

1 HB553
2 138962-1
3 By Representative Carns
4 RFD: Commerce and Small Business
5 First Read: 15-MAR-12

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8 SYNOPSIS: Under existing law, hospitals and skilled
9 nursing homes may use machines or mechanical
10 devices for the storage and dispensing of
11 prescription drugs. The machines are required to be
12 stocked under the supervision of a licensed
13 pharmacist and dispensed in accordance with
14 institutional hospital policy. Also, under existing
15 law, many nursing homes use off-site pharmacies to
16 dispense prescription drugs and the drugs are then
17 delivered and stored in the medicine or drug room
18 at the nursing home.

19 This bill would specify that prescription
20 drugs may be stored in a machine, mechanical
21 device, or other automated pharmacy system unit at
22 a nursing home and dispensed on-site under the
23 supervision of a licensed pharmacist who may be
24 located at an off-site pharmacy. The drugs would be
25 stored in the medicine or drug room of the nursing
26 home and dispensed in individual sealed containers
27 for each patient. The bill would define and

1 regulate the automated pharmacy systems used for
2 the purposes of this act. The use of the term
3 "skilled" in relation to a nursing home would be
4 deleted to conform to existing law.

5
6 A BILL
7 TO BE ENTITLED
8 AN ACT
9

10 To amend Section 34-23-74 of the Code of Alabama
11 1975, relating to hospital and other institutional pharmacies;
12 to specify that machines, mechanical devices, or other
13 dispensing units may be used to dispense prescription drugs in
14 individualized sealed doses of a drug or drugs for a patient
15 under the supervision of a licensed pharmacist who may be
16 located at an off-site pharmacy; and to specifically define
17 and regulate automated pharmacy systems.

18 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

19 Section 1. Section 34-23-74 of the Code of Alabama
20 1975, is amended to read as follows:

21 "§34-23-74.

22 "Every pharmacy located in or serving, whether
23 remotely or otherwise, a hospital, ~~skilled~~ nursing home, or
24 other related institution in this state shall be under the
25 supervision of a licensed pharmacist as provided herein. In
26 general hospitals, ~~skilled~~ nursing homes, and extended care
27 facilities not operating a pharmacy, the drug or medicine room

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

1 or cartridges that are placed in the machines, devices, or
2 other systems shall be stocked only under the supervision of a
3 licensed pharmacist; the containers or cartridges storing
4 legend drugs shall be placed in the machine, device, or
5 automated pharmacy system only by a licensed pharmacist or by
6 a licensed pharmacy technician subject to the supervision of a
7 licensed pharmacist who may or may not be at an off-site
8 location; the machine, device, or automated pharmacy system
9 shall be located in the drug or medicine room or other secure
10 room; and the drugs may be dispensed from the machine, device,
11 or automated pharmacy system that dispenses the drugs in an
12 individual sealed container for each patient in accordance
13 with established policy of the nursing home. The State Board
14 of Pharmacy may at any time adopt such additional rules and
15 regulations consistent with this chapter as may be deemed
16 necessary after advising with the Alabama Society of Hospital
17 Pharmacists in regard to the storage and handling of drugs
18 and medicines and the disposition of unused portion of drugs
19 and medicines in hospitals and other related institutions
20 under this section."

21 Section 2. For the purposes of Sections 2 and 3 of
22 this act and Section 34-23-74, Code of Alabama 1975, the
23 following words have the following meanings:

24 (1) AUTOMATED PHARMACY SYSTEM. A mechanical system
25 that performs operations or activities, other than compounding
26 or administration, relative to the storage, packaging,

1 dispensing, or distribution of medications, and which collect,
2 control, and maintain all transaction information.

3 (2) COORDINATING PHARMACY. A pharmacy responsible
4 for the operations performed at a remote dispensing site.

5 (3) REMOTE DISPENSING SITE. A site located within a
6 hospital or nursing home that utilizes an automated pharmacy
7 system and that is electronically linked to the coordinating
8 pharmacy via a computer system or a video/auditory
9 communication system, or both.

