

1 SB510
2 119801-1
3 By Senator Butler
4 RFD: Health
5 First Read: 09-MAR-10

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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.

14
15 A BILL
16 TO BE ENTITLED
17 AN ACT

18
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
3 words and phrases shall have the following meanings:

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

5 "(2) BOARD or STATE BOARD. The Alabama State Board
6 of Pharmacy.

7 "(3) CHEMICAL. Any substance of a medicinal nature,
8 whether simple or compound, obtained through the process of
9 the science and art of chemistry, whether of organic or
10 inorganic origin.

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

14 "(5) DRUGS. All medicinal substances, preparations,
15 and devices recognized by the United States Pharmacopoeia and
16 National Formulary, or any revision thereof, and all
17 substances and preparations intended for external and internal
18 use in the cure, diagnosis, mitigation, treatment, or
19 prevention of disease in man or animal and all substances and
20 preparations other than food intended to affect the structure
21 or any function of the body of man or animal.

22 "(6) EXTERN. A candidate for licensure as a
23 pharmacist during the time prior to graduation from an
24 accredited college of pharmacy.

25 "(7) HOSPITAL. An institution for the care and
26 treatment of the sick and injured, licensed by the Alabama
27 State Board of Health and authorized to be entrusted with the

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

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

12 "(8)(9) INTERN. An individual who is currently
13 licensed by this state to engage in the practice of pharmacy
14 while under the personal supervision of a pharmacist and is
15 satisfactorily progressing toward meeting the requirements for
16 licensure as a pharmacist; or a graduate of an approved
17 college of pharmacy who is currently licensed by the State
18 Board of Pharmacy for the purpose of obtaining practical
19 experience as a requirement for licensure as a pharmacist; or
20 a qualified applicant awaiting examination for licensure.

21 "(9)(10) LEGEND DRUG. Any drug, medicine, chemical,
22 or poison bearing on the label the words, "caution, federal
23 law prohibits dispensing without prescription," or similar
24 wording indicating that such drug, medicine, chemical, or
25 poison may be sold or dispensed only upon the prescription of
26 a licensed medical practitioner.

1 "~~(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 "~~(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 "~~(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 "~~(14)~~(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.

26 "b. A narcotic or drug containing a narcotic.

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

5 "d. A drug intended for injection.

6 "~~(15)~~(16) PERMIT. The grant of authority by the
7 State Board of Pharmacy to any person, firm, or corporation
8 authorizing the operation of a pharmacy, wholesale drug
9 distributor, repackager, bottler, manufacturer, or packer of
10 drugs, medicines, chemicals, or poisons for medicinal
11 purposes. Nonresident wholesale drug distributors registered
12 with the appropriate agency, in the state in which they are
13 domiciled, and operating in compliance with Prescription Drug
14 Marketing Act standards, shall be allowed to do business in
15 this state. No permit shall be required of any physician
16 licensed to practice medicine for any act or conduct related
17 to or connected with his or her professional practice.

18 "~~(16)~~(17) PERSON. Any individual, partnership,
19 corporation, association, trust, or other entity.

20 "~~(17)~~(18) PHARMACIST. Any person licensed by the
21 Alabama State Board of Pharmacy to practice the profession of
22 pharmacy in the State of Alabama and whose license is in good
23 standing.

24 "~~(18)~~(19) PHARMACY. A place licensed by the Alabama
25 State Board of Pharmacy in which prescriptions, drugs,
26 medicines, medical devices, chemicals, and poisons are sold,
27 offered for sale, compounded, or dispensed, and shall include

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

4 "~~(19)~~(20) POISON. Any substance other than
5 agricultural products and pesticides which when applied to,
6 introduced into, or developed within the body in relatively
7 small quantities by its inherent chemical action uniformly
8 produces serious bodily injury, disease, or death.

9 "~~(20)~~(21) PRECEPTOR. A person who is duly licensed
10 to practice pharmacy in the state and meets the requirements
11 as established by the State Board of Pharmacy.

