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Employee Benefits Security Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

RIN 0938-AI08

Final Rules for Nondiscrimination and Wellness Programs in Health Coverage in the Group

Market

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final rules governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

DATES: Effective date. These final regulations are effective February 12, 2006.

Applicability dates. These final regulations apply for plan years beginning on or after July 1, 2007.

FOR FURTHER INFORMATION CONTACT: Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Amy Turner or Elena Lynett, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; or Karen Levin or Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267-2323 extension 65445 and 61091, respectively.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining copies of Department of Labor publications concerning health care laws may request copies by calling the Department of Labor (DOL), Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or may request a copy of the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) publication entitled “Protecting Your Health Insurance Coverage” by calling 1-800-633-4227. These regulations as well as other information on

HIPAA's nondiscrimination rules and other health care laws are also available on the Department of Labor's website (<http://www.dol.gov/ebsa>), including the interactive web pages Health Elaws.

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 (110 Stat. 1936), was enacted on August 21, 1996. HIPAA amended the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) to provide for, among other things, improved portability and continuity of health coverage. HIPAA added section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act, which prohibit discrimination in health coverage based on a health factor. Interim final rules implementing the HIPAA provisions were published in the **Federal Register** on April 8, 1997 (62 FR 16894) (1997 interim rules). On December 29, 1997, the Department of Labor, the Department of Health and Human Services, and the Department of the Treasury (the Departments) published a clarification of the April 1997 interim rules as they relate to individuals who were denied coverage before the effective date of HIPAA on the basis of any health factor (62 FR 67689).

On January 8, 2001, the Departments published interim final regulations (2001 interim rules) on many issues under the HIPAA nondiscrimination provisions (66 FR 1378) and proposed regulations on wellness programs under those nondiscrimination provisions (66 FR 1421). These regulations being published today in the **Federal Register** finalize both the 2001 interim rules and the proposed rules.

II. Overview of the Regulations

Section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act (the

HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries. The 2001 interim rules --

- \$ Explained the application of these provisions to benefits;
- \$ Clarified the relationship between the HIPAA nondiscrimination provisions and the HIPAA preexisting condition exclusion limitations;
- \$ Explained the application of these provisions to premiums;
- \$ Described similarly situated individuals;
- \$ Explained the application of these provisions to actively-at-work and nonconfinement clauses; and
- \$ Clarified that more favorable treatment of individuals with medical needs generally is permitted.

In general, these final regulations do not change the 2001 interim rules or the proposed rules on wellness programs. However, these regulations do not republish the expired transitional rules regarding individuals who were denied coverage based on a health factor prior to the applicability date of the 2001 interim rules. (These regulations do republish, and slightly modify, the special transitional rule for self-funded nonfederal governmental plans that had denied any individual coverage due to the plan's election to opt out of the nondiscrimination requirements under 45 CFR 146.180, in cases where the plan sponsor subsequently chooses to bring the plan into compliance with those requirements). These regulations clarify how the source-of-injury rules apply to the timing of a diagnosis of a medical condition and add an example to illustrate how the benefits rules apply to the carryover feature of health

reimbursement arrangements (HRAs). For wellness programs, the final regulations clarify some ambiguities in the proposed rules, make some changes in terminology and organization, and add a description of wellness programs not required to satisfy additional standards.

Application to Benefits

Under the 2001 interim rules and these regulations, a plan or issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals. However, benefits provided must be uniformly available to all similarly situated individuals. Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances).

With respect to these benefit rules, the Departments received many inquiries about HRAs and one comment about nondiscrimination requirements under other laws. Under HRAs, employees are reimbursed for medical expenses up to a maximum amount for a period, based on the employer's contribution to the plan. These plans may or may not be funded. Another common feature is that the plans typically allow amounts remaining available at the end of the period to be used to reimburse medical expenses in later periods. Because the maximum reimbursement available under a plan to an employee in any single period may vary based on the claims experience of the employee, concerns have arisen about the application of the HIPAA nondiscrimination rules to these plans.

To address these concerns, these final regulations include an example under which the carryforward of unused employer-provided medical care reimbursement amounts to later years does not violate the HIPAA nondiscrimination requirements, even though the maximum reimbursement

amount for a year varies among employees within the same group of similarly situated individuals based on prior claims experience. In the example, an employer sponsors a group health plan under which medical care expenses are reimbursed up to an annual maximum amount. The maximum reimbursement amount with respect to an employee for a year is a uniform amount multiplied by the number of years the employee has participated in the plan, reduced by the total reimbursements for prior years. Because employees who have participated in the plan for the same length of time are eligible for the same total benefit over that length of time, the example concludes that the arrangement does not violate the HIPAA nondiscrimination requirements.

The Equal Employment Opportunity Commission (EEOC) asked the Departments to clarify that certain plan practices or provisions permitted under the benefits paragraphs of the 2001 interim rules may violate the Americans with Disabilities Act of 1990 (ADA) or Title VII of the Civil Rights Act of 1964 (Title VII). Specifically, the 2001 interim rules allow plans to exclude or limit benefits for certain types of conditions or treatments. The EEOC commented that, if such a benefit limit were applied to AIDS, it would be a disability-based distinction that violates the ADA (unless it is permitted under section 501(c) of the ADA). In addition, the EEOC commented that an exclusion from coverage of prescription contraceptives, but not of other preventive treatments, would violate Title VII because prescription contraceptives are used exclusively by women.

