

Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Relation to section 2762(a) of the PHS Act.* The preemption provisions contained in section 2762(a) of the PHS Act and §148.210(b) do not supersede a state law described in paragraph (e)(1) of this section.

(f) *Applicability date.* Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

[73 FR 62427, Oct. 20, 2008]

§ 148.180 Prohibition of discrimination based on genetic information.

(a) *Definitions.* For purposes of this section, the following definitions as set forth in §146.122 of this subchapter pertain to health insurance issuers in the individual market to the extent that those definitions are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect or operated in the individual market:

Collect has the meaning set forth at §146.122(a).

Family member has the meaning set forth at §146.122(a).

Genetic information has the meaning set forth at §146.122(a).

Genetic services has the meaning set forth at §146.122(a).

Genetic test has the meaning set forth at §146.122(a).

Manifestation or manifested has the meaning set forth at §146.122(a).

Preexisting condition exclusion has the meaning set forth at §144.103.

Underwriting purposes has the meaning set forth at §148.180(f)(1).

(b) *Prohibition on genetic information as a condition of eligibility.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section precludes an issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of that individual when the family member is covered under the policy that covers the individual.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A State implements the HIPAA guaranteed availability requirement in the individual health insurance market in accordance with §148.120. Individual *A* and his spouse *S* are not “eligible individuals” as that term is defined at §148.103 and, therefore, they are not entitled to obtain individual health insurance coverage on a guaranteed available basis. They apply for individual coverage with Issuer *M*. As part of the application for coverage, *M* receives health information about *A* and *S*. Although *A* has no known medical conditions, *S* has high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 1*, *M* permissibly may decline to offer coverage to *S* because *S* has a manifested disorder (high blood pressure) that makes her ineligible for coverage under the policy’s rules for eligibility.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *S* does not have high blood pressure or any other known medical condition. The only health information relevant to *S* that *M* receives in the application indicates that both of *S*’s parents are overweight and have high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 2*, *M* cannot decline to offer coverage to *S* because *S* does not have a manifested disease or disorder. The only health information *M* has that relates to her pertains to a manifested disease or disorder of family members, which as family medical history constitutes genetic information with respect to *S*. If *M* denies eligibility to *S* based on genetic information, the denial will violate this paragraph (b).

(c) *Prohibition on genetic information in setting premium rates.*

(1) *In general.* An issuer offering health insurance coverage in the individual market must not adjust premium amounts for an individual on the basis of genetic information regarding the individual or a family member of the individual.

(2) *Rule of construction.* (i) Nothing in paragraph (c)(1) of this section precludes an issuer from adjusting premium amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or on the basis of a manifestation of a disease or disorder in a family member of that individual when the family member is covered under the policy that covers the individual.

(ii) The manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to that individual and to further increase premium amounts.

(3) *Examples.* The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *B* is covered under an individual health insurance policy through Issuer *N*. Every other policy year, before renewal, *N* requires policyholders to submit updated health information before the policy renewal date for purposes of determining an appropriate premium, in excess of any increases due to inflation, based on the policyholders' health status. *B* complies with that requirement. During the past year, *B*'s blood glucose levels have increased significantly. *N* increases its premium for renewing *B*'s policy to account for *N*'s increased risk associated with *B*'s elevated blood glucose levels.

(ii) *Conclusion.* In this *Example 1*, *N* is permitted to increase the premium for *B*'s policy on the basis of a manifested disorder (elevated blood glucose) in *B*.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *B*'s blood glucose levels have not increased and are well within the normal range. In providing updated health information to *N*, *B* indicates that both his mother and sister are being treated for adult onset diabetes mellitus (Type 2 diabetes). *B* provides this information voluntarily and not in response to a specific request for family medical history or other genetic information. *N* increases *B*'s premium to account for *B*'s genetic predisposition to develop Type 2 diabetes in the future.

(ii) *Conclusion.* In this *Example 2*, *N* cannot increase *B*'s premium on the basis of *B*'s family medical history of Type 2 diabetes, which is genetic information with respect to

B. Since there is no manifestation of the disease in *B* at this point in time, *N* cannot increase *B*'s premium.

(d) *Prohibition on genetic information as preexisting condition.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion with respect to that coverage.

