

HOUSE BILL NO. 622

INTRODUCED BY L. BANGERTER

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4 A BILL FOR AN ACT ENTITLED: "AN ACT CREATING A PILOT PROJECT TO FUND PATIENT-CARE
5 INITIATIVE SERVICES FOR INDIVIDUALS WHO ARE UNDERGOING CANCER CLINICAL TRIALS;
6 PROVIDING FOR THE DESIGN OF THE PROJECT; PROVIDING FOR ADMINISTRATION OF THE PROJECT
7 BY THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; PROVIDING FOR REPORTS ON THE
8 PROJECT; PROVIDING A STATUTORY APPROPRIATION; REVISING THE ALLOCATION OF CIGARETTE
9 TAXES; AMENDING SECTIONS 16-11-119 AND 17-7-502, MCA; AND PROVIDING AN EFFECTIVE DATE AND
10 A TERMINATION DATE."
11

12 WHEREAS, over 100,000 cancer clinical trials are enrolling patients in the United States today, only 140
13 of which are taking place in Montana, thereby forcing Montanans to travel out of state; and

14 WHEREAS, cancer patients in Montana wanting to participate in cancer clinical trials often have to take
15 on the great personal expenses of travel to and lodging in cities in other states where the cancer clinical trials are
16 taking place; and

17 WHEREAS, without public assistance, the average Montanan cannot afford to participate in a cancer
18 clinical trial due to the travel, lodging, and other miscellaneous expenses involved; and

19 WHEREAS, Native Americans make up 6.4% of the population in Montana and are the largest minority
20 group in the state; and

21 WHEREAS, Native Americans and Alaska Natives have some of the highest cancer-related mortality
22 rates of all racial and ethnic groups in the United States, but both groups are severely underrepresented in cancer
23 clinical trials.
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25 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
26

27 NEW SECTION. **Section 1. Legislative findings and purpose.** The legislature finds that Montanans,
28 especially Native Americans, are underrepresented in potentially lifesaving cancer clinical trials. The purpose of
29 [sections 1 through 10] is to create a pilot program to educate Montanans and encourage greater participation,
30 especially among underrepresented populations, in cancer clinical trials.

1
2 **NEW SECTION. Section 2. Definitions.** As used in [sections 1 through 10], the following definitions
3 apply:

4 (1) "Administrator" means a tax-exempt organization under the provisions of section 501(c)(3) of the
5 Internal Revenue Code, 26 U.S.C. 501(c)(3), that qualifies for and is awarded a contract to administer and provide
6 patient-care initiative services pursuant to [section 6].

7 (2) (a) "Cancer clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is
8 conducted in relation to the prevention, detection, or treatment of cancer and is not designed exclusively to test
9 toxicity or disease pathophysiology.

10 (b) The trial must be:

11 (i) conducted under an investigational new drug application reviewed by the United States food and drug
12 administration;

13 (ii) exempt from obtaining an investigational new drug application; or

14 (iii) approved or funded by:

15 (A) the national institutes of health, the centers for disease control and prevention, the agency for
16 healthcare research and quality, the centers for medicare and medicaid services, or a cooperative group or center
17 of any of the entities described in this subsection (2)(b)(iii)(A);

18 (B) a cooperative group or center of the United States department of defense or the United States
19 department of veterans affairs;

20 (C) a qualified nongovernmental research entity identified in the guidelines issued by the national
21 institutes of health for center support groups; or

22 (D) the United States departments of veterans affairs, defense, or energy if the study or investigation
23 has been reviewed and approved through a system of peer review determined by the United States secretary
24 of health and human services to be comparable to the system of peer review of studies and investigations used
25 by the national institutes of health and provide unbiased scientific review by individuals who have no interest in
26 the outcome of the review.

27 (3) "Department" means the department of public health and human services provided for in 2-15-2201.

28 (4) "Participant" means an individual who is participating in a cancer clinical trial and who is chosen in
29 the manner provided in [section 5] to participate in the pilot project.

30 (5) "Patient-care initiative services" means the following services that are not paid for as part of a cancer

- 1 clinical trial and that are paid directly by or provided through the pilot project by an administrator:
- 2 (a) travel, lodging, and transportation expenses of a participant and a companion of the participant;
- 3 (b) medical procedures and diagnostics and medical professional and enrolling fees;
- 4 (c) outreach efforts to:
- 5 (i) increase the percentage of participation of underrepresented populations in cancer clinical trials;
- 6 (ii) increase the rate of early detection among underrepresented populations; and
- 7 (iii) reduce the rate of mortality among underrepresented populations as compared to white non-Hispanic
- 8 Americans; and
- 9 (d) services to remove the concerns that prevent a participant from being able to focus on the
- 10 participant's health, treatment, and recovery, including but not limited to developing a medical directive, organizing
- 11 personal financial information, accounts, and passwords, and facilitating discussions about the importance of
- 12 documenting last wishes.
- 13 (6) "Pilot project" or "project" means the patient-care initiative services pilot project established by
- 14 [sections 1 through 10].
- 15

16 **NEW SECTION. Section 3. Patient-care initiative services -- pilot project elements -- project**

17 **timelines -- contracts.** (1) The department shall design a pilot project in accordance with [section 4] and this

18 section for the provision of patient-care initiative services. The department shall establish and administer the pilot

19 project.

