

SENATE BILL No. 396

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-7.4; IC 27-8-14.3; IC 27-13-7-15.

Synopsis: Insurance coverage for costs associated with clinical trials. Defines "associated treatment cost" for purposes of payment for medically necessary treatment and drugs and devices associated with clinical trial treatments. Requires group health benefit plans for public employees, individual and group accident and sickness insurance policies, and individual and group health maintenance organization contracts to provide coverage for associated treatment cost. Prohibits dollar limits, deductibles, copayments, or coinsurance requirements on coverage of associated treatment cost that are less favorable than those for physical illness generally. Requires health benefit plan administrators, insurers, and health maintenance organizations to submit annual reports to the commissioner of the department of
(Continued next page)

Effective: July 1, 1999.

Gard

January 11, 1999, read first time and referred to Committee on Health and Provider Services.



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Digest Continued

insurance describing clinical trials for which associated treatment cost was covered. Requires the insurance commissioner to compile information gathered and make an annual report available to the public. Establishes a work group on health care coverage for associated treatment cost to study and make recommendations regarding costs and benefits of the coverage required under this act.

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Introduced

First Regular Session 111th General Assembly (1999)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 1998 General Assembly.

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SENATE BILL No. 396



A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

- 1 SECTION 1. IC 5-10-8-7.4 IS ADDED TO THE INDIANA CODE
- 2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
- 3 1, 1999]: **Sec. 7.4. (a) As used in this chapter, "administrator"**
- 4 **means:**
- 5 (1) **the state personnel department;**
- 6 (2) **an entity with which the state contracts to administer**
- 7 **health coverage under section 7(b) of this chapter; or**
- 8 (3) **a prepaid health care delivery plan with which the state**
- 9 **contracts under section 7(c) of this chapter.**
- 10 (b) **As used in this section, "associated treatment cost" means**
- 11 **the cost of a medically necessary treatment associated with clinical**
- 12 **trial treatment. The term does not include the cost:**
- 13 (1) **of an investigational drug or device used as part of the**
- 14 **clinical trial treatment;**
- 15 (2) **of nonhealth care services associated with the clinical trial**



- 1 treatment;
 2 (3) of managing the research associated with the clinical trial
 3 treatment; or
 4 (4) not covered under the health benefit plan for
 5 noninvestigational treatments.
- 6 (c) As used in this section, "clinical trial treatment" means:
 7 (1) treatment provided in a phase II, phase III, or phase IV
 8 clinical trial for a life threatening condition;
 9 (2) prevention studies in a phase I, phase II, phase III, or
 10 phase IV clinical trial for cancer;
 11 (3) early detection studies in a phase I, phase II, phase III, or
 12 phase IV clinical trial for cancer; or
 13 (4) treatment studies in a phase I, phase II, phase III, or phase
 14 IV clinical trial for cancer;
- 15 approved by the National Institutes of Health or one (1) of its
 16 cooperative groups or centers, the federal Food and Drug
 17 Administration in the form of an investigational new drug
 18 application, the federal Department of Veterans Affairs, or an
 19 institutional review board of an institution in Indiana that has a
 20 multiple project assurance contract approved by the office of
 21 protection from research risks of the National Institutes of Health.
- 22 (d) As used in this section, "cooperative group" means a formal
 23 network of facilities that collaborate on research projects and have
 24 an established peer review program operating within the group
 25 that is approved by the National Institutes of Health. The term
 26 includes:
 27 (1) the National Cancer Institute Clinical Cooperative Group;
 28 (2) the National Cancer Institute Community Clinical
 29 Oncology Program;
 30 (3) the AIDS Clinical Trials Group; and
 31 (4) the Community Programs for Clinical Research in AIDS.
- 32 (e) As used in this section, "covered individual" means an
 33 individual who is:
 34 (1) covered under a self-insurance program established under
 35 section 7(b) of this chapter to provide group health coverage;
 36 or
 37 (2) entitled to services under a contract for health services
 38 entered into or renewed under section 7(c) of this chapter.
- 39 (f) As used in this chapter, "health benefit plan" means:
 40 (1) a self-insurance program established under section 7(b) of
 41 this chapter to provide group health coverage; or
 42 (2) a contract for health services entered into or renewed



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1 under section 7(c) of this chapter.

2 (g) As used in this section, "multiple project assurance
3 contract" means a contract between an institution and the federal
4 Department of Health and Human Services that defines the
5 relationship between the institution and the federal Department of
6 Health and Human Services and specifies the responsibilities of the
7 institution and procedures that will be used by the institution to
8 protect human research subjects.

