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(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 CYP₂D6 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.

(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 do not apply to individual health insurance 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.

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(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.

(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), or hospital indemnity or other fixed indemnity insurance (for example, \$100/day) if the policies meet the requirements of §146.145(b)(4)(ii)(B) and (b)(4)(ii)(C) of this subchapter regarding noncoordination of benefits.

(4) 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>).

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

(6) Similar supplemental coverage provided to coverage under a group health plan.

[62 FR 16995, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 74 FR 51696, Oct. 7, 2009]

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 the grants and outlines the grant review and grant award processes.

[73 FR 22285, Apr. 25, 2008]

§ 148.308 Definitions.

For the purposes of this subpart, the following definitions apply:

Bonus grants means funds that the Secretary provides from the appropriated grant funds to be used to provide supplemental consumer benefits to enrollees or potential enrollees in qualified high risk pools.

CMS stands for Centers for Medicare & Medicaid Services.

Loss means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and the premiums collected by the pool.

Qualified high risk pool as defined in sections 2744(c)(2) and 2745(g) of the PHS Act means a risk pool that—

(1) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, except that it may provide for enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 2744 of the PHS Act) that includes a high risk pool as a component; and

(2) Provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act that was in effect at the time of the enactment of the Health Insurance Portability and Accountability Act of 1996 (August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

Standard risk rate means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard rate may be adjusted based upon age, sex, and geographical location.

State means any of the 50 States and the District of Columbia and includes the U.S. Territories of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State fiscal year, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.310 Eligibility requirements for a grant.

A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in § 148.308.

(b) The pool restricts premiums charged under the pool to no more than