



Health Care Reform Survival Guide

Following are factors affected by Health Reform which have been settled; at least in the interim.

Grandfathered Plans: A grandfathered plan is any group health plan or individual policy in effect as of March 23, 2010. These plans will keep their grandfathered status as long as no major changes are made to the plan. Please see Grandfathering FAQ's for further explanation of how an employer may keep or lose their grandfathered status.

Pre-Existing Conditions: As defined by HIPAA, a pre-existing condition is a limitation or exclusion of benefits due to the fact the condition was present prior to the enrollment date for coverage. This is regardless of whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

Rescission: a cancellation or discontinuance of coverage with a retroactive effect. Please see "2011 Key Provisions/Coverage Mandates" for additional information

Essential Health Benefits: EHB's includes the following general categories and the items and services covered within the categories*:

- ambulatory patient services
- emergency services
- Hospitalization
- maternity and newborn care
- mental health and substance use disorder services, including behavioral health treatment
- prescription drugs
- rehabilitative and habilitative services and devices
- laboratory services
- preventive and wellness services
- chronic disease management
- pediatric services, including oral and vision care

Governing agencies to issue regulations to further define essential health benefits-until then, will take into account good-faith efforts using a reasonable interpretation of the term.

*See "2011 Key Provisions-Coverage Mandates" for additional information

Dependent child: A child up to the age of 26. An employer may use either the birth date of the child or the plan year as the determining date of coverage end.*

*See "2011 Key Provisions-Coverage Mandates" for additional information

2010 Key Provisions

Auto Enrollment

- Employers with 200 or more employees and offer one or more health plans must:
 - Automatically enroll all new full-time employees
 - Continue the enrollment of current employees
 - Provide an opt-out notice
- Effective date uncertain but likely will not be until after regulations are issued. One must determine whether or not to make good faith compliance effort now or await further guidance

Temporary Programs

- High Risk Pool
 - Established by 6/21/2010
 - Expires 1/1/2014

Ensure the plan and "management" does not encourage dis-enrolling from the plan to enroll in the high risk pool through training and communication. (If enrollment in the high risk pool occurs due to encouragement then the employer must reimburse the High Risk Pool dollar for dollar.)

- Early Retiree Reinsurance Program
 - HHS program that reimburses health plan 80% of eligible expenses
 - Expenses must be between \$15K and \$90K for retirees between ages 55-64
 - Effective 6/21/2010
 - Expires 1/1/2014 or when \$5B runs out
 - Reinsurance amount must be used to reduce retiree health costs

Evaluate claims information and apply for reinsurance at

<http://www.hhs.gov/ociio/Documents/application.pdf>

Employee Protections

- Whistleblower provision
 - No retaliation for exercising rights under PPACA
 - Cannot waive rights
- Break time for nursing mothers
 - Employer must provide break time and private location for mothers to express breast milk for child up to one year old (Restroom is not considered a private location)
 - No requirement for break time to be paid (breaks are taken as often and as long as needed)

- Hardship exception for employer with under 50 employees
- Determine if more stringent state law requirements apply. As this provision modifies Fair Labor Standards Act, policy must be developed and distributed to employees

2011 Key Provisions

Coverage Mandates

Annual Limits

- Annual limits on EHB's may not be less than the following:
 - \$750,000 for plan years beginning on or after 9/23/2010
 - \$1.25M for plan years beginning on or after 9/23/2011
 - \$2M for plan years on or after 9/23/2012
 - Annual limits are prohibited as of 1/1/2014 and applies to grandfathered and non-grandfathered plans.
- Process to waive annual limit requirements for “mini-med” type plans. Procedures for waivers have been issued by HHS
- Annual limit rules do not apply to health FSA's, MSA's, or HSA's.
- Amend plan and issue SSM or new SPD with revised annual limits

Lifetime Limits

- Lifetime dollar limits on EHB's (essential health benefits) are prohibited beginning with next plan year on or after 9/23/10
- Individuals who previously reached a lifetime limit and are otherwise still eligible for coverage must be notified and given a special enrollment opportunity
- Amend plan and issue SMM or SPD eliminating lifetime limits
- Distribute notice of special enrollment rights (model notice available)

Rescission

- May only rescind coverage in cases of fraud or intentional misrepresentation
- Must give 30 day advance notice of a rescission
- Develop template advance notice form for rescissions

Age 26 Dependent Coverage

- If provide dependent coverage, must provide until age 26 without regard to residency, student status, or dependency (Grandfathered plans may reject an adult child who has access to other employer based coverage)
- If coverage previously lost due to current plan dependent definition rules and dependent is under 26 must allow adult dependent child back into the plan
- IRS Notice allows dependent coverage to be pre-tax up until end of tax year (calendar year) dependent has not attained age 27
- ACA states that children of an adult child are not considered as part of the definition of the dependent coverage change
- Consult with TPA and determine whether to comply early

