



## 99TH GENERAL ASSEMBLY

### State of Illinois

2015 and 2016

HB2562

by Rep. Robyn Gabel

#### SYNOPSIS AS INTRODUCED:

215 ILCS 5/364.01  
305 ILCS 5/5-5.27 new

Amends the Illinois Insurance Code. Amends provisions that prohibit individual or group policies of accident and health insurance from canceling or non-renewing policies for any individual based on that individual's participation in a qualified cancer trial to include other qualified clinical trials. Provides that the cancer or other qualified clinical trial may be at Phase I of investigation. Requires research trials to be authorized by an institutional review board of an institution approved by the Office of Human Research Protections of the federal Department of Health and Human Services. Amends the Medical Assistance Article of the Illinois Public Aid Code. Provides that no person shall be denied medical assistance based upon that individual's participation in a cancer or other qualified clinical trial if such trial meets the conditions for clinical trials established in the Illinois Insurance Code. Effective January 1, 2016.

LRB099 07591 MLM 27721 b

1 AN ACT concerning healthcare.

2 **Be it enacted by the People of the State of Illinois,**  
3 **represented in the General Assembly:**

4 Section 5. The Illinois Insurance Code is amended by  
5 changing Section 364.01 as follows:

6 (215 ILCS 5/364.01)

7 Sec. 364.01. Qualified clinical ~~cancer~~ trials.

8 (a) No individual or group policy of accident and health  
9 insurance issued or renewed in this State may be cancelled or  
10 non-renewed for any individual based on that individual's  
11 participation in a cancer or other qualified clinical ~~cancer~~  
12 trial.

13 (b) Cancer or other qualified ~~Qualified~~ clinical ~~cancer~~  
14 trials must meet the following criteria:

15 (1) the effectiveness of the treatment has not been  
16 determined relative to established therapies;

17 (2) the trial is under clinical investigation as part  
18 of an approved cancer research or other disease research  
19 trial in Phase I, Phase II, Phase III, or Phase IV of  
20 investigation;

21 (3) the trial is authorized by an institutional review  
22 board of an institution that is approved by the Office of  
23 Human Research Protections of the federal Department of

1           Health and Human Services and is:

2                   (A) approved by the Food and Drug Administration;

3                   or

4                   (B) approved and funded by the National Institutes  
5                   of Health, the Centers for Disease Control and  
6                   Prevention, the Agency for Healthcare Research and  
7                   Quality, the United States Department of Defense, the  
8                   United States Department of Veterans Affairs, or the  
9                   United States Department of Energy in the form of an  
10                   investigational new drug application, or a cooperative  
11                   group or center of any entity described in this  
12                   subdivision (B); and

13                   (4) the patient's primary care physician, if any, is  
14                   involved in the coordination of care.

15                   (c) No group policy of accident and health insurance shall  
16                   exclude coverage for any routine patient care administered to  
17                   an insured who is a qualified individual participating in a  
18                   qualified clinical cancer trial, if the policy covers that same  
19                   routine patient care of insureds not enrolled in a cancer or  
20                   other qualified clinical ~~cancer~~ trial.

21                   (d) The coverage that may not be excluded under subsection  
22                   (c) of this Section is subject to all terms, conditions,  
23                   restrictions, exclusions, and limitations that apply to the  
24                   same routine patient care received by an insured not enrolled  
25                   in a cancer or other qualified clinical ~~cancer~~ trial, including  
26                   the application of any authorization requirement, utilization

1 review, or medical management practices. The insured or  
2 enrollee shall incur no greater out-of-pocket liability than  
3 had the insured or enrollee not enrolled in a cancer or other  
4 qualified clinical ~~cancer~~ trial.

5 (e) If the group policy of accident and health insurance  
6 uses a preferred provider program and a preferred provider  
7 provides routine patient care in connection with a cancer or  
8 other qualified clinical ~~cancer~~ trial, then the insurer may  
9 require the insured to use the preferred provider if the  
10 preferred provider agrees to provide to the insured that  
11 routine patient care.

12 (f) A cancer or other qualified clinical ~~cancer~~ trial may  
13 not pay or refuse to pay for routine patient care of an  
14 individual participating in the trial, based in whole or in  
15 part on the person's having or not having coverage for routine  
16 patient care under a group policy of accident and health  
17 insurance.

