- 1 HB687
- 2 119801-1
- 3 By Representative Johnson
- 4 RFD: Health
- 5 First Read: 09-MAR-10

1	119801-1:n:03/09/2010:FC/tan LRS2010-1721
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8	SYNOPSIS: Under existing law, pharmacies are required
9	to have permits from the State Board of Pharmacy to
10	operate.
11	This bill would define the term hospital
12	pharmacy services permit and would provide for
13	issuance of the permits.
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15	A BILL
16	TO BE ENTITLED
17	AN ACT
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19	To amend Sections 34-23-1, 34-23-30, 34-23-70, and
20	34-23-74, Code of Alabama 1975, relating to the regulations of
21	pharmacies by the State Board of Pharmacy; to define the term
22	hospital pharmacy services permit; and to provide for the
23	issuance of the permits.
24	BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:
25	Section 1. Sections 34-23-1, 34-23-30, 34-23-70, and
26	34-23-74, Code of Alabama 1975, are amended to read as
27	follows.

1 "\$34-23-1.

2 "For the purpose of this chapter, the following words and phrases shall have the following meanings:

- "(1) ASSOCIATION. The Alabama Pharmacy Association.
- 5 "(2) BOARD or STATE BOARD. The Alabama State Board of Pharmacy.
  - "(3) CHEMICAL. Any substance of a medicinal nature, whether simple or compound, obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.
  - "(4) DISPENSE. To sell, distribute, administer, leave with, give away, dispose of, deliver, or supply a drug or medicine to the ultimate user or their agent.
  - "(5) DRUGS. All medicinal substances, preparations, and devices recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment, or prevention of disease in man or animal and all substances and preparations other than food intended to affect the structure or any function of the body of man or animal.
  - "(6) EXTERN. A candidate for licensure as a pharmacist during the time prior to graduation from an accredited college of pharmacy.
  - "(7) HOSPITAL. An institution for the care and treatment of the sick and injured, licensed by the Alabama State Board of Health and authorized to be entrusted with the

custody of drugs and medicines, the professional use of drugs and medicines being under the direct supervision of a medical practitioner or pharmacist.

"(8) HOSPITAL PHARMACY SERVICES PERMIT. The grant of authority by the board to any person, firm, or corporation which offers or performs hospital pharmacy services. Hospital pharmacy services shall be defined by board rule, but shall not include any requirement for the receipt or inventory of any drugs, medicines, medical devices, chemicals, or poisons. The board, by rule, shall further provide the qualifications and fees for the issuance of a permit.

"(8)(9) INTERN. An individual who is currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or a graduate of an approved college of pharmacy who is currently licensed by the State Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or a qualified applicant awaiting examination for licensure.

"(9)(10) LEGEND DRUG. Any drug, medicine, chemical, or poison bearing on the label the words, "caution, federal law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

1	" $\frac{(10)}{(11)}$ LICENSE. The grant of authority by the
2	State Board of Pharmacy to a person authorizing him or her to
3	engage in the practice of pharmacy in this state.
4	" $\frac{(11)}{(12)}$ MANUFACTURER. A person, except a pharmacy,
5	who prepares, derives, produces, compounds, or packages any
6	drug, medicine, chemical, or poison.
7	"(12)(13) MEDICAL PRACTITIONER. Any physician,
8	dentist, or veterinarian, or any other person authorized by
9	law to treat, use, or prescribe medicine and drugs for sick
10	and injured human beings or animals in this state.
11	" $\frac{(13)}{(14)}$ MEDICINE. Any drug or combination of drugs
12	that has the property of curing, diagnosing, preventing,
13	treating, or mitigating diseases or that which may be used for
14	those purposes.
15	" <del>(14)</del> (15) PATENT OR PROPRIETARY MEDICINES.
16	Completely compounded nonprescription packaged drugs,
17	medicines, and nonbulk chemicals which are sold, offered,
18	promoted, or advertised by the manufacturer or primary
19	distributor under a trademark, trade name, or other trade
20	symbol, and the labeling of which conforms to the requirements
21	of the Federal Food, Drug, and Cosmetic Act; provided, that
22	this definition shall not include:
23	"a. Drugs which are only advertised and promoted
24	professionally to licensed physicians, dentists, or
25	veterinarians by manufacturers or primary distributors.