- Determine when coverage will end-at age 26,until end of plan year, or end of calendar year
- Amend plan and issue SMM or SPD
- Distribute notice of special enrollment (model notice available)

Coverage Mandates

Preventative Services

(Not Applicable to Grandfathered plans)

- The provisions are effective for plan years beginning on or after 9/23/2010 or 1/1/2011 calendar year plans
 - Preventative care coverage required on first dollar basis
 - Non-discrimination requirements extended to fully insured plans (greater than 5% shareholder and/or top 25% of highest paid within the company)
 - Internal and external appeals process required
 - Must cover emergency services as in-network and without prior authorization
 - Must allow designation for OB/GYN and Pediatricians as Primary Care Provider
 - Preventive services are to be covered without any cost-sharing requirement when delivered by a network provider.
 - Employers and insurers are not required to provide coverage for recommended preventive services delivered by an out-of-network provider or may impose cost-sharing for recommended preventive services delivered by an out-of-network health care provider.
 - If a guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the service, the plan or issuer may use "reasonable medical management techniques" to determine any coverage limitations on the service.
- Identify grandfathered plans
- Amend non-grandfathered plans prior to beginning of plan year and distribute SMM or new SPD
- Coordinate with TPA to implement changes
- Consider financial impact of the change and make any necessary changes to the plans(only non-grandfathered plans)
- Evaluate the impact of first dollar preventative care coverage on wellness programs and make any necessary changes
- Distribute Patient Protection Disclosure Notice (model notice available)

Reporting Requirements

- Medical Loss Ratio report must be provided to HHS annually by insurers
 - If amount of premium revenue spent on non-claims cost exceed 15% (20% small group) then rebate is owed to participants
 - Effective 1/1/2011

- W-2 reporting
 - Must disclose value of employer-provided health coverage on W-2
 - Right now, employees will not be required to pay income taxes on value of health coverage. Information, at this time, is merely being gathered
 - Use the actuarial value of medical coverages (COBRA rate for Self-Insured Plans-minus 2% admin fee, if applicable)
 - Excludes employee contributions to health FSA's, HSA's, and MSA's
 - Effective 1/1/2011 (for W-2 reporting in 2012)
 - As of November 2010, the effective date has been modified to 1/1/2012.
- Ensure Payroll and/or HRIS is able to capture the necessary information for W-2 reporting

Health Related Accounts

- OTC drugs require prescription for reimbursement under health FSA's, HRA's, or HSA's unless it is insulin
- Increased penalty from 10% to 20% excise tax for ineligible distribution from HSA
- Both provisions effective 1/1/2011 regardless of plan year start
- Incorporate the changes into your communication plan.
- Amend the plan documents and distribute SMM or new SPD prior to the effective date of the changes

New Programs

- CLASS Act
 - effective 1/1/2011
 - government-run long term care insurance program
 - voluntary program
- Workplace Wellness Incentive
 - Effective 1/1/2011-12/31/2015
 - HHS grant program to help small employers establish comprehensive workplace wellness programs
 - Funding limited to \$200M total
 - Employers with no workplace wellness program in place as of 3/23/10 are eligible
- Determine if your company will automatically enroll employees into the CLASS Act program and/or if premium payment will be allowed via payroll deduction
- If eligible, apply for the wellness program grant ASAP
- Consult legal counsel regarding the details of the wellness program to ensure it does not violate applicable laws

Simple Cafeteria Plans

- Small employers with simple cafeteria plans are exempt from certain non-discrimination requirements

- Must have employed an average of 100 or less employees during either of 2 preceding years
- Cafeteria plan must meet employer contribution and eligibility requirements
- Exemption from non-discrimination requirements for cafeteria plans and certain other benefits provided under the cafeteria plan (i.e. life insurance, health insurance, dependent care assistance benefits)
- Effective 1/1/2011

**Determine if your company can meet the requirements for a simple cafeteria plan
Seek legal counsel to help draft the plan document**

Mini-Med Waivers

The mini-med waiver process is designed to waive the requirement of adherence to the restricted annual limits for essential health benefits (i.e. 750,000 in 2011). The health reform law does not prohibit a plan from imposing treatment limits in lieu of dollar limits. Mini-med waiver applications may be submitted via mail to:

The Health and Human Services Department
Office of Consumer Information and Insurance Oversight
ATTN: James Mayhew
Room 737-F-04
200 Independence Ave., S.W.
Washington D.C. 20201

The preferred method of communication is via email at healthinsurance@hhs.gov (use “waiver” as the subject of the email). If you have further questions with regard to form, format, and required information for a mini-med waiver, please call the Hewitt Coleman Team or you may view the letter from Steve Larson, Director, Office of Oversight, dated September 3, 2010 at http://www.hhs.gov/ociio/regulations/patient/ociio_2010-1_20100903_508.pdf