20 (2) The pilot project consists of the following elements:

- 21 (a) a design plan prepared by the department pursuant to [section 4];
- 22 (b) procurement of one or more administrators by the department and funding and management of
- 23 patient-care initiative services for participants chosen pursuant to [section 5] by an administrator or administrators
- 24 pursuant to a contract required by [section 6];
- 25 (c) evaluation of the pilot project in the manner provided by [section 8] and reports to the department and
- 26 the children, families, health, and human services interim committee in the manner provided by [section 9].

27 (3) The pilot project begins with commencement of the design plan provided by [section 4]. Elements

28 of the project as provided in subsection (2) of this section may be begun and completed at times determined by

29 the department consistent with [sections 1 through 10]. However, the provision of patient-care initiative services

30 to each participant must begin no later than January 1, 2015.

1 (4) Requests for proposals and contracts required or authorized by [sections 1 through 10] must comply
2 in all respects with the provisions of Title 18. The department may also consult with the department of
3 administration, the state insurance commissioner, and recognized experts in contracts for the types of services
4 required or authorized by [sections 1 through 10] before committing the state to those contracts.

5
6 **NEW SECTION. Section 4. Pilot project design plan required.** (1) The department shall create a
7 design plan to carry out the pilot project. The design plan must comply with [sections 1 through 10] and must
8 include the following elements:

9 (a) defining core goals and objectives of the pilot project;

10 (b) developing requests for proposals for awarding contracts for the administration and provision of
11 patient-care initiative services pursuant to [section 6];

12 (c) developing a methodology for measuring project outcomes in subject areas, including but not limited
13 to cost, access, and health status of participants as provided in [section 8]; and

14 (d) providing for the method and subjects of reports provided for in [section 9].

15 (2) In defining core goals and objectives of the pilot project, the department shall:

16 (a) estimate the number of participants who will be served by the pilot project but who would not
17 otherwise receive care; and

18 (b) provide public awareness goals for educating the public on cancer clinical trials.

19 (3) The department may contract with outside entities to develop the design plan.

20
21 **NEW SECTION. Section 5. Choice of pilot project participants.** (1) Each administrator shall offer
22 participation in the pilot project to adult and minor individuals in a manner chosen by the administrator.
23 Participation in the pilot project by those individuals chosen by the administrator is voluntary. In offering
24 participation in the project, the administrator shall explain the aspects and objectives of the project as they will
25 affect participants and explain the responsibilities of participants.

26 (2) An administrator shall offer participation in the pilot project only to residents of Montana and shall give
27 preference to individuals belonging to populations that are underrepresented in cancer clinical trials.

28
29 **NEW SECTION. Section 6. Patient-care initiative services -- administration -- payments -- terms**
30 **and conditions.** (1) The department shall contract with administrators for the administration of patient-care

1 initiative services for each participant. The department shall consider a bid only from an entity that:

2 (a) is and has been for at least 5 years a tax-exempt organization under the provisions of section
3 501(c)(3) of the Internal Revenue Code, 26 U.S.C. 501(c)(3);

4 (b) has volunteer or paid staff to facilitate cancer clinical trial navigation services on behalf of participants;

5 (c) has the ability to provide cancer clinical trial navigation services for participants of all ages and with
6 all types of cancers;

7 (d) has worked with individuals ranging in age from 7 to 75 years of age;

8 (e) has provided financial assistance to at least 120 individuals for at least 35 different cancer clinical
9 indications;

10 (f) has had individuals enrolled in at least 35 different cancer clinical trials that were conducted in at least
11 25 different medical facilities within the United States;

12 (g) has an established general community outreach program and diversity outreach program, both of
13 which must have been in place for at least 6 months and are designed to reach underrepresented populations,
14 including but not limited to Native American populations, to provide education about cancer, cancer clinical trials,
15 screenings, and early detection;

16 (h) has an accounting system to track financial assistance provided to participants for patient-care
17 initiative services; and

18 (i) has provided financial assistance to at least 25 companions of cancer patients.

19 (2) The term of a contract entered into may be for a fiscal year or for another period determined by the
20 department that is consistent with appropriations for and the objectives of the pilot project.