Paragraph (h) of the 2001 interim rules and these final regulations is entitled “No effect on other laws.” This section clarifies that compliance with the nondiscrimination rules is not determinative of compliance with any other provision of ERISA, or any other State or Federal law, including the ADA. Moreover, in paragraph (b) of the 2001 interim rules and these final regulations, the general rule

governing the application of the nondiscrimination rules to benefits clarifies that whether any plan provision or practice with respect to benefits complies with these rules does not affect whether the provision or practice is permitted under any other provision of the Code, ERISA, or the PHS Act, the Americans with Disabilities Act, or any other law, whether State or Federal.

Many other laws may regulate plans and issuers in their provision of benefits to participants and beneficiaries. These laws include the ADA, Title VII, the Family and Medical Leave Act, ERISA's fiduciary provisions, and State law. The Departments have not attempted to summarize the requirements of those laws in the HIPAA nondiscrimination rules. Instead, these rules clarify the application of the HIPAA nondiscrimination rules to group health plans, which may permit certain practices that other laws prohibit. Nonetheless, to avoid misleading plans and issuers as to the permissibility of any plan provision under other laws, the Departments included, in both paragraph (h) and paragraph (b) of the regulations, references to the potential applicability of other laws. Employers, plans, issuers, and other service providers should consider the applicability of these laws to their coverage and contact legal counsel or other government agencies such as the EEOC and State insurance departments if they have questions under those laws.

Source-of-Injury Exclusions

Some plans and issuers, while generally providing coverage for the treatment of an injury, deny benefits if the injury arose from a specified cause or activity. These kinds of exclusions are known as source-of-injury exclusions. Under the 2001 interim rules, if a plan or issuer provides benefits for a particular injury, it may not deny benefits otherwise provided for treatment of the injury due to the fact that the injury results from a medical condition or an act of domestic violence. Two examples in the

2001 interim rules illustrate the application of this rule, to injuries resulting from an attempted suicide due to depression and to injuries resulting from bungee jumping.

These final regulations retain the provisions in the 2001 interim rules and add a clarification. Some people have inquired if a suicide exclusion can apply if an individual had not been diagnosed with a medical condition such as depression before the suicide attempt. These final regulations clarify that benefits may not be denied for injuries resulting from a medical condition even if the medical condition was not diagnosed before the injury.

Some comments expressed concern that the discussion of the source-of-injury rule in the 2001 interim rules might be used to support the use of vague language to identify plan benefit exclusions, especially to identify source-of-injury exclusions. Requirements for plan benefit descriptions are generally outside of the scope of these regulations. Nonetheless, Department of Labor regulations at 29 CFR 2520.102-2(b) provide, “The format of the summary plan description must not have the effect of misleading, misinforming or failing to inform participants and beneficiaries. Any description of exception, limitations, reductions, and other restrictions of plan benefits shall not be minimized, rendered obscure or otherwise made to appear unimportant ... The advantages and disadvantages of the plan shall be presented without either exaggerating the benefits or minimizing the limitations.” State laws governing group insurance or nonfederal governmental plans may provide additional protections.

The Departments received thousands of comments protesting that the source-of-injury provisions in the 2001 interim rules would generally permit plans or issuers to exclude benefits for the treatment of injuries sustained in the activities listed in the conference report to HIPAA (motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities). Many

comments requested that the source-of-injury rule be amended to provide that a source-of-injury exclusion could not apply if the injury resulted from (in addition to an act of domestic violence or a medical condition) participation in legal recreational activities such as those listed in the conference report. Some comments expressed the concern that the rule in the 2001 interim rules would cause plans and issuers to begin excluding benefits for treatment of injuries sustained in these kinds of activities.

One comment generally supported the position in the 2001 interim rules. That comment expressed the belief that Congress intended with this issue, as with many other issues, to continue its longstanding deference to the States on the regulation of benefit design under health insurance. The comment also noted that the source-of-injury rule in the 2001 interim rules would not change the practice of plans or issuers with regard to the activities listed in the conference report and that the practice of plans and issuers in this regard would continue to be governed, as they had been before HIPAA, by market conditions and the States.

The Departments have not added the list of activities from the conference report to the source-of-injury rule in the final regulations. The statute itself is unclear about how benefits in general are affected by the nondiscrimination requirements and is silent with respect to source-of-injury exclusions in particular. The legislative history provides that the inclusion of evidence of insurability in the list of health factors is intended to ensure, among other things, that individuals are not excluded from health care coverage due to their participation in the activities listed in the conference report. This language is unclear because the term “health care coverage” could mean only eligibility to enroll for coverage under the plan, so that people who participate in the activities listed in the conference report could not be kept out of the plan but could be denied benefits for injuries sustained in those activities. Alternatively, it

could mean eligibility both to enroll for coverage and for benefits, so that people who participate in those activities could not be kept out of the plan or denied benefits for injuries sustained in those activities. Without any indication in the statute and without a clear indication in the legislative history about this issue, and in light of the overall scheme of the statute, the Departments have made no changes to the regulations.

Moreover, to the extent not prohibited by State law, plans and issuers have been free to impose source-of-injury exclusions since before HIPAA. There is no reason to believe that plans and issuers will begin to impose source-of-injury exclusions with respect to the conference report activities merely because such exclusions are not prohibited under the 2001 interim rules and these final regulations.

