

Amendment No. 1 to HB1222

Sexton C
Signature of Sponsor

AMEND Senate Bill No. 518*

House Bill No. 1222

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:

(a) This chapter does not apply to a facility to the extent the facility engages in the distribution of dialysate or devices necessary to perform home peritoneal kidney dialysis to patients with end stage renal disease if:

(1) The dialysate are comprised of dextrose or icodextrin, and the dialysate and devices are approved or cleared by the federal food and drug administration, as required by federal law;

(2) The dialysate and devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the board as a manufacturer or third-party logistics provider;

(3) The dialysate and devices are held and delivered in their original, sealed packaging from the facility;

(4) The dialysate and devices are delivered only by the manufacturer or the manufacturer's agent and only upon receipt and review of a physician's prescription by a pharmacist licensed in this state before dispensing; and

(5) The manufacturer or manufacturer's agent delivers the dialysate and devices directly to:

(A) Patients with end stage renal disease or such patient's designee for the patient's self-administration of the dialysis therapy; or

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(B) Healthcare providers or institutions for administration or
delivery of the dialysis therapy to a patient with end stage renal disease.

(b) Records of all sales and distribution of dialysate and devices made pursuant
to this section must be retained and made readily available for inspection and copying by
the board of pharmacy for two (2) years from the date of distribution.

(c) The board of pharmacy retains oversight of all of drugs for peritoneal dialysis
except dialysate.

SECTION 2. This act shall take effect July 1, 2017, the public welfare requiring it.