9 (h) A health benefit plan must provide a covered individual with
10 coverage for associated treatment cost if:

11 (1) the facility and personnel providing the clinical trial
12 treatment are approved by the organization sponsoring the
13 clinical trial protocol and the institutional review board of the
14 institution providing the clinical trial treatment;

15 (2) there is no clearly superior, noninvestigational treatment
16 alternative to the clinical trial treatment; and

17 (3) the available clinical or preclinical data provide a
18 reasonable expectation that the clinical trial treatment will be
19 at least as effective as a noninvestigational alternative.

20 (i) The coverage required under subsection (h) includes
21 associated treatment cost for a drug or device approved for sale by
22 the federal Food and Drug Administration to the extent that the
23 manufacturer, distributor, or provider of the drug or device does
24 not pay the cost, regardless of whether the drug or device is
25 approved for the covered individual's particular condition.

26 (j) The coverage required under subsections (h) and (i) may not
27 be subject to dollar limits, deductibles, copayments, or coinsurance
28 provisions that are less favorable to a covered individual than the
29 dollar limits, deductibles, copayments, or coinsurance provisions
30 applying to physical illness generally under the health benefit plan.

31 (k) On or before June 1 of each year, each administrator shall
32 submit to the insurance commissioner, on a form approved by the
33 insurance commissioner, a report describing clinical trials for
34 which the health benefit plan covered associated treatment cost
35 during the prior year.

36 (l) The insurance commissioner shall compile an annual
37 summary report of the information gathered under subsection (k)
38 and make copies available to the public.

39 (m) The insurance commissioner shall adopt rules under
40 IC 4-22-2 to implement subsections (k) and (l).

41 SECTION 2. IC 27-8-14.3 IS ADDED TO THE INDIANA CODE
42 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE



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1 JULY 1, 1999]:

2 **Chapter 14.3. Coverage Associated With Clinical Trials**

3 **Sec. 1. (a) As used in this chapter, "accident and sickness**
4 **insurance policy" means an insurance policy that:**

- 5 (1) provides one (1) or more of the types of insurance
6 described in IC 27-1-5-1, classes 1(b) and 2(a); and
7 (2) is issued on an individual or group basis.

8 (b) As used in this chapter, "associated treatment cost" means
9 the cost of a medically necessary treatment associated with clinical
10 trial treatment. The term does not include the cost:

- 11 (1) of an investigational drug or device used as part of the
12 clinical trial treatment;
13 (2) of nonhealth care services associated with the clinical trial
14 treatment;
15 (3) of managing the research associated with the clinical trial
16 treatment; or
17 (4) not covered under the accident and sickness insurance
18 policy for noninvestigational treatments.

19 (c) As used in this chapter, "clinical trial treatment" means:

- 20 (1) treatment provided in a phase II, phase III, or phase IV
21 clinical trial for a life threatening condition;
22 (2) prevention studies in a phase I, phase II, phase III, or
23 phase IV clinical trial for cancer;
24 (3) early detection studies in a phase I, phase II, phase III, or
25 phase IV clinical trial for cancer; or
26 (4) treatment studies in a phase I, phase II, phase III, or phase
27 IV clinical trial for cancer;

28 that is approved by the National Institutes of Health or one (1) of
29 its cooperative groups or centers, the federal Food and Drug
30 Administration in the form of an investigational new drug
31 application, the federal Department of Veterans Affairs, or an
32 institutional review board of an institution in Indiana that has a
33 multiple project assurance contract approved by the office of
34 protection from research risks of the National Institutes of Health.

35 (d) As used in this chapter, "cooperative group" means a formal
36 network of facilities that collaborate on research projects and have
37 an established peer review program operating within the group
38 that is approved by the National Institutes of Health. The term
39 includes:

- 40 (1) the National Cancer Institute Clinical Cooperative Group;
41 (2) the National Cancer Institute Community Clinical
42 Oncology Program;



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1 (3) the Aids Clinical Trials Group; and

2 (4) the community programs for clinical research in AIDS.

3 (e) As used in this chapter, "insured" means an individual who
4 is entitled to coverage under an accident and sickness insurance
5 policy that the insurer issues in Indiana.

6 (f) As used in this chapter, "multiple project assurance
7 contract" means a contract between an institution and the federal
8 Department of Health and Human Services that defines the
9 relationship between the institution and the federal Department of
10 Health and Human Services and specifies the responsibilities of the
11 institution and procedures that will be used by the institution to
12 protect human research subjects.

