

FEB 16 2005
HUMAN RESOURCES

HOUSE FILE 325
BY CARROLL

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act creating a prescription drug donation and redispensing
2 pilot program, and providing penalties.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 325

1 Section 1. NEW SECTION. 135M.1 PURPOSE.

2 The purpose of this chapter is to improve the health of
3 low-income Iowans through a prescription drug donation and
4 redispensing program that authorizes charitable clinic
5 pharmacies to redispense prescription drugs that would
6 otherwise be destroyed.

7 Sec. 2. NEW SECTION. 135M.2 DEFINITIONS.

8 As used in this chapter, unless the context otherwise
9 requires:

10 1. "Charitable clinic" means a charitable nonprofit
11 corporation or facility organized under chapter 504 or 504A
12 that meets all of the following criteria:

13 a. Is described in the federal Internal Revenue Code, 26
14 U.S.C. § 501(c)(3), and is exempt from income taxation under
15 26 U.S.C. § 501(a).

16 b. Provides advice, counseling, diagnosis, treatment,
17 surgery, care, or services relating to the preservation or
18 maintenance of health on an outpatient basis for a period of
19 less than twenty-four consecutive hours per day to persons not
20 residing in or confined to the facility.

21 c. Charges an administrative fee or requests a donation
22 not to exceed ten dollars per visit.

23 d. Has a licensed outpatient pharmacy.

24 2. "Charitable clinic pharmacy" means a pharmacy at a site
25 where prescriptions are dispensed by a charitable clinic free
26 of charge to appropriately screened and qualified indigent
27 patients.

28 3. "Controlled substance" means the same as defined in
29 section 155A.3.

30 4. "Department" means the Iowa department of public
31 health.

32 5. "Indigent" means a person with an income that is below
33 two hundred percent of the federal poverty level as defined by
34 the most recently revised poverty income guidelines published
35 by the United States department of health and human services.

1 6. "Nursing facility" means the same as defined in section
2 135C.1.

3 7. "Prescription drug" means the same as defined in
4 section 155A.3, but does not include controlled substances.

5 8. "Proper transfer" means the storage, handling, and
6 distribution of a prescription drug in accordance with its
7 label and in its dispensed, sealed, tamper-evident, single-
8 user unit.

9 Sec. 3. NEW SECTION. 135M.3 PRESCRIPTION DRUG DONATION
10 AND REDISPENSING PILOT PROGRAM.

11 1. The Iowa department of public health, in cooperation
12 with the board of pharmacy examiners, shall establish a pilot
13 program, consistent with public health and safety, to provide
14 for the proper transfer of unused prescription drugs from
15 nursing facilities to charitable clinic pharmacies for the
16 purpose of redistributing the prescription drugs to indigent
17 individuals.

18 2. Participation in the program by nursing facilities,
19 charitable clinics, charitable clinic pharmacies, drug
20 manufacturers, and individuals shall be voluntary.

21 Sec. 4. NEW SECTION. 135M.4 PROGRAM REQUIREMENTS --
22 RULES.

23 The department shall adopt rules, in cooperation with the
24 board of pharmacy examiners, to provide for all of the
25 following:

26 1. Specific requirements for a charitable clinic pharmacy
27 to qualify for participation in and to participate in the
28 pilot program.

29 2. Contract forms to be used by charitable clinics and
30 nursing facilities in entering into contractual agreements
31 under the program.

32 3. Forms and procedures for authorization of individuals
33 to physically transfer the prescription drugs from a nursing
34 facility to a charitable clinic.

35 4. Forms and procedures to authorize a donor to donate

1 unused prescription drugs and to consent to voluntarily
2 donating the prescription drugs.

3 5. Waiver of liability forms to be signed by indigent
4 individuals receiving prescription drugs under the program.

5 Sec. 5. NEW SECTION. 135M.5 DONATIONS OF UNUSED
6 PRESCRIPTION DRUGS -- REDISPENSING.

7 1. A charitable clinic may accept prescription drugs
8 obtained from a nursing facility for relabeling and
9 redispensing by the charitable clinic pharmacy free of charge
10 and pursuant to a valid prescription order to an indigent
11 patient.