Grandfathering FAQ's

Maintaining grandfathered status

(The following will not change a health plan's status as grandfathered)

- enrolling a new employee or adding a dependent after March 23, 2010 (this will not independently change the status of the grandfathered health plan)
- change in premium (as long as premium change to employee is less than 5%)
- changes to comply with state or federal law
- changing TPAs or insurance carriers

Losing grandfathered status

(The following will change a plan's status as grandfathered)

- a merger or acquisition for the main purpose of adding new individuals to a grandfathered health plan
- a change in plan eligibility
- a transfer of health insurance coverage (unless there is a genuine employment-based reason for the transfer; that is, if an employer maintains two separate plans and an employee chooses a different plan at open enrollment, the employer maintains its status)
- the elimination of benefits to diagnose or treat a condition
- increase in fixed cost sharing (co-payments) if the total increase in the co-payment exceeds the greater of:
 - \$5 increased by medical inflation, plus \$5 or
 - Medical inflation, expressed as a percentage plus 15 percentage points. This is determined by expressing the co-payment as a percentage
- Increase in fixed cost sharing (such as OOP, and deductibles) that exceeds medical cost inflation plus 15% points. (Calculations should be based on the unadjusted medical care component of the CPI for all Urban Consumers)
- Increase in fixed cost sharing (co-insurance) percentage by ANY amount
- Addition of an annual limit, if the annual limit is lower than the lifetime maximum limit on March 23, 2010
- A decrease in the annual limit in place on March 23, 2010
- A decrease in employer contributions toward the cost of any tier of coverage (i.e. single, family, etc.) by more than 5%
- Imposition of new annual limit (assuming one did not exist before)
- Any benefit option (i.e. had Basic health option on 3/23/10 and added High health option) added after 3/23/10 is not grandfathered

Regaining Grandfathered Status

(Changes made after March 23, 2010 but before the issuance of the regulations)

If a plan made changes prior to the regulations date, the plan will not automatically lose its grandfathered status if the changes are later revoked or modified effective on the first day of the first plan year. However, any change will be considered adopted before March 23 if it was effective before that date (pursuant to a filing with a state insurance department). In other words, if the change was filed before the compliance date—but approved after—the change will not alter the status of the grandfathered health plan.

The importance of disclosure of status

A grandfathered health plan must maintain records documenting its status, and make records available for examination upon request. To maintain its status, a health plan must include a statement in plan materials stating that the coverage is a grandfathered health plan within the meaning of section 1251 of the ACA. The disclosure must include a contact for questions and complaints. Any changes to the plan that don't cause a change in status must be documented and given to the enrollees.

Preventative Services FAQ's

General list of services to be offered without copay, coinsurance or deductible:

Evidence-based preventive services: This list of items is taken from the current recommendations of the United States Preventive Services. They are included only if they have a rating of A or B. This broad list generally includes:

- Breast cancer and cervical cancer screenings
- Colon cancer screenings
- Screening for vitamin deficiencies during pregnancy
- Screenings for diabetes, high cholesterol and high blood pressure

Routine vaccinations: A list of immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention are included in the rule. They are considered routine for use with children, adolescents, and adults and range from childhood immunizations to periodic tetanus shots for adults.

Prevention for children: The rule includes preventive care guidelines for children from birth to age 21 developed by the Health Resources and Services Administration with the American Academy of Pediatrics. Services include regular pediatrician visits, vision and hearing screening, developmental assessments, immunizations, and screening and counseling to address obesity.

Prevention for women: The regulation mandates certain preventive care measures for women. These recommendations will be in place until new requirements for prevention for women are issued by the United States Preventive Services Task Force or appear in comprehensive guidelines supported by the Health Resources and Services Administration.

Full list of covered preventive services issued as part of the Interim Final Regulations:
<http://www.healthcare.gov/center/regulations/prevention/taskforce.html>

To learn more about these services, visit these Web sites:

<http://www.ahrq.gov/clinic/pocketgd.htm>
<http://www.ahrq.gov/clinic/pocketgd09/gcp09s1.htm>
<http://www.cdc.gov/vaccines/pubs/acip-list.htm>

Billing and Office Visits.

If a recommended preventive item or service is billed separately from an office visit, then cost-sharing may be applied to the office visit.

If a recommended preventive item or service is not billed separately from an office visit and the primary purpose of the office visit is the delivery of such item or service, then cost-sharing requirements may not be imposed with respect to the office visit.

If a recommended preventive item or service is not billed separately from an office visit and the primary purpose of the office visit is not the delivery of the preventive item or service, then cost-sharing may be applied to the office visit.

Affordable Care Act: Questions and Answers on Over-the-Counter Medicines and Drugs

Q. How are the rules changing for reimbursing the cost of over-the-counter medicines and drugs from health flexible spending arrangements (health FSAs) and health reimbursement arrangements (HRAs)?