Relationship of Prohibition on Nonconfinement Clauses to State Extension-of-Benefits Laws

Questions have arisen about the relationship of the prohibition on nonconfinement clauses in the 2001 interim rules to State extension-of-benefits laws. Plan provisions that deny an individual benefits based on the individual's confinement to a hospital or other health care institution at the time coverage would otherwise become effective are often called nonconfinement clauses. The 2001 interim rules prohibit such nonconfinement clauses. At the same time, many States require issuers to provide benefits beyond the date on which coverage under the policy would otherwise have ended to individuals who continue to be hospitalized beyond that date. Example 2 in the 2001 interim rules illustrated that a current issuer cannot impose a nonconfinement clause that restricts benefits for an individual based on whether that individual is entitled to continued benefits from a prior issuer pursuant to a State law requirement. The final sentence in Example 2 provided that HIPAA does not affect the prior issuer's

obligation under State law and does not affect any State law governing coordination of benefits.

Under the laws of some States, a prior issuer has the obligation to provide health benefits to an individual confined to a hospital beyond the nominal end of the policy only if the hospitalization is not covered by a succeeding issuer. Because HIPAA requires a succeeding issuer to provide benefits that it would otherwise provide if not for the nonconfinement clause, in such a case State law would not require the prior issuer to provide benefits for a confinement beyond the nominal end of the policy. In this context, the statement in the final sentence of Example 2 -- that HIPAA does not affect the prior issuer's obligation under State law -- could be read to conflict with the text of the rule and the main point of Example 2 that the succeeding issuer must cover the confinement.

There has been some dispute about how this potential ambiguity should be resolved. One interpretation is that the succeeding issuer can never impose a nonconfinement clause, and if this has the effect under State law of not requiring the prior issuer to provide benefits beyond the nominal end of the policy, then the prior issuer is not obligated to provide the extended benefits. This interpretation is consistent with the text of the nonconfinement rule and the main point of Example 2, though it could be read to conflict with the last sentence in Example 2.

Another interpretation proposed by some is that, consistent with the last sentence of Example 2, the obligation of a prior issuer is never affected by the HIPAA prohibition against nonconfinement clauses. Under this interpretation, if a State law conditions a prior issuer's obligation on there being no succeeding issuer with the obligation, then in order to leave the prior issuer's obligation unaffected under State law, the succeeding issuer could apply a nonconfinement clause and the HIPAA prohibition would not apply. This interpretation elevates a minor clarification at the end of an example to supersede not

only the main point of the example but also the express text of the rule the example illustrates. This proposed interpretation is clearly contrary to the intent of the 2001 interim rules.

To avoid other interpretations, these final rules have replaced the final sentence of Example 2 in the 2001 interim rules with three sentences. The new language clarifies that: State law cannot change the succeeding issuer's obligation under HIPAA; a prior issuer may also have an obligation; and in a case in which a succeeding issuer has an obligation under HIPAA and a prior issuer has an obligation under State law to provide benefits for a confinement, any State laws designed to prevent more than 100 percent reimbursement, such as State coordination-of-benefits laws, continue to apply. Thus, under HIPAA a succeeding issuer cannot deny benefits to an individual on the basis of a nonconfinement clause. If this requirement under HIPAA has the effect under State law of removing a prior issuer's obligation to provide benefits, then the prior issuer is not obligated to provide benefits for the confinement. If under State law this requirement under HIPAA has the effect of obligating both the prior issuer and the succeeding issuer to provide benefits, then any State coordination-of-benefits law that is used to determine the order of payment and to prevent more than 100 percent reimbursement continues to apply.

Actively-at-Work Rules and Employer Leave Policies

The final regulations make no changes to the 2001 interim rules relating to actively-at-work provisions. Actively-at-work clauses are generally prohibited, unless individuals who are absent from work due to any health factor are treated, for purposes of health coverage, as if they are actively at work. Nonetheless, a plan or issuer may distinguish between groups of similarly situated individuals (provided the distinction is not directed at individual participants or beneficiaries based on a health

factor). Examples in the regulations illustrate that a plan or issuer may condition coverage on an individual's meeting the plan's requirement of working full-time (such as a minimum of 250 hours in a three-month period or 30 hours per week).

Several members of the regulated community have asked the Departments to clarify the applicability of the actively-at-work rules to various plan provisions that require an individual to perform a minimum amount of service per week in order to be eligible for coverage. It is the Departments' experience that much of the complexity in applying these rules derives from the myriad variations in the operation of employers' leave policies. The Departments believe that the 2001 interim rules provide adequate principles for applying the actively-at-work provisions to different types of eligibility provisions. In order to comply with these rules, a plan or issuer should apply the plan's service requirements consistently to all similarly situated employees eligible for coverage under the plan without regard to whether an employee is seeking eligibility to enroll in the plan or continued eligibility to remain in the plan. Accordingly, if a plan imposes a 30-hour-per-week requirement and treats employees on paid leave (including sick leave and vacation leave) who are already in the plan as if they are actively-at-work, the plan generally is required to credit time on paid leave towards satisfying the 30-hour-per-week requirement for employees seeking enrollment in the plan. Similarly, if a plan allowed employees to continue eligibility under the plan while on paid leave and for an additional period of 30 days while on unpaid leave, the plan is generally required to credit these same periods for employees seeking enrollment in the plan.¹ To help ensure consistency in application, plans and issuers may wish to clarify,

¹ These nondiscrimination rules do not address the applicability of the Family and Medical Leave Act to employers or group health coverage.

in writing, how employees on various types of leave are treated for purposes of interpreting a service requirement. Without clear plan rules, plans and issuers might slip into inconsistent applications of their rules, which could lead to violations of the actively-at-work provisions.