(2) *Rule of construction.* Nothing in paragraph (d)(1) of this section precludes an issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(3) *Examples:* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *C* has encountered delays in receiving payment from the issuer of his individual health insurance policy for covered services. He decides to switch carriers and applies for an individual health insurance policy through Issuer *O*. *C* is generally in good health, but has arthritis for which he has received medical treatment. *O* offers *C* an individual policy that excludes coverage for a 12-month period for any services related to *C*'s arthritis.

(ii) *Conclusion.* In this *Example 1*, *O* is permitted to impose a preexisting condition exclusion with respect to *C* because *C* has a manifested disease (arthritis).

Example 2. (i) *Facts.* Individual *D* applies for individual health insurance coverage through Issuer *P*. *D* has no known medical conditions. However, in response to *P*'s request for medical information about *D*, *P* receives information from *D*'s physician that indicates that both of *D*'s parents have adult onset diabetes mellitus (Type 2 diabetes). *P* offers *D* an individual policy with a rider that permanently excludes coverage for any treatment related to diabetes that *D* may receive while covered by the policy, based on the fact that both of *D*'s parents have the disease.

(ii) *Conclusion.* In this *Example 2*, the rider violates this paragraph (d) because the preexisting condition exclusion is based on genetic information with respect to *D* (family medical history of Type 2 diabetes).

(e) *Limitation on requesting or requiring genetic testing.*

(1) *General rule.* Except as otherwise provided in this paragraph (e), an issuer offering health insurance coverage in the individual market must

not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (e)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (e)(1) and (e)(2) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *E* goes to a physician for a routine physical examination. The physician reviews *E*'s family medical history, and *E* informs the physician that *E*'s mother has been diagnosed with Huntington's Disease. The physician advises *E* that Huntington's Disease is hereditary, and recommends that *E* undergo a genetic test.

(ii) *Conclusion.* In this *Example 1*, the physician is a health care professional who is providing health care services to *E*. Therefore, the physician's recommendation that *E* undergo the genetic test does not violate this paragraph (e).

Example 2. (i) *Facts.* Individual *F* is covered by a health maintenance organization (HMO). *F* is a child being treated for leukemia. *F*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *F*'s physician recommends that *F* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion.* In this *Example 2*, even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *F*. Therefore, the physician's recommendation that *F* undergo the genetic test does not violate this paragraph (e).

(4) *Determination regarding payment.*

(i) *In general.* As provided in this paragraph (e)(4), nothing in paragraph (e)(1) of this section precludes an issuer offering health insurance in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, "payment" has the meaning given such term in §164.501 of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if an issuer conditions pay-

ment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on a covered individual's genetic makeup, the issuer is permitted to condition payment on the outcome of a genetic test, and may refuse payment if the covered individual does not undergo the genetic test.

(ii) *Limitation.* An issuer in the individual market is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in §164.502(b) of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples.* See paragraph (g) of this section for examples illustrating the rules of this paragraph (e)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (e)(1) of this section, an issuer may request, but not require, that an individual or family member covered under the same policy undergo a genetic test if all of the conditions of this paragraph (e)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The issuer makes the request pursuant to research, as defined in §46.102(d) of this subtitle, that complies with Part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The issuer makes the request in writing, and the request clearly indicates to each individual (or, in the case of a minor child, to the child's legal guardian) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in paragraph (b) of this section) or premium amounts (as described in paragraph (c) of this section).

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (e)(5) can

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be used for underwriting purposes (as described in paragraph (f)(1) of this section).

(iv) *Notice to Federal agencies.* The issuer completes a copy of the “Notice of Research Exception under the Genetic Information Nondiscrimination Act” authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(f) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* An issuer offering health insurance coverage in the individual market must not collect (as defined in paragraph (a) of this section) genetic information for underwriting purposes. See paragraph (g) of this section for examples illustrating the rules of this paragraph (f)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (f)(1)(iii) of this section, *underwriting purposes* means, with respect to any issuer offering health insurance coverage in the individual market—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the coverage;

(B) The computation of premium amounts under the coverage;

(C) The application of any pre-existing condition exclusion under the coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance.

