

IN THE SENATE

SENATE BILL NO. 1097

BY HEALTH AND WELFARE COMMITTEE

AN ACT

1 RELATING TO HEALTH BENEFIT PLANS; AMENDING TITLE 41, IDAHO CODE, BY THE  
2 ADDITION OF A NEW CHAPTER 65, TITLE 41, IDAHO CODE, TO DEFINE A TERM,  
3 TO REQUIRE CERTAIN COVERAGE FOR PERSONS ENROLLED IN APPROVED CLINICAL  
4 TRIALS, TO ESTABLISH PROVISIONS REGARDING RESEARCH INSTITUTIONS, TO  
5 PROVIDE LIMITATIONS ON COVERAGE, TO ESTABLISH PROVISIONS REGARDING IN-  
6 SURER LIABILITY, TO PROVIDE FOR DEDUCTIBLE, COINSURANCE, AND COPAYMENT  
7 REQUIREMENTS, AND TO PROHIBIT CANCELLATION OR NONRENEWAL OF A HEALTH  
8 BENEFIT PLAN UNDER CERTAIN CIRCUMSTANCES.  
9

10 Be It Enacted by the Legislature of the State of Idaho:

11 SECTION 1. That Title 41, Idaho Code, be, and the same is hereby amended  
12 by the addition thereto of a NEW CHAPTER, to be known and designated as Chap-  
13 ter 65, Title 41, Idaho Code, and to read as follows:

14 CHAPTER 65

15 COVERAGE FOR PARTICIPANTS IN CLINICAL TRIALS

16 41-6501. "ROUTINE PATIENT CARE COSTS" DEFINED. "Routine patient care  
17 costs" means the costs of any medically necessary health care service for  
18 which benefits are provided under a health benefit plan, without regard to  
19 whether the enrollee is participating in a clinical trial. Routine patient  
20 care costs do not include the cost:

21 (1) Of an investigational new drug or device that is not approved for  
22 any indication by the United States food and drug administration;

23 (2) Of a service that is not a health care service, regardless of  
24 whether the service is required in connection with participation in a clini-  
25 cal trial;

26 (3) Of a service that is inconsistent with widely accepted and estab-  
27 lished standards of care for a particular diagnosis;

28 (4) Associated with managing a clinical trial; or

29 (5) Of a health care service that is specifically excluded from cover-  
30 age under a health benefit plan.

31 41-6502. REQUIRED COVERAGE. The issuer of a health benefit plan shall  
32 provide benefits for routine patient care costs to an enrollee in connection  
33 with an approved clinical trial. For purposes of this chapter, "approved  
34 clinical trial" means a phase I, phase II, phase III, or phase IV clinical  
35 trial that is conducted in relation to the prevention, detection, or treat-  
36 ment of a disease or condition and:

37 (1) The study or investigation is approved or funded, which may include  
38 funding through in-kind contributions, by one (1) or more of the following:

39 (a) The national institutes of health;

40 (b) The centers for disease control and prevention;

- 1 (c) The agency for healthcare research and quality;  
2 (d) The centers for medicare and medicaid services;  
3 (e) A cooperative group or center of any of the entities through the de-  
4 partment of defense or the department of veterans affairs; or  
5 (f) A qualified nongovernmental research entity identified in the  
6 guidelines issued by the national institutes of health for center sup-  
7 port grants;
- 8 (2) The study or investigation is conducted under an investigational  
9 new drug application reviewed by the food and drug administration;
- 10 (3) The study or investigation is not a new drug trial and therefore ex-  
11 empt from having such an investigational new drug application by the food and  
12 drug administration; or
- 13 (4) The study or investigation has been reviewed and approved by an  
14 institutional review board of an institution that has an agreement with the  
15 office for human research protections of the United States department of  
16 health and human services.

17 41-6503. RESEARCH INSTITUTIONS. The issuer of a health benefit plan is  
18 not required to:

- 19 (1) Reimburse a research institution conducting a clinical trial for  
20 the cost of routine patient care provided through the research institution  
21 unless the research institution, and each health care professional provid-  
22 ing routine patient care through the research institution, agrees to accept  
23 reimbursement under the health benefit plan at the rates established under  
24 the plan as payment in full for the routine patient care provided in connec-  
25 tion with the clinical trial; or
- 26 (2) Provide benefits under this section for services that are custom-  
27 arily paid for by the research institution conducting the clinical trial in  
28 accordance with centers for medicare and medicaid services billing guide-  
29 lines.

30 41-6504. LIMITATIONS ON COVERAGE. The issuer of a health benefit plan  
31 is not required to provide benefits for routine patient care services pro-  
32 vided outside:

- 33 (1) Of the plan's health care provider network, unless out-of-network  
34 benefits are otherwise provided under the plan; or
- 35 (2) This state, unless the health benefit plan otherwise provides bene-  
36 fits for health care services provided outside this state.

37 41-6505. INSURER LIABILITY. An insurer that provides coverage re-  
38 quired by this chapter is not, based on that coverage, liable for any adverse  
39 effects of the approved clinical trial.

40 41-6506. DEDUCTIBLE, COINSURANCE, AND COPAYMENT REQUIREMENTS. Bene-  
41 fits may be made subject to a deductible, coinsurance, or copayment require-  
42 ment comparable to other deductible, coinsurance, or copayment requirements  
43 applicable under the health benefit plan.

1           41-6507. CANCELLATION OR NONRENEWAL PROHIBITED. The issuer of a  
2 health benefit plan may not cancel or refuse to renew coverage under a plan  
3 solely because an enrollee in the plan participates in a clinical trial.