Wellness Programs

The HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. The 1997 interim rules refer to these programs as “bona fide wellness programs.” In the preamble to the 1997 interim rules, the Departments invited comments on whether additional guidance was needed concerning, among other things, the permissible standards for determining bona fide wellness programs. The Departments also stated their intent to issue further regulations on the nondiscrimination requirements and that in no event would the Departments take any enforcement action against a plan or issuer that had sought to comply in good faith with section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act before the publication of additional guidance. The preambles to the 2001 interim final and proposed rules noted that the period for nonenforcement in cases of good faith compliance with the HIPAA nondiscrimination provisions generally ended on the applicability date of those regulations but continued with respect to wellness programs until the issuance of further guidance. Accordingly, the nonenforcement policy of the Departments ends upon the applicability date of these final regulations for cases in which a plan or issuer fails to comply with the regulations but complies in good faith with an otherwise reasonable interpretation of the statute.

The HIPAA nondiscrimination provisions generally prohibit a plan or issuer from charging

similarly situated individuals different premiums or contributions based on a health factor. These final regulations also generally prohibit a plan or issuer from requiring similarly situated individuals to satisfy differing deductible, copayment, or other cost-sharing requirements. However, the HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. Thus, there is an exception to the general rule prohibiting discrimination based on a health factor if the reward, such as a premium discount or waiver of a cost-sharing requirement, is based on participation in a program of health promotion or disease prevention.

Both the 1997 interim rules and the 2001 proposed regulations refer to programs of health promotion and disease prevention allowed under this exception as “bona fide wellness programs.” These regulations generally adopt the provisions in the 2001 proposed rules. However, as more fully explained below, the final regulations no longer use the term “bona fide” in connection with wellness programs, add a description of wellness programs that do not have to satisfy additional requirements in order to comply with the nondiscrimination requirements, reorganize the four requirements from the proposed rules into five requirements, provide that the reward for a wellness program -- coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor -- must not exceed 20% of the total cost of coverage under the plan, and add examples and make other changes to more accurately describe how the requirements apply.

The term “wellness program”. Comments suggested that the use of the term “bona fide” with respect to wellness programs was confusing because, under the proposed rules, some wellness

programs that are not “bona fide” within the narrow meaning of that term in the proposed rules nonetheless satisfy the HIPAA nondiscrimination requirements. To address this concern, these final regulations do not use the term “bona fide wellness program.” Instead the final regulations treat all programs of health promotion or disease prevention as wellness programs and specify which of those wellness programs must satisfy additional standards to comply with the nondiscrimination requirements.

Programs not subject to additional standards. The preamble to the 2001 proposed rules described a number of wellness programs that comply with the HIPAA nondiscrimination requirements without having to satisfy any additional standards. However, the text of the regulation did not make such a distinction. The Departments have received many comments and inquiries about whether programs like those described in the 2001 preamble would have to satisfy the additional standards in the proposed rules. As a result, a paragraph has been added to the final regulations defining and illustrating programs that comply with the nondiscrimination requirements without having to satisfy any additional standards (assuming participation in the program is made available to all similarly situated individuals). Such programs are those under which none of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor or under which no reward is offered. The final regulations include the following list to illustrate the wide range of programs that would not have to satisfy any additional standards to comply with the nondiscrimination requirements:

- \$ A program that reimburses all or part of the cost for memberships in a fitness center.
- \$ A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.
- \$ A program that encourages preventive care through the waiver of the copayment or

deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits.

\$ A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.

\$ A program that provides a reward to employees for attending a monthly health education seminar.

Only programs under which any of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor must meet the five additional requirements described in paragraph (f)(2) of these regulations in order to comply with the nondiscrimination requirements.

Limit on the reward. As under the proposed rules, the total reward that may be given to an individual under the plan for all wellness programs is limited. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. Under the proposed rule, the reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed a specified percentage of the cost of employee-only coverage under the plan. The cost of employee-only coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is receiving coverage.

Comments indicated that in some circumstances dependents are permitted to participate in the

wellness program in addition to the employee and that in those circumstances the reward should be higher to reflect dependent participation in the program. These final regulations provide that if, in addition to employees, any class of dependents (such as spouses or spouses and dependent children) may participate in the wellness program, the limit on the reward is based on the cost of the coverage category in which the employee and any dependents are enrolled.

The proposed regulations specified three alternative percentages: 10, 15, and 20. The final regulations provide that the amount of the reward may not exceed 20 percent of the cost of coverage. The proposed regulations solicited comments on the appropriate percentage. The percentage limit is designed to avoid a reward or penalty being so large as to have the effect of denying coverage or creating too heavy a financial penalty on individuals who do not satisfy an initial wellness program standard that is related to a health factor. Comments from one employer and two national insurance industry associations requested that the level of the percentage for rewards should provide plans and issuers maximum flexibility for designing wellness programs. Comments suggested that plans and issuers have a greater opportunity to encourage healthy behaviors through programs of health promotion and disease prevention if they are allowed flexibility in designing such programs. The 20 percent limit on the size of the reward in the final regulations allows plans and issuers to maintain flexibility in their ability to design wellness programs, while avoiding rewards or penalties so large as to deny coverage or create too heavy a financial penalty on individuals who do not satisfy an initial wellness program standard that is related to a health factor.

Reasonably-designed and at-least-once-per-year requirements. In the 2001 proposed rules, the second of four requirements was that the program must be reasonably designed to promote good

health or prevent disease. The regulations also provided that a program did not meet this standard unless it gave individuals eligible for the program the opportunity to qualify for the reward at least once per year.