12 2. The donor resident of the nursing facility shall be
13 considered the owner of the prescription drug and entitled to
14 donate the prescription drug for use by a charitable clinic.

15 3. a. A nursing facility may enter into a contract with
16 any charitable clinic for the transfer of prescription drugs
17 under this section. Prescription drugs shall not be
18 transferred under this section without such contract.

19 b. A contract entered into under this subsection shall be
20 approved by the board of pharmacy examiners, in cooperation
21 with the department.

22 c. A contract entered into under this subsection shall
23 specify procedures for ensuring a safe chain of custody to
24 protect the safety of all transferred prescription drugs.

25 d. The contract may specify that the charitable clinic
26 will do one of the following:

27 (1) Define a specified set of prescription drugs that will
28 be transferred from the nursing facility to the charitable
29 clinic.

30 (2) Periodically request the transfer of particular
31 prescription drugs.

32 (3) Receive all prescription drugs that the nursing
33 facility is authorized to transfer under this chapter.

34 (4) Make such other provisions for transfer of
35 prescription drugs as may be approved by the board of pharmacy

1 examiners.

2 e. The pharmacist in charge of a charitable clinic shall
3 determine the description of the prescription drugs to be
4 included in the contract.

5 4. Donations of prescription drugs to a charitable clinic
6 shall meet all of the following requirements:

7 a. Only prescription drugs in their original sealed and
8 tamper-evident packaging shall be accepted. However,
9 prescription drugs in single-unit doses or blister packs with
10 the outside packaging opened may be accepted if the single-
11 unit dose packaging remains intact.

12 b. The pharmacist of the charitable clinic pharmacy
13 determines that the prescription drug is not adulterated or
14 misbranded and is safe to redispense.

15 c. If the integrity of a prescription drug cannot be
16 assured, the prescription drug is not accepted for
17 redispensing by the pharmacist of the charitable clinic
18 pharmacy.

19 d. The prescription drugs are physically transferred from
20 the nursing facility to a charitable clinic pharmacy by a
21 person authorized by the board of pharmacy examiners to
22 transfer the prescription drugs for the charitable clinic.

23 e. The donor executes a form stating that the donor is the
24 owner of the prescription drugs and intends to voluntarily
25 donate them to a charitable clinic pharmacy and the nursing
26 facility in which the donor resides retains the donor form.

27 f. The donor's name, prescription number, and any other
28 identifying marks are obliterated from the packaging before
29 the nursing facility transfers the prescription drug to the
30 charitable clinic.

31 g. The name, strength, and expiration date of the
32 prescription drug remain on the package label.

33 h. The redispensed drug is assigned the same expiration
34 date as appears on the original package.

35 i. Expired prescription drugs accepted by a charitable

1 clinic pharmacy are not redispensed and are destroyed
2 according to the charitable clinic pharmacy's destruction
3 procedures.

4 j. The charitable clinic pharmacy does not accept
5 controlled substances.

6 5. a. If a nursing facility that transfers prescription
7 drugs to a charitable clinic receives a notice from a pharmacy
8 that a prescription drug has been recalled, the nursing
9 facility shall inform the clinic of the recall.

10 b. If a charitable clinic receives a recall notification
11 from a nursing facility, the clinic shall perform a uniform
12 destruction of all of the recalled prescription drugs in the
13 nursing facility.

14 6. A prescription drug dispensed through a charitable
15 clinic pharmacy shall not be eligible for reimbursement under
16 the medical assistance program.

17 7. Indigent individuals receiving prescription drugs under
18 the program shall sign a waiver form releasing the nursing
19 facility, the charitable clinic, the charitable clinic
20 pharmacy, the donor, and the donor's estate from liability.

