

IC 27-13-7

Chapter 7. Requirements for Group Contracts, Individual Contracts, and Evidence of Coverage

IC 27-13-7-0.1

Application of certain amendments to chapter

Sec. 0.1. The following amendments to this chapter apply as follows:

(1) The addition of sections 15.3 and 16 of this chapter by P.L.170-1999 applies to health maintenance organization contracts that are issued, delivered, or renewed after June 30, 1999.

(2) The addition of section 18 of this chapter by P.L.166-2003 applies to a health maintenance organization contract that is entered into, delivered, amended, or renewed after December 31, 2003.

(3) The amendments made to section 14 of this chapter by P.L.204-2003 apply to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2003.

(4) The amendments made to section 14.8 of this chapter by P.L.226-2003 apply to a group or an individual contract with a health maintenance organization that is entered into, delivered, amended, or renewed after June 30, 2003.

(5) The amendments made to section 14.5 of this chapter by P.L.196-2005 apply to a health maintenance organization contract that is entered into, delivered, amended, or renewed after June 30, 2005.

(6) The amendments made to section 3 of this chapter by P.L.218-2007 apply to a health maintenance organization contract that is entered into, delivered, amended, or renewed after June 30, 2007.

(7) The addition of section 19 of this chapter by P.L.109-2008 applies to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2008.

As added by P.L.220-2011, SEC.457.

IC 27-13-7-1

Persons entitled to copies of contracts

Sec. 1. Any holder of a group or an individual contract with a health maintenance organization is entitled to a copy of the group or individual contract.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-2

Deceptive contract provisions prohibited

Sec. 2. A contract or an evidence of coverage referred to in section 1 or section 5 of this chapter may not contain provisions or statements that are unjust, unfair, inequitable, misleading, or

deceptive or that encourage misrepresentation prohibited by IC 27-1-15.6-12 or IC 27-4-1-4.

As added by P.L.26-1994, SEC.25. Amended by P.L.132-2001, SEC.16.

IC 27-13-7-3

Contract provisions

Sec. 3. (a) A contract referred to in section 1 of this chapter must clearly state the following:

- (1) The name and address of the health maintenance organization.
- (2) Eligibility requirements.
- (3) Benefits and services within the service area.
- (4) Emergency care benefits and services.
- (5) Any out-of-area benefits and services.
- (6) Copayments, deductibles, and other out-of-pocket costs.
- (7) Limitations and exclusions.
- (8) Enrollee termination provisions.
- (9) Any enrollee reinstatement provisions.
- (10) Claims procedures.
- (11) Enrollee grievance procedures.
- (12) Continuation of coverage provisions.
- (13) Conversion provisions.
- (14) Extension of benefit provisions.
- (15) Coordination of benefit provisions.
- (16) Any subrogation provisions.
- (17) A description of the service area.
- (18) The entire contract provisions.
- (19) The term of the coverage provided by the contract.
- (20) Any right of cancellation of the group or individual contract holder.
- (21) Right of renewal provisions.
- (22) Provisions regarding reinstatement of a group or an individual contract holder.
- (23) Grace period provisions.
- (24) A provision on conformity with state law.
- (25) A provision or provisions that comply with the:
 - (A) guaranteed renewability; and
 - (B) group portability;requirements of the federal Health Insurance Portability and Accountability Act of 1996 (26 U.S.C. 9801(c)(1)).
- (26) That the contract provides, upon request of the subscriber, coverage for a child of the subscriber until the date the child becomes twenty-six (26) years of age.

(b) For purposes of subsection (a), an evidence of coverage which is filed with a contract may be considered part of the contract.

As added by P.L.26-1994, SEC.25. Amended by P.L.91-1998, SEC.22; P.L.218-2007, SEC.50; P.L.160-2011, SEC.27.

IC 27-13-7-4

Compliance with requirements; ten day grace period

Sec. 4. (a) An individual contract must comply with all provisions of section 3(a) of this chapter and provide for a period of ten (10) days during which the individual entering into the contract with the health maintenance organization may:

- (1) examine the contract; and
- (2) if the individual decides, return the contract to the health maintenance organization and obtain a refund of the premium paid.