One comment suggested a safe harbor under which a wellness program that allows individuals to qualify at least once a year for the reward under the program would satisfy the “reasonably designed” standard without regard to other attributes of the program. The Departments have not adopted this suggestion. The “reasonably designed” standard is a broad standard. A wide range of factors could affect the reasonableness of the design of a wellness program, not just the frequency with which a participant could qualify for the reward. For example, a program might not be reasonably designed to promote good health or prevent disease if it imposed, as a condition to obtaining the reward, an overly burdensome time commitment or a requirement to engage in illegal behavior. The once-per-year requirement was included in the proposed rules merely as a bright-line standard for determining the minimum frequency that is consistent with a reasonable design for promoting good health or preventing disease. Thus, this second requirement of the proposed rules has been divided into two requirements in the final rules (the second and the third requirements). This division was made to emphasize that a program that must satisfy the additional standards in order to comply with the nondiscrimination requirements must allow eligible individuals to qualify for the reward at least once per year and must also be otherwise reasonably designed to promote health or prevent disease.

Comments also expressed other concerns about the “reasonably designed” requirement. While acknowledging that this standard provides significant flexibility, these comments were concerned that this flexible approach might also require substantial resources in evaluating all the facts and

circumstances of a proposed program to determine whether it was reasonable in its design.

The “reasonably designed” requirement is intended to be an easy standard to satisfy. To make this clear, the final regulations have added language providing that if a program has a reasonable chance of improving the health of participants and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease, it satisfies this standard. There does not need to be a scientific record that the method promotes wellness to satisfy this standard. The standard is intended to allow experimentation in diverse ways of promoting wellness. For example, a plan or issuer could satisfy this standard by providing rewards to individuals who participated in a course of aromatherapy. The requirement of reasonableness in this standard prohibits bizarre, extreme, or illegal requirements in a wellness program.

One comment requested that the final regulations set forth one or more safe harbors that would demonstrate compliance with the “reasonably designed” standard. The examples in the proposed and final regulations present a range of wellness programs that are well within the borders of what is considered reasonably designed to promote health or prevent disease. The examples serve as safe harbors, so that a plan or issuer could adopt a program identical to one described as satisfying the wellness program requirements in the examples and be assured of satisfying the requirements in the regulations. Wellness programs similar to the examples also would satisfy the “reasonably designed” requirement. The Departments, though, do not want plans or issuers to feel constrained by the relatively narrow range of programs described by the examples but want plans and issuers to feel free to consider innovative programs for motivating individuals to make efforts to improve their health.

Reasonable alternative standard. Under the 2001 proposed rules and these final regulations, a wellness program that provides a reward requiring satisfaction of a standard related to a health factor must provide a reasonable alternative standard for obtaining the reward for certain individuals. This alternative standard must be available for individuals for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, or for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard. A program does not need to establish the specific reasonable alternative standard before the program commences. It is sufficient to determine a reasonable alternative standard once a participant informs the plan that it is unreasonably difficult for the participant due to a medical condition to satisfy the general standard (or that it is medically inadvisable for the participant to attempt to achieve the general standard) under the program.

Some comments suggested that the requirement to devise and offer such a reasonable alternative standard potentially creates a significant burden on plans and issuers. Comments also suggested that the Departments should define a “safe harbor” for what constitutes a reasonable alternative standard, and that plans and issuers should be permitted to establish a single alternative standard, rather than having to tailor a standard for each individual for whom a reasonable alternative standard must be offered.

The Departments understand that, in devising wellness programs, plans and issuers strive to improve the health of participating individuals in a way that is not administratively burdensome or expensive. Under the proposed and final rules, it is permissible for a plan or issuer to devise a reasonable alternative standard by lowering the threshold of the existing health-factor-related standard,

substituting a different standard, or waiving the standard. (For the alternative standard to be reasonable, the individual must be able to satisfy it without regard to any health factor.) To address the concern regarding the potential burden of this requirement, the final regulations explicitly provide that a plan or issuer can waive the health-factor-related standard for all individuals for whom a reasonable alternative standard must be offered. Additionally, the final regulations include an example demonstrating that a reasonable alternative standard could include following the recommendations of an individual's physician regarding the health factor at issue. Thus, a plan or issuer need not assume the burden of designing a discrete alternative standard for each individual for whom an alternative standard must be offered. An example also illustrates that if an alternative standard is health-factor-related (i.e., walking three days a week for 20 minutes a day), the wellness program must provide an additional alternative standard (i.e., following the individual's physician's recommendations regarding the health factor at issue) to the appropriate individuals.

The 2001 proposed rules included an example illustrating a smoking cessation program. Comments expressed concern that, under the proposed regulations, individuals addicted to nicotine who comply with a reasonable alternative standard year after year would always be entitled to the reward even if they did not quit using tobacco. Comments questioned whether this result is consistent with the goal of promoting wellness. The final regulations retain the example from the proposed rules. Comments noted that overcoming an addiction sometimes requires a cycle of failure and renewed effort. For those individuals for whom it remains unreasonably difficult due to an addiction, a reasonable alternative standard must continue to be offered. Plans and issuers can accommodate this health factor by continuing to offer the same or a new reasonable alternative standard. For example, a plan or issuer

using a smoking cessation class might use different classes from year to year or might change from using a class to providing nicotine replacement therapy. These final regulations provide an additional example of a reasonable alternative standard of viewing, over a period of 12 months, a 12-hour video series on health problems associated with tobacco use.

Concern has been expressed that individuals might claim that it would be unreasonably difficult or medically inadvisable to meet the wellness program standard, when in fact the individual could meet the standard. The final rules clarify that plans may seek verification, such as a statement from a physician, that a health factor makes it unreasonably difficult or medically inadvisable for an individual to meet a standard.

Disclosure requirements. The fifth requirement for a wellness program that provides a reward requiring satisfaction of a standard related to a health factor is that all plan materials describing the terms of the program must disclose the availability of a reasonable alternative standard. This requirement is unchanged from the proposed rules. The 2001 proposed rules and these final regulations include the same model language that can be used to satisfy this requirement; examples also illustrate substantially similar language that would satisfy the requirement.

