

FEB 9 2005  
HUMAN RESOURCES

HOUSE FILE 245  
BY MURPHY and SHOULTZ

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 cancer drug  
2 repository program.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 245

1 Section 1. NEW SECTION. 135.27 CANCER DRUG REPOSITORY  
2 PROGRAM.

3 1. DEFINITIONS. For the purposes of this section, unless  
4 the context otherwise requires:

5 a. "Cancer drug" means a prescription drug that is used to  
6 treat any of the following:

7 (1) Cancer or the side effects of cancer.

8 (2) The side effects of any prescription drug that is used  
9 to treat cancer or the side effects of cancer.

10 b. "Medical facility" means a physician's office,  
11 hospital, or health clinic.

12 2. The department shall establish and maintain a cancer  
13 drug repository program, under which any person may donate a  
14 cancer drug or supplies needed to administer a cancer drug for  
15 use by an individual who meets eligibility criteria specified  
16 by the department by rule. Donations may be made on the  
17 premises of a medical facility or pharmacy that elects to  
18 participate in the program and meets requirements established  
19 by the department. The medical facility or pharmacy may  
20 charge an individual who receives a cancer drug or supplies  
21 needed to administer a cancer drug a handling fee that may not  
22 exceed an amount established by the department. A medical  
23 facility or pharmacy that receives a donated cancer drug or  
24 supplies needed to administer a cancer drug may distribute the  
25 cancer drug or supplies to another eligible medical facility  
26 or pharmacy for use pursuant to the program.

27 3. A cancer drug or supplies needed to administer a cancer  
28 drug may be accepted and dispensed under the program only if  
29 all of the following conditions are met:

30 a. The cancer drug or supplies needed to administer a  
31 cancer drug are in their original, unopened, sealed, and  
32 tamper-evident unit dose packaging or, if packaged in single-  
33 unit doses, the single-unit-dose packaging is unopened.

34 b. The cancer drug bears an expiration date that is later  
35 than six months after the date the drug was donated.

1 c. The cancer drug or supplies needed to administer a  
2 cancer drug are not adulterated or misbranded, as determined  
3 by a licensed pharmacist employed by, or under contract with,  
4 the medical facility or pharmacy, who shall inspect the drug  
5 or supplies needed to administer a cancer drug before the drug  
6 or supplies are dispensed.

7 d. The cancer drug or supplies needed to administer a  
8 cancer drug are prescribed by a health care practitioner for  
9 use by an eligible individual and are dispensed by a  
10 pharmacist.

11 4. A cancer drug or supplies needed to administer a cancer  
12 drug that are donated for use under this section may not be  
13 resold.

14 5. A medical facility, pharmacy, pharmacist, or health  
15 care practitioner shall not be required to participate in the  
16 program.

17 6. a. Unless the manufacturer of a drug or supplies  
18 exercises bad faith, the manufacturer is not subject to  
19 criminal or civil liability for injury, death, or loss to a  
20 person or property for matters related to the donation,  
21 acceptance, or dispensing of a cancer drug or supplies  
22 manufactured by the manufacturer that are donated by any  
23 person under this section, including liability for failure to  
24 transfer or communicate product or consumer information or the  
25 expiration date of the donated cancer drug or supplies.

26 b. Except as provided in paragraph "c", any person, except  
27 the manufacturer of a cancer drug or supplies, is immune from  
28 civil liability for injury to or the death of the individual  
29 to whom the cancer drug or supplies are dispensed and may not  
30 be found guilty of unprofessional conduct for the person's  
31 acts or omissions relating to donating, accepting,  
32 distributing, or dispensing a cancer drug or supplies under  
33 this section.

34 c. The immunity or the prohibition on a finding of guilty  
35 of unprofessional conduct under paragraph "b" does not extend

1 to donation, acceptance, distribution, or dispensation of a  
2 cancer drug by a person whose act or omission involves  
3 reckless, wanton, or intentional misconduct.

4 7. The department shall adopt rules establishing the  
5 following:

6 a. Requirements for medical facilities and pharmacies to  
7 accept and dispense donated cancer drugs or supplies needed to  
8 administer cancer drugs under this section, including:

9 (1) Eligibility criteria.

10 (2) Standards and procedures for accepting, safely  
11 storing, and dispensing donated cancer drugs or supplies  
12 needed to administer cancer drugs.