A. Section 9003 of the Affordable Care Act established a new uniform standard for medical expenses. Effective Jan. 1, 2011, distributions from health FSAs and HRAs will be allowed to reimburse the cost of over-the-counter medicines or drugs only if they are purchased with a prescription. This new rule does not apply to reimbursements for the cost of insulin, which will continue to be permitted, even if purchased without a prescription.

Q. How are the rules changing for distributions from health savings accounts (HSAs) and Archer Medical Savings Accounts (Archer MSAs) that are used to reimburse the cost of over-the-counter medicines and drugs?

A. In accordance with Section 9003 of the Affordable Care Act, only prescribed medicines or drugs (including over-the-counter medicines and drugs that are prescribed) and insulin (even if purchased without a prescription) will be considered qualifying medical expenses and subject to preferred tax treatment.

Q. When will the changes become effective?

A. The changes are effective for purchases of over-the-counter medicines and drugs without a prescription after Dec. 31, 2010. The changes do not affect purchases of over-the-counter medicines and drugs in 2010, even if they are reimbursed after Dec. 31, 2010.

Q. How do I prove that I have purchased an over-the-counter medicine or drug with a prescription so that I can get reimbursed from my employer's health FSA or an HRA?

A. If your employer's health FSA or HRA reimburses these expenses, you would provide the prescription (or a copy of the prescription or another item showing that a prescription for the item has been issued) and the customer receipt (or similar third-party documentation showing the date of the sale and the amount of the charge). For

example, documentation could consist of a customer receipt issued by a pharmacy that reflects the date of sale and the amount of the charge, along with a copy of the prescription; or it could consist of a customer receipt that identifies the name of the purchaser (or the name of the person for whom the prescription applies), the date and amount of the purchase and an Rx number.

Q. How does this change affect over-the-counter medical devices and supplies?

A. The new rule does not apply to items for medical care that are not medicines or drugs. Thus, equipment such as crutches, supplies such as bandages, and diagnostic devices such as blood sugar test kits will still qualify for reimbursement by a health FSA or HRA if purchased after Dec. 31, 2010, and a distribution from an HSA or Archer MSA for the cost of such items will still be tax-free, regardless of whether the items are purchased using a prescription.

Q. Will I need a prescription to use my health FSA, HRA, HSA or Archer MSA funds for insulin purchases after Dec. 31, 2010?

A. No. You can continue to use your health FSA, HRA, HSA or Archer MSA funds to purchase insulin without a prescription after Dec. 31, 2010.

Q. I use health FSA funds for my co-pays and deductibles. Will I still be able to reimburse those expenses with health FSA funds after Dec. 31, 2010?

A. Yes. Co-pays and deductibles continue to be reimbursable from a health FSA after Dec. 31, 2010. Similarly, funds from an HRA can continue to be used for these expenses and a distribution from an HSA or Archer MSA for these purposes will be tax-free.

Q. My company gives me two extra months beyond the end of the year to submit claims for health FSA expenses incurred during the year. What happens if I purchase over-the-counter medicines or drugs without a prescription in 2010 but do not submit the claim for those expenses until January 2011? Will they qualify for reimbursement?

A. Yes. The new restriction on plan reimbursements for the cost of over-the-counter medicines or drugs without a prescription applies only to purchases that are made after 2010.

Q. My company's health FSA includes a provision for a grace period, so that if I don't spend all of the money in my health FSA by Dec. 31 in a given year, I can still use the

amount left in my health FSA at the end of the year to reimburse expenses I incur during the first 2 ½ months of the following year. If I buy over-the-counter medicines or drugs without a prescription during the 2 ½ month grace period of 2011, can I still use the amount left in my health FSA at the end of 2010 to reimburse those expenses?

A. No. The change applies to purchases made on or after Jan. 1, 2011. Thus, even if your employer's plan includes the 2 ½ month grace period provision, the cost of over-the-counter medicines and drugs purchased without a prescription during the first 2 ½ months of 2011 will not be eligible to be reimbursed by a health FSA.

Q. If my plan issues a debit or credit card that I use to pay for over-the-counter medicines or drugs, will I still be able to use the card to purchase over the counter medicines or drugs after Dec. 31, 2010?

A. Generally, no. The plan must ensure that the card is reprogrammed no later than Jan. 15, 2011, so that the card can no longer be used to purchase over-the-counter medicines or drugs. For further information, see IRS Notice 2010-59. If your employer's plan reimburses expenses for over-the-counter medicines and drugs, you can seek reimbursement for these expenses by presenting the information described above in the answer to the question "How do I prove that I have purchased an over-the-counter medicine or drug with a prescription so that I can get reimbursed from my employer's health FSA or an HRA?"

Q. If I use HSA or Archer MSA funds to reimburse the cost of over-the-counter medicines or drugs purchased after Dec. 31, 2010 without a prescription, what taxes will I incur?