(b) If:

- (1) services were received during the ten (10) day period referred to in subsection (a); and
- (2) the individual returns the contract to receive a refund of the premium paid;

the individual must pay for the services received during the ten (10) day period.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-5

Evidence of coverage

Sec. 5. (a) A subscriber under a group contract must receive an evidence of coverage from:

- (1) the group contract holder; or
- (2) the health maintenance organization.

(b) A group contract holder or health maintenance organization may provide the evidence of coverage required under subsection (a) in electronic or paper form. The group contract holder or health maintenance organization shall provide the evidence of coverage in paper form upon the request of the subscriber.

(c) A health maintenance organization shall include in the health maintenance organization's enrollment materials information concerning the manner in which a subscriber may:

- (1) obtain an evidence of coverage; and
- (2) request the evidence of coverage in paper form.

As added by P.L.26-1994, SEC.25. Amended by P.L.125-2005, SEC.6.

IC 27-13-7-6

Evidence of coverage; prohibited provisions

Sec. 6. The evidence of coverage required by section 5 of this chapter may not contain provisions or statements:

- (1) that are unfair, unjust, inequitable, misleading, or deceptive; or
- (2) that encourage misrepresentation prohibited by IC 27-1-15.6-12 or IC 27-4-1-4.

As added by P.L.26-1994, SEC.25. Amended by P.L.132-2001, SEC.17.

IC 27-13-7-7

Evidence of coverage; required statement

Sec. 7. The evidence of coverage required by section 5 of this chapter must contain a clear statement of the matters set forth in section 3(a) of this chapter.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-8

Readability standards

Sec. 8. The commissioner may adopt rules under IC 4-22-2 establishing readability standards for individual contracts and evidence of coverage forms.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-9

Approval of forms by commissioner

Sec. 9. Subject to sections 10 and 11 of this chapter:

- (1) a group or an individual contract;
- (2) an evidence of coverage; or
- (3) an amendment to:
 - (A) a group or an individual contract; or
 - (B) an evidence of coverage;

may not be delivered or issued for delivery in Indiana unless the form has been filed with and approved by the commissioner.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-10

Coverage outside Indiana; commissioner's approval not required

Sec. 10. If:

- (1) an evidence of coverage that is issued under and incorporated into a contract issued in Indiana is intended for delivery in another state;
- (2) the evidence of coverage has been approved for use in the state in which it is to be delivered; and
- (3) the evidence of coverage is not delivered in Indiana;

the evidence of coverage need not be submitted to the commissioner in Indiana for approval.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-11

Filing of form with commissioner; review period; approval; withdrawal of approval; hearing

Sec. 11. (a) A form required by this chapter must be filed with the commissioner at least thirty (30) days before the form is:

- (1) delivered; or
- (2) issued for delivery;

in Indiana.

(b) At any time during the thirty (30) day period referred to in subsection (a), the commissioner may extend the period for review for an additional thirty (30) days.

(c) The commissioner must give notice in writing of an extension of a review period under subsection (b).

(d) If the commissioner does not take action on a form submitted to the commissioner within the thirty (30) day period and any period of extension, the form is considered approved.

(e) At any time after notice and for cause shown, the commissioner may withdraw approval of any form, effective thirty (30) days after notice of the withdrawal of the approval is issued.

(f) When the commissioner:

(1) disapproves a filing; or

(2) withdraws approval of a form;

under this section, the commissioner shall give the health maintenance organization written notice of the reasons for the disapproval or withdrawal of approval. The notice must inform the health maintenance organization that it may, not more than thirty (30) days after it receives the notice, request a hearing concerning the disapproval or withdrawal of approval. If the health maintenance organization requests a hearing not more than thirty (30) days after it receives the notice, the commissioner shall hold a hearing upon not less than ten (10) days notice to the health maintenance organization.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-12

Additional information required by commissioner

Sec. 12. The commissioner may require the submission of any information the commissioner considers necessary to determine whether to approve or disapprove a filing under this chapter.