The final regulations retain the two clarifications of this requirement. First, plan materials are not required to describe specific reasonable alternative standards. It is sufficient to disclose that some reasonable alternative standard will be made available. Second, any plan materials that describe the general standard would also have to disclose the availability of a reasonable alternative standard. However, if the program is merely mentioned (and does not describe the general standard), disclosure of the availability of a reasonable alternative standard is not required.

Special Rule for Self-Funded Nonfederal Governmental Plans Exempted Under 45 CFR 146.180

The sponsor of a self-funded nonfederal governmental plan may elect under section 2721(b)(2) of the PHS Act and 45 CFR 146.180 to exempt its group health plan from the nondiscrimination requirements of section 2702 of the PHS Act and 45 CFR 146.121. Under the interim final nondiscrimination rules, if the plan sponsor subsequently chooses to bring the plan into compliance with the nondiscrimination requirements, the plan must provide notice to that effect to individuals who were denied enrollment based on one or more health factors, and afford those individuals an opportunity, that continues for at least 30 days, to enroll in the plan. (An individual is considered to have been denied coverage if he or she failed to apply for coverage because, given an exemption election under 45 CFR 146.180, it was reasonable to believe that an application for coverage would have been denied based on a health factor). The notice must specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan comes into compliance. The plan may not treat the individual as a late enrollee or a special enrollee. These final regulations retain this transitional rule, and state that the plan must permit coverage to be effective as of the first day of plan coverage for which an exemption election under 45 CFR 146.180 (with regard to the nondiscrimination requirements) is no longer in effect. (These final regulations delete the reference giving the plan the option of having the coverage start July 1, 2001, because that option implicated the expired transitional rules regarding individuals who were denied coverage based on a health factor prior to the applicability of the 2001 interim rules. As previously stated, those transitional rules have not been republished in these final regulations.) Additionally, the examples illustrating how the special rule for nonfederal governmental plans operates have been revised slightly.

Applicability Date

These regulations apply for plan years beginning on or after July 1, 2007. Until the applicability date for this regulation, plans and issuers are required to comply with the corresponding sections of the regulations previously published in the **Federal Register** (66 FR 1378) and other applicable regulations.

III. Economic Impact and Paperwork Burden

Summary - Department of Labor and Department of Health and Human Services

HIPAA's nondiscrimination provisions generally prohibit group health plans and group health insurance issuers from discriminating against individuals in eligibility or premiums on the basis of health factors. The Departments have crafted these regulations to secure the protections from discrimination as intended by Congress in as economically efficient a manner as possible, and believe that the economic benefits of the regulations justify their costs.

The primary economic benefits associated with securing HIPAA's nondiscrimination provisions derive from increased access to affordable group health plan coverage for individuals with health problems. Increased access benefits both newly-covered individuals and society at large. It fosters expanded health coverage, timelier and more complete medical care, better health outcomes, and improved productivity and quality of life. This is especially true for the individuals most affected by HIPAA's nondiscrimination provisions - those with adverse health conditions. Denied health coverage, individuals in poorer health are more likely to suffer economic hardship, to forego badly needed care for financial reasons, and to suffer adverse health outcomes as a result. For them, gaining health coverage is more likely to mean gaining economic security, receiving timely, quality care, and living healthier, more

productive lives. Similarly, participation by these individuals in wellness programs fosters better health outcomes, increases productivity and quality of life, and has the same outcome in terms of overall gains in economic security. The wellness provisions of these regulations will result in fewer instances in which wellness programs shift costs to high-risk individuals, and more instances in which these individuals succeed at improving health habits and health.

Additional economic benefits derive directly from the improved clarity provided by the regulations. The regulations will reduce uncertainty and costly disputes and promote confidence in health benefits' value, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans and their wellness program provisions.

The Departments estimate that the dollar value of the expanded coverage attributable to HIPAA's nondiscrimination provisions is approximately \$850 million annually. The Departments believe that the cost of HIPAA's nondiscrimination provisions is borne by covered workers. Costs can be shifted to workers through increases in employee premium shares or reductions (or smaller increases) in pay or other components of compensation, by increases in deductibles or other cost sharing, or by reducing the richness of health benefits. Whereas the benefits of the nondiscrimination provisions are concentrated in a relatively small population, the costs are distributed broadly across plans and enrollees.

The proposed rules on wellness programs impose certain requirements on wellness programs providing rewards that would otherwise discriminate based on a health factor in order to ensure that the exception for wellness programs does not eviscerate the general rule contained in HIPAA's nondiscrimination provisions. Costs associated with the wellness program provisions are justified by the

benefits received by those individuals now able, through alternative standards, to participate in such programs. Because the new provisions limit rewards for wellness programs that require an individual to satisfy a standard related to a health factor to 20 percent of the cost of single coverage (with additional provisions related to rewards that apply also to classes of dependents), some rewards will be reduced and this reduction might compel some individuals to decline coverage. The number of individuals affected, however, is thought to be small. Moreover, the Departments estimate that the cost of the reduction in rewards that would exceed the limit will amount to only \$6 million. Establishing reasonable alternative standards, which should increase coverage for those now eligible for discounts as well as their participation in programs designed to promote health or prevent disease, is expected to cost between \$2 million to \$9 million. The total costs should therefore fall within a range between \$8 million and \$15 million annually.