A. If you have an HSA or Archer MSA, the amount of the distribution for expenses that are not qualifying medical expenses will be includable in your gross income and subject to an additional tax of 20%.

Frequently Asked Questions Regarding the Genetic Information Nondiscrimination Act

U.S. Department of Labor Employee Benefits Security Administration

August 2010

Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) includes provisions that generally prohibit group health plans and health insurance issuers from discriminating based on genetic information. These provisions amend the Employee Retirement Income Security Act (ERISA), administered by the Department of Labor; the Public Health Service Act (PHS Act), administered by the Department of Health and Human Services; and the Internal Revenue Code (the Code), administered by the Department of Treasury (the Treasury) and the Internal Revenue Service (IRS). The Department of Labor has jurisdiction with respect to employment-based group health plans. HHS in conjunction with the States administers these provisions with respect to health insurance issuers. The Treasury and IRS administer these provisions with respect to employers. Title I of GINA also includes individual insurance market provisions under the PHS Act and privacy and confidentiality provisions under the Social Security Act, which are both within the jurisdiction of HHS. Title II of GINA, under the jurisdiction of the Equal Employment Opportunity Commission, addresses discrimination in employment based on genetic information. The subject of these Frequently Asked Questions are the requirements of Title I of GINA under ERISA, prohibiting discrimination in group health plan coverage based on genetic information. GINA expands the genetic information nondiscrimination protections included in Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under GINA, group health plans and health insurance issuers cannot base premiums for a plan or a group of similarly situated individuals on genetic information. GINA generally prohibits plans and issuers from requesting or requiring an individual to undergo genetic tests, and prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment, or for underwriting purposes. GINA applies generally to group health plans. Unlike the provisions under Title I of HIPAA, there is no exception for very small health plans with less than two participants who are current employees. The statutory provisions of GINA are effective for plan years beginning on or after May 21, 2009. The regulations implementing the provisions of GINA were published on October 7, 2009 and are applicable for plan years beginning on or after December 7, 2009. Therefore, for calendar year plans the statute and regulations apply as of January 1, 2010. You can access a copy of these regulations at <http://www.dol.gov/federalregister/PdfDisplay.aspx?DocId=23182>.

Q1: How does GINA expand the genetic information nondiscrimination protections in HIPAA?

HIPAA prevents a plan or issuer from imposing a preexisting condition exclusion based solely on genetic information, and prohibits discrimination in individual eligibility, benefits, or premiums based on any health factor (including genetic information). GINA provides additional underwriting protections, prohibits requesting or requiring genetic testing, and restricts the collection of genetic information. Specifically: GINA provides that group health plans and health insurance issuers cannot adjust premiums or

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contribution amounts for a plan, or any group of similarly situated individuals under the plan, based on genetic information of one or more individuals in the group. (However, premiums may be increased for the group based upon the manifestation of a disease or disorder of an individual enrolled in the plan.) GINA generally prohibits plans and issuers from requesting or requiring an individual to undergo a genetic test. However, a health care professional providing health care services to an individual is permitted to request a genetic test. A plan or issuer may request the results of a genetic test to determine payment of a claim for benefits, but only the minimum amount of information necessary in order to determine payment. There is also a research exception that permits a plan or issuer under certain conditions to request (but not require) that a participant or beneficiary undergo a genetic test. GINA prohibits a plan from collecting genetic information (including family medical history) from an individual prior to or in connection with their enrollment in the plan, or at any time for underwriting purposes. Under GINA, underwriting purposes includes rules for determination of eligibility for benefits and the computation of premium and contribution amounts. Thus, under GINA, plans and issuers are generally prohibited from offering rewards in return for the provision of genetic information, including family medical history information collected as part of a Health Risk Assessment (HRA). GINA includes an exception for incidental collection of genetic information, provided the information is not used for underwriting purposes. However, the regulations make clear that the incidental collection exception is not available if it is reasonable for the plan or issuer to anticipate that health information will be received in response to a collection, unless the collection explicitly states that genetic information should not be provided.

Q2: What is genetic information?

Genetic information means information about an individual's genetic tests, the genetic tests of family members of the individual, the manifestation of a disease or disorder in family members of the individual or any request for or receipt of genetic services, or participation in clinical research that includes genetic services by the individual or a family member of the individual. The term genetic information includes, with respect to a pregnant woman (or a family member of a pregnant woman) genetic information about the fetus and with respect to an individual using assisted reproductive technology, genetic information about the embryo. Genetic information does not include information about the sex or age of any individual.

Q3: Genetic information includes information about an individual's genetic services and tests. What do these include?

Genetic services mean genetic tests, genetic counseling, or genetic education. Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. A genetic test does not include an analysis of proteins or metabolites directly related to a manifested disease, disorder, or pathological condition. Therefore, some examples of genetic tests are tests to determine whether an individual has a BRCA1, BRCA2, or colorectal cancer genetic variant. In contrast, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

Q4: Genetic information includes an individual's genetic tests and information about the manifestation of a disease or disorder in an individual's family member. A genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. What is a manifested disease?