As added by P.L.26-1994, SEC.25.

IC 27-13-7-13

Continuation of coverage statement

Sec. 13. (a) A health maintenance organization must include in each contract a written statement that if the contract is terminated by the health maintenance organization, an enrollee who is hospitalized for a medical or surgical condition on the date of termination will have continuation of coverage for inpatient covered services.

(b) The continuation of coverage referred to in subsection (a) is not required after one (1) of the following occurs:

(1) The discharge of the enrollee from the hospital.

(2) Sixty (60) days pass after the contract is terminated by the health maintenance organization.

(3) The hospitalized enrollee obtains from another carrier coverage that includes the coverage provided by the terminating health maintenance organization.

(4) A contract holder terminates the contract with the health maintenance organization, as determined by:

(A) the effective date specified in written communication sent by the contract holder to the health maintenance organization, which effective date shall be at least fifteen (15) days after the date the written communication is placed in the United States mail or sent by facsimile transmission;

or

- (B) the failure to pay a premium within the grace period permitted under the contract.
 - (5) Termination of an enrollee by a health maintenance organization due to:
 - (A) the enrollee knowingly providing false information to the health maintenance organization;
 - (B) the enrollee's failure to comply with the rules of the health maintenance organization stated in the contract; or
 - (C) the enrollee's failure to pay a premium within the grace period permitted under contract.
 - (c) In order to satisfy the requirements of subsection (a), a health maintenance organization may provide benefits that exceed the continuation of coverage required by this section, either in the types or time period of health care services covered, or both.
 - (d) If an enrollee terminates the enrollee's coverage, the health maintenance organization is not required to provide continuation of coverage to that enrollee under this section after the termination.
 - (e) This section does not apply to a termination of coverage as the result of the receivership of a health maintenance organization.
- As added by P.L.26-1994, SEC.25.*

IC 27-13-7-14

Post-mastectomy coverage

- Sec. 14. (a) As used in this section, "mastectomy" means the removal of all or part of the breast for reasons that are determined by a licensed physician to be medically necessary.
- (b) A contract with a health maintenance organization that provides coverage for a mastectomy must provide coverage as required under 29 U.S.C. 1185b, including coverage for:
- (1) prosthetic devices; and
 - (2) reconstructive surgery incident to a mastectomy including:
 - (A) all stages of reconstruction of the breast on which the mastectomy has been performed; and
 - (B) surgery and reconstruction of the other breast to produce symmetry;
- in the manner determined by the attending physician and the patient to be appropriate.
- (c) Coverage required under this section is subject to:
- (1) the deductible and coinsurance provisions applicable to a mastectomy; and
 - (2) all other terms and conditions applicable to other services under the contract.
- (d) A health maintenance organization shall provide to an enrollee, at the time that an individual contract or a group contract is entered into and annually thereafter, written notice of the coverage required under this section. Notice that is sent by the health maintenance organization that meets the requirements set forth in 29 U.S.C. 1185b constitutes compliance with this subsection.
- (e) The coverage required under this section applies to a contract with a health maintenance organization that provides coverage for a

mastectomy, regardless of whether an individual who:

- (1) underwent a mastectomy; and
- (2) is covered under the contract;

was covered under the contract at the time of the mastectomy.

(f) This section does not require a health maintenance organization to provide coverage related to post mastectomy care that exceeds the coverage required for post mastectomy care under federal law.

As added by P.L.150-1997, SEC.5. Amended by P.L.2-1998, SEC.71; P.L.96-2002, SEC.3; P.L.204-2003, SEC.2.

IC 27-13-7-14.5

Coverage for nonexperimental, surgical treatment of morbid obesity

Sec. 14.5. (a) As used in this section, "health care provider" means a:

- (1) physician licensed under IC 25-22.5; or
- (2) hospital licensed under IC 16-21;

that provides health care services for surgical treatment of morbid obesity.