"b. A narcotic or drug containing a narcotic.

"c. A drug the label of which bears substantially either the statements "caution--federal law prohibits dispensing without prescription" or "warning--may be habit-forming".

"d. A drug intended for injection.

"(15)(16) PERMIT. The grant of authority by the State Board of Pharmacy to any person, firm, or corporation authorizing the operation of a pharmacy, wholesale drug distributor, repackager, bottler, manufacturer, or packer of drugs, medicines, chemicals, or poisons for medicinal purposes. Nonresident wholesale drug distributors registered with the appropriate agency, in the state in which they are domiciled, and operating in compliance with Prescription Drug Marketing Act standards, shall be allowed to do business in this state. No permit shall be required of any physician licensed to practice medicine for any act or conduct related to or connected with his or her professional practice.

" $\frac{(16)(17)}{(17)}$  PERSON. Any individual, partnership, corporation, association, trust, or other entity.

"(17)(18) PHARMACIST. Any person licensed by the Alabama State Board of Pharmacy to practice the profession of pharmacy in the State of Alabama and whose license is in good standing.

"(18)(19) PHARMACY. A place licensed by the Alabama State Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed, and shall include

all places whose title may imply the sale, offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons.

"(19)(20) POISON. Any substance other than agricultural products and pesticides which when applied to, introduced into, or developed within the body in relatively small quantities by its inherent chemical action uniformly produces serious bodily injury, disease, or death.

"(20)(21) PRECEPTOR. A person who is duly licensed to practice pharmacy in the state and meets the requirements as established by the State Board of Pharmacy.

"(21)(22) PRESCRIPTION. Any order for drug or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit television, or other means of communication by a legally competent practitioner, licensed by law to prescribe and administer such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist.

"(22) PROFESSIONAL DEGREE. A degree in pharmacy requiring a minimum of five academic years.

"(23)(24) REPACKAGER. A person who purchases or acquires from a manufacturer or distributor, a drug, medicine, chemical, or poison for the purpose of bottling, labeling, or otherwise repackaging for sale or distribution. This definition shall not apply to a physician licensed to practice medicine who as a part of his or her professional practice

dispenses, administers, sells, or otherwise distributes any drug to a patient.

"(24)(25) SALE. Barter, exchange, or gift, or offer of barter, exchange, or gift, and shall include each transaction made by any person, whether a principal, proprietor, agent, servant, or employee.

"(25)(26) WHOLESALE DRUG DISTRIBUTORS. A person engaged in the business of distributing drugs and medicines for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs or medicines. The sale, purchase, or trade of a drug by a retail pharmacy to another retail pharmacy or practitioner, for relief of temporary shortages, is exempt from this definition. Also exempt from this definition shall be (a) intracompany sales, (b) manufacturer and distributor sales representatives who distribute drug samples, (c) charitable organizations distributing to nonprofit affiliates of that organization, (d) certain purchases by hospitals or other health care entities that are members of a group purchasing organization, and (e) the distributors of blood and blood components.

"\$34-23-30.

"Every pharmacy, hospital pharmacy, hospital pharmacy, hospital pharmacy service provider, drugstore, pharmacy department, prescription department, prescription laboratory, dispensary, apothecary, or any other establishment with a title implying the sale, offering for sale, compounding, or dispensing of drugs or providing hospital pharmacy services in this state

shall register biennially and receive a permit from the Board of Pharmacy. Any person desiring to open, operate, maintain, or establish a pharmacy or provide hospital pharmacy services in this state shall apply to the board for a permit at least 30 days prior to the opening of the business. No pharmacy shall open for the transaction of business until it has been registered, inspected, and a permit issued by the board. The application for a permit shall be made on a form prescribed and furnished by the board which when properly executed shall indicate the ownership desiring such permit and the names and license numbers of all licensed pharmacists employed as well as the location of the pharmacy and other information as the board may require. If more than one pharmacy is operated by the same owner, a separate application for registration shall be made and a separate permit issued for each such establishment. All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Every application for a permit for a new pharmacy shall be accompanied by a fee to be determined by the board, but the fee shall not be less than one hundred dollars (\$100) nor more than two hundred dollars (\$200). A hospital pharmacy services permit or renewal permit shall be issued on an annual basis and the application for the permit shall be accompanied by a fee of not more than one hundred dollars (\$100). Every application for a renewal permit shall be accompanied by a fee to be determined by the board, but the fee shall not be less than fifty dollars (\$50) nor