A manifested disease is a disease, disorder, or pathological condition for which an individual has been or could reasonably be diagnosed by a health care professional (with appropriate training and expertise in the field of medicine involved). A disease is not manifested if a diagnosis is based principally on genetic information. For example, an individual whose genetic tests indicate a genetic variant associated with colorectal cancer and another that indicates an increased risk of developing cancer, but who has no signs or symptoms of disease and has not and could not reasonably be diagnosed with a disease does not have a manifested disease. While plans and issuers are prohibited from adjusting group premiums or contributions based on genetic information, plans and issuers can increase the premium or contribution based on the manifested disease or disorder of an individual enrolled in the plan. This is because information about an individual's manifested disease or disorder is not genetic information with respect to that individual. This is discussed further at Q6.

Q5: GINA prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment, or at any time for underwriting purposes. What does "collect" include?

Collect means to request, require, or purchase genetic information.

Q6: Can a group health plan adjust the premium that an employer or group of similarly situated individuals must pay under the plan based on genetic information of an individual or individuals covered under the group?

No. GINA prohibits a group health plan from adjusting group premium or contribution amounts for a group of similarly situated individuals based on the genetic information of members of the group. This is a change from HIPAA's prior nondiscrimination requirements, which allowed plans to adjust premiums or contributions for the group health plan or group of similarly situated individuals (but not for specific individuals within the group) based on genetic information, as well as other health factors. Therefore, even if a plan obtained individual genetic information about group members before GINA's effective date, it cannot be used to adjust the group premium. Under GINA and HIPAA, a plan can charge a higher overall, blended per-participant amount based on the manifestation of a disease or a disorder of an individual enrolled in the plan. However, a plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other group members to further increase the group premium. A plan can take into account the costs associated with providing benefits for covered genetic tests or genetic services in determining overall premium or contribution amounts. Note, under HIPAA, a plan cannot charge an individual more for coverage than other similarly situated individuals in the group based on any health factor, including a manifested disease or disorder. For further discussion of what "manifested disease" means, see Q4.

Q7: Can an individual's doctor or other health care provider request that the individual undergo a genetic test?

Generally, yes. GINA prohibits a group health plan from requesting or requiring an individual or a family member of an individual undergo genetic tests. Nonetheless, under GINA, a health care professional who is providing health care services to an individual can request that an individual undergo a genetic test. A health care professional includes but is not limited to a physician, nurse, physician's assistant, or technicians that provide health care services to patients. For example, if during the course of a routine physical exam, a physician learns that an individual has family medical history indicating a potential risk for Huntington's disease, the physician can recommend that the individual undergo a related genetic test. This would not violate GINA. This would be true even if the doctor were employed by an HMO, so long as the physician was providing health care services to the individual for whom the genetic test was recommended.

Q8: Can a health plan obtain the results of a genetic test to make a determination regarding payment of a claim for benefits under the plan?

Generally, yes. If a plan conditions payment for an item or service based on medical appropriateness and the medical appropriateness depends on the genetic makeup of the patient, then the plan is permitted to condition payment for the item or service on the outcome of a genetic test. The plan may also refuse payment in that situation if the patient does not undergo the genetic test. The plan may request only the minimum amount of information necessary to make a determination regarding payment.

Q9: If a plan normally covers mammograms for participants and beneficiaries starting at age 40, but covers them at age 30 for individuals with a high risk of breast cancer, may the plan require that an individual under 40 submit genetic test results or family medical history as evidence of high risk of breast cancer, in order to have a claim for a mammogram paid?

Generally, yes. Under GINA, a plan may request and use the results of a genetic test to make a determination regarding payment, as long as the plan requests only the minimum amount of information necessary. Plans may also request genetic information for the purpose of determining the medical appropriateness of a treatment or service. Because the medical appropriateness of the mammogram depends on the patient's genetic makeup, the minimum amount of information necessary for determining payment of the claim may include the results of a genetic test or the individual's family medical history.

Q10: Can a plan request that a participant or beneficiary undergo a genetic test for research purposes?

Under GINA, a plan is permitted to request, but not to require, that a participant or beneficiary undergo a genetic test for research purposes if the following four requirements are met:

I. The plan makes the request pursuant to research. (Research is defined in 45 CFR 46.102(d)). The research must comply with 45 CFR Part 46 or equivalent Federal regulations and any applicable State or local law or regulation for the protection of human subjects in research.

II. The plan must make the request for the genetic test in writing and clearly indicate to each participant and beneficiary that the request is voluntary and will have no effect on eligibility.

III. No genetic information collected pursuant to this research exception can be used for underwriting purposes.

IV. The plan must complete a copy of the “Notice of Research Exception under the Genetic Information Nondiscrimination Act” and provide the notice to the address specified in the instructions.