New economic costs may be also incurred in connection with the wellness provisions if reductions in rewards result in the reduction of wellness programs' effectiveness, but this effect is expected to be very small. Other new economic costs may be incurred by plan sponsors to make available reasonable alternative standards where required. The Departments are unable to estimate these costs due to the variety of options available to plan sponsors for bringing wellness programs into compliance with these rules.

Executive Order 12866 - Department of Labor and Department of Health and Human Services

Under Executive Order 12866, the Departments must determine whether a regulatory action is “significant” and therefore subject to the requirements of the Executive Order and subject to review by

the Office of Management and Budget (OMB). Under section 3(f), the order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of the Executive Order, this action is “economically significant” and subject to OMB review under Section 3(f) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this regulatory action. The Departments performed a comprehensive, unified analysis to estimate the costs and benefits attributable to the final regulations for purposes of compliance with the Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The Departments’ analyses and underlying assumptions are detailed below. The Departments believe that the benefits of the final regulations justify their costs.

Regulatory Flexibility Act – Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the

Administrative Procedure Act (5 U.S.C. 551 et seq.) and likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a final rule will not have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires that the agency present a final regulatory flexibility analysis (FRFA) at the time of the publication of the notice of final rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations, and governmental jurisdictions.

Because the 2001 interim rules were issued as final rules and not as a notice of proposed rulemaking, the RFA did not apply and the Departments were not required to either certify that the rule would not have a significant impact on a substantial number of small entities or conduct a regulatory flexibility analysis. The Departments nonetheless crafted those regulations in careful consideration of effects on small entities, and conducted an analysis of the likely impact of the rules on small entities. This analysis was detailed in the preamble to the interim final rule.

The Departments also conducted an initial regulatory flexibility analysis in connection with the proposed regulations on wellness programs and present here a FRFA with respect to the final regulations on wellness programs pursuant to section 604 of the RFA. For purposes of their unified FRFA, the Departments adhered to EBSA's proposed definition of small entities. The Departments consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants. The Departments believe that assessing the impact of this final rule on small plans is an appropriate substitute for evaluating the effect on small entities as that term is defined in the RFA. This definition of small entity differs,

however, from the definition of small business based on standards promulgated by the Small Business Administration (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 et seq.).

Because of this difference, the Departments requested comments on the appropriateness of this size standard for evaluating the impact of the proposed regulations on small entities. No comments were received.

The Departments estimate that 35,000 plans with fewer than 100 participants vary employee premium contributions or cost-sharing across similarly situated individuals based on health factors.² While this represents just one percent of all small plans, the Departments believe that because of the large number of plans, this may constitute a substantial number of small entities. The Departments also note that at least some premium rewards may be large. Premium discounts associated with wellness programs are believed to range as high as \$920 per affected participant per year. Therefore, the Departments believe that the impact of this regulation on at least some small entities may be significant.

Under these final regulations on wellness programs, such programs are not subject to additional requirements if none of the conditions for obtaining a reward is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward).

² Based on tabulations of the 2003 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and 1997 Survey of Government Finances (SGF), the Departments estimate that roughly 2.4 million small health plans exist. Of these, 1.2 percent of these plans are believed to vary premiums (as suggested in a 1993 study by the Robert Wood Johnson Foundation) while .5 percent are thought to vary benefits (as suggested in, *Spec Summary. United States Salaried Managed Health/Health Promotion Initiatives, 2003-2004*, Hewitt Associates, July, 2003.). Assuming that half of those that vary premiums also vary benefits, the Departments conclude that 1.5 percent of all small plans are potentially affected by the statute.

Where a condition for obtaining a reward is based on an individual satisfying a standard related to a health factor, the wellness program will not violate the nondiscrimination provisions if additional requirements are met. The first requirement limits the maximum allowable reward or total of rewards to a maximum of 20 percent of the cost of employee-only coverage under the plan (with additional provisions related to rewards that apply also to classes of dependents). The magnitude of the limit is intended to offer plans maximum flexibility while avoiding the effect of denying coverage or creating an excessive financial penalty for individuals who cannot satisfy the initial standard based on a health factor.

The Departments estimate that 4,000 small plans and 22,000 small plan participants will be affected by this limit.³ These plans can comply with this requirement by reducing the discount to the regulated maximum. This will result in an increase in premiums (or decrease in cost-sharing) by about \$1.3 million on aggregate for those participants receiving qualified premium discounts⁴ This constitutes an ongoing, annual cost of \$338 on average per affected plan. The regulation does not limit small plans' flexibility to shift this cost to all participants in the form of small premium increases or benefit cuts.

The second requirement provides that wellness programs must be reasonably designed to promote health or prevent disease. Comments received by the Departments and available literature on

³ Simulations run by the Departments suggest that 10.7 percent of all plans exceed the capped premium discount. For the purposes of this analysis, it was assumed that the affected plans were proportionally distributed between large and small plans. However, it is likely that larger plans would have more generous welfare programs and therefore, this estimate is likely an upper bound.

⁴ Estimate is based on the 2003-04 Hewitt Study and various measures of the general health of the labor force suggest that roughly 30 percent of health plan participants will not qualify for the discount. While plans exceeding the capped discount could meet the statutes requirements by transferring the excess amount, on average \$57, to the non-qualifying participants, given current trends in the health insurance industry, it is considered more likely that plans would instead lower the amount of the discount given to the 70 percent of participants that qualify. This

employee wellness programs suggest that existing wellness programs generally satisfy this requirement. The requirement therefore is not expected to compel small plans to modify existing wellness programs.

