

1 AN ACT relating to pharmacists.

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

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

- 4 (1) Except as provided in subsection (2) of this section:
- 5 (a) Every person or pharmacy located outside this Commonwealth which does
6 business, physically or by means of the Internet, facsimile, phone, mail, or
7 any other means, inside this Commonwealth within the meaning of KRS
8 Chapter 315, shall hold a current pharmacy permit as provided in KRS
9 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy
10 shall be designated an "out-of-state pharmacy" and the permit shall be
11 designated an "out-of-state pharmacy permit." The fee for the permit shall not
12 exceed the current in-state pharmacy permit fee as provided under KRS
13 315.035;
- 14 (b) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the
15 board shall disclose to the board the location, names, and titles of all principal
16 corporate officers and all pharmacists who are dispensing prescription drugs
17 to residents of the Commonwealth. A report containing this information shall
18 be made to the board on an annual basis and within thirty (30) days after any
19 change of office, corporate officer, or pharmacist;
- 20 (c) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall
21 comply with all statutorily-authorized directions and requests for information
22 from any regulatory agency of the Commonwealth and from the board in
23 accordance with the provisions of this section. The out-of-state pharmacy
24 shall maintain at all times a valid unexpired permit, license, or registration to
25 conduct the pharmacy in compliance with the laws of the jurisdiction in which
26 it is a resident. As a prerequisite to seeking a permit from the Kentucky Board
27 of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent

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

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

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

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

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

1 *charge shall be required to be licensed by the Commonwealth;*

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

3 (i) Any out-of-state pharmacy that dispenses more than twenty-five percent
4 (25%) of its total prescription volume as a result of an original prescription
5 order received or solicited by use of the Internet, including but not limited to
6 electronic mail, shall receive and display in every medium in which it
7 advertises itself a seal of approval for the National Association of Boards of
8 Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site
9 (VIPPS) or a seal certifying approval of a substantially similar program
10 approved by the Kentucky Board of Pharmacy. VIPPS, or any other
11 substantially similar accreditation, shall be maintained and remain current;

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

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

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

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

- 1 1. The dialysate solutions or devices are approved or cleared by the federal
2 Food and Drug Administration, as required by federal law;
- 3 2. The dialysate solutions or devices are lawfully held by a manufacturer
4 or manufacturer's agent that is properly registered with or licensed by
5 the board as a manufacturer, wholesale distributor, or third-party
6 logistics provider under this chapter;
- 7 3. The dialysate solutions or devices are held and delivered in their
8 original, sealed packaging from a Food and Drug Administration-
9 approved manufacturing facility;
- 10 4. The dialysate solutions or devices are only delivered upon receipt of a
11 physician's prescription by a Kentucky licensed pharmacy and the
12 transmittal of an order from the Kentucky licensed pharmacy to the
13 manufacturer or manufacturer's agent; and
- 14 5. The manufacturer or manufacturer's agent delivers the dialysate
15 solutions or devices directly to:
 - 16 a. A patient with end-stage renal disease or the patient's designee for
17 the patient's self-administration of dialysis therapy; or
 - 18 b. A health-care provider or institution for administration or delivery
19 of dialysis therapy to a patient with end-stage renal disease.
- 20 (b) 1. A manufacturer or manufacturer's agent who sells or distributes
21 dialysate solutions or devices under this subsection shall employ or
22 contract with a pharmacist who is licensed to engage in the practice of
23 pharmacy by the Commonwealth to conduct a retrospective audit on ten
24 percent (10%) of the orders processed by that manufacturer or
25 manufacturer's agent each month.
- 26 2. On or before February 1 of each year, an annual summary of the
27 monthly audits shall be prepared and submitted to the board, in the form

1 prescribed by the board.

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

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

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

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

13 ➔Section 2. KRS 315.191 is amended to read as follows:

14 (1) The board is authorized to:

15 (a) Promulgate administrative regulations pursuant to KRS Chapter 13A
16 necessary to regulate and control all matters set forth in this chapter relating to
17 pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale
18 distributors, and manufacturers, to the extent that regulation and control of
19 same have not been delegated to some other agency of the Commonwealth,
20 but administrative regulations relating to drugs shall be limited to the
21 regulation and control of drugs sold pursuant to a prescription drug order.
22 However, nothing contained in this chapter shall be construed as authorizing
23 the board to promulgate any administrative regulations relating to prices or
24 fees or to advertising or the promotion of the sales or use of commodities or
25 services;

26 (b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to
27 schedule and conduct hearings on behalf of the board on any matter under the