18 (g) Nothing in this Section shall be construed to limit an  
19 insurer's coverage with respect to clinical trials.

20 (h) Nothing in this Section shall require coverage for  
21 out-of-network services where the underlying health benefit  
22 plan does not provide coverage for out-of-network services.

23 (i) As used in this Section, "routine patient care" means  
24 all health care services provided in the cancer or other  
25 qualified clinical ~~cancer~~ trial that are otherwise generally  
26 covered under the policy if those items or services were not

1 provided in connection with a cancer or other qualified  
2 clinical ~~cancer~~ trial consistent with the standard of care for  
3 the treatment of that illness ~~cancer~~, including the type and  
4 frequency of any diagnostic modality, that a provider typically  
5 provides to a ~~cancer~~ patient who is not enrolled in a cancer or  
6 other qualified clinical ~~cancer~~ trial. "Routine patient care"  
7 does not include, and a group policy of accident and health  
8 insurance may exclude, coverage for:

9 (1) a health care service, item, or drug that is the  
10 subject of the cancer or other qualified clinical trial;

11 (2) a health care service, item, or drug provided  
12 solely to satisfy data collection and analysis needs for  
13 the cancer or other qualified clinical ~~cancer~~ trial that is  
14 not used in the direct clinical management of the patient;

15 (3) an investigational drug or device that has not been  
16 approved for market by the United States Food and Drug  
17 Administration;

18 (4) transportation, lodging, food, or other expenses  
19 for the patient or a family member or companion of the  
20 patient that are associated with the travel to or from a  
21 facility providing the cancer or other qualified clinical  
22 ~~cancer~~ trial, unless the policy covers these expenses for a  
23 ~~cancer~~ patient who is not enrolled in a cancer or other  
24 qualified clinical ~~cancer~~ trial;

25 (5) a health care service, item, or drug customarily  
26 provided by the cancer or other qualified clinical ~~cancer~~

1 trial sponsors free of charge for any patient;

2 (6) a health care service or item, which except for the  
3 fact that it is being provided in a cancer or other  
4 qualified clinical ~~cancer~~ trial, is otherwise specifically  
5 excluded from coverage under the insured's policy,  
6 including:

7 (A) costs of extra treatments, services,  
8 procedures, tests, or drugs that would not be performed  
9 or administered except for the fact that the insured is  
10 participating in the cancer or other qualified ~~cancer~~  
11 clinical trial; and

12 (B) costs of nonhealth care services that the  
13 patient is required to receive as a result of  
14 participation in the approved cancer or other  
15 qualified ~~cancer~~ clinical trial;

16 (7) costs for services, items, or drugs that are  
17 eligible for reimbursement from a source other than a  
18 patient's contract or policy providing for third-party  
19 payment or prepayment of health or medical expenses,  
20 including the sponsor of the approved cancer or other  
21 qualified ~~cancer~~ clinical trial;

22 (8) costs associated with approved cancer or other  
23 qualified ~~cancer~~ clinical trials designed exclusively to  
24 test toxicity or disease pathophysiology, unless the  
25 policy covers these expenses for a ~~cancer~~ patient who is  
26 not enrolled in a cancer or other qualified clinical ~~cancer~~

1 trial; or

2 (9) a health care service or item that is eligible for  
3 reimbursement by a source other than the insured's policy,  
4 including the sponsor of the cancer or other qualified  
5 clinical ~~cancer~~ trial.

6 The definitions of the terms "health care services",  
7 "Non-Preferred Provider", "Preferred Provider", and "Preferred  
8 Provider Program", stated in 50 IL Adm. Code Part 2051  
9 Preferred Provider Programs apply to these terms in this  
10 Section.

11 (j) The external review procedures established under the  
12 Health Carrier External Review Act shall apply to the  
13 provisions under this Section.

14 (Source: P.A. 97-91, eff. 1-1-12; 97-813, eff. 7-13-12.)

15 Section 10. The Illinois Public Aid Code is amended by  
16 adding Section 5-5.27 as follows:

17 (305 ILCS 5/5-5.27 new)

18 Sec. 5-5.27. Clinical trials. No person shall be denied  
19 medical assistance under this Article based upon that  
20 individual's participation in a cancer or other qualified  
21 clinical trial if such trial meets the conditions for clinical  
22 trials specified in Section 364.01 of the Illinois Insurance  
23 Code.

24 Section 99. Effective date. This Act takes effect January

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