(b) As used in this section, "morbid obesity" means:

- (1) a body mass index of at least thirty-five (35) kilograms per meter squared with comorbidity or coexisting medical conditions such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes; or
- (2) a body mass index of at least forty (40) kilograms per meter squared without comorbidity.

For purposes of this subsection, body mass index equals weight in kilograms divided by height in meters squared.

(c) Except as provided in subsection (d), a health maintenance organization that provides coverage for basic health care services under a group contract shall offer coverage for nonexperimental, surgical treatment by a health care provider of morbid obesity:

- (1) that has persisted for at least five (5) years; and
- (2) for which nonsurgical treatment that is supervised by a physician has been unsuccessful for at least six (6) consecutive months.

(d) A health maintenance organization that provides coverage for basic health care services may not provide coverage for surgical treatment of morbid obesity for an enrollee who is less than twenty-one (21) years of age unless two (2) physicians licensed under IC 25-22.5 determine that the surgery is necessary to:

- (1) save the life of the enrollee; or
- (2) restore the enrollee's ability to maintain a major life activity (as defined in IC 4-23-29-6);

and each physician documents in the enrollee's medical record the reason for the physician's determination.

As added by P.L.78-2000, SEC.3. Amended by P.L.196-2005, SEC.6; P.L.102-2006, SEC.5.

IC 27-13-7-14.7

Coverage for pervasive developmental disorders

Sec. 14.7. (a) As used in this section, "pervasive developmental disorder" means a neurological condition, including Asperger's syndrome and autism, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

(b) A group contract with a health maintenance organization that provides basic health care services must provide services for the treatment of a pervasive developmental disorder of an enrollee. Services provided to an enrollee under this subsection are limited to services that are prescribed by the enrollee's treating physician in accordance with a treatment plan. A health maintenance organization may not deny or refuse to provide services to, or refuse to renew, refuse to reissue, or otherwise terminate or restrict coverage under a group contract to services to an individual solely because the individual is diagnosed with a pervasive developmental disorder.

(c) The services required under subsection (b) may not be subject to dollar limits, deductibles, copayments, or coinsurance provisions that are less favorable to an enrollee than the dollar limits, deductibles, copayments, or coinsurance provisions that apply to physical illness generally under the contract with the health maintenance organization.

(d) A health maintenance organization that enters into an individual contract that provides basic health care services must offer to provide services for the treatment of a pervasive developmental disorder of an enrollee. Services provided to an enrollee under this subsection are limited to services that are prescribed by the enrollee's treating physician in accordance with a treatment plan. A health maintenance organization may not deny or refuse to provide services to, or refuse to renew, refuse to reissue, or otherwise terminate or restrict coverage under an individual contract to services to an individual solely because the individual is diagnosed with a pervasive developmental disorder.

(e) The services that must be offered under subsection (d) may not be subject to dollar limits, deductibles, copayments, or coinsurance provisions that are less favorable to an enrollee than the dollar limits, deductibles, copayments, or coinsurance provisions that apply to physical illness generally under the contract with the health maintenance organization.

As added by P.L.148-2001, SEC.3.

IC 27-13-7-14.8

Treatment limitations or financial requirements on coverage of services for mental illness

Sec. 14.8. (a) As used in this section, "coverage of services for a mental illness" includes the services defined under the contract with the health maintenance organization. However, the term does not include services for the treatment of substance abuse or chemical dependency.

(b) This section applies to a group or individual contract with a health maintenance organization that:

(1) is issued, entered into, or renewed after December 31, 1999; and

(2) is issued to an employer that employs more than fifty (50) full-time employees.

(c) This section does not apply to a legal business entity that has obtained an exemption under IC 27-8-5-15.7.

(d) A group or individual contract with a health maintenance organization may not permit treatment limitations or financial requirements on the coverage of services for a mental illness if similar limitations or requirements are not imposed on the coverage of services for other medical or surgical conditions.

(e) A health maintenance organization that enters into an individual contract or a group contract that provides coverage of services for the treatment of substance abuse and chemical dependency when the services are required in the treatment of a mental illness shall offer to provide the coverage without treatment limitations or financial requirements if similar limitations or requirements are not imposed on the coverage of services for other medical or surgical conditions.