- 1 jurisdiction of the board;
- 2 (c) Prescribe the time, place, method, manner, scope, and subjects of
3 examinations, with at least two (2) examinations to be held annually;
- 4 (d) Issue and renew all licenses, certificates, and permits for all pharmacists,
5 pharmacist interns, pharmacies, pharmacy technicians, wholesale distributors,
6 and manufacturers engaged in the manufacture, distribution, or dispensation
7 of drugs;
- 8 (e) Investigate all complaints or violations of the state pharmacy laws and the
9 administrative regulations promulgated by the board, and bring all these cases
10 to the notice of the proper law enforcement authorities;
- 11 (f) Promulgate administrative regulations, pursuant to KRS Chapter 13A, that are
12 necessary and to control the storage, retrieval, dispensing, refilling, and
13 transfer of prescription drug orders within and between pharmacists and
14 pharmacies licensed or issued a permit by it;
- 15 (g) Perform all other functions necessary to carry out the provisions of law and
16 the administrative regulations promulgated by the board relating to
17 pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale
18 distributors, and manufacturers;
- 19 (h) Establish or approve programs for training, qualifications, and registration of
20 pharmacist interns;
- 21 (i) Assess reasonable fees, in addition to the fees specifically provided for in this
22 chapter and consistent with KRS 61.870 to 61.884, for services rendered to
23 perform its duties and responsibilities, including, but not limited to, the
24 following:
- 25 1. Issuance of duplicate certificates;
- 26 2. Mailing lists or reports of data maintained by the board;
- 27 3. Copies of documents; or

- 1 4. Notices of meetings;
- 2 (j) Seize any drug or device found by the board to constitute an imminent danger
- 3 to public health and welfare;
- 4 (k) 1. Establish an advisory council to advise the board on statutes,
- 5 administrative regulations, and other matters, within the discretion of the
- 6 board, pertinent to the regulation of pharmacists, pharmacist interns,
- 7 pharmacy technicians, pharmacies, drug distribution, and drug
- 8 manufacturing. The council shall provide recommendations for
- 9 changes in statutes or administrative regulations to the board and
- 10 shall be consulted by the board prior to the submission of
- 11 recommendations for changes in statutes or administrative regulations
- 12 by the board to the Legislative Research Commission.
- 13 2. The council shall consist of nine (9) pharmacists broadly representative
- 14 of the profession of pharmacy and one (1) citizen at large who is not
- 15 associated with or financially interested in the practice of pharmacy.
- 16 For purposes of this subparagraph, "broadly representative" means
- 17 one (1) pharmacist employed by and who practices or specializes
- 18 primarily in each of the following practice areas:
- 19 a. Specialized pharmacy that solely or mostly provides medication
- 20 to persons living with serious health conditions requiring
- 21 complex therapies;
- 22 b. Chain community pharmacy with five (5) or more locations in
- 23 Kentucky;
- 24 c. Independent community pharmacy with four (4) or fewer
- 25 locations in Kentucky;
- 26 d. Hospital or health facility pharmacy;
- 27 e. Mail order pharmacy that solely sends prescriptions to patients

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via mail;

f. Long-term care pharmacy that solely or mostly provides medications to persons living in residential care facilities;

g. Mail order pharmacy with compounding capability that primarily serves companion animals;

h. Home-infusion or home-care services pharmacy; and

i. Wholesale facility.

3. Each pharmacist member shall be licensed by the board, a resident of Kentucky, and employed for at least two (2) consecutive years in the practice area he or she represents.

4. Members shall serve terms of up to four (4) years, and shall not serve more than two (2) consecutive terms.

5. Members shall be selected by the board from a list of qualified candidates submitted by the Kentucky Pharmacists Association, Kentucky Society of Health-System Pharmacists, and other interested parties.

6. Members shall be confirmed by roll call vote of the board at a meeting conducted in accordance with the Open Meetings Act, KRS 61.805 to

~~61.850[nine (9) members selected by the board for terms of up to four (4) years. No member shall serve on the council for more than eight (8) years. Membership of the council shall include nine (9) individuals broadly representative of the profession of pharmacy and the general public. Members shall be selected by the board from a list of qualified candidates submitted by the association, society, or other interested parties]; and~~

(1) Promulgate administrative regulations establishing the qualifications that pharmacy technicians are required to attain prior to engaging in pharmacy

1 practice activities outside the immediate supervision of a pharmacist.

2 (2) The board shall have other authority as may be necessary to enforce pharmacy laws
3 and administrative regulations of the board including, but not limited to:

4 (a) Joining or participating in professional organizations and associations
5 organized exclusively to promote improvement of the standards of practice of
6 pharmacy for the protection of public health and welfare or facilitate the
7 activities of the board; and

8 (b) Receiving and expending funds, in addition to its biennial appropriation,
9 received from parties other than the state, if:

10 1. The funds are awarded for the pursuit of a specific objective which the
11 board is authorized to enforce through this chapter, or which the board is
12 qualified to pursue by reason of its jurisdiction or professional expertise;

13 2. The funds are expended for the objective for which they were awarded;

14 3. The activities connected with or occasioned by the expenditure of the
15 funds do not interfere with the performance of the board's
16 responsibilities and do not conflict with the exercise of its statutory
17 powers;

18 4. The funds are kept in a separate account and not commingled with funds
19 received from the state; and

20 5. Periodic accountings of the funds are maintained at the board office for
21 inspection or review.

22 (3) In addition to the sanctions provided in KRS 315.121, the board or its hearing
23 officer may direct any licensee, permit holder, or certificate holder found guilty of a
24 charge involving pharmacy or drug laws, rules, or administrative regulations of the
25 state, any other state, or federal government, to pay to the board a sum not to
26 exceed the reasonable costs of investigation and prosecution of the case, not to
27 exceed twenty-five thousand dollars (\$25,000).

- 1 (4) In an action for recovery of costs, proof of the board's order shall be conclusive
2 proof of the validity of the order of payment and any terms for payment.