12 "~~(21)~~(22) PRESCRIPTION. Any order for drug or
13 medical supplies, written or signed or transmitted by word of
14 mouth, telephone, telegraph, closed circuit television, or
15 other means of communication by a legally competent
16 practitioner, licensed by law to prescribe and administer such
17 drugs and medical supplies intended to be filled, compounded,
18 or dispensed by a pharmacist.

19 "~~(22)~~(23) PROFESSIONAL DEGREE. A degree in pharmacy
20 requiring a minimum of five academic years.

21 "~~(23)~~(24) REPACKAGER. A person who purchases or
22 acquires from a manufacturer or distributor, a drug, medicine,
23 chemical, or poison for the purpose of bottling, labeling, or
24 otherwise repackaging for sale or distribution. This
25 definition shall not apply to a physician licensed to practice
26 medicine who as a part of his or her professional practice

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

3 "~~(24)~~(25) SALE. Barter, exchange, or gift, or offer
4 of barter, exchange, or gift, and shall include each
5 transaction made by any person, whether a principal,
6 proprietor, agent, servant, or employee.

7 "~~(25)~~(26) WHOLESALE DRUG DISTRIBUTORS. A person
8 engaged in the business of distributing drugs and medicines
9 for resale to pharmacies, hospitals, practitioners, government
10 agencies, or other lawful outlets permitted to sell drugs or
11 medicines. The sale, purchase, or trade of a drug by a retail
12 pharmacy to another retail pharmacy or practitioner, for
13 relief of temporary shortages, is exempt from this definition.
14 Also exempt from this definition shall be (a) intracompany
15 sales, (b) manufacturer and distributor sales representatives
16 who distribute drug samples, (c) charitable organizations
17 distributing to nonprofit affiliates of that organization, (d)
18 certain purchases by hospitals or other health care entities
19 that are members of a group purchasing organization, and (e)
20 the distributors of blood and blood components.

21 "§34-23-30.

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

1 shall register biennially and receive a permit from the Board
2 of Pharmacy. Any person desiring to open, operate, maintain,
3 or establish a pharmacy or provide hospital pharmacy services
4 in this state shall apply to the board for a permit at least
5 30 days prior to the opening of the business. No pharmacy
6 shall open for the transaction of business until it has been
7 registered, inspected, and a permit issued by the board. The
8 application for a permit shall be made on a form prescribed
9 and furnished by the board which when properly executed shall
10 indicate the ownership desiring such permit and the names and
11 license numbers of all licensed pharmacists employed as well
12 as the location of the pharmacy and other information as the
13 board may require. If more than one pharmacy is operated by
14 the same owner, a separate application for registration shall
15 be made and a separate permit issued for each such
16 establishment. All permits issued under this section shall
17 become due on October 31 and shall become null and void on
18 December 31 of even-numbered years. Every application for a
19 permit for a new pharmacy shall be accompanied by a fee to be
20 determined by the board, but the fee shall not be less than
21 one hundred dollars (\$100) nor more than two hundred dollars
22 (\$200). A hospital pharmacy services permit or renewal permit
23 shall be issued on an annual basis and the application for the
24 permit shall be accompanied by a fee of not more than one
25 hundred dollars (\$100). Every application for a renewal permit
26 shall be accompanied by a fee to be determined by the board,
27 but the fee shall not be less than fifty dollars (\$50) nor

