

MAR 1 3 2005
Place On Calendar

HOUSE FILE 724
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 325)

Passed House, Date 4-5-05 Passed Senate, Date 4-14-05
Vote: Ayes 100 Nays 0 Vote: Ayes 50 Nays 0
Approved 5/3/05

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 724

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.

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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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HOUSE FILE 724

H-1269

1 Amend House File 724 as follows:

2 1. By striking everything after the enacting
3 clause and inserting the following:

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

5 The purpose of this chapter is to improve the
6 health of low-income Iowans through a prescription
7 drug donation repository that authorizes medical
8 facilities and pharmacies to redispense prescription
9 drugs and supplies that would otherwise be destroyed.

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

11 1. "Anti-rejection drug" means a prescription drug
12 that suppresses the immune system to prevent or
13 reverse rejection of a transplanted organ.

14 2. "Cancer drug" means a prescription drug that is
15 used to treat any of the following:

16 a. Cancer or the side effects of cancer.

17 b. The side effects of any prescription drug that
18 is used to treat cancer or the side effects of cancer.

19 3. "Controlled substance" means the same as
20 defined in section 155A.3.

21 4. "Department" means the Iowa department of
22 public health.

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

28 6. "Medical facility" means any of the following:

29 a. A physician's office.

30 b. A hospital.

31 c. A health clinic.

32 d. A nonprofit health clinic which includes a
33 federally qualified health center as defined in 42
34 U.S.C. § 1396d(1)(2)(B); a rural health clinic as
35 defined in 42 U.S.C. § 1396d(1)(1); and a nonprofit
36 health clinic that provides medical care to patients
37 who are indigent, uninsured, or underinsured.

38 e. A free clinic as defined in section 135.24

39 f. A charitable organization as defined in section
40 135.24.

41 g. A nursing facility as defined in section
42 135C.1.

43 7. "Pharmacy" means a pharmacy as defined in
44 section 155A.3.

45 8. "Prescription drug" means the same as defined
46 in section 155A.3, and includes cancer drugs and anti-
47 rejection drugs, but does not include controlled
48 substances.

49 9. "Supplies" means the supplies necessary to
50 administer the prescription drugs donated.

H-1269

1 Sec. 3. NEW SECTION. 135M.3 PRESCRIPTION DRUG
2 DONATION REPOSITORY PROGRAM AUTHORIZED.

3 1. The department, in cooperation with the board
4 of pharmacy examiners, may establish and maintain a
5 prescription drug donation repository program under
6 which any person may donate prescription drugs and
7 supplies for use by an individual who meets
8 eligibility criteria specified by the department by
9 rule. The department may contract with a third party
10 to implement and administer the program.

11 2. Donations of prescription drugs and supplies
12 under the program may be made on the premises of a
13 medical facility or pharmacy that elects to
14 participate in the program and meets the requirements
15 established by the department.

16 3. The medical facility or pharmacy may charge an
17 individual who receives a prescription drug or
18 supplies a handling fee that shall not exceed an
19 amount established by rule by the department.

20 4. A medical facility or pharmacy that receives
21 prescription drugs or supplies may distribute the
22 prescription drugs or supplies to another eligible
23 medical facility or pharmacy for use pursuant to the
24 program.

25 5. Participation in the program shall be
26 voluntary.

27 Sec. 4. NEW SECTION. 135M.4. PRESCRIPTION DRUG
28 DONATION REPOSITORY PROGRAM REQUIREMENTS.

29 1. A prescription drug or supplies may be accepted
30 and dispensed under the prescription drug donation
31 repository program if all of the following conditions
32 are met:

33 a. The prescription drug is in its original sealed
34 and tamper-evident packaging. However, a prescription
35 drug in a single-unit dose or blister pack with the
36 outside packaging opened may be accepted if the
37 single-unit dose packaging remains intact.

38 b. The prescription drug bears an expiration date
39 that is more than six months after the date the
40 prescription drug was donated.

41 c. The prescription drug or supplies are inspected
42 before the prescription drug or supplies are dispensed
43 by a licensed pharmacist employed by or under contract
44 with the medical facility or pharmacy, and the
45 licensed pharmacist determines that the prescription
46 drug or supplies are not adulterated or misbranded.