(f) This section does not require a group or individual contract with a health maintenance organization to offer mental health benefits.

As added by P.L.42-1997, SEC.3. Amended by P.L.81-1999, SEC.5; P.L.226-2003, SEC.2.

IC 27-13-7-15

Dental care provisions required

Sec. 15. (a) As used in this section, "child" means an individual who is less than nineteen (19) years of age.

(b) As used in this section, "enrollee" means an enrollee who is a child or an individual:

(1) with a physical or mental impairment that substantially limits one (1) or more of the major life activities of the individual; and

(2) who:

(A) has a record of; or

(B) is regarded as;

having an impairment described in subdivision (1).

(c) A health maintenance organization that provides basic health care services shall include coverage under the terms and conditions of the benefits contract for anesthesia and hospital charges for an enrollee for dental care if the mental or physical condition of the enrollee requires dental treatment to be rendered in a hospital or an ambulatory outpatient surgical center. The Indications for General Anesthesia, as published in the reference manual of the American Academy of Pediatric Dentistry, are the utilization standards for determining whether performing dental procedures necessary to treat the enrollee's condition under general anesthesia constitutes

appropriate treatment.

(d) A health maintenance organization may:

(1) require prior authorization for hospitalization or treatment in an ambulatory outpatient surgical center for dental care procedures in the same manner that prior authorization is required for hospitalization or treatment of other covered medical conditions; and

(2) restrict coverage to include only procedures performed by a licensed dentist who has privileges at the hospital or ambulatory outpatient surgical center.

(e) This section does not apply to treatment rendered for temporal mandibular joint disorders (TMJ).

As added by P.L.189-1999, SEC.3.

IC 27-13-7-15.3

Breast cancer screening mammography

Sec. 15.3. (a) As used in this section, "breast cancer screening mammography" has the meaning set forth in IC 27-8-14-2.

(b) As used in this section, "woman at risk" has the meaning set forth in IC 27-8-14-5.

(c) Except as provided in subsection (g), a health maintenance organization issued a certificate of authority in Indiana shall provide breast cancer screening mammography as a covered service under every group contract that provides coverage for basic health care services.

(d) Except as provided in subsection (g), the coverage that a health maintenance organization must provide under this section must include the following:

(1) If the enrollee is at least thirty-five (35) years of age but less than forty (40) years of age and a female, coverage for at least one (1) baseline breast cancer screening mammography performed upon the enrollee before the enrollee becomes forty (40) years of age.

(2) If the enrollee is less than forty (40) years of age and a woman at risk, one (1) breast cancer screening mammography performed upon the enrollee every year.

(3) If the enrollee is at least forty (40) years of age and a female, one (1) breast cancer screening mammography performed upon the enrollee every year.

(4) Any additional mammography views that are required for proper evaluation.

(5) Ultrasound services, if determined medically necessary by the physician treating the enrollee.

(e) Except as provided in subsection (g), the coverage that a health maintenance organization must provide under this section may not be subject to a contract provision that is less favorable to an enrollee or a subscriber than contract provisions applying to physical illness generally under the health maintenance organization contract.

(f) Except as provided in subsection (g), the coverage that a health maintenance organization must provide under this section is in

addition to services specifically provided for x-rays, laboratory testing, or wellness examinations.

(g) In the case of coverage that is not employer based, the health maintenance organization must offer to provide the coverage described in subsections (c) through (f).

As added by P.L.170-1999, SEC.5.

IC 27-13-7-16

Prostate specific antigen test

Sec. 16. (a) As used in this section, "prostate specific antigen test" means a standard blood test performed to determine the level of prostate specific antigen in the blood.

(b) Except as provided in subsection (f), a health maintenance organization issued a certificate of authority in Indiana shall provide prostate specific antigen testing as a covered service under every group contract that provides coverage for basic health care services.

(c) Except as provided in subsection (f), the coverage required under subsection (b) must include the following:

(1) At least one (1) prostate specific antigen test annually for a male enrollee who is at least fifty (50) years of age.