10 Section 3. (a) All drugs dispensed for use by
11 patients of a nursing home when the drug is not in the
12 possession of the ultimate user prior to administration, and
13 when a multiple-dose drug distribution system is utilized,
14 including dispensing of single-unit packages, shall be
15 dispensed in a container to which is affixed a label
16 containing all of the following information:

17 (1) The identification of the dispensing pharmacy.

18 (2) The patient's name.

19 (3) The date of dispensing.

20 (4) The nonproprietary or proprietary name of the
21 drug dispensed.

22 (5) The strength, expressed in the metric system
23 whenever possible.

24 (b) A remote dispensing site shall utilize an
25 automated pharmacy system located in an area accessible only
26 to authorized personnel.

1 (c) The supervising pharmacist of the coordinating
2 pharmacy shall do all of the following:

3 (1) Be responsible for the pharmacy services
4 performed at remote dispensing sites, including the
5 supervision of any automated pharmacy system.

6 (2) Be responsible for ensuring that the
7 coordinating pharmacy and remote dispensing site have entered
8 into a written agreement that outlines the services to be
9 provided and the responsibilities and accountability of each
10 party in fulfilling the terms of the agreement in compliance
11 with federal and state laws and regulations. Such contract or
12 agreement is not required if the remote dispensing site is
13 under common control or ownership of the coordinating
14 pharmacy.

15 (3) Ensure the coordinating pharmacy has sufficient
16 pharmacists on duty for the safe operation and supervision of
17 all remote dispensing sites.

18 (4) Ensure that the automated pharmacy system is in
19 good working order and accurately dispenses the correct
20 strength, dosage form, and quantity of the drug prescribed
21 while maintaining appropriate recordkeeping and security
22 safeguards.

23 (d) Remote dispensing sites shall utilize an
24 automated pharmacy system for the purposes of dispensing. The
25 pharmacist at the coordinating pharmacy shall have the
26 necessary patient information to perform a drug utilization
27 review prior to dispensing.

1 (e) (1) All drugs shall be stored in compliance with
2 state and federal laws.

3 (2) Drugs stored at remote dispensing sites shall be
4 stored in an area that is both of the following:

5 a. Separate from any other drugs used by the
6 hospital, nursing home, or health care facility.

7 b. Locked by key or combination, so as to prevent
8 access by unauthorized personnel.

9 (3) Access to the area where drugs are stored at the
10 remote dispensing site shall be limited to the following:

11 a. Pharmacists, pharmacy technicians, interns, or
12 externs of the coordinating pharmacy.

13 b. Personnel employed at the nursing home where the
14 remote dispensing site is located who meet all of the
15 following requirements:

16 1. Are licensed health care providers.

17 2. Are designated in writing by the supervising
18 pharmacist or the person responsible for the supervision and
19 on-site operation of the facility where the automated pharmacy
20 system is located.

21 3. Have completed documented training concerning
22 their duties associated with the remote dispensing site.

23 (4) Remote dispensing sites shall have adequate
24 security to comply with federal and state laws and regulations
25 and maintain patient confidentiality.

26 (5) The coordinating pharmacy shall have procedures
27 that specify that drugs may only be delivered to the remote

1 dispensing site in accordance with the policies and procedures
2 of the coordinating pharmacy.

3 (f) The coordinating pharmacy and remote dispensing
4 site shall operate in compliance with written policies and
5 procedures that are established by the coordinating pharmacy.
6 The policy and procedure manual shall include, but not be
7 limited to, all of the following:

8 (1) A current list containing the name and business
9 address of the supervising pharmacist and personnel designated
10 by the supervising pharmacist to have access to the area where
11 drugs are stored at the remote dispensing site.

12 (2) The duties that may only be performed by a
13 pharmacist.

14 (3) The date of last review and revision of the
15 policy and procedure manual.

16 (4) The policies and procedures for the following:

17 a. Operation of the video/auditory communication
18 system.

19 b. Security.

20 c. Sanitation.

21 d. Storage of drugs.

22 e. Dispensing.

23 f. Supervision.

24 g. Drug procurement, receipt, and delivery. The
25 policies and procedures shall require both of the following:

1 1. That all drugs shall be delivered to the remote
2 dispensing site in a secure, tamper-evident cartridge or
3 container with a list of drugs delivered.

