

§ 90-85.21C. Pharmacy permit exemption for dispensing and delivery of home renal products.

Each location or facility within or outside this State from which dialysate or drugs necessary to perform home renal dialysis are dispensed and delivered to a patient in this State is exempt from the pharmacy permit requirements established by G.S. 90-85.21 and G.S. 90-8.21A, provided that all the following criteria are met:

- (1) The dialysate or drugs have been approved or cleared by United States Food and Drug Administration.
- (2) The dialysate or drugs are lawfully held by a manufacturer or an agent of the manufacturer that is properly licensed by the North Carolina Department of Agriculture and Consumer Services as a manufacturer, or as a wholesaler, or as both, as required by G.S. 106-145.3.
- (3) The dialysate or drugs are held, delivered, and dispensed in their original, sealed packaging from the manufacturing facility.
- (4) The dialysate or drugs are delivered only by the manufacturer, or an agent of the manufacturer, and only upon receipt of a physician's order.
- (5) The manufacturer or an agent of the manufacturer delivers the dialysate or drugs directly to either of the following:
 - a. A patient with chronic kidney failure or a designee of the patient, for self-administration of the dialysis therapy.
 - b. A health care provider, or health care facility licensed under Chapter 122C, 131D, or 131E of the General Statutes, for administration or delivery of the dialysis therapy to a patient with chronic kidney failure. (2015-28, s. 1.)