1 more than one hundred fifty dollars (\$150). Every application
2 for a permit due to transfer of ownership shall be accompanied
3 by a fee to be determined by the board, but the fee shall not
4 be less than fifty dollars (\$50) nor more than one hundred
5 fifty dollars (\$150). Each application for the renewal of a
6 permit shall be made on or before October 31 of each
7 even-numbered year, at which time the previous permit shall
8 become null and void on December 31 of even-numbered years. A
9 penalty of twenty-five dollars (\$25) for each overdue month
10 shall be assessed in addition to the permit fee for renewal of
11 delinquent permits. The secretary of the board shall issue a
12 permit for each pharmacy whose application is found to be
13 satisfactory by the board. Permits issued under this section
14 shall not be transferable. Any change in the control of
15 ownership or licensed pharmacists shall be reported to the
16 board in writing within 10 days of such occurrence. If the
17 pharmacy is owned by a corporation, the permit shall be issued
18 in the name of the corporation. It shall be the duty of the
19 owners of pharmacies who are not licensed pharmacists to
20 immediately notify the board upon the termination of
21 employment of licensed pharmacists and to cause the surrender
22 of permits as indicated. The further operation of the pharmacy
23 in the absence of licensed pharmacists is forbidden; provided,
24 that the nonregistered owner shall have a period of 30 days
25 within which to comply with this provision. The next of kin of
26 any deceased licensed pharmacist owner shall have a period of
27 30 days within which to comply with the provisions of this

1 chapter, during which time no prescriptions shall be filled
2 unless a licensed pharmacist is on duty. No mail order
3 pharmacy shall transact business in this state without a
4 permit from the board.

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

7 "§34-23-70.

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

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

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

4 "(d) The sale of poisons is restricted to the
5 immediate supervision of a licensed pharmacist, and such
6 poison shall not be displayed in a pharmacy in such a manner
7 that a customer may obtain possession of such poisons when
8 standing in an area allocated for customer use. No sale of a
9 poison shall be made or delivered to any minor under 12 years
10 of age or to any person known to be of unsound mind or under
11 the influence of alcohol.

12 "(e) No pharmacy shall authorize any person, firm or
13 business establishment to serve as a pick-up station or
14 intermediary for the purpose of having prescriptions filled or
15 delivered, whether for profit or gratuitously. Except with
16 respect to controlled substances, the following federally
17 qualified health care centers are expressly exempt from this
18 subsection: Birmingham Health Care, Inc., Central Alabama
19 Comprehensive Health, Inc., Health Services, Inc., Family
20 Oriented Primary Health Care Clinic/Mobile County Health
21 Department, Franklin Primary Health Center, Quality of Life
22 Health Services, Inc., and Whatley Health Services, Inc. Each
23 named federally qualified health center is authorized to fill
24 certain prescriptions at one location and deliver medications
25 to clinics for patient pick-up subject to the review of the
26 Board of Pharmacy.

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

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

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

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

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

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

9 "(i) If a prescription is refilled, a record of the
10 date upon which the prescription is refilled must appear on
11 the prescription or in a permanent prescription record book.
12 On prescriptions which may be refilled, written or oral
13 authorization must be received before refilling unless the
14 number of refills is indicated on the original prescription.
15 Those prescriptions marked "refill prn" or equivalent
16 designation shall be refilled only in quantities commensurate
17 with the dosage scheduled.

18 "(j) Each prescription must be written in a manner
19 so that it can be compounded by any registered pharmacist. The
20 coding of any prescription is in violation of this chapter. No
21 prescription shall be written in any characters, figures or
22 ciphers, other than in the English or Latin language,
23 generally in use among medical and pharmaceutical
24 practitioners.

25 "(k) A prescription file or files shall be kept by
26 every pharmacy for a period of not less than two years in
27 which the original of every prescription compounded or

1 dispensed shall be filed in the order of compounding with
2 number and date of dispensing placed on each prescription.
3 Each pharmacy shall produce any prescription file whenever
4 legally required to do so. Such prescription file shall at all
5 times be open for inspection by the prescriber, the board of
6 pharmacy or its inspectors.

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

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

21 "§34-23-74.

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

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

1 this chapter as may be deemed necessary after advising with
2 the Alabama Society of ~~Hospital Pharmacists~~ Health System
3 Pharmacists in regard to the storage and handling of drugs
4 and medicines and the disposition of unused portion of drugs
5 and medicines in hospitals and other related institutions
6 under this section."

7 Section 2. The State Board of Pharmacy shall
8 promulgate rules to implement this act pursuant to the Alabama
9 Administrative Procedure Act within three months of the
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
14 Governor, or its otherwise becoming law.