21 (3) (a) Upon receipt of an appropriation for the purposes of this section, the department shall pay to the
22 administrator an amount of money based on the number of estimated patients an administrator has in accordance
23 with [section 7], with no more than 50% of the money released prior to July 1, 2014, for the purpose of advertising
24 and outreach.

25 (b) An administrator shall maintain accounting records for all funds received and paid for patient-care
26 initiative services and utilize basic cost control methods and may not use money received pursuant to subsection
27 (3)(a) for administrative costs.

28 (c) If the actual number of participants served by an administrator is 5% less or more than the number
29 estimated by the administrator, the department shall recover excess money awarded to the administrator.

30

1 **NEW SECTION. Section 7. Payment for patient-care initiative services.** The department shall require
2 administrators to distribute funds for patient-care initiative services in accordance with the following schedule:

3 (1) If the participant is enrolled in a cancer clinical trial in which all health care services are delivered at
4 the site of the cancer clinical trial, the administrator may receive up to \$600 per month per participant.

5 (2) If the participant is enrolled in a remote cancer clinical trial in which some but not all health care
6 services are delivered at the site of the cancer clinical trial, the administrator may receive up to \$2,350 per month
7 per participant.

8

9 **NEW SECTION. Section 8. Project evaluation -- outcomes -- assessment.** (1) The department shall
10 require administrators to provide for evaluation and to track the following information:

11 (a) outreach to treatment facilities;

12 (b) referring oncologists and community members;

13 (c) sources of patient referral;

14 (d) the number of patients accepted into a trial who would not have been able to participate without
15 assistance under the pilot project; and

16 (e) demographics, clinical indication, clinical trial selection, and overall experiences.

17 (2) The evaluation must include an evaluation of the cost-effectiveness of the project, the degree of
18 access to health care available to participants, and the health status of participants.

19

20 **NEW SECTION. Section 9. Reporting.** An administrator shall, at the request of the department or the
21 children, families, health, and human services interim committee, provide reports containing any information
22 requested.

23

24 **NEW SECTION. Section 10. Cancer clinical care pilot project account.** There is a cancer clinical
25 care pilot project account in the state special revenue fund consisting of money from cigarette taxes deposited
26 under 16-11-119(1)(e), all other money transferred by the legislature, all monetary contributions, gifts, and grants
27 donated to the account, and all interest and income earned on money in the account. The money in the account
28 is statutorily appropriated, as provided in 17-7-502, to the department of public health and human services to
29 administer and distribute for the purposes provided in [sections 1 through 10].

30

1 **Section 11.** Section 16-11-119, MCA, is amended to read:

2 **"16-11-119. Disposition of taxes.** (1) Cigarette taxes collected under the provisions of 16-11-111 must,
3 in accordance with the provisions of 17-2-124, be deposited as follows:

4 (a) 8.3% or \$2 million, whichever is greater, in the state special revenue fund to the credit of the
5 department of public health and human services for the operation and maintenance of state veterans' nursing
6 homes;

7 (b) for fiscal years beginning July 1, 2011, and ending June 30, 2015, 1.2% in the state special revenue
8 fund to the credit of the account established in section 2, Chapter 461, Laws of 2009, for the construction of the
9 state veterans' home in southwestern Montana;

10 (c) 2.6% in the long-range building program account provided for in 17-7-205;

11 (d) 44% in the state special revenue fund to the credit of the health and medicaid initiatives account
12 provided for in 53-6-1201; and

13 (e) for the fiscal year beginning July 1, 2013, and ending June 30, 2014, \$900,000 in the state special
14 revenue fund to the credit of the cancer clinical care pilot project account provided for in [section 10] for the
15 creation and administration of the patient-care initiative services pilot project; and

16 ~~(e)~~(f) the remainder to the state general fund.

17 (2) If money in the state special revenue fund for the operation and maintenance of state veterans'
18 nursing homes exceeds \$2 million at the end of the fiscal year, the excess must be transferred to the state
19 general fund.

20 (3) The taxes collected on tobacco products, other than cigarettes, must in accordance with the
21 provisions of 17-2-124 be deposited as follows:

22 (a) one-half in the state general fund; and

23 (b) one-half in the state special revenue fund account for health and medicaid initiatives provided for in
24 53-6-1201."

25

26 **Section 12.** Section 17-7-502, MCA, is amended to read:

27 **"17-7-502. Statutory appropriations -- definition -- requisites for validity.** (1) A statutory
28 appropriation is an appropriation made by permanent law that authorizes spending by a state agency without the
29 need for a biennial legislative appropriation or budget amendment.

30 (2) Except as provided in subsection (4), to be effective, a statutory appropriation must comply with both

1 of the following provisions:

2 (a) The law containing the statutory authority must be listed in subsection (3).

3 (b) The law or portion of the law making a statutory appropriation must specifically state that a statutory
4 appropriation is made as provided in this section.

