AN ACT relating to pharmacists.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 315.0351 is amended to read as follows:

(1) Except as provided in subsection (2) of this section:

(a) Every person or pharmacy located outside this Commonwealth which does business, physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth within the meaning of KRS Chapter 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy permit." The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035;

(b) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist;

(c) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent

inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the jurisdiction in which it is located;

(d) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed;

(e) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy;

(f) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth;

(g) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to engage in the practice of pharmacy by the Commonwealth that shall be responsible for compliance by the pharmacy with the provisions of this section and for the distribution and sale of dialysate solutions and devices pursuant to subsection (2) of this section***. No pharmacist employed by or contracted with the out-of-state pharmacy other than the pharmacist in***

charge shall be required to be licensed by the Commonwealth;

(h) Each out-of-state pharmacy shall comply with KRS 218A.202;

(i) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current;

(j) Any out-of-state pharmacy doing business in the Commonwealth of Kentucky shall certify the percentage of its annual business conducted via the Internet and electronic mail and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal;

(k) Any pharmacy doing business within the Commonwealth of Kentucky shall use the address on file with the Kentucky Board of Pharmacy as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner; and

(l) The Kentucky Board of Pharmacy may waive the permit requirements of this chapter for an out-of-state pharmacy that only does business within the Commonwealth of Kentucky in limited transactions.

(2) (a) Only subsection (1)(g) of this section shall apply to the sale or distribution of dialysate solutions or devices necessary to perform home peritoneal kidney dialysis to patients with end-stage renal disease, if:

1. The dialysate solutions or devices are approved or cleared by the federal Food and Drug Administration, as required by federal law;
2. The dialysate solutions or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with or licensed by the board as a manufacturer, wholesale distributer, or third-party logistics provider under this chapter;
3. The dialysate solutions or devices are held and delivered in their original, sealed packaging from a Food and Drug Administration-approved manufacturing facility;
4. The dialysate solutions or devices are only delivered upon receipt of a physician's prescription by a Kentucky licensed pharmacy and the transmittal of an order from the Kentucky licensed pharmacy to the manufacturer or manufacturer's agent; and
5. The manufacturer or manufacturer's agent delivers the dialysate solutions or devices directly to:
   a. A patient with end-stage renal disease or the patient's designee for the patient's self-administration of dialysis therapy; or
   b. A health-care provider or institution for administration or delivery of dialysis therapy to a patient with end-stage renal disease.

(b) 1. A manufacturer or manufacturer's agent who sells or distributes dialysate solutions or devices under this subsection shall employ or contract with a pharmacist who is licensed to engage in the practice of pharmacy by the Commonwealth to conduct a retrospective audit on ten percent (10%) of the orders processed by that manufacturer or manufacturer's agent each month.

2. On or before February 1 of each year, an annual summary of the monthly audits shall be prepared and submitted to the board, in the form

prescribed by the board.

3. On or before June 1 of each year, the board shall compile the summaries of monthly audits into a single report and submit that report to the Interim Joint Committee on Health and Welfare and Family Services.

(c) Prescriptions and records of delivery for dialysate solutions or devices sold or distributed under this subsection shall be maintained by the manufacturer or manufacturer's agent for a minimum of two (2) years and shall be made available to the board upon request.

(d) As used in this subsection, "dialysate solutions" means dextrose or icodextrin when used to perform home peritoneal kidney dialysis.

(e) The Kentucky Board of Pharmacy will retain oversight of the distribution of dialysate solutions and devices under this section.