47 d. The prescription drug or supplies are
48 prescribed by a health care practitioner for use by an
49 eligible individual and are dispensed by a pharmacist.

50 2. A prescription drug or supplies donated under

1 this chapter shall not be resold.

2 3. a. If a person who donates prescription drugs
3 under this chapter to a medical facility or pharmacy
4 receives a notice from a pharmacy that a prescription
5 drug has been recalled, the person shall inform the
6 medical facility or pharmacy of the recall.

7 b. If a medical facility or pharmacy receives a
8 recall notification from a person who donated
9 prescription drugs under this chapter, the medical
10 facility or pharmacy shall perform a uniform
11 destruction of all of the recalled prescription drugs
12 in the medical facility or pharmacy.

13 4. A prescription drug dispensed through the
14 prescription drug donation repository program shall
15 not be eligible for reimbursement under the medical
16 assistance program.

17 5. The department shall adopt rules establishing
18 all of the following:

19 a. Requirements for medical facilities and
20 pharmacies to accept and dispense donated prescription
21 drugs and supplies, including all of the following:

22 (1) Eligibility criteria for participation by
23 medical facilities and pharmacies.

24 (2) Standards and procedures for accepting, safely
25 storing, and dispensing donated prescription drugs and
26 supplies.

27 (3) Standards and procedures for inspecting
28 donated prescription drugs to determine if the
29 prescription drugs are in their original sealed and
30 tamper-evident packaging, or if the prescription drugs
31 are in single-unit doses or blister packs and the
32 outside packaging is opened, if the single-unit dose
33 packaging remains intact.

34 (4) Standards and procedures for inspecting
35 donated prescription drugs and supplies to determine
36 that the prescription drugs and supplies are not
37 adulterated or misbranded.

38 b. Eligibility criteria for individuals to receive
39 donated prescription drugs and supplies dispensed
40 under the program. The standards shall prioritize
41 dispensing to individuals who are indigent or
42 uninsured, but may permit dispensing to other
43 individuals if an uninsured or indigent individual is
44 unavailable.

45 c. Necessary forms for administration of the
46 prescription drug donation repository program,
47 including forms for use by individuals who donate,
48 accept, distribute, or dispense the prescription drugs
49 or supplies under the program.

50 d. A means by which an individual who is eligible

1 to receive donated prescription drugs and supplies may
2 indicate such eligibility.

3 e. The maximum handling fee that a medical
4 facility or pharmacy may charge for accepting,
5 distributing, or dispensing donated prescription drugs
6 and supplies under the program.

7 f. A list of prescription drugs that the
8 prescription drug donation repository program will
9 accept.

10 Sec. 5. NEW SECTION. 135M.5 EXEMPTION FROM
11 DISCIPLINARY ACTION, CIVIL LIABILITY, AND CRIMINAL
12 PROSECUTION.

13 1. In the absence of bad faith, a drug
14 manufacturer is not subject to criminal prosecution or
15 civil liability for injury, death, or loss to a person
16 or property for matters related to the donation,
17 acceptance, or dispensing of a prescription drug
18 manufactured by the drug manufacturer that is donated
19 under this chapter, including liability for failure to
20 transfer or communicate product or consumer
21 information or the expiration date of the donated
22 prescription drug.

23 2. Except as provided in subsection 3, a person
24 other than a drug manufacturer subject to subsection
25 1, is immune from civil liability and criminal
26 prosecution for injury to or the death of an
27 individual to whom a donated prescription drug is
28 dispensed under this chapter and shall be exempt from
29 disciplinary action related to the person's acts or
30 omissions related to the donation, acceptance,
31 distribution, or dispensing of a donated prescription
32 drug under this chapter.

33 3. The immunity and exemption provided in
34 subsection 2 do not extend to any of the following:

35 a. The donation, acceptance, distribution, or
36 dispensing of a donated prescription drug under this
37 chapter by a person if the person's acts or omissions
38 involve reckless, wanton, or intentional misconduct.