5 (3) The following laws are the only laws containing statutory appropriations: 2-17-105; 5-11-120;
6 5-11-407; 5-13-403; 7-4-2502; 10-1-108; 10-1-1202; 10-1-1303; 10-2-603; 10-3-203; 10-3-310; 10-3-312;
7 10-3-314; 10-4-301; 15-1-121; 15-1-218; 15-31-906; 15-35-108; 15-36-332; 15-37-117; 15-39-110; 15-65-121;
8 15-70-101; 15-70-369; 15-70-601; 16-11-509; 17-3-106; 17-3-112; 17-3-212; 17-3-222; 17-3-241; 17-6-101;
9 18-11-112; 19-3-319; 19-6-404; 19-6-410; 19-9-702; 19-13-604; 19-17-301; 19-18-512; 19-19-305; 19-19-506;
10 19-20-604; 19-20-607; 19-21-203; 20-8-107; 20-9-534; 20-9-622; 20-26-1503; 22-3-1004; 23-4-105; 23-5-306;
11 23-5-409; 23-5-612; 23-7-301; 23-7-402; 30-10-1004; 37-43-204; 37-51-501; 39-71-503; 41-5-2011; 42-2-105;
12 44-4-1101; 44-12-206; 44-13-102; 50-4-623; 53-1-109; section 10; 53-9-113; 53-24-108; 53-24-206; 60-11-115;
13 61-3-415; 69-3-870; 75-1-1101; 75-5-1108; 75-6-214; 75-11-313; 76-13-416; 77-1-108; 77-2-362; 80-2-222;
14 80-4-416; 80-11-518; 81-1-112; 81-7-106; 81-10-103; 82-11-161; 85-20-1504; 85-20-1505; 87-1-230; 87-1-603;
15 87-1-621; 90-1-115; 90-1-205; 90-1-504; 90-3-1003; 90-6-331; and 90-9-306.

16 (4) There is a statutory appropriation to pay the principal, interest, premiums, and costs of issuing,
17 paying, and securing all bonds, notes, or other obligations, as due, that have been authorized and issued
18 pursuant to the laws of Montana. Agencies that have entered into agreements authorized by the laws of Montana
19 to pay the state treasurer, for deposit in accordance with 17-2-101 through 17-2-107, as determined by the state
20 treasurer, an amount sufficient to pay the principal and interest as due on the bonds or notes have statutory
21 appropriation authority for the payments. (In subsection (3): pursuant to sec. 10, Ch. 360, L. 1999, the inclusion
22 of 19-20-604 terminates when the amortization period for the teachers' retirement system's unfunded liability is
23 10 years or less; pursuant to sec. 10, Ch. 10, Sp. L. May 2000, secs. 3 and 6, Ch. 481, L. 2003, and sec. 2, Ch.
24 459, L. 2009, the inclusion of 15-35-108 terminates June 30, 2019; pursuant to sec. 17, Ch. 593, L. 2005, and
25 sec. 1, Ch. 186, L. 2009, the inclusion of 15-31-906 terminates January 1, 2015; pursuant to sec. 73, Ch. 44, L.
26 2007, the inclusion of 19-6-410 terminates upon the death of the last recipient eligible under 19-6-709(2) for the
27 supplemental benefit provided by 19-6-709; pursuant to sec. 8, Ch. 330, L. 2009, the inclusion of 87-1-621
28 terminates June 30, 2013; pursuant to sec. 14, Ch. 374, L. 2009, the inclusion of 53-9-113 terminates June 30,
29 2015; pursuant to sec. 8, Ch. 427, L. 2009, the inclusion of 87-1-230 terminates June 30, 2013; pursuant to sec.
30 5, Ch. 442, L. 2009, the inclusion of 90-6-331 terminates June 30, 2019; pursuant to sec. 47, Ch. 19, L. 2011,

1 the inclusion of 87-1-621 terminates June 30, 2013; pursuant to sec. 16, Ch. 58, L. 2011, the inclusion of
2 30-10-1004 terminates June 30, 2017; pursuant to sec. 6, Ch. 61, L. 2011, the inclusion of 76-13-416 terminates
3 June 30, 2019; and pursuant to sec. 13, Ch. 339, L. 2011, the inclusion of 81-1-112 and 81-7-106 terminates
4 June 30, 2017.)"

5

6 NEW SECTION. **Section 13. Codification instruction.** [Sections 1 through 10] are intended to be
7 codified as an integral part of Title 53, chapter 6, and the provisions of Title 53, chapter 6, apply to [sections 1
8 through 10].

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10 NEW SECTION. **Section 14. Effective date.** [This act] is effective July 1, 2013.

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12 NEW SECTION. **Section 15. Termination.** [This act] terminates December 31, 2016.

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- END -