

# House Study Bill 689

HOUSE FILE \_\_\_\_\_  
BY (PROPOSED COMMITTEE ON  
HUMAN RESOURCES BILL BY  
CHAIRPERSON BODDICKER)

Passed House, Date \_\_\_\_\_ Passed Senate, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

## A BILL FOR

1 An Act providing for the establishment of a drug repository  
2 program.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:  
4 TLSB 6547HC 80  
5 rn/pj/5

PAG LIN

1 1 Section 1. NEW SECTION. 135.26 DRUG REPOSITORY PROGRAM.  
1 2 The department shall establish a drug repository program  
1 3 for accepting and distributing donated drugs. For purposes of  
1 4 this section, "drug" shall have the same meaning as defined in  
1 5 section 155A.3.  
1 6 1. Any person or entity, including, but not limited to, a  
1 7 drug manufacturer or health care facility as defined in  
1 8 section 135C.1, may donate drugs to the drug repository  
1 9 program. Drugs may be donated at a physician's office,  
1 10 pharmacy, hospital, or health clinic that elects to  
1 11 participate in the program and meets criteria for such  
1 12 participation established by the department. Participation in  
1 13 the program shall be on a voluntary basis.  
1 14 2. A drug shall only be accepted or distributed under the  
1 15 program if the drug is in its original, unopened, sealed, and  
1 16 tamper-evident unit dose packaging, except that a drug  
1 17 packaged in single unit doses may be accepted and distributed  
1 18 if the outside packaging is opened but the single-unit-dose  
1 19 packaging is unopened. A drug shall not be accepted or  
1 20 distributed if the drug bears an expiration date that is  
1 21 earlier than six months after the date the drug was donated,  
1 22 or is adulterated or misbranded. Subject to the limitations  
1 23 provided in this subsection, unused drugs distributed under  
1 24 the medical assistance program established in chapter 249A may  
1 25 be accepted and distributed under the drug repository program.  
1 26 3. A physician's office, pharmacy, hospital, or health  
1 27 clinic that accepts donated drugs under the program shall  
1 28 comply with all applicable provisions of state and federal law  
1 29 relating to the storage and distribution of such drugs and  
1 30 shall inspect all such drugs prior to acceptance and  
1 31 distribution to determine if they are adulterated or  
1 32 misbranded. Drugs accepted into the program shall be  
1 33 distributed by the physician's office, pharmacy, hospital, or  
1 34 health clinic to the university of Iowa hospitals and clinics  
1 35 for dispensation pursuant to the indigent care program and for  
2 1 the benefit of department of corrections patients. A  
2 2 physician's office, pharmacy, hospital, or health clinic may  
2 3 charge a handling fee for accepting or distributing drugs  
2 4 under the program, in an amount to be determined by the  
2 5 department by rule. Drugs donated under the program shall not  
2 6 be resold.  
2 7 4. Any person or entity, including a drug manufacturer,  
2 8 exercising reasonable care in donating, accepting,  
2 9 distributing, or dispensing drugs under the program shall be  
2 10 immune from civil or criminal liability or professional  
2 11 disciplinary action for any injury, death, or loss to person  
2 12 or property relating to such activities. The donation of a  
2 13 drug by a drug manufacturer does not, however, absolve the  
2 14 manufacturer of any criminal or civil liability that would  
2 15 have existed but for the donation, nor shall such donation  
2 16 increase any liability of such drug manufacturer which  
2 17 otherwise would have existed.  
2 18 5. The department, upon the recommendation of the board of  
2 19 pharmacy examiners, shall adopt rules relating to the  
2 20 establishment of the program. The rules shall include, but  
2 21 not be limited to, determining eligibility criteria and other  
2 22 standards and procedures relating to the acceptance,

2 23 distribution, or dispensing of donated drugs; forms necessary  
2 24 for administration of the program; the fees that may be  
2 25 imposed by physician's offices, pharmacies, hospitals, or  
2 26 health clinics; and categories of drugs deemed suitable or  
2 27 unsuitable for acceptance by the program.

2 28 EXPLANATION

2 29 This bill provides for the establishment by the Iowa  
2 30 department of public health of a voluntary program for  
2 31 accepting donated drugs and distributing such drugs to  
2 32 university of Iowa hospitals and clinics for dispensation  
2 33 pursuant to the indigent care program or for department of  
2 34 corrections patients.

2 35 The bill provides that for the purposes of the drug  
3 1 repository program, "drug" shall be defined as in Code section  
3 2 155A.3. That section defines a "drug" to mean a substance  
3 3 recognized as a drug in the current official United States  
3 4 Pharmacopoeia and National Formulary, official Homeopathic  
3 5 Pharmacopoeia, or other drug compendium or any supplement to  
3 6 any of them; a substance intended for use in the diagnosis,  
3 7 cure, mitigation, treatment, or prevention of disease in  
3 8 humans or other animals; a substance, other than food,  
3 9 intended to affect the structure or any function of the body  
3 10 of humans or other animals; a substance intended for use as a  
3 11 component of any of the preceding substances; or a controlled  
3 12 substance.

3 13 The bill provides that any person or entity may donate  
3 14 drugs to the drug repository program, at a physician's office,  
3 15 pharmacy, hospital, or health clinic that elects to  
3 16 participate in the program and meets criteria for such  
3 17 participation established by the department. The bill  
3 18 provides that a drug shall only be accepted or distributed if  
3 19 the drug is in its original, unopened, sealed, and tamper=  
3 20 evident unit dose packaging, but that a drug packaged in  
3 21 single unit doses may be accepted and dispensed if the outside  
3 22 packaging is opened but the single-unit-dose packaging is  
3 23 unopened. The bill provides that a drug shall not be accepted  
3 24 or distributed if the drug bears an expiration date that is  
3 25 earlier than six months after the date the drug was donated,  
3 26 or is adulterated or misbranded. The bill provides that  
3 27 unused drugs distributed under the medical assistance program  
3 28 established in Code chapter 249A may be accepted and  
3 29 distributed under the program.

3 30 The bill provides that a physician's office, pharmacy,  
3 31 hospital, or health clinic that accepts donated drugs under  
3 32 the program shall comply with all applicable provisions of  
3 33 state and federal law relating to the storage and distribution  
3 34 of such drugs, and that all drugs shall be inspected. The  
3 35 bill provides that a physician's office, pharmacy, hospital,  
4 1 or health clinic may charge a handling fee for accepting or  
4 2 distributing drugs in an amount to be determined by the  
4 3 department by rule, and that drugs donated under the program  
4 4 shall not be resold.

4 5 The bill provides that a person or entity, including a drug  
4 6 manufacturer, exercising reasonable care in donating,  
4 7 accepting, distributing, or dispensing drugs under the program  
4 8 shall be immune from civil or criminal liability or  
4 9 professional disciplinary action for any injury, death, or  
4 10 loss to person or property, and that the donation of a drug by  
4 11 a drug manufacturer does not absolve the manufacturer of any  
4 12 criminal or civil liability that would have existed but for  
4 13 the donation or increase any liability which otherwise would  
4 14 have existed.

4 15 The bill provides for the adoption of administrative rules  
4 16 by the Iowa department of public health, acting with the  
4 17 recommendation of the board of pharmacy examiners. The bill  
4 18 provides that the rules shall include, but not be limited to,  
4 19 determining eligibility criteria relating to the acceptance,  
4 20 distribution, or dispensing of the drugs, necessary  
4 21 administrative forms, fees, and categories of drugs deemed  
4 22 suitable or unsuitable for acceptance.

4 23 LSB 6547HC 80

4 24 rn/pj/5