

## § 148.210

section because an issuer is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and the genetic information is not used for underwriting purposes).

*Example 3.* (i) *Facts.* Individual *K* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *K*'s physician, *K* has been taking a regular dose of tamoxifen to help prevent a recurrence. *K* has an individual health insurance policy through Issuer *W* which adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients with certain variations of the gene for making the CYP<sub>2</sub>D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3*, *W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K*'s undergoing a genetic test to determine the genetic markers *K* has for making the CYP<sub>2</sub>D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *K*.

(h) *Applicability date.* The provisions of this section are effective with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

[74 FR 51693, Oct. 7, 2009]

## Subpart D—Preemption; Excepted Benefits

### § 148.210 Preemption.

(a) *Scope.* (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

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(b) *Regulation of insurance issuers.* The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

### § 148.220 Excepted benefits.

The requirements of this part and part 147 of this subchapter do not apply to any individual coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(9) Travel insurance, within the meaning of § 144.103 of this subchapter.

(b) *Other excepted benefits.* The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following:

(1) Limited scope dental or vision benefits. These benefits are dental or vision benefits that are limited in scope to a narrow range or type of benefits that are generally excluded from benefit packages that combine hospital, medical, and surgical benefits.

(2) Long-term care benefits. These benefits are benefits that are either—

(i) Subject to State long-term care insurance laws;

(ii) For qualified long-term care insurance services, as defined in section 7702B(c)(1) of the Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Code; or

(iii) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(3) Coverage only for a specified disease or illness (for example, cancer policies) if the policies meet the requirements of §146.145(b)(4)(ii)(B) and (C) of this subchapter regarding non-coordination of benefits.

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) The benefits are provided only to individuals who attest, in their fixed indemnity insurance application, that they have other health coverage that is minimum essential coverage within the meaning of section 5000A(f) of the Internal Revenue Code, or that they are treated as having minimum essential coverage due to their status as a bona fide resident of any possession of the United States pursuant to Code section 5000A(f)(4)(B).

(ii) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage.

(iii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, \$100/day or \$50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage.

(iv) A notice is displayed prominently in the application materials in at least 14 point type that has the following language: “THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.”

(v) The requirement of paragraph (b)(4)(iv) of this section applies to all hospital or other fixed indemnity insurance policy years beginning on or after January 1, 2015, and the require-

ment of paragraph (b)(4)(i) of this section applies to hospital or other fixed indemnity insurance policies issued on or after January 1, 2015, and to hospital or other fixed indemnity policies issued before that date, upon their first renewal occurring on or after October 1, 2016.

(5) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act, 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance). The requirements of this part 148 (including genetic non-discrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic non-discrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at <http://www.naic.org>).

(6) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(7) Similar supplemental coverage provided to coverage under a group health plan (as described in §146.145(b)(5)(i)(C) of this subchapter).

[62 FR 16995, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 74 FR 51696, Oct. 7, 2009; 79 FR 30341, May 27, 2014; 81 FR 75327, Oct. 31, 2016]

### Subpart E—Grants to States for Operation of Qualified High Risk Pools

SOURCE: 68 FR 23414, May 2, 2003, unless otherwise noted.

#### § 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (PHS Act). It extends grants to States that have qualified high risk pools that meet the specific requirements described in §148.310. It also provides specific instructions on how to apply for