You can access this notice at <http://www.dol.gov/ebsa/GINAexceptioninstructions.html>.

Q11: GINA prohibits a group health plan from collecting genetic information for underwriting purposes. What does underwriting purposes mean?

Under GINA, the definition of underwriting purposes is broader than merely activities relating to rating and pricing a group policy. Under GINA, underwriting purposes means, with respect to a group health plan:

I. Rules for or determination of eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program);

II. Computation of premium or contribution amounts under the plan (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing an HRA or participating in a wellness program);

III. The application of any preexisting condition exclusion under the plan; and

IV. Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

Q12: Can a plan require an individual to complete a health risk assessment (HRA) prior to or as part of the enrollment process for the plan?

GINA prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment. Thus, under GINA, plans and issuers must ensure that any HRA conducted prior to or in connection with enrollment does not collect genetic information, including family medical history. Under GINA, there is an exception for genetic information that is obtained incidental to the collection of other information, if 1) the genetic information that is obtained is not used for underwriting purposes and 2) if it is reasonable to anticipate that the collection will result in the plan receiving health information, the plan explicitly notifies the person providing the

information that genetic information should not be provided. Therefore, a plan conducting an HRA prior to or in connection with enrollment, should ensure that the HRA explicitly states that genetic information should not be provided.

Q13: Can a plan require that an individual complete a health risk assessment (HRA) that requests family medical history in order to receive a wellness program reward, such as a financial incentive, in return for the completion of the HRA?

GINA prohibits a plan from collecting genetic information (including family medical history):

1. prior to or in connection with enrollment; or
2. at any time for underwriting purposes.

Because completing the HRA results in a reward, the request is for underwriting purposes and is prohibited. A plan may use an HRA that requests family medical history, if it is requested to be completed after and unrelated to enrollment and if there is no premium reduction or any other reward for completing the HRA. A plan may offer a premium discount or other reward for completion of an HRA that does not request family medical history or other genetic information, such as information about any genetic tests the individual has undergone. The plan should ensure that the HRA explicitly states that genetic information should not be provided. This is because GINA provides an exception for genetic information that is obtained incidental to the collection of other information, if 1) the genetic information that is obtained is not used for underwriting purposes and 2) if in connection with any collection it is reasonable to anticipate that health information will be received, the collection explicitly states that genetic information should not be provided.

Plans may use two separate HRAs; one that collects genetic information, such as family medical history, which is conducted after and unrelated to enrollment and is not tied to a reward, and another HRA that does not request genetic information, which can be tied to a reward. In addition, under GINA group health plans may also reward:

I. Participation in an annual physical examination with a physician (or other health care professional) who is providing health care services to the individual, even if the physician may ask for family medical history as part of the examination;

II. More favorable cost-sharing for preventive services, including genetic screening; and

III. Participation in certain disease management or prevention programs. The incentives to participate in such programs must also be available to individuals who qualify for the program but have not volunteered family medical history information through an HRA.

FAQ's - Grandfathered Health Plans-As of April 2011

What is the scope of the anti-abuse rule in paragraph (b)(2) of the interim final regulations relating to grandfather status? In particular, what is a "bona fide employment-based reason" for employees enrolled in a benefit package that is being eliminated to be transferred into another benefit package?

The interim final regulations relating to status as a grandfathered health plan generally state that transferring employees from one grandfathered plan or benefit package (transferor plan) to another (transferee plan) will cause the transferee plan to relinquish grandfather status if amending the transferor plan to replicate the terms of the transferee plan would have caused the transferor plan to relinquish grandfather status. However, the interim final regulations also provide that this rule applies only if there was no bona fide employment-based reason to transfer the employees.

For purposes of paragraph (b)(2) of the interim final regulations relating to status as a grandfathered health plan, the Departments interpret the term "bona fide employment-based reason" to embrace a variety of circumstances. These circumstances (under which a transfer would not cause cessation of grandfather status) include, but are not limited to, any of the following:

When a benefit package is being eliminated because the issuer is exiting the market;

When a benefit package is being eliminated because the issuer no longer offers the product to the employer (for example, because the employer no longer satisfies the issuer's minimum participation requirement);

When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

The foregoing is not intended to be an exhaustive list of circumstances that will be deemed to satisfy the bona fide employment-based reason condition. There may be

many other circumstances in which a benefit package is considered to be eliminated for a bona fide employment-based reason.

My plan bases the level of cost sharing for brand-name prescription drugs on the classification of the drugs under the plan as having or not having generic alternatives. The classification of a drug that had no generic alternative changes because a generic alternative becomes available and is added to the formulary, with a resulting increase in the cost-sharing level for the brand-name drug. Does that increase cause my plan to relinquish its grandfather status?

