

AMENDMENTS TO LB 994

Introduced by McDonald, 41

1           1. Insert the following sections:

2           Section 1. Sections 1 to 8 of this act shall be known and  
3 may be cited as the Immunosuppressant Drug Repository Program Act.

4           Sec. 2. For purposes of the Immunosuppressant Drug  
5 Repository Program Act:

6           (1) Department means the Department of Health and Human  
7 Services Regulation and Licensure;

8           (2) Immunosuppressant drug means anti-rejection drugs  
9 that are used to reduce the body's immune system response to  
10 foreign material and inhibit a transplant recipient's immune system  
11 from rejecting a transplanted organ. Immunosuppressant drugs are  
12 available only as prescription drugs and come in tablet, capsule,  
13 and liquid forms. The recommended dosage depends on the type  
14 and form of immunosuppressant drug and the purpose for which  
15 it is being used. Immunosuppressant drug does not include drugs  
16 prescribed for inpatient use;

17           (3) Participant means a transplant center that has  
18 elected to voluntarily participate in the program, that has  
19 submitted written notification to the department of its intent  
20 to participate in the program, and that accepts donated  
21 immunosuppressant drugs under the rules and regulations adopted and  
22 promulgated by the department for the program;

23           (4) Prescribing practitioner means a health care

1 practitioner licensed under the Uniform Licensing Law who is  
2 authorized to prescribe immunosuppressant drugs;

3 (5) Prescription drug has the definition found in section  
4 71-1,142;

5 (6) Program means the immunosuppressant drug repository  
6 program established pursuant to section 3 of this act;

7 (7) Transplant center means a hospital that operates  
8 an organ transplant program, including qualifying patients for  
9 transplant, registering patients on the national waiting list,  
10 performing transplant surgery, and providing care before and after  
11 transplant; and

12 (8) Transplant program means the organ-specific facility  
13 within a transplant center. A transplant center may have transplant  
14 programs for the transplantation of hearts, lungs, liver, kidneys,  
15 pancreata, or intestine.

16 Sec. 3. The department shall establish an  
17 immunosuppressant drug repository program for accepting donated  
18 immunosuppressant drugs and dispensing such drugs. Participation in  
19 the program shall be voluntary.

20 Sec. 4. Any person or entity, including, but not limited  
21 to, an immunosuppressant drug manufacturer or transplant center,  
22 may donate immunosuppressant drugs to a participant or return  
23 previously prescribed immunosuppressant drugs to the transplant  
24 center where they were originally prescribed.

25 Sec. 5. (1) An immunosuppressant drug shall only be  
26 accepted or dispensed under the program if such drug is in  
27 its original, unopened, sealed, and tamper-evident packaging.

1 An immunosuppressant drug packaged in single unit doses may be  
2 accepted and dispensed if the outside packaging is opened but  
3 the single-unit-dose packaging is unopened. There shall be no  
4 limitation on the number of doses that can be donated to the  
5 program as long as the donated drugs meet the requirements of this  
6 section.

7 (2) An immunosuppressant drug shall not be accepted or  
8 dispensed under the program if (a) such drug bears an expiration  
9 date prior to the date of donation or (b) such drug is adulterated  
10 or misbranded as described in section 71-2401 or 71-2402.

11 (3) Subject to limitations provided in this section,  
12 unused immunosuppressant drugs dispensed under the medical  
13 assistance program established in section 68-1018 may be accepted  
14 and dispensed under the program.

15 Sec. 6. (1) A participant shall comply with all  
16 applicable provisions of state and federal law relating to the  
17 storage, distribution, and dispensing of donated immunosuppressant  
18 drugs and shall inspect all such drugs prior to dispensing to  
19 determine if they are adulterated or misbranded as described in  
20 section 71-2401 or 71-2402 or if the drug has expired while in  
21 the repository. Such drugs shall only be dispensed pursuant to a  
22 prescription issued by a prescribing practitioner. Such drugs may  
23 be distributed to another participant for dispensing.

24 (2) Immunosuppressant drugs donated under the program  
25 shall not be resold.

26 Sec. 7. The department, upon the recommendation of the  
27 Board of Pharmacy, shall adopt and promulgate rules and regulations

1 to carry out the Immunosuppressant Drug Repository Program Act.

2 Such rules and regulations shall include, but not be limited to:

3 (1) Eligibility criteria and other standards and  
4 procedures for participants that accept and distribute or dispense  
5 donated immunosuppressant drugs;

6 (2) Necessary forms for administration of the program,  
7 including, but not limited to, forms for use by persons or entities  
8 that donate, accept, distribute, or dispense immunosuppressant  
9 drugs under the program. The forms shall include the name of the  
10 person to whom the drug was originally prescribed; and

11 (3) (a) Categories of immunosuppressant drugs that may  
12 be donated or returned under the program and (b) categories of  
13 immunosuppressant drugs that cannot be donated or returned under  
14 the program and the reason that such drugs cannot be donated or  
15 returned.

16 Sec. 8. (1) Any person or entity, including an  
17 immunosuppressant drug manufacturer, which exercises reasonable  
18 care in donating, accepting, distributing, or dispensing  
19 immunosuppressant drugs under the Immunosuppressant Drug Repository  
20 Program Act or rules and regulations adopted and promulgated under  
21 the act shall be immune from civil or criminal liability or  
22 professional disciplinary action of any kind for any injury, death,  
23 or loss to person or property relating to such activities.

24 (2) Notwithstanding subsection (1) of this section, the  
25 donation of an immunosuppressant drug by a drug manufacturer does  
26 not absolve the manufacturer of any criminal or civil liability  
27 that would have existed but for the donation, nor shall such

1 donation increase the liability of such drug manufacturer that  
2 would have existed but for the donation.

3           2. Amend the operative date provisions so that the  
4 sections added by this amendment become operative on their  
5 effective date with the emergency clause.

6           3. Renumber the remaining sections and correct internal  
7 references accordingly.