39 b. To acts or omissions outside the scope of the
40 program.

41 Sec. 6. NEW SECTION. 135M.6 SAMPLE PRESCRIPTION
42 DRUGS.

43 This chapter shall not be construed to restrict the
44 use of samples by a physician or other person legally
45 authorized to prescribe drugs pursuant to section
46 147.107 during the course of the physician's or other
47 person's duties at a medical facility or pharmacy.

48 Sec. 7. NEW SECTION. 135M.7 RESALE PROHIBITED.

49 This chapter shall not be construed to authorize
50 the resale of prescription drugs by any person."

H-1269

Page 5

1 2. Title page, line 1, by striking the words "and
2 redispensing".

3 3. Title page, by striking line 2 and inserting
4 the following: "repository program."

By KURTENBACH of Story

MURPHY of Dubuque

CARROLL of Poweshiek

SHOULTZ of Black Hawk

H-1269 FILED MARCH 31, 2005

HOUSE FILE 724

H-1323

1 Amend the amendment, H-1269 to House File 724, as
2 follows:

3 1. Page 4, by striking lines 13 and 14, and
4 inserting the following:

5 "1. A drug manufacturer acting reasonably and in
6 good faith, is not subject to criminal prosecution
7 or".

8 2. Page 4, line 25, by inserting after the figure
9 "1," the following: "acting reasonably and in good
10 faith,".

11 3. Page 4, by striking line 38, and inserting the
12 following: "are not performed reasonably and in good
13 faith."

By SWAIM of Davis
MURPHY of Dubuque
CARROLL of Poweshiek

H-1323 FILED APRIL 5, 2005

ADOPTED

HOUSE FILE 724
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 325)

(As Amended and Passed by the House April 5, 2005)

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

A BILL FOR

* 1 An Act creating a prescription drug donation repository program.
2 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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House Amendments _____
All New Language
Deleted Language *

1 a. The prescription drug is in its original sealed and
2 tamper-evident packaging. However, a prescription drug in a
3 single-unit dose or blister pack with the outside packaging
4 opened may be accepted if the single-unit dose packaging
5 remains intact.

6 b. The prescription drug bears an expiration date that is
7 more than six months after the date the prescription drug was
8 donated.

9 c. The prescription drug or supplies are inspected before
10 the prescription drug or supplies are dispensed by a licensed
11 pharmacist employed by or under contract with the medical
12 facility or pharmacy, and the licensed pharmacist determines
13 that the prescription drug or supplies are not adulterated or
14 misbranded.

15 d. The prescription drug or supplies are prescribed by a
16 health care practitioner for use by an eligible individual and
17 are dispensed by a pharmacist.

18 2. A prescription drug or supplies donated under this
19 chapter shall not be resold.

20 3. a. If a person who donates prescription drugs under
21 this chapter to a medical facility or pharmacy receives a
22 notice from a pharmacy that a prescription drug has been
23 recalled, the person shall inform the medical facility or
24 pharmacy of the recall.

25 b. If a medical facility or pharmacy receives a recall
26 notification from a person who donated prescription drugs
27 under this chapter, the medical facility or pharmacy shall
28 perform a uniform destruction of all of the recalled
29 prescription drugs in the medical facility or pharmacy.

30 4. A prescription drug dispensed through the prescription
31 drug donation repository program shall not be eligible for
32 reimbursement under the medical assistance program.

33 5. The department shall adopt rules establishing all of
34 the following:

35 a. Requirements for medical facilities and pharmacies to

HOUSE FILE 724
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 325)

(As Amended and Passed by the House April 5, 2005)

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

A BILL FOR

* 1 An Act creating a prescription drug donation repository program.
2 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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House Amendments _____
All New Language
Deleted Language *

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
4 repository that authorizes medical facilities and pharmacies
5 to redispense prescription drugs and supplies that would
6 otherwise be destroyed.

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

8 1. "Anti-rejection drug" means a prescription drug that
9 suppresses the immune system to prevent or reverse rejection
10 of a transplanted organ.