13 Sec. 2. (a) An insurer must provide coverage for associated
14 treatment cost in an accident and sickness insurance policy that the
15 insurer issues in Indiana if:

16 (1) the facility and personnel providing the clinical trial
17 treatment are approved by the organization sponsoring the
18 clinical trial protocol and the institutional review board of the
19 institution providing the clinical trial treatment;

20 (2) there is no clearly superior, noninvestigational treatment
21 alternative to the clinical trial treatment; and

22 (3) the available clinical or preclinical data provide a
23 reasonable expectation that the clinical trial treatment will be
24 at least as effective as a noninvestigational alternative.

25 (b) The coverage required under subsection (a) includes
26 associated treatment cost for a drug or device approved for sale by
27 the federal Food and Drug Administration to the extent that the
28 manufacturer, distributor, or provider of the drug or device does
29 not pay the cost, regardless of whether the drug or device is
30 approved for the insured's particular condition.

31 (c) The coverage required under this chapter may not be subject
32 to dollar limits, deductibles, or coinsurance provisions that are less
33 favorable to an insured than the dollar limits, deductibles, or
34 coinsurance provisions applying to physical illness generally under
35 the accident and sickness insurance policy.

36 Sec. 3. (a) On or before June 1 of each year, each insurer shall
37 submit to the commissioner, on a form approved by the
38 commissioner, a report describing clinical trials for which the
39 insurer covered associated treatment cost during the prior year.

40 (b) The commissioner shall compile an annual summary report
41 of the information gathered under subsection (a) and make copies
42 available to the public.



1 (c) The commissioner shall adopt rules under IC 4-22-2 to
2 implement this section.

3 SECTION 3. IC 27-13-7-15 IS ADDED TO THE INDIANA CODE
4 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
5 1, 1999]: Sec. 15. (a) As used in this section, "associated treatment
6 cost" means the cost of a medically necessary treatment associated
7 with clinical trial treatment. The term does not include the cost:

8 (1) of an investigational drug or device used as part of the
9 clinical trial treatment;

10 (2) of nonhealth care services associated with the clinical trial
11 treatment;

12 (3) of managing the research associated with the clinical trial
13 treatment; or

14 (4) not covered under the health maintenance organization
15 contract for noninvestigational treatments.

16 (b) As used in this section, "clinical trial treatment" means:

17 (1) treatment provided in a phase II, phase III, or phase IV
18 clinical trial for a life threatening condition;

19 (2) prevention studies in a phase I, phase II, phase III, or
20 phase IV clinical trial for cancer;

21 (3) early detection studies in a phase I, phase II, phase III, or
22 phase IV clinical trial for cancer; or

23 (4) treatment studies in a phase I, phase II, phase III, or phase
24 IV clinical trial for cancer;

25 that is approved by the National Institutes of Health or one (1) of
26 its cooperative groups or centers, the federal Food and Drug
27 Administration in the form of an investigational new drug
28 application, the federal Department of Veterans Affairs, or an
29 institutional review board of an institution in Indiana that has a
30 multiple project assurance contract approved by the office of
31 protection from research risks of the National Institutes of Health.

32 (c) As used in this section, "cooperative group" means a formal
33 network of facilities that collaborate on research projects and have
34 an established peer review program operating within the group
35 that is approved by the National Institutes of Health. The term
36 includes:

37 (1) the National Cancer Institute Clinical Cooperative Group;

38 (2) the National Cancer Institute Community Clinical
39 Oncology Program;

40 (3) the AIDS Clinical Trials Group; and

41 (4) the community programs for clinical research in AIDS.

42 (d) As used in this section, "multiple project assurance

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1 contract" means a contract between an institution and the federal
 2 Department of Health and Human Services that defines the
 3 relationship between the institution and the federal Department of
 4 Health and Human Services and specifies the responsibilities of the
 5 institution and procedures that will be used by the institution to
 6 protect human research subjects.

7 (e) A health maintenance organization issued a certificate of
 8 authority in Indiana shall provide coverage for associated
 9 treatment cost under an individual or group contract that provides
 10 coverage for basic health care services if:

11 (1) the facility and personnel providing the clinical trial
 12 treatment are approved by the organization sponsoring the
 13 clinical trial protocol and the institutional review board of the
 14 institution providing the clinical trial treatment;

15 (2) there is no clearly superior, noninvestigational treatment
 16 alternative to the clinical trial treatment; and

17 (3) the available clinical or preclinical data provide a
 18 reasonable expectation that the clinical trial treatment will be
 19 at least as effective as a noninvestigational alternative.

