AMENDMENTS TO LB1035

Introduced by Hughes, 24.

1	1. Strike the original sections and insert the following new
2	sections:
3	Section 1. <u>Sections 1 to 7 of this act shall be known and may be</u>
4	cited as the Prescription Drug Donation Program Act.
5	Sec. 2. For purposes of the Prescription Drug Donation Program Act:
6	(1) Department means the Department of Health and Human Services;
7	(2) Health care facility has the definition found in section 71-413
8	and includes the office of an individual licensed to practice medicine
9	and surgery or osteopathic medicine and surgery;
10	(3) Pharmacy has the definition found in section 71-425;
11	(4) Prescribing practitioner means a health care practitioner
12	licensed under the Uniform Credentialing Act who is authorized to
13	prescribe drugs;
14	(5) Prescription drug has the definition found in section 38-2841
15	excluding controlled substances as defined in section 28-401 and any
16	drugs subject to the requirements of 21 U.S.C. 355-1(f)(3); and
17	(6) Program means the Prescription Drug Donation Program approved
18	pursuant to section 3 of this act.
19	Sec. 3. The department shall approve a prescription drug donation
20	program that meets the criteria set forth in section 5 of this act and
21	may designate or appoint a nonprofit organization to administer the
22	program. Participation in the program shall be voluntary.
23	Sec. 4. Any individual or entity, including, but not limited to, a
24	prescription drug manufacturer or health care facility, may donate
25	prescription drugs, over-the-counter medicines and products, and supplies
26	to the program. A health care facility or pharmacy may charge a handling

27 <u>fee for distributing or dispensing prescription drugs or supplies under</u>

1 <u>the program.</u>

Sec. 5. <u>The department shall ensure that donated prescription drugs</u>
meet the following requirements:

4 (1) A prescription drug or supply is in its original, unopened,
5 sealed, and tamper-evident packaging. A prescription drug packaged in
6 single-unit doses may be accepted and dispensed if the outside packaging
7 is opened but the single-unit-dose packaging is unopened. There shall be
8 no limitation on the number of doses that can be donated to the program;

9 (2) The prescription drug or supply is inspected by the program 10 before the prescription drug or supply is dispensed by a licensed 11 pharmacist and such drugs are only dispensed pursuant to a prescription 12 issued by a prescribing practitioner. Such drugs may be distributed to 13 another health care facility or pharmacy for dispensing; and

14 (3) The prescription drug (a) bears an expiration date that is more 15 than six months after the date the prescription drug was donated, except 16 that such drug may be accepted and distributed if the drug is in high 17 demand as determined by the program and can be dispensed for use, (b) is 18 not adulterated or misbranded as defined in section 71-2461 or 71-2470, 19 (c) has not expired, and (d) does not have restricted distribution by the 20 federal Food and Drug Administration.

21 Sec. 6. <u>(1) The program shall (a) comply with all applicable</u> 22 provisions of state and federal law relating to the storage, 23 distribution, and dispensing of donated prescription drugs and (b) not 24 resell donated prescription drugs and supplies.

(2) Nothing in the Prescription Drug Donation Program Act shall be
 construed to restrict the use of samples by a prescribing practitioner
 during the course of such practitioner's duties at a health care facility
 or pharmacy.

29 Sec. 7. <u>(1) Any individual or entity which exercises reasonable</u> 30 <u>care in donating, accepting, distributing, or dispensing prescription</u> 31 <u>drugs or supplies under the Prescription Drug Donation Program Act or</u>

rules and regulations adopted and promulgated by the department shall be 1 2 immune from civil or criminal liability or professional disciplinary 3 action of any kind for any injury, death, or loss to person or property 4 relating to such activities. 5 (2) Any nonprofit organization administering such program shall be 6 immune from civil or criminal liability or professional disciplinary 7 action of any kind for any injury, death, or loss to person or property 8 relating to such activities. 9 (3) A drug manufacturer shall not, in the absence of bad faith or a finding of gross negligence, be subject to criminal prosecution or 10 11 liability in tort or other civil action, for injury, death, or loss to a 12 person or property for matters related to the donation, acceptance, or 13 dispensing of a drug manufactured by the drug manufacturer that is 14 donated by any person under the program, including, but not limited to, 15 liability for failure to transfer or communicate product or consumer 16 information or the expiration date of the donated prescription drug.