- 1 HB393
- 2 137451-5
- 3 By Representatives Greer and Black
- 4 RFD: Boards, Agencies and Commissions
- 5 First Read: 23-FEB-12

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To amend Sections 34-23-1 and 34-23-30, Code of Alabama 1975, relating to the practice of pharmacy and the operation of pharmacies; to define pharmacy services; to authorize the Alabama State Board of Pharmacy to provide by rule for the issuance, renewal, and fees relating to a pharmacy services permit; and to provide that the creation of a pharmacy services permit does not expand or limit the existing practice of pharmacy or medicine.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Section 34-23-1 of the Code of Alabama 13 1975, is amended to read as follows:

14 "\$34-23-1.

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

- "(1) ASSOCIATION. The Alabama Pharmacy Association.
- "(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.

1	"(4) DISPENSE. To sell, distribute, administer,
2	leave with, give away, dispose of, deliver, or supply a drug
3	or medicine to the ultimate user or their agent.

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- "(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) 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

1	college of pharmacy who is currently licensed by the State
2	Board of Pharmacy for the purpose of obtaining practical
3	experience as a requirement for licensure as a pharmacist; or
4	a qualified applicant awaiting examination for licensure.

- "(9) 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.
- "(10) LICENSE. The grant of authority by the State Board of Pharmacy to a person authorizing him or her to engage in the practice of pharmacy in this state.
- "(11) MANUFACTURER. A person, except a pharmacy, who prepares, derives, produces, compounds, or packages any drug, medicine, chemical, or poison.
- "(12) MEDICAL PRACTITIONER. Any physician, dentist, or veterinarian, or any other person authorized by law to treat, use, or prescribe medicine and drugs for sick and injured human beings or animals in this state.
- "(13) MEDICINE. Any drug or combination of drugs that has the property of curing, diagnosing, preventing, treating, or mitigating diseases or that which may be used for those purposes.

1	"(14) PATENT OR PROPRIETARY MEDICINES. Completely
2	compounded nonprescription packaged drugs, medicines, and
3	nonbulk chemicals which are sold, offered, promoted, or
4	advertised by the manufacturer or primary distributor under a
5	trademark, trade name, or other trade symbol, and the labeling
6	of which conforms to the requirements of the Federal Food,
7	Drug, and Cosmetic Act; provided, that this definition shall
8	not include:

"a. Drugs which are only advertised and promoted professionally to licensed physicians, dentists, or veterinarians by manufacturers or primary distributors.

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"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) 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

1	Marketing Act standards, shall be allowed to do business in
2	this state. No permit shall be required of any physician
3	licensed to practice medicine for any act or conduct related
4	to or connected with his or her professional practice.

"(16) PERSON. Any individual, partnership, corporation, association, trust, or other entity.

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- "(17) 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) 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) PHARMACY SERVICES PERMIT. Certain services

performed by a pharmacy, as defined by board rule, and

specifically excluding, the receipt or inventory of drugs,

medicines, chemicals, poisons, or medical devices. This

subdivision, and any rule promulgated by the board pursuant to

this subdivision, may not be interpreted to expand the

practice of pharmacy as the practice of pharmacy and permits

are limited by this section and Sections 34-23-11 and

1	34-23-70, or to restrict the practice of medicine as defined
2	<u>in Section 34-24-50.</u>
3	This subdivision, and any rule promulgated by the
4	board pursuant to this subdivision, is subject to the
5	restrictions contained in subsection (b) of Section 34-23-30.
6	This subdivision shall not be interpreted to allow
7	the board to promulgate any rule that would authorize a
8	pharmacist to sell, offer for sale, or dispense any
9	prescription drug except pursuant to the terms of a valid
10	prescription issued by a licensed practitioner authorized to
11	prescribe such druq or govern pharmacy benefit managers.
12	" $(20)$ $(19)$ POISON. Any substance other than
13	agricultural products and pesticides which when applied to,
14	introduced into, or developed within the body in relatively
15	small quantities by its inherent chemical action uniformly
16	produces serious bodily injury, disease, or death.
17	" $(21)$ $(20)$ PRECEPTOR. A person who is duly licensed
18	to practice pharmacy in the state and meets the requirements
19	as established by the State Board of Pharmacy.
20	" $(22)$ PRESCRIPTION. Any order for drug or
21	medical supplies, written or signed or transmitted by word of
22	mouth, telephone, telegraph, closed circuit television, or
23	other means of communication by a legally competent
24	practitioner, licensed by law to prescribe and administer sucl

L	drugs	and	medical	supplies	intended	to	be	filled,	compounded,
2	or dis	spens	sed by a	pharmacis	st.				

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

- "(24) (23) 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.
  - "(25) (24) 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.
  - "(26) (25) 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.

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"(a) Every pharmacy, hospital pharmacy, 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 in this state, or any person performing 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 perform 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 or entity performing pharmacy services 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 or entity where pharmacy services are performed and other

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information as the board may require. If more than one pharmacy or entity where pharmacy services are performed 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 or entity where pharmacy services are performed 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). 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 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 or entity

<u>where</u>	pharmacy services are performed whose application is
found	to be satisfactory by the board. Permits issued under
this s	ection shall not be transferable. Any change in the
contro	l of ownership or licensed pharmacists shall be reported
to the	board in writing within 10 days of such occurrence. If
the ph	armacy or entity where pharmacy services are performed
is own	ed by a corporation, the permit shall be issued in the
name o	f the corporation. It shall be the duty of the owners of
pharma	cies or the owners of entities where pharmacy services
are pe	rformed who are not licensed pharmacists to immediately
notify	the board upon the termination of employment of
licens	ed pharmacists and to cause the surrender of permits as
indica	ted. The further operation of the pharmacy or entity
where	pharmacy services are performed in the absence of
licens	ed pharmacists is forbidden; provided, that the
nonreg	istered owner shall have a period of 30 days within
which	to comply with this provision. The next of kin of any
deceas	ed licensed pharmacist owner shall have a period of 30
days w	ithin which to comply with the provisions of this
chapte	r, during which time no prescriptions shall be filled
unless	a licensed pharmacist is on duty. No mail order
pharma	cy shall transact business in this state without a
permit	from the board.

1	"(b) Requirements for the grant of authority by the
2	board to any person who offers or performs pharmacy services
3	shall be by board rule.
4	Nothing contained in this section shall be
5	interpreted to delegate to the board the authority to
6	promulgate regulations governing pharmacy benefit managers.
7	Nothing contained in this section related to
8	pharmacy services permits shall be interpreted to delegate to
9	the board the authority to promulgate regulations governing
10	<pre>pharmacy benefit managers.</pre>
11	"(c) Any person who violates this section shall be
12	guilty of a misdemeanor."
13	Section 2. This act shall become effective
14	immediately following its passage and approval by the
15	Governor, or its otherwise becoming law.

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4		Speaker of the House of Repr	resentatives			
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6	I	President and Presiding Office	er of the Senate			
7		House of Representative	es			
8 9	I hereby certify that the within Act originated in and was passed by the House 14-MAR-2012, as amended.					
10 11 12 13	F	Greg Pappas Clerk				
14						
15	Senate	05-APR-12	<pre>-    Amended and Passed</pre>			
16	House	10-APR-12	Concurred in Sen- ate Amendment			