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more than one hundred fifty dollars (\$150). Every application for a permit due to transfer of ownership shall be accompanied by a fee to be determined by the board, but the fee shall not be less than fifty dollars (\$50) nor more than one hundred fifty dollars (\$150). Each application for the renewal of a permit shall be made on or before October 31 of each even-numbered year, at which time the previous permit shall become null and void on December 31 of even-numbered years. A penalty of twenty-five dollars (\$25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. The secretary of the board shall issue a permit for each pharmacy whose application is found to be satisfactory by the board. Permits issued under this section shall not be transferable. Any change in the control of ownership or licensed pharmacists shall be reported to the board in writing within 10 days of such occurrence. If the pharmacy is owned by a corporation, the permit shall be issued in the name of the corporation. It shall be the duty of the owners of pharmacies who are not licensed pharmacists to immediately notify the board upon the termination of employment of licensed pharmacists and to cause the surrender of permits as indicated. The further operation of the pharmacy in the absence of licensed pharmacists is forbidden; provided, that the nonregistered owner shall have a period of 30 days within which to comply with this provision. The next of kin of any deceased licensed pharmacist owner shall have a period of 30 days within which to comply with the provisions of this

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chapter, during which time no prescriptions shall be filled unless a licensed pharmacist is on duty. No mail order pharmacy shall transact business in this state without a

"Any person who violates this section shall be guilty of a misdemeanor.

"\$34-23-70.

permit from the board.

"(a) Every pharmacy when opened for business shall be under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time. During temporary absences of the licensed pharmacist, not to exceed three hours daily or more than one and one-half hours at any one time, nor more than one week for temporary illness, the prescription department shall be closed, and no prescriptions are to be filled. During the temporary absence of a pharmacist, a sign shall be placed on the prescription counter in a prominent location easily seen by the public stating, "Prescription Department Closed, No Pharmacist on Duty."

"(b) The permit issued to each pharmacist by the board and the licensure certificates issued to the licensed pharmacist employed by each pharmacy must be prominently and conspicuously displayed in the pharmacy. The name of the licensed pharmacist on duty must be conspicuously displayed in the prescription department in a place readily observable by the public.

"(c) No licensed pharmacist or pharmacy operating within this state shall accept for refund purposes or otherwise any unused portion of any dispensed prescription.

- "(d) The sale of poisons is restricted to the immediate supervision of a licensed pharmacist, and such poison shall not be displayed in a pharmacy in such a manner that a customer may obtain possession of such poisons when standing in an area allocated for customer use. No sale of a poison shall be made or delivered to any minor under 12 years of age or to any person known to be of unsound mind or under the influence of alcohol.
- "(e) No pharmacy shall authorize any person, firm or business establishment to serve as a pick-up station or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Except with respect to controlled substances, the following federally qualified health care centers are expressly exempt from this subsection: Birmingham Health Care, Inc., Central Alabama Comprehensive Health, Inc., Health Services, Inc., Family Oriented Primary Health Care Clinic/Mobile County Health Department, Franklin Primary Health Center, Quality of Life Health Services, Inc., and Whatley Health Services, Inc. Each named federally qualified health center is authorized to fill certain prescriptions at one location and deliver medications to clinics for patient pick-up subject to the review of the Board of Pharmacy.

"(f) No prescription blank supplied by a pharmacy or pharmacist to a practitioner shall bear the imprint thereon of the name or address of any pharmacy or bear the name or address of any person registered under this chapter.

"(g) No person shall fill or compound a prescription or drug order in an institution unless he is a duly licensed pharmacist or otherwise permitted to do so under the provisions of this chapter. The act of filling or compounding prescriptions or drug orders in an institution and hospital pharmacy services shall be as defined in the rules and regulations adopted by the board of pharmacy.

"However, such rules and regulations shall not apply to the reading, interpreting and writing or verifying the writing of adequate directions as are necessary to assure patient's understanding of the prescriber's intentions by a duly qualified nurse practicing her/his profession in a licensed hospital or similar institution.

"Nothing in this chapter shall authorize the Board of Pharmacy to promulgate or to enforce any rule or regulation which governs, regulates or restricts the professional practice of a physician licensed to practice medicine in this state. No provision of this chapter, or any rule promulgated under the authority of this chapter shall be interpreted to amend, alter or modify the provisions of Section 34-23-11.

