**A** **BILL**

TO AMEND SECTION 40-43-75 OF THE 1976 CODE, RELATING TO RENAL DIALYSIS FACILITIES, TO PROVIDE THAT A RENAL DRUG MANUFACTURER OR ITS AGENT MAY DELIVER A LEGEND DRUG OR DEVICE TO A PATIENT OF A RENAL DIALYSIS FACILITY IF CERTAIN CRITERIA ARE MET, AND TO DEFINE NECESSARY TERMS.

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

SECTION 1. Section 40-43-75 of the 1976 Code is amended to read:

“Section 40-43-75. (A) For purposes of this section:

(1) ‘Renal dialysis facility’ or ‘RDF’ means an outpatient facility that treats and offers staff‑assisted dialysis or training and support services for self‑dialysis patients to end‑stage renal disease patients, as defined by Centers for Medicare and Medicaid Services. An RDF may be composed of one or more fixed buildings, mobile units, or a combination of them, as defined in R. 61‑97. An RDF must be certified by Medicare to provide dialysis‑related services to ESRD patients and must have a medical director licensed as a physician, pursuant to Chapter 47, Title 40, on staff.

(2) ‘End‑stage renal disease’ or ‘ESRD’ means the disease state, and associated conditions, defined under 42 C.F.R. 406.13 and the United States Social Security Act.

(3) ‘Renal drug manufacturer’ means a manufacturer of legend drugs or devices for self-dialysis by RDF patients.

(B) An RDF may deliver a legend drug or device to a patient of an RDF if:

(1) the drug or device is for home use by the patient or for administration in the facility as required by the prescriber's order or prescription;

(2) the drug or device is dispensed to the RDF by a properly licensed resident or nonresident pharmacy licensed by the board or administered by a properly licensed health care practitioner;

(3) the drug or device is dispensed by the pharmacy pursuant to a valid prescription issued by a licensed practitioner, as defined in Section 40‑43‑30(72);

(4) the drug or device delivered by the RDF is properly labeled in accordance with state and federal law;

(5) the drug or device is held by the RDF in a secure location in an area not accessible to the public, and packages containing drugs or devices are delivered by RDF staff, unopened, to the patient;

(6) the patient is given a choice of receiving the drug or device from the RDF, at their home, or from another agent;

(7) the drugs exclude controlled substances; and

(8) the RDF maintains policies and procedures concerning how it will receive, store, maintain, and return any drugs or devices that are not picked up by the patient and returned to the dispensing pharmacy.

(C) A renal drug manufacturer may deliver a legend drug or device to a patient of an RDF if the following criteria are met:

(1) the dialysate drugs or devices are approved by the United States Food and Drug Administration as required by federal law;

(2) the dialysate drugs or devices are lawfully held by a renal drug manufacturer or a renal drug manufacturer’s agent that is properly registered with the board as a manufacturer or wholesale drug distributor;

(3) the dialysate drugs or devices are held and delivered in their original sealed and labeled packaging from the renal drug manufacturing facility;

(4) the dialysate drugs or devices are delivered only by the renal drug manufacturer or the renal drug manufacturer’s agent and only upon receipt of a physician’s order; and

(5) the renal drug manufacturer or the renal drug manufacturer’s agent delivers dialysate drugs or devices directly to a patient with end-stage renal disease, or his designee, for the patient’s self-administration of dialysis therapy, or to a health care provider or institution for administration or delivery of dialysis therapy to a patient with end-stage renal disease.

(D) The provisions of this section do not waive any other requirements to obtain licensure, permits, or certification as required by law to possess legend drug products. A facility engaged in an activity related to the delivery or distribution of legend drugs still shall hold the requisite licensure or drug permits required by law.”

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

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