11 2. "Cancer drug" means a prescription drug that is used to
12 treat any of the following:

13 a. Cancer or the side effects of cancer.

14 b. The side effects of any prescription drug that is used
15 to treat cancer or the side effects of cancer.

16 3. "Controlled substance" means the same as defined in
17 section 155A.3.

18 4. "Department" means the Iowa department of public
19 health.

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

24 6. "Medical facility" means any of the following:

25 a. A physician's office.

26 b. A hospital.

27 c. A health clinic.

28 d. A nonprofit health clinic which includes a federally
29 qualified health center as defined in 42 U.S.C. §
30 1396d(1)(2)(B); a rural health clinic as defined in 42 U.S.C.
31 § 1396d(1)(1); and a nonprofit health clinic that provides
32 medical care to patients who are indigent, uninsured, or
33 underinsured.

34 e. A free clinic as defined in section 135.24

35 f. A charitable organization as defined in section 135.24.

1 g. A nursing facility as defined in section 135C.1.

2 7. "Pharmacy" means a pharmacy as defined in section
3 155A.3.

4 8. "Prescription drug" means the same as defined in
5 section 155A.3, and includes cancer drugs and anti-rejection
6 drugs, but does not include controlled substances.

7 9. "Supplies" means the supplies necessary to administer
8 the prescription drugs donated.

9 Sec. 3. NEW SECTION. 135M.3 PRESCRIPTION DRUG DONATION
10 REPOSITORY PROGRAM AUTHORIZED.

11 1. The department, in cooperation with the board of
12 pharmacy examiners, may establish and maintain a prescription
13 drug donation repository program under which any person may
14 donate prescription drugs and supplies for use by an
15 individual who meets eligibility criteria specified by the
16 department by rule. The department may contract with a third
17 party to implement and administer the program.

18 2. Donations of prescription drugs and supplies under the
19 program may be made on the premises of a medical facility or
20 pharmacy that elects to participate in the program and meets
21 the requirements established by the department.

22 3. The medical facility or pharmacy may charge an
23 individual who receives a prescription drug or supplies a
24 handling fee that shall not exceed an amount established by
25 rule by the department.

26 4. A medical facility or pharmacy that receives
27 prescription drugs or supplies may distribute the prescription
28 drugs or supplies to another eligible medical facility or
29 pharmacy for use pursuant to the program.

30 5. Participation in the program shall be voluntary.

31 Sec. 4. NEW SECTION. 135M.4 PRESCRIPTION DRUG DONATION
32 REPOSITORY PROGRAM REQUIREMENTS.

33 1. A prescription drug or supplies may be accepted and
34 dispensed under the prescription drug donation repository
35 program if all of the following conditions are met:

1 a. The prescription drug is in its original sealed and
2 tamper-evident packaging. However, a prescription drug in a
3 single-unit dose or blister pack with the outside packaging
4 opened may be accepted if the single-unit dose packaging
5 remains intact.

6 b. The prescription drug bears an expiration date that is
7 more than six months after the date the prescription drug was
8 donated.

9 c. The prescription drug or supplies are inspected before
10 the prescription drug or supplies are dispensed by a licensed
11 pharmacist employed by or under contract with the medical
12 facility or pharmacy, and the licensed pharmacist determines
13 that the prescription drug or supplies are not adulterated or
14 misbranded.

15 d. The prescription drug or supplies are prescribed by a
16 health care practitioner for use by an eligible individual and
17 are dispensed by a pharmacist.

18 2. A prescription drug or supplies donated under this
19 chapter shall not be resold.

20 3. a. If a person who donates prescription drugs under
21 this chapter to a medical facility or pharmacy receives a
22 notice from a pharmacy that a prescription drug has been
23 recalled, the person shall inform the medical facility or
24 pharmacy of the recall.

25 b. If a medical facility or pharmacy receives a recall
26 notification from a person who donated prescription drugs
27 under this chapter, the medical facility or pharmacy shall
28 perform a uniform destruction of all of the recalled
29 prescription drugs in the medical facility or pharmacy.

30 4. A prescription drug dispensed through the prescription
31 drug donation repository program shall not be eligible for
32 reimbursement under the medical assistance program.