(2) At least one (1) prostate specific antigen test annually for a male enrollee who is less than fifty (50) years of age and who is at high risk for prostate cancer according to the most recent published guidelines of the American Cancer Society.

(d) Except as provided in subsection (f), the coverage that a health maintenance organization must provide under this section may not be subject to a contract provision that is less favorable to an enrollee than a contract provision applying to physical illness generally under the health maintenance organization contract.

(e) Except as provided in subsection (f), the coverage that a health maintenance organization must provide under this section is in addition to services specifically provided for x-rays, laboratory testing, or wellness examinations.

(f) In the case of coverage that is not employer based, the health maintenance organization must offer to provide the coverage described in subsections (b) through (e).

As added by P.L.170-1999, SEC.6.

IC 27-13-7-17

Colorectal cancer testing coverage

Sec. 17. (a) As used in this section, "colorectal cancer testing" means examinations and laboratory tests for cancer for any nonsymptomatic enrollee, in accordance with the current American Cancer Society guidelines.

(b) Except as provided in subsection (e), a health maintenance organization issued a certificate of authority in Indiana shall provide colorectal cancer testing as a covered service under every group contract that provides coverage for basic health care services.

(c) For an enrollee who is:

(1) at least fifty (50) years of age; or

(2) less than fifty (50) years of age and at high risk for colorectal cancer according to the most recent published guidelines of the American Cancer Society; the colorectal cancer testing required under this section must meet the requirements set forth in subsection (d).

(d) An enrollee may not be required to pay a copayment for the colorectal cancer examination and laboratory testing benefit that is greater than a copayment established for similar benefits under a group contract. If the group contract does not cover a similar covered service, the copayment may not be set at a level that materially diminishes the value of the colorectal cancer examination and laboratory testing benefit required under this section.

(e) In the case of coverage that is not employer based, the health maintenance organization is required only to offer to provide the colorectal cancer testing described in subsections (b) through (d) as a covered service under a proposed group contract providing coverage for basic health care services.

As added by P.L.54-2000, SEC.3. Amended by P.L.1-2001, SEC.34.

IC 27-13-7-18

Inherited metabolic disease coverage

Sec. 18. (a) As used in this section, "inherited metabolic disease" means a disease:

- (1) caused by inborn errors of amino acid, organic acid, or urea cycle metabolism; and
- (2) treatable by the dietary restriction of one (1) or more amino acids.

(b) As used in this section, "medical food" means a formula that is:

- (1) intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation; and
- (2) formulated to be consumed or administered enterally under the direction of a physician.

(c) A group health maintenance organization contract that provides coverage for basic health care services must provide coverage for medical food that is:

- (1) medically necessary; and
- (2) prescribed for an enrollee by the enrollee's treating physician for treatment of the enrollee's inherited metabolic disease.

(d) The coverage that must be provided under this section shall not be subject to dollar limits, copayments, or deductibles that are less favorable to an enrollee than the dollar limits, copayments, or deductibles that apply to coverage for:

- (1) prescription drugs generally under the group contract, if prescription drugs are covered under the group contract; or
- (2) physical illness generally under the group contract, if prescription drugs are not covered under the group contract.

As added by P.L.166-2003, SEC.3.

IC 27-13-7-19

Coverage for prosthetic devices

Sec. 19. (a) As used in this section, "orthotic device" means a medically necessary custom fabricated brace or support that is designed as a component of a prosthetic device.

(b) As used in this section, "prosthetic device" means an artificial leg or arm.

(c) An individual contract or a group contract that provides coverage for basic health care services must provide coverage for orthotic devices and prosthetic devices, including repairs or replacements, that:

(1) are provided or performed by a person that is:

(A) accredited as required under 42 U.S.C. 1395m(a)(20); or

(B) a qualified practitioner (as defined in 42 U.S.C. 1395m(h)(1)(F)(iii));

(2) are determined by the enrollee's physician to be medically necessary to restore or maintain the enrollee's ability to perform activities of daily living or essential job related activities; and

(3) are not solely for comfort or convenience.

