FEB 9 2004 HUMAN RESOURCES

HOUSE FILE 2191 BY MURPHY

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

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A BILL FOR
1 An Act providing for the establishment of a cancer drug
      repository program.
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 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
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s.f. _____ H.f. <u>2(9)</u>

- 1 Section 1. <u>NEW SECTION</u>. 135.26 CANCER DRUG REPOSITORY 2 PROGRAM.
- 3 The department shall establish a cancer drug repository
- 4 program for accepting donated cancer drugs and dispensing such
- 5 drugs to residents of this state.
- 6 l. Any person or entity, including, but not limited to, a
- 7 cancer drug manufacturer, or health care facility as defined
- 8 in section 135C.1, may donate cancer drugs to the cancer drug
- 9 repository program. Cancer drugs may be donated at a
- 10 physician's office, pharmacy, hospital, or health clinic that
- 11 elects to participate in the program and meets criteria for
- 12 such participation established by the department.
- 13 Participation in the program shall be on a voluntary basis.
- 14 2. A cancer drug shall only be accepted or dispensed under
- 15 the program if the drug is in its original, unopened, sealed,
- 16 and tamper-evident unit dose packaging, except that a cancer
- 17 drug packaged in single unit doses may be accepted and
- 18 dispensed if the outside packaging is opened but the single-
- 19 unit-dose packaging is unopened. A cancer drug shall not be
- 20 accepted or dispensed if the drug bears an expiration date
- 21 that is earlier than six months after the date the drug was
- 22 donated, or is adulterated or misbranded. Subject to the
- 23 limitations provided in this subsection, unused cancer drugs
- 24 dispensed under the medical assistance program established in
- 25 chapter 249A may be accepted and dispensed under the cancer
- 26 drug repository program.
- 3. A physician's office, pharmacy, hospital, or health
- 28 clinic that accepts donated cancer drugs under the program
- 29 shall comply with all applicable provisions of state and
- 30 federal law relating to the storage, distribution, and
- 31 dispensing of such drugs and shall inspect all such drugs
- 32 prior to dispensing to determine if they are adulterated or
- 33 misbranded. Drugs accepted into the program shall only be
- 34 dispensed to eligible persons pursuant to a prescription
- 35 issued by a prescribing practitioner, as defined in section

- 1 155A.3, and may be distributed to another participating
- 2 physician's office, pharmacy, hospital, or health clinic for
- 3 dispensing. A physician's office, pharmacy, hospital, or
- 4 health clinic may charge a handling fee for distributing or
- 5 dispensing cancer drugs under the program, in an amount to be
- 6 determined by the department by rule. Cancer drugs donated
- 7 under the program shall not be resold.
- 8 4. Any person or entity, including a cancer drug
- 9 manufacturer, exercising reasonable care in donating,
- 10 accepting, distributing, or dispensing cancer drugs under the
- ll program shall be immune from civil or criminal liability or
- 12 professional disciplinary action for any injury, death, or
- 13 loss to person or property relating to such activities. The
- 14 donation of a cancer drug by a cancer drug manufacturer does
- 15 not, however, absolve the manufacturer of any criminal or
- 16 civil liability that would have existed but for the donation,
- 17 nor shall such donation increase any liability of such cancer
- 18 drug manufacturer which otherwise would have existed.
- 19 5. The department, upon the recommendation of the board of
- 20 pharmacy examiners, shall adopt rules relating to the
- 21 establishment of the program. The rules shall include, but
- 22 not be limited to, determining eligibility criteria and other
- 23 standards and procedures relating to the acceptance,
- 24 distribution, or dispensing of donated cancer drugs; forms
- 25 necessary for administration of the program; the fees that may
- 26 be imposed by physician's offices, pharmacies, hospitals, or
- 27 health clinics; and categories of cancer drugs deemed suitable
- 28 or unsuitable for acceptance by the program.
- 29 EXPLANATION
- 30 This bill provides for the establishment by the Iowa
- 31 department of public health of a voluntary program for
- 32 accepting donated cancer drugs and dispensing such drugs to
- 33 residents of this state.
- The bill provides that any person or entity may donate
- 35 cancer drugs to the cancer drug repository program, at a

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- 1 physician's office, pharmacy, hospital, or health clinic that 2 elects to participate in the program and meets criteria for 3 such participation established by the department. 4 provides that a cancer drug shall only be accepted or 5 dispensed if the drug is in its original, unopened, sealed, 6 and tamper-evident unit dose packaging, but that a drug 7 packaged in single unit doses may be accepted and dispensed if 8 the outside packaging is opened but the single-unit-dose 9 packaging is unopened. The bill provides that a cancer drug 10 shall not be accepted or dispensed if the drug bears an 11 expiration date that is earlier than six months after the date 12 the drug was donated, or is adulterated or misbranded. 13 bill provides that unused cancer drugs dispensed under the 14 medical assistance program established in Code chapter 249A 15 may be accepted and dispensed under the program. 16 The bill provides that a physician's office, pharmacy, 17 hospital, or health clinic that accepts donated cancer drugs 18 under the program shall comply with all applicable provisions 19 of state and federal law relating to the storage, 20 distribution, and dispensing of such drugs, that all drugs 21 shall be inspected prior to dispensing, and that drugs 22 accepted into the program shall only be dispensed to eligible 23 persons pursuant to a prescription issued by a prescribing 24 practitioner as defined in Code section 155A.3. 25 provides that a physician's office, pharmacy, hospital, or 26 health clinic may charge a handling fee for distributing or 27 dispensing cancer drugs in an amount to be determined by the 28 department by rule, and that cancer drugs donated under the 29 program shall not be resold.
- The bill provides that a person or entity, including a
- 31 cancer drug manufacturer, exercising reasonable care in
- 32 donating, accepting, distributing, or dispensing cancer drugs
- 33 under the program shall be immune from civil or criminal
- 34 liability or professional disciplinary action for any injury,
- 35 death, or loss to person or property, and that the donation of

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1 a cancer drug by a cancer drug manufacturer does not absolve
 2 the manufacturer of any criminal or civil liability that would
 3 have existed but for the donation or increase any liability
 4 which otherwise would have existed.
      The bill provides for the adoption of administrative rules
6 by the Iowa department of public health, acting with the
7 recommendation of the board of pharmacy examiners.
8 provides that the rules shall include, but not be limited to,
9 determining eligibility criteria relating to the acceptance,
10 distribution, or dispensing of the drugs, necessary
11 administrative forms, fees, and categories of cancer drugs
12 deemed suitable or unsuitable for acceptance.
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