33 5. The department shall adopt rules establishing all of
34 the following:

35 a. Requirements for medical facilities and pharmacies to

1 accept and dispense donated prescription drugs and supplies,
2 including all of the following:

3 (1) Eligibility criteria for participation by medical
4 facilities and pharmacies.

5 (2) Standards and procedures for accepting, safely
6 storing, and dispensing donated prescription drugs and
7 supplies.

8 (3) Standards and procedures for inspecting donated
9 prescription drugs to determine if the prescription drugs are
10 in their original sealed and tamper-evident packaging, or if
11 the prescription drugs are in single-unit doses or blister
12 packs and the outside packaging is opened, if the single-unit
13 dose packaging remains intact.

14 (4) Standards and procedures for inspecting donated
15 prescription drugs and supplies to determine that the
16 prescription drugs and supplies are not adulterated or
17 misbranded.

18 b. Eligibility criteria for individuals to receive donated
19 prescription drugs and supplies dispensed under the program.
20 The standards shall prioritize dispensing to individuals who
21 are indigent or uninsured, but may permit dispensing to other
22 individuals if an uninsured or indigent individual is
23 unavailable.

24 c. Necessary forms for administration of the prescription
25 drug donation repository program, including forms for use by
26 individuals who donate, accept, distribute, or dispense the
27 prescription drugs or supplies under the program.

28 d. A means by which an individual who is eligible to
29 receive donated prescription drugs and supplies may indicate
30 such eligibility.

31 e. The maximum handling fee that a medical facility or
32 pharmacy may charge for accepting, distributing, or dispensing
33 donated prescription drugs and supplies under the program.

34 f. A list of prescription drugs that the prescription drug
35 donation repository program will accept.

1 Sec. 5. NEW SECTION. 135M.5 EXEMPTION FROM DISCIPLINARY
2 ACTION, CIVIL LIABILITY, AND CRIMINAL PROSECUTION.

3 1. A drug manufacturer acting reasonably and in good
4 faith, is not subject to criminal prosecution or civil
5 liability for injury, death, or loss to a person or property
6 for matters related to the donation, acceptance, or dispensing
7 of a prescription drug manufactured by the drug manufacturer
8 that is donated under this chapter, including liability for
9 failure to transfer or communicate product or consumer
10 information or the expiration date of the donated prescription
11 drug.

12 2. Except as provided in subsection 3, a person other than
13 a drug manufacturer subject to subsection 1, acting reasonably
14 and in good faith, is immune from civil liability and criminal
15 prosecution for injury to or the death of an individual to
16 whom a donated prescription drug is dispensed under this
17 chapter and shall be exempt from disciplinary action related
18 to the person's acts or omissions related to the donation,
19 acceptance, distribution, or dispensing of a donated
20 prescription drug under this chapter.

21 3. The immunity and exemption provided in subsection 2 do
22 not extend to any of the following:

23 a. The donation, acceptance, distribution, or dispensing
24 of a donated prescription drug under this chapter by a person
25 if the person's acts or omissions are not performed reasonably
26 and in good faith.

27 b. To acts or omissions outside the scope of the program.

28 Sec. 6. NEW SECTION. 135M.6 SAMPLE PRESCRIPTION DRUGS.

29 This chapter shall not be construed to restrict the use of
30 samples by a physician or other person legally authorized to
31 prescribe drugs pursuant to section 147.107 during the course
32 of the physician's or other person's duties at a medical
33 facility or pharmacy.

34 Sec. 7. NEW SECTION. 135M.7 RESALE PROHIBITED.

35 This chapter shall not be construed to authorize the resale

1 of prescription drugs by any person.

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HOUSE FILE 724

AN ACT

CREATING A PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.

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

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

The purpose of this chapter is to improve the health of low-income Iowans through a prescription drug donation repository that authorizes medical facilities and pharmacies to redispense prescription drugs and supplies that would otherwise be destroyed.