21 Sec. 6. NEW SECTION. 135M.6 EXEMPTION FROM DISCIPLINARY
22 ACTION, CIVIL LIABILITY, AND CRIMINAL PROSECUTION.

23 1. All of the following persons shall be exempt from
24 professional disciplinary action, civil liability, or criminal
25 prosecution for actions taken under the program in the absence
26 of bad faith and if the person acts in conformity with any
27 applicable professional standards and requirements:

28 a. The donor and the donor's estate.

29 b. The nursing facility that transfers the prescription
30 drugs.

31 c. The prescribing physician or other person to whom
32 prescribing is delegated by the physician.

33 d. The charitable clinic.

34 e. The charitable clinic pharmacy.

35 f. The pharmacy that originally dispensed the prescription

1 drugs.

2 g. The pharmacist who originally dispensed the
3 prescription drugs and the pharmacist who redispensed the
4 donated prescription drugs.

5 h. The Iowa department of public health.

6 i. The department of human services.

7 j. The board of pharmacy examiners.

8 2. In the absence of bad faith, a drug manufacturer shall
9 not be subject to criminal prosecution or civil liability for
10 injury, death, or loss to persons or property for matters
11 related to the donation, acceptance, or redispensing of a drug
12 manufactured by the drug manufacturer that is donated by any
13 person under the program, including but not limited to
14 liability for failure to provide the product or consumer
15 package insert information or the expiration date of the
16 donated prescription drugs. This subsection does not exempt a
17 drug manufacturer from criminal prosecution or civil liability
18 for a previously undisclosed product defect.

19 3. This chapter shall not be construed to apply to issues
20 of liability outside the scope of the program.

21 Sec. 7. NEW SECTION. 135M.7 SAMPLE PRESCRIPTION DRUGS.

22 This chapter shall not be construed to restrict the use of
23 samples by a physician or other health care professional
24 during the course of work at a charitable clinic whether or
25 not the charitable clinic has a licensed outpatient pharmacy.

26 Sec. 8. NEW SECTION. 135M.8 RESALE PROHIBITED.

27 This chapter shall not be construed to authorize the resale
28 of prescription drugs by any person.

29 Sec. 9. NEW SECTION. 135M.9 CRIMINAL PENALTY --
30 PROFESSIONAL DISCIPLINARY ACTION.

31 Any person who knowingly violates any provision of this
32 chapter, or of the rules of the department adopted under this
33 chapter, is guilty of a serious misdemeanor and is subject to
34 professional disciplinary action, if applicable.

35 Sec. 10. NEW SECTION. 135M.10 ANNUAL PROGRAM REPORT.

1 The department shall submit a report to the governor and
2 the general assembly by September 1, 2006, and annually
3 thereafter, regarding the progress of the program and any
4 recommendations regarding the program.

5 EXPLANATION

6 This bill directs the Iowa department of public health, in
7 cooperation with the board of pharmacy examiners, to establish
8 a pilot program to provide for the proper transfer of unused
9 prescription drugs from nursing facilities to charitable
10 clinic pharmacies for the purpose of redistributing the
11 prescription drugs to indigent individuals. Participation in
12 the program by nursing facilities, charitable clinics,
13 charitable clinic pharmacies, drug manufacturers, and
14 individuals is voluntary.

15 The bill provides definitions and procedures and
16 requirements for the donation of unused prescription drugs and
17 the redispensing of such drugs; provides for the adoption of
18 rules for the pilot program; provides for exemption from
19 disciplinary action, civil liability, and criminal prosecution
20 for those involved in the program in the absence of bad faith
21 and adherence to applicable professional standards and
22 requirements; provides that the program does not restrict the
23 use of sample prescription drugs; provides that the bill does
24 not authorize the resale of prescription drugs; and requires
25 the submission of annual reports regarding the program by the
26 Iowa department of public health to the governor and the
27 general assembly.

28 The bill also provides that a person who knowingly violates
29 any provision of the chapter or any rule adopted under the
30 chapter is guilty of a serious misdemeanor and is subject to
31 professional disciplinary action, if applicable.

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