"(h) Only a licensed pharmacist or registered intern may accept an oral prescription of any nature. Upon so accepting such oral prescription, it must immediately be

reduced to writing, and only a licensed pharmacist or an intern supervised by a licensed pharmacist may prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written; and, when said copy is given, a notation shall be made upon the prescription that a copy has been given, the date given and to whom given.

- "(i) If a prescription is refilled, a record of the date upon which the prescription is refilled must appear on the prescription or in a permanent prescription record book. On prescriptions which may be refilled, written or oral authorization must be received before refilling unless the number of refills is indicated on the original prescription. Those prescriptions marked "refill prn" or equivalent designation shall be refilled only in quantities commensurate with the dosage scheduled.
- "(j) Each prescription must be written in a manner so that it can be compounded by any registered pharmacist. The coding of any prescription is in violation of this chapter. No prescription shall be written in any characters, figures or ciphers, other than in the English or Latin language, generally in use among medical and pharmaceutical practitioners.
- "(k) A prescription file or files shall be kept by every pharmacy for a period of not less than two years in which the original of every prescription compounded or

dispensed shall be filed in the order of compounding with
number and date of dispensing placed on each prescription.

Each pharmacy shall produce any prescription file whenever
legally required to do so. Such prescription file shall at all
times be open for inspection by the prescriber, the board of
pharmacy or its inspectors.

"(1) All drugs or drug preparations bearing upon the package the words, "caution, federal law prohibits dispensing without prescription" or words to the same effect, otherwise known as "legend drugs," shall be stored within the confines of the prescription department or the prescription department storage room of each pharmacy. Such drugs shall be sold or dispensed only on the prescription of a licensed practitioner authorized to prescribe such drugs and shall not be sold or dispensed as a refilled prescription except upon the express authorization of the prescriber. This shall not be construed to prohibit return to authorized suppliers or sale or transfer to others licensed to possess legend drugs.

"(m) Any person who violates any of the provisions of this section shall be guilty of a misdemeanor.

"\$34-23-74.

"Every pharmacy located in a hospital, skilled nursing home, or other related institution in this state shall be under the supervision of a licensed pharmacist. Hospital pharmacy services permits shall allow employed pharmacists and pharmacists under contract with a hospital to provide pharmacy services to hospital patients from locations outside the

physical location of the licensed hospital pharmacy. In general hospitals, skilled nursing homes, and extended care facilities not operating a pharmacy, the drug or medicine room shall be under the direct supervision and direction of a consulting pharmacist or a member of the medical staff who shall be a licensed practitioner of medicine. In nursing homes which are not classified by the State Board of Health as skilled nursing homes, maternity homes, homes for the aged, domiciliary institutions, and all related institutions except those operated by and in conjunction with a licensed hospital, medicines or drugs bearing the wording on the label "caution, federal law prohibits dispensing without prescription" or similar wording that causes the medicines or drugs to be known as prescription legend drugs shall be furnished by a licensed pharmacy on the prescription of a licensed practitioner of medicine for individual patients, and there shall be no prescription legend drugs on the premises of these institutions other than those so prescribed except an emergency kit as authorized by the State Board of Health. In hospitals and skilled nursing homes using vending machines or mechanical devices for the storage and dispensing of drugs, the machines or devices shall be stocked only under the supervision of a licensed pharmacist, and the drugs may be dispensed from the machine or device only by an individual acting in accordance with established institutional hospital pharmacy policy. The State Board of Pharmacy may at any time adopt such additional rules and regulations consistent with

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this chapter as may be deemed necessary after advising with 1 2 the Alabama Society of Hospital Pharmacists Health System Pharmacists in regard to the storage and handling of drugs 3 and medicines and the disposition of unused portion of drugs and medicines in hospitals and other related institutions 5 under this section." 6 7 Section 2. The State Board of Pharmacy shall promulgate rules to implement this act pursuant to the Alabama 8 Administrative Procedure Act within three months of the 9 10 effective date of this act, after advising with the Alabama 11 Society of Health System Pharmacists. 12 Section 3. This act shall become effective 13 immediately following its passage and approval by the

Governor, or its otherwise becoming law.