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

1. "Anti-rejection drug" means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ.
2. "Cancer drug" means a prescription drug that is used to treat any of the following:
 - a. Cancer or the side effects of cancer.
 - b. The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.
3. "Controlled substance" means the same as defined in section 155A.3.
4. "Department" means the Iowa department of public health.
5. "Indigent" means a person with an income that is below two hundred percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services.
6. "Medical facility" means any of the following:
 - a. A physician's office.

- b. A hospital.
 - c. A health clinic.
 - d. A nonprofit health clinic which includes a federally qualified health center as defined in 42 U.S.C. § 1396d(1)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(1)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.
 - e. A free clinic as defined in section 135.24.
 - f. A charitable organization as defined in section 135.24.
 - g. A nursing facility as defined in section 135C.1.
 7. "Pharmacy" means a pharmacy as defined in section 155A.3.
 8. "Prescription drug" means the same as defined in section 155A.3, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances.
 9. "Supplies" means the supplies necessary to administer the prescription drugs donated.
- Sec. 3. NEW SECTION. 135M.3 PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM AUTHORIZED.
1. The department, in cooperation with the board of pharmacy examiners, may establish and maintain a prescription drug donation repository program under which any person may donate prescription drugs and supplies for use by an individual who meets eligibility criteria specified by the department by rule. The department may contract with a third party to implement and administer the program.
 2. Donations of prescription drugs and supplies under the program may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements established by the department.
 3. The medical facility or pharmacy may charge an individual who receives a prescription drug or supplies a handling fee that shall not exceed an amount established by rule by the department.
 4. A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription

drugs or supplies to another eligible medical facility or pharmacy for use pursuant to the program.

5. Participation in the program shall be voluntary.

Sec. 4. NEW SECTION. 135M.4 PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM REQUIREMENTS.

1. A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

a. The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact.

b. The prescription drug bears an expiration date that is more than six months after the date the prescription drug was donated.

c. The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded.

d. The prescription drug or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a pharmacist.

2. A prescription drug or supplies donated under this chapter shall not be resold.

3. a. If a person who donates prescription drugs under this chapter to a medical facility or pharmacy receives a notice from a pharmacy that a prescription drug has been recalled, the person shall inform the medical facility or pharmacy of the recall.

b. If a medical facility or pharmacy receives a recall notification from a person who donated prescription drugs under this chapter, the medical facility or pharmacy shall perform a uniform destruction of all of the recalled prescription drugs in the medical facility or pharmacy.

4. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

5. The department shall adopt rules establishing all of the following:

a. Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(1) Eligibility criteria for participation by medical facilities and pharmacies.

(2) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies.

(3) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact.

(4) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded.

b. Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed under the program. The standards shall prioritize dispensing to individuals who are indigent or uninsured, but may permit dispensing to other individuals if an uninsured or indigent individual is unavailable.

c. Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program.

d. A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate such eligibility.

e. The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program.

f. A list of prescription drugs that the prescription drug donation repository program will accept.

Sec. 5. NEW SECTION. 135M.5 EXEMPTION FROM DISCIPLINARY ACTION, CIVIL LIABILITY, AND CRIMINAL PROSECUTION.

1. A drug manufacturer acting reasonably and in good faith, is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this chapter, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

2. Except as provided in subsection 3, a person other than a drug manufacturer subject to subsection 1, acting reasonably and in good faith, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this chapter and shall be exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter.

3. The immunity and exemption provided in subsection 2 do not extend to any of the following:

a. The donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter by a person if the person's acts or omissions are not performed reasonably and in good faith.

b. To acts or omissions outside the scope of the program.

Sec. 6. NEW SECTION. 135M.6 SAMPLE PRESCRIPTION DRUGS.

This chapter shall not be construed to restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to section 147.107 during the course of the physician's or other person's duties at a medical facility or pharmacy.

Sec. 7. NEW SECTION. 135M.7 RESALE PROHIBITED.

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

CHRISTOPHER C. RANTS
Speaker of the House

JOHN P. KIBBIE
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 724, Eighty-first General Assembly.

MARGARET THOMSON
Chief Clerk of the House

Approved 5/3, 2005

THOMAS J. VILSACK
Governor