13 (3) Standards and procedures for inspecting donated cancer  
14 drugs or supplies needed to administer cancer drugs to  
15 determine if the cancer drug or supplies needed to administer  
16 a cancer drug are in their original, unopened, sealed, and  
17 tamper-evident unit dose packaging or, if packaged in single-  
18 unit doses, the single-unit-dose packaging is unopened.

19 (4) Standards and procedures for inspecting donated cancer  
20 drugs or supplies needed to administer cancer drugs to  
21 determine that the cancer drug or supplies needed to  
22 administer a cancer drug are not adulterated or misbranded.

23 b. Eligibility criteria for individuals to receive donated  
24 cancer drugs or supplies needed to administer cancer drugs  
25 dispensed under the program. The standards shall prioritize  
26 dispensation to individuals who are uninsured or indigent, but  
27 shall permit dispensation to others if an uninsured or  
28 indigent individual is unavailable.

29 c. A means, such as an identification card, by which an  
30 individual who is eligible to receive a donated cancer drug or  
31 supplies needed to administer a cancer drug may indicate that  
32 eligibility.

33 d. Necessary forms for administration of the cancer drug  
34 repository program, including forms for use by persons that  
35 donate, accept, distribute, or dispense cancer drugs or

1 supplies needed to administer cancer drugs under the program.

2 e. The maximum handling fee that a medical facility or  
3 pharmacy may charge for accepting, distributing, or dispensing  
4 donated cancer drugs or supplies needed to administer cancer  
5 drugs.

6 f. A list of cancer drugs and supplies needed to  
7 administer cancer drugs, arranged by category or by individual  
8 cancer drug or supply, that the cancer drug repository program  
9 will not accept for dispensing. The list shall include a  
10 statement that specifies the reason that the cancer drug or  
11 supplies needed to administer a cancer drug are ineligible for  
12 donation.

13 EXPLANATION

14 This bill provides for the establishment of a cancer drug  
15 repository program by the Iowa department of public health.

16 The bill defines a "cancer drug" to mean a prescription  
17 drug that is used to treat cancer or the side effects of  
18 cancer, or to treat the side effects of any prescription drug  
19 that is used to treat cancer or the side effects of cancer.  
20 The bill provides that the program allows for the donation of  
21 a cancer drug or supplies needed to administer a cancer drug  
22 for use by an individual who meets eligibility criteria  
23 specified by the department by rule. The bill specifies that  
24 donations may be made on the premises of a medical facility or  
25 pharmacy that elects to participate in the program and meets  
26 requirements established by the department by rule, and that  
27 the medical facility or pharmacy may charge an individual who  
28 receives a cancer drug or supplies needed to administer a  
29 cancer drug a handling fee that may not exceed an amount  
30 established by the department by rule. The bill provides that  
31 a medical facility or pharmacy that receives a donated cancer  
32 drug or supplies needed to administer a cancer drug may  
33 distribute the cancer drug or supplies to another eligible  
34 medical facility or pharmacy for use pursuant to the program.  
35 The bill specifies a number of requirements relating to

1 acceptance and dispensation of cancer drugs or supplies. The  
2 bill provides that a cancer drug or supplies must be in their  
3 original, unopened, sealed, and tamper-evident unit dose  
4 packaging or in unopened single-unit-dose packaging, and must  
5 bear an expiration date later than six months after the date  
6 the drug was donated. The bill provides that the cancer drug  
7 or supplies must not be adulterated or misbranded, as  
8 determined by a licensed pharmacist, that the cancer drug or  
9 supplies must be prescribed by a health care practitioner for  
10 use by an eligible individual and dispensed by a pharmacist,  
11 and that they may not be resold. The bill also provides that  
12 a medical facility, pharmacy, pharmacist, or health care  
13 practitioner cannot be required to participate in the program.  
14 The bill provides for immunity from civil or criminal  
15 liability for manufacturers and dispensers under specified  
16 circumstances. The bill also provides that the department  
17 shall adopt rules relating to eligibility criteria to  
18 participate in the program and receive distributions; rules  
19 relating to standards and procedures for accepting, storing,  
20 dispensing, and inspecting drugs and supplies; necessary forms  
21 for administration of the program; the level of fees which may  
22 be imposed; and a listing of drugs and supplies which may not  
23 be accepted for dispensation.

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