES AND PROCEDURES MANUALS.

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

SECTION 1. 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 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; or

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

(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; and

(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.”

SECTION 2. This act takes effect upon approval by the Governor.

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