No. For example, if, on March 23, 2010, the terms of the plan included prescription drug benefits with different cost sharing divided into tiers as follows:

Tier 1 includes generic drugs only;

Tier 2 includes brand name drugs with no generic available;

Tier 3 includes brand name drugs with a generic available in Tier 1; and

Tier 4 includes IV chemotherapy drugs.

A drug was previously classified in Tier 2 as a brand name drug with no generic available. However, a generic alternative for the drug has just been released and is added to the formulary. Since the generic is now available, the plan moves the brand name drug into Tier 3 and adds the generic to Tier 1. This movement of the brand name drug into a higher cost-sharing tier does not cause the plan to relinquish grandfather status.

A previous FAQ addressed the interaction of value-based insurance design (VBID) and the no cost-sharing preventive care services requirements. See <http://www.dol.gov/ebsa/faqs/faq-aca5.html>. In that example, a group health plan did not impose a copayment for colorectal cancer preventive services when performed in an in-network ambulatory surgery center. In contrast, the same preventive service provided at an in-network outpatient hospital setting generally required a \$250 copayment, although the copayment was waived for individuals for whom it would be medically inappropriate to have the preventive service provided in the ambulatory setting. The FAQ indicated that this VBID did not cause the plan to fail to comply with the no cost-sharing preventive care requirements.

A question about a different situation has been raised. Under a group health plan, similar preventive services are available both at an in-network ambulatory surgery center and at an in-network outpatient hospital setting, but currently no copayment is imposed for these services in either setting. This has been the case since March 23, 2010. If this plan wished to adopt the VBID approach described in the example above by imposing a \$250 copayment for these preventive services only when performed in the in-network outpatient hospital setting (i.e., not when performed in an in-network ambulatory surgery center), and with the same waiver of the copayment for any individuals for whom it would be medically inappropriate to have these preventive services provided in the ambulatory setting, would implementation of that new design now cause the plan to relinquish grandfather status?

No. This increase in the copayment for these preventive services solely in the in-network outpatient hospital setting (subject to the waiver arrangement described above) without any change in the copayment in the in-network ambulatory surgery center setting would not be considered to exceed the thresholds described in paragraph (g)(1) of the interim final regulations on grandfather status and thus would not cause the plan to relinquish grandfather status.

The Departments are seeking further information on VBID and wellness programs and are planning to address issues relating to those designs and programs in future regulations. Comments from plan sponsors have expressed an interest in being able to retain grandfather status notwithstanding certain changes in plan terms that are intended to implement VBID and wellness programs. As the regulatory process progresses, the Departments will be giving close attention to these comments, and further guidance may be issued addressing other circumstances in which plan changes implementing those designs and programs may be made without relinquishing grandfather status.

A plan operating on a calendar plan year is considering an amendment to plan terms that will exceed the thresholds described in paragraph (g)(1) of the interim final regulations and cause it to relinquish grandfather status. If the plan sponsor decides to adopt this amendment on July 1, 2011, and the change becomes effective for the plan year beginning on January 1, 2012, at what point in time does the plan relinquish grandfather status?

A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms, which exceeds the thresholds described in paragraph (g)(1)

of the interim final regulations, becomes effective – regardless of when the amendment is adopted. Therefore, in this example, the plan would cease to be a grandfathered health plan on January 1, 2012, the first day of the first plan year for which the change is effective.

A plan operating on a calendar plan year is considering an amendment to plan terms that will cause it to relinquish grandfather status, but wants the amendment to become effective before the first day of the next plan year. If the plan sponsor decides to make this amendment effective on July 1, 2011, does the plan relinquish grandfather status in the middle of the plan year?

Yes. A plan or coverage will cease to be a grandfathered health plan when a plan amendment becomes effective. Therefore, if a plan sponsor chooses to make an amendment to plan terms effective in the middle of a plan year, the plan will cease to be a grandfathered health plan at that time.

If a plan sponsor wishes to avoid relinquishing grandfathered status in the middle of a plan year, any changes that will cause a plan or coverage to relinquish grandfather status should be made effective the first day of a plan year that begins after the change is adopted.

A plan covers both retirees and active employees and is subject to the market reform requirements of the Affordable Care Act. For retirees, the employer that sponsors the plan contributes \$300 per year multiplied by the individual's years of service for the employer, capped at \$10,000 per year. As the cost of coverage increases over time, how is it determined whether the employer's contribution rate has decreased for purposes of maintaining grandfather status?

In this example, the employer makes contributions based on a formula. Accordingly, the plan will cease to be a grandfathered health plan if the employer decreases its contribution rate towards the cost of coverage by more than five percent below the contribution rate on March 23, 2010. If the formula does not change, the employer is not considered to have reduced its contribution rate, regardless of any increase in the total cost of coverage. However, if the dollar amount that is multiplied by years of service decreases by more than five percent (or if the \$10,000 maximum employer contribution cap decreases by more than five percent), the plan will cease to be a grandfathered health plan.