**South Carolina General Assembly**

124th Session, 2021-2022

**A48, R61, S427**

**STATUS INFORMATION**

General Bill

Sponsors: Senators Alexander, Hutto and Scott

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Introduced in the Senate on January 12, 2021

Introduced in the House on March 2, 2021

Last Amended on May 5, 2021

Passed by the General Assembly on May 11, 2021

Governor's Action: May 17, 2021, Signed

Summary: Renal dialysis

**HISTORY OF LEGISLATIVE ACTIONS**

Date Body Action Description with journal page number

1/12/2021 Senate Introduced and read first time ([Senate Journal‑page 308](file:///h:\sj\20210112.docx))

1/12/2021 Senate Referred to Committee on **Medical Affairs** ([Senate Journal‑page 308](file:///h:\sj\20210112.docx))

2/18/2021 Senate Committee report: Favorable with amendment **Medical Affairs** ([Senate Journal‑page 7](file:///h:\sj\20210218.docx))

2/24/2021 Senate Committee Amendment Adopted ([Senate Journal‑page 22](file:///h:\sj\20210224.docx))

2/24/2021 Senate Read second time ([Senate Journal‑page 22](file:///h:\sj\20210224.docx))

2/24/2021 Senate Roll call Ayes‑42 Nays‑0 ([Senate Journal‑page 22](file:///h:\sj\20210224.docx))

2/25/2021 Senate Read third time and sent to House ([Senate Journal‑page 15](file:///h:\sj\20210225.docx))

3/2/2021 House Introduced and read first time ([House Journal‑page 13](file:///h:\hj\20210302.docx))

3/2/2021 House Referred to Committee on **Medical, Military, Public and Municipal Affairs** ([House Journal‑page 13](file:///h:\hj\20210302.docx))

4/29/2021 House Committee report: Favorable with amendment **Medical, Military, Public and Municipal Affairs** ([House Journal‑page 79](file:///h:\hj\20210429.docx))

5/5/2021 House Amended ([House Journal‑page 10](file:///h:\hj\20210505.docx))

5/5/2021 House Read second time ([House Journal‑page 10](file:///h:\hj\20210505.docx))

5/5/2021 House Roll call Yeas‑103 Nays‑0 ([House Journal‑page 11](file:///h:\hj\20210505.docx))

5/6/2021 House Returned to Senate with amendments ([House Journal‑page 14](file:///h:\hj\20210506.docx))

5/11/2021 Senate Concurred in House amendment and enrolled ([Senate Journal‑page 31](file:///h:\sj\20210511.docx))

5/11/2021 Senate Roll call Ayes‑44 Nays‑0 ([Senate Journal‑page 31](file:///h:\sj\20210511.docx))

5/13/2021 Ratified R 61

5/17/2021 Signed By Governor

6/1/2021 Effective date 05/17/21

6/1/2021 Act No.  48

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**VERSIONS OF THIS BILL**

[1/12/2021](file:///p:\pprever\2021-22\427_20210112.docx)

[2/18/2021](file:///p:\pprever\2021-22\427_20210218.docx)

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[5/5/2021](file:///p:\pprever\2021-22\427_20210505.docx)

(A48, R61, S427)

**AN ACT** **TO AMEND SECTION 40‑43‑75, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO PROVISIONS IN THE PHARMACY PRACTICE ACT REGARDING RENAL DIALYSIS FACILITIES, SO AS TO PROVIDE RENAL DRUG MANUFACTURERS OR THEIR AGENTS MAY DELIVER CERTAIN LEGEND DIALYSATE DRUGS OR DEVICES TO RENAL DIALYSIS FACILITY PATIENTS IF CERTAIN CRITERIA ARE MET, AND TO DEFINE NECESSARY TERMS; AND TO AMEND SECTION 40‑43‑130, RELATING TO CONTINUING EDUCATION REQUIREMENTS IN THE PHARMACY PRACTICE ACT, SO AS TO REMOVE MINIMUM IN‑PERSON CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS AND PHARMACY TECHNICIANS.**

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

**Renal dialysis facilities, drug and device delivery by manufacturers**

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 dialysate drug comprised of dextrose or icodextrin or a 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.”

**Continuing education requirements, pharmacists**

SECTION 2. Section 40‑43‑130(B) of the 1976 Code is amended to read:

“(B) Each licensed pharmacist, as a condition of an active status license renewal, shall complete fifteen hours (1.5 CEU’s) of American Council on Pharmaceutical Education (ACPE) accredited continuing pharmacy education or continuing medical education (CME), Category I, or both, each license year. At least fifty percent of the total number of hours required must be in drug therapy or patient management and at least one hour must be related to approved procedures for monitoring controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44‑53‑210, 44‑53‑230, and 44‑53‑250.”

**Continuing education requirements, pharmacy technicians**

SECTION 3. Section 40‑43‑130(G)(1) of the 1976 Code is amended to read:

“(1) As a condition of registration renewal, a registered pharmacy technician shall complete ten hours of American Council on Pharmaceutical Education or CME I approved continuing education each year, beginning with the next renewal period after June 30, 2003.”

**Time effective**

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

Ratified the 13th day of May, 2021.

Approved the 17th day of May, 2021.

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