4 2. That all drugs delivered to the remote dispensing
5 site shall be checked by personnel designated by the
6 supervising pharmacist to verify that the drugs sent were
7 actually received. The designated person who checks the order
8 shall document the verification by signing and dating the list
9 of drugs delivered.

10 h. Recordkeeping.

11 (5) A coordinating pharmacy providing pharmacy
12 services at a remote dispensing site, when necessary, shall
13 review and revise as necessary its written policies and
14 procedures and document its review.

15 (6) A coordinating pharmacy providing pharmacy
16 services at a remote dispensing site shall maintain a written
17 plan for recovery from an event that interrupts the ability of
18 a pharmacist to electronically supervise the dispensing of
19 drugs at the remote dispensing site. The written plan for
20 recovery shall include the following:

21 a. A statement that drugs shall not be dispensed at
22 the remote dispensing site if a pharmacist is not able to
23 electronically supervise the dispensing.

24 b. Procedures for response when the video/auditory
25 communication system is experiencing downtime.

26 c. Procedures for the maintenance and testing of the
27 written plan for recovery.

1 (7) All policies and procedures shall be maintained
2 and made available for inspection upon request by the Board of
3 Pharmacy in the coordinating pharmacy responsible for the
4 automated pharmacy system and at the remote dispensing site
5 where the automated pharmacy system is being used.

6 (g) A coordinating pharmacy that provides pharmacy
7 services via a remote dispensing site shall operate according
8 to a written program for quality assurance that does both of
9 the following:

10 (1) Requires a pharmacist of the coordinating
11 pharmacy to be accessible to respond to inquiries or requests
12 pertaining to drugs dispensed from the automated pharmacy
13 system located at the remote dispensing site.

14 (2) Establishes procedures to test the operation of
15 all automated pharmacy systems and all video/auditory
16 communication systems at a minimum of every six months and
17 whenever any upgrade or change is made to the system and
18 document the testing of each such system.

19 (h) (1) A coordinating pharmacy shall keep a record
20 of all drugs received, dispensed, and distributed from the
21 coordinating pharmacy.

22 (2) A coordinating pharmacy shall keep a record of
23 all drugs received, dispensed, and distributed from each
24 remote dispensing site.

25 (3) All records of receipt, dispensing, and
26 distribution shall be kept at the coordinating pharmacy.

1 Records of the coordinating pharmacy and remote dispensing
2 site shall be kept separate from each other.

3 (i) (1) A coordinating pharmacy shall keep a
4 perpetual inventory of controlled substances and other drugs
5 required to be inventoried according to state and federal law
6 that are held in the coordinating pharmacy and each remote
7 dispensing site.

8 (2) All inventory records shall be kept at the
9 coordinating pharmacy. The coordinating pharmacy and remote
10 dispensing site inventory records shall be kept separate from
11 each other.

12 (j) An automated pharmacy system may be utilized at
13 remote dispensing sites. A pharmacist shall not be required to
14 be physically present at the site of the automated pharmacy
15 system if the system is supervised electronically by a
16 pharmacist. The coordinating pharmacy shall comply with all of
17 the following:

18 (1) Maintain documentation of the type of equipment,
19 serial numbers, content, policies and procedures for each
20 remote dispensing site operated by the coordinating pharmacy
21 for review by the Board of Pharmacy. The documentation shall
22 include, but not be limited to, the following:

23 a. The name and address of the coordinating pharmacy
24 and the remote dispensing site where the automated pharmacy is
25 being used.

26 b. The manufacturer's name and model.

27 c. The description of how the device is used.

1 d. The quality assurance procedures to determine
2 continued appropriate use of the automated device.

3 e. The policies and procedures for system operation,
4 safety, security, accuracy, patient confidentiality, access,
5 and malfunction.

6 f. The documentation evidencing that the automated
7 pharmacy system has been tested prior to initial use and on a
8 periodic basis at each location to ensure that the automated
9 pharmacy system is operating properly.