(iii) *Medical appropriateness.* An issuer in the individual market may limit or exclude a benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an issuer conditions a benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on a covered individual’s genetic information, the issuer is permitted to condition the benefit on the genetic information. An issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness, and may deny the benefit if the covered in-

dividual does not provide the genetic information required to determine medical appropriateness. See paragraph (g) of this section for examples illustrating the applicability of this paragraph (f)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.*

(i) *In general.* An issuer offering health insurance coverage in the individual market must not collect genetic information with respect to any individual prior to that individual’s enrollment under the coverage or in connection with that individual’s enrollment. Whether or not an individual’s information is collected prior to that individual’s enrollment is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (f)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly provides that genetic information should not be provided.

(iii) *Examples.* The rules of this paragraph (f)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *G* applies for a health insurance policy through Issuer *Q*. *Q*’s application materials ask for the applicant’s medical history, but not for family medical history. The application’s instructions state that no genetic information, including family medical history, should be provided. *G* answers the questions in the application completely and truthfully, but volunteers certain health information about diseases his parents had, believing that *Q* also needs this information.

(ii) *Conclusion.* In this *Example 1*, *G*’s family medical history is genetic information with respect to *G*. However, since *Q* did not request this genetic information, and *Q*’s instructions stated that no genetic information should be provided, *Q*’s collection is an incidental collection under paragraph

(f)(2)(ii). However, *Q* may not use the genetic information it obtained incidentally for underwriting purposes.

Example 2. (i) *Facts.* Individual *H* applies for a health insurance policy through Issuer *R*. *R*'s application materials request that an applicant provide information on his or her individual medical history, including the names and contact information of physicians from whom the applicant sought treatment. The application includes a release which authorizes the physicians to furnish information to *R*. *R* forwards a request for health information about *H*, including the signed release, to his primary care physician. Although the request for information does not ask for genetic information, including family medical history, it does not state that no genetic information should be provided. The physician's office administrator includes part of *H*'s family medical history in the package to *R*.

(ii) *Conclusion.* In this *Example 2*, *R*'s request was for health information solely about its applicant, *H*, which is not genetic information with respect to *H*. However, *R*'s materials did not state that genetic information should not be provided. Therefore, *R*'s collection of *H*'s family medical history (which is genetic information with respect to *H*), violates the rule against collection of genetic information and does not qualify for the incidental collection exception under paragraph (f)(2)(ii).

Example 3. (i) *Facts.* Issuer *S* acquires Issuer *T*. *S* requests *T*'s records, stating that *S* should not provide genetic information and should review the records to excise any genetic information. *T* assembles the data requested by *S* and, although *T* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *S* receives genetic information about some of *T*'s covered individuals.

(ii) *Conclusion.* In this *Example 3*, *S*'s request for health information explicitly stated that genetic information should not be provided. Therefore, its collection of genetic information was within the incidental collection exception. However, *S* may not use the genetic information it obtained incidentally for underwriting purposes.

(g) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (e) and (f) of this section to issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts.* Individual *I* has an individual health insurance policy through Issuer *U* that covers genetic testing for celiac disease for individuals who have family members with this condition. *I*'s policy includes dependent coverage. After *I*'s son is

diagnosed with celiac disease, *I* undergoes a genetic test and promptly submits a claim for the test to *U* for reimbursement. *U* asks *I* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion.* In this *Example 1*, under the rules of paragraph (e)(4) of this section, *U* is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for *U* to make a decision regarding the payment of *I*'s claim, *U*'s request for the results of the genetic test violates paragraph (e) of this section.

Example 2. (i) *Facts.* Individual *J* has an individual health insurance policy through Issuer *V* that covers a yearly mammogram for participants starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *J* is 33 years old and has the BRCA2 mutation. *J* undergoes a mammogram and promptly submits a claim to *V* for reimbursement. *V* asks *J* for evidence of increased risk of breast cancer, such as the results of a genetic test, before the claim for the mammogram is paid.

(ii) *Conclusion.* In this *Example 2*, *V* does not violate paragraphs (e) or (f) of this section. Under paragraph (e), an issuer is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the issuer requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the covered individual's genetic makeup, the minimum amount of information necessary includes the results of the genetic test. Similarly, *V* does not violate paragraph (f) of this 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 CYP₂D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

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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