20 (f) The coverage required under subsection (e) includes
 21 associated treatment cost for a drug or device approved for sale by
 22 the federal Food and Drug Administration to the extent that the
 23 manufacturer, distributor or provider of the drug or device does
 24 not pay the cost, regardless of whether the drug or device is
 25 approved for the enrollee's particular condition.

26 (g) The coverage required by subsections (e) and (f) may not be
 27 subject to dollar limits, deductibles, copayments, or coinsurance
 28 provisions that are less favorable to an enrollee than the dollar
 29 limits, deductibles, copayments, or coinsurance provisions applying
 30 to physical illness generally under the health maintenance
 31 organization contract.

32 (h) On or before June 1 of each year, each health maintenance
 33 organization shall submit to the commissioner, on a form approved
 34 by the commissioner, a report describing clinical trials for which
 35 the health maintenance organization covered associated treatment
 36 cost during the prior year.

37 (i) The commissioner shall compile an annual summary report
 38 of the information gathered under subsection (h) and make copies
 39 available to the public.

40 (j) The commissioner shall adopt rules under IC 4-22-2 to
 41 implement subsections (h) and (i).

42 SECTION 4. [EFFECTIVE JULY 1, 1999] (a) The work group on

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1 health care coverage for associated treatment cost is created to
2 assess the costs and benefits of health care coverage by:

- 3 (1) state employee health benefit plans under IC 5-10-8-7.4, as
4 added by this act;
5 (2) insurers under IC 27-8-14.3, as added by this act; and
6 (3) health maintenance organizations under IC 27-13-7-15, as
7 added by this act;

8 for associated treatment cost.

9 (b) The work group on health care coverage for associated
10 treatment cost consists of nine (9) members appointed by the
11 insurance commissioner before January 1, 2000, as follows:

- 12 (1) One (1) member from the Indiana University School of
13 Medicine.
14 (2) One (1) member from the Indiana State Medical
15 Association.
16 (3) Two (2) representatives, including one (1) medical director
17 licensed to practice medicine in Indiana, from accident and
18 sickness insurers granted certificates of authority in Indiana.
19 (4) Two (2) representatives, including one (1) medical director
20 licensed to practice medicine in Indiana, from health
21 maintenance organizations granted certificates of authority in
22 Indiana.
23 (5) One (1) member from the state personnel department.
24 (6) One (1) member of the public.
25 (7) The commissioner, or the commissioner's designee.

26 (c) The insurance commissioner, or the commissioner's
27 designee, shall serve as chairperson.

28 (d) Members shall serve until the final report is submitted under
29 subsection (g).

30 (e) Each member of the work group who is not a state employee
31 is entitled to the minimum salary per diem provided by
32 IC 4-10-11-2.1(b). The member is also entitled to reimbursement
33 for traveling expenses and other expenses actually incurred in
34 connection with the member's duties, as provided in the state travel
35 policies and procedures established by the department of
36 administration and approved by the budget agency.

37 (f) The work group on health care coverage for associated
38 treatment cost for clinical trials shall:

- 39 (1) develop a methodology for assessing the economic and
40 clinical impact of the health care coverage required under this
41 chapter, IC 5-10-8-7.4, as added by this act, and
42 IC 27-13-7-15, as added by this act, for associated treatment

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- 1 cost;
- 2 (2) collect from health care providers and payers pertinent
- 3 aggregate clinical and financial data on insured treatments to
- 4 assess differences in associated treatment cost and clinical
- 5 outcomes between insureds treated in clinical trials and
- 6 insureds treated outside clinical trials;
- 7 (3) review any other issues the workgroup considers
- 8 appropriate; and
- 9 (4) make recommendations to the insurance commissioner
- 10 pertaining to coverage for associated treatment cost.
- 11 (g) The work group shall submit a final report, including
- 12 findings and recommendations, to the legislative council on or
- 13 before June 30, 2003.
- 14 (h) This SECTION expires June 30, 2004.
- 15 SECTION 5. [EFFECTIVE JULY 1, 1999] (a) IC 5-10-8-7.4, as
- 16 added by this act, applies to a self-insurance program or a contract
- 17 with a prepaid health care delivery plan established, entered into,
- 18 or renewed after June 30, 1999.
- 19 (b) IC 27-8-14.3, as added by this act, applies to an accident and
- 20 sickness insurance policy entered into, issued, delivered, or
- 21 renewed after June 30, 1999.
- 22 (c) IC 27-13-7-15, as added by this act, applies to a health
- 23 maintenance organization contract entered into, issued, delivered,
- 24 or renewed after June 30, 1999.
- 25 (d) This SECTION expires June 30, 2005.

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