10 (2) An automated pharmacy system should be used only
11 where medication orders are reviewed by a pharmacist in
12 accordance with established policies and procedures. A
13 pharmacist shall be accessible to respond to inquiries or
14 requests pertaining to drugs dispensed from the automated
15 pharmacy system.

16 (3) All policies and procedures shall be maintained
17 in the coordinating pharmacy responsible for the automated
18 pharmacy system and at the remote dispensing site where the
19 automated pharmacy system is being used.

20 (4) An automated pharmacy system shall have adequate
21 security systems and procedures, evidenced by written policies
22 and procedures, to do all of the following:

23 a. Prevent unauthorized access.

24 b. Comply with federal and state regulations.

25 c. Prevent the illegal use or disclosure of
26 protected health information.

1 (5) Records or electronic data, or both, kept by
2 automated pharmacy systems shall meet all of the following
3 requirements:

4 a. All events involving the contents of the
5 automated pharmacy system shall be recorded electronically.

6 b. All records shall be maintained by the pharmacy
7 and shall be readily available to the board. The records shall
8 include all of the following:

9 1. The identity of system accessed.

10 2. The identification of the individual accessing
11 the system.

12 3. The type of transaction.

13 4. The name, strength, dosage form, and quantity of
14 the drug accessed.

15 5. The name of the patient for whom the drug was
16 ordered.

17 6. Any additional information as the supervising
18 pharmacist may deem necessary.

19 (6) Access to and limits on access, including
20 security levels, to the automated pharmacy system shall be
21 defined by policy and procedures and shall comply with state
22 and federal regulations.

23 (7) The supervising pharmacist shall have the sole
24 responsibility to do all of the following:

25 a. Assign, discontinue, or change access to the
26 system.

1 b. Ensure that access to the medications comply with
2 state and federal regulations.

3 c. Ensure that the automated pharmacy system is
4 filled or stocked accurately and in accordance with
5 established, written policies and procedures.

6 (8) The filling or stocking of all medications in
7 the automated pharmacy system shall be completed by a
8 pharmacist or pharmacy technician under the direct supervision
9 of a pharmacist, except as provided below:

10 a. If the automated pharmacy system uses removable
11 cartridges or containers to hold drugs, the prepackaging of
12 the cartridges or containers shall occur at the coordinating
13 pharmacy unless provided by an FDA approved repackager.

14 b. The prepackaged cartridges or containers may be
15 sent to the remote dispensing site to be loaded into the
16 automated pharmacy system by personnel designated by the
17 supervising pharmacist provided all of the following
18 requirements are met:

19 1. A pharmacist verifies the cartridge or container
20 has been properly filled and labeled.

21 2. The individual cartridges or containers are
22 transported to the remote dispensing site in a secure,
23 tamper-evident container.

24 3. The automated pharmacy system uses bar-coding,
25 microchip, or other technologies to ensure that the cartridges
26 or containers are accurately loaded in the automated pharmacy
27 system.

1 4. All drugs to be stocked in the automated pharmacy
2 system shall be delivered to the remote dispensing site by the
3 coordinating pharmacy.

4 c. For purposes of this section, direct supervision
5 shall not require physical presence of a pharmacist. The
6 supervision may be done remotely or electronically.

7 (9) A record of medications filled or stocked into
8 an automated pharmacy system shall be maintained and shall
9 include identification of the persons filling or stocking the
10 medications and checking for accuracy.

11 (10) All cartridges or containers of medications
12 stored in the automated pharmacy system shall be packaged and
13 labeled in accordance with federal and state laws and
14 regulations.

15 (11) All aspects of handling controlled substances
16 shall meet the requirements of all state and federal laws and
17 regulations.

18 (12) The automated pharmacy system shall provide a
19 procedure for securing and accounting for medications removed
20 from and subsequently returned to the automated pharmacy
21 system in accordance with existing state and federal law.

22 (13) The automated pharmacy system shall provide a
23 procedure for securing and accounting for wasted medications
24 or discarded medications in accordance with existing state and
25 federal law.

1 Section 4. This act shall become effective on the
2 first day of the third month following its passage and
3 approval by the Governor, or its otherwise becoming law.