(d) The:

(1) coverage required under subsection (c) must be equal to the coverage that is provided for the same device, repair, or replacement under the federal Medicare program (42 U.S.C. 1395 et seq.); and

(2) reimbursement under the coverage required under subsection (c) must be equal to the reimbursement that is provided for the same device, repair, or replacement under the federal Medicare reimbursement schedule, unless a different reimbursement rate is negotiated.

This subsection does not require a deductible under an individual contract or a group contract to be equal to a deductible under the federal Medicare program.

(e) Except as provided in subsections (f) and (g), the coverage required under subsection (c):

(1) may be subject to; and

(2) may not be more restrictive than;

the provisions that apply to other benefits under the individual contract or group contract.

(f) The coverage required under subsection (c) may be subject to utilization review, including periodic review, of the continued medical necessity of the benefit.

(g) Any lifetime maximum coverage limitation that applies to prosthetic devices and orthotic devices:

(1) must not be included in; and

(2) must be equal to;

the lifetime maximum coverage limitation that applies to all other items and services generally under the individual contract or group contract.

(h) For purposes of this subsection, "items and services" does not include preventive services for which coverage is provided under a

high deductible health plan (as defined in 26 U.S.C. 220(c)(2) or 26 U.S.C. 223(c)(2)). The coverage required under subsection (c) may not be subject to a deductible, copayment, or coinsurance provision that is less favorable to an enrollee than the deductible, copayment, or coinsurance provisions that apply to other items and services generally under the individual contract or group contract.

As added by P.L.109-2008, SEC.3.

IC 27-13-7-20

Prohibition on chemotherapy coverage limitations

Sec. 20. (a) This section applies to an individual contract or a group contract that provides coverage for both of the following:

- (1) Orally administered cancer chemotherapy.
- (2) Cancer chemotherapy that is administered intravenously or by injection.

(b) As used in this section, "cancer chemotherapy" means medication that is prescribed by a physician to kill or slow the growth of cancer cells.

(c) Coverage for orally administered cancer chemotherapy under an individual contract or a group contract must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an enrollee than the dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for cancer chemotherapy that is administered intravenously or by injection under the individual contract or group contract.

As added by P.L.46-2009, SEC.2.

IC 27-13-7-20.2

Coverage for care related to cancer clinical trials

Sec. 20.2. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

- (1) that is conducted:
 - (A) using a particular care method to prevent, diagnose, or treat a cancer for which:
 - (i) there is no clearly superior, noninvestigational alternative care method; and
 - (ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;
 - (B) in a facility where personnel providing the care method to be followed in the research study have:
 - (i) received training in providing the care method;
 - (ii) expertise in providing the type of care required for the research study; and
 - (iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

- (C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and
- (2) that is approved or funded by one (1) of the following:
 - (A) A National Institutes of Health institute.
 - (B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.
 - (C) The federal Food and Drug Administration.
 - (D) The United States Department of Veterans Affairs.
 - (E) The United States Department of Defense.
 - (F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.
 - (G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.
- (c) As used in this section, "nonparticipating provider" means a health care provider that has not entered into an agreement described in IC 27-13-1-24.
- (d) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:
 - (1) The health care service, item, or investigational drug that is the subject of the clinical trial.
 - (2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.
 - (3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
 - (4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.
 - (5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.
 - (6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.
 - (7) A service, item, or drug that is eligible for reimbursement from a source other than an enrollee's individual contract or group contract, including the sponsor of the clinical trial.
- (e) An individual contract or a group contract must provide coverage for routine care costs that are incurred in the course of a clinical trial if the individual contract or group contract would provide coverage for the same routine care costs not incurred in a clinical trial.
- (f) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and

limitations that apply generally under the individual contract or group contract, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(g) This section does not do any of the following:

(1) Require a health maintenance organization to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit a health maintenance organization from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement under an individual contract or a group contract for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

(h) This section does not create a cause of action against a person for any harm to an enrollee resulting from a clinical trial.

As added by P.L.109-2009, SEC.4.