The third requirement is that the program give individuals eligible for the program the opportunity to qualify for the reward at least once per year. This provision was included within the terms of the requirements for reasonable design in the proposed regulations. The Departments did not anticipate that a cost would arise from the requirements related to reasonable design when taken together, but requested comments on their assumptions. Because no comments were received, the Departments have not attributed a cost to this provision of the final rule.

The fourth requirement provides that rewards under wellness programs must be available to all similarly situated individuals. Rewards are not available to similarly situated individuals unless a program allows a reasonable alternative standard or waiver of the applicable standard, if it is unreasonably difficult due to a medical condition or medically inadvisable to attempt to satisfy the otherwise applicable standard. The Departments believe that some small plans' wellness programs do not currently satisfy this requirement and will have to be modified.

transfer would roughly total \$1.3 million dollars.

The Departments estimate that 3,000 small plans' wellness programs include initial standards that may be unreasonably difficult due to a medical condition or medically inadvisable for some participants to meet.⁵ These plans are estimated to include 4,000 participants for whom the standard is in fact unreasonably difficult due to a medical condition or medically inadvisable to meet.⁶ Satisfaction of alternative standards by these participants will result in cost increases for plans as these individuals qualify for discounts or avoid surcharges. If all of these participants request and then satisfy an alternative standard, the cost would amount to about \$2 million annually. If one-half request alternative standards and one-half of those meet them, the cost would be \$0.5 million.⁷

In addition to the costs associated with new participants qualifying for discounts through alternative standards, small plans may also incur new economic costs by simply providing alternative standards. However, plans can satisfy this requirement by providing inexpensive alternative standards and have the flexibility to select whatever reasonable alternative standard is most desirable or cost effective. Plans not wishing to provide alternative standards also have the option of eliminating health status-based variation in employee premiums or waiving standards for individuals for whom the program standard is unreasonably difficult due to a medical condition or medically inadvisable to meet. The Departments expect that the economic cost to provide alternatives combined with the associated cost of

⁵ The 2003-04 Hewitt Survey finds that 9 percent of its respondents require participants to achieve a certain health standard to be eligible for discounts. Based on assumptions about the general health of the labor force, approximately 2.3 percent of health plan participants may and 1.5 percent will find these standards difficult to achieve.

⁶ Many small plans are very small, having fewer than 10 participants. Hence, many small plans will include no participant for whom either of these standards apply.

⁷ Simulations run by the Departments find that the average premium discount for all health plans after the cap is enforced will be approximately \$450 dollars. This average is then applied to the upper and lower bounds of those able to pass the alternative standards in small health plans in order to determine the upper and lower bound of the

granting discounts or waiving surcharges will not exceed the cost associated with granting discounts or waiving surcharges for all participants who qualify for an alternative. Those costs are estimated here at \$0.5 million to \$2 million, or about \$160 to \$650 per affected plan. Plans have the flexibility to pass back some or all of this cost to all participants in the form of small premium increases or benefit cuts.

The fifth requirement provides that plan materials describing wellness program standards disclose the availability of reasonable alternative standards. This requirement will affect the approximately 4,000 small plans that condition rewards on satisfaction of a standard. These plans will incur economic costs to revise affected plan materials. The estimated 1,000 to 4,000 small plan participants who will succeed at satisfying these alternative standards will benefit from these disclosures. The disclosures need not specify what alternatives are available unless the plan describes the initial standard in writing and the regulation provides sample language that can be used to satisfy this requirement. Legal requirements other than this regulation generally require plans and issuers to maintain accurate materials describing plans. Plans and issuers generally update such materials on a regular basis as part of their normal business practices. This requirement is expected to represent a negligible fraction of the ongoing, normal cost of updating plans' materials. This analysis therefore attributes no cost to this requirement.

Paperwork Reduction Act - Department of Labor and Department of the Treasury

The 2001 interim rules included an information collection request (ICR) related to the notice of the opportunity to enroll in a plan where coverage had been denied based on a health factor before the effective date of HIPAA. That ICR was approved under OMB control numbers 1210-0120 and

transfer cost.

1545-1728, and was subsequently withdrawn from OMB inventory because the notice, if applicable, was to have been provided only once.

The proposed regulations on wellness programs did not include an information collection request. Like the proposed regulations, the final regulations include a requirement that, if a plan's wellness program requires individuals to meet a standard related to a health factor in order to qualify for a reward and if the plan materials describe this standard, the materials must also disclose the availability of a reasonable alternative standard. If plan materials merely mention that a program is available, the disclosure relating to alternatives is not required. The regulations include samples of disclosures that could be used to satisfy the requirements of the final regulations.

In concluding that the proposed rules did not include an information collection request, the Departments reasoned that much of the information required was likely already provided as a result of state and local mandates or the usual business practices of group health plans and group health insurance issuers in connection with the offer and promotion of health care coverage. In addition, the sample disclosures would enable group health plans to make any modifications necessary with minimal effort.

Finally, although neither the proposed or final regulations include a new information collection request, the regulations might have been interpreted to require a revision to an existing collection of information. Administrators of group health plans covered under Title I of ERISA are generally required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description (SPD) or Summary of Material Modifications (SMM) pursuant to sections 101(a) and 102(a) of ERISA and related regulations. The ICR related to the SPD and SMM is currently approved

under OMB control number 1210-0039. While these materials may in some cases require revisions to comply with the final regulations, the associated burden is expected to be negligible, and is in fact already accounted for in connection with the SPD and SMM ICR by a burden estimation methodology that anticipates ongoing revisions. Therefore, any change to the existing information collection request arising from these final regulations is not substantive or material. Accordingly, no application for approval of a revision to the existing ICR has been made to OMB in connection with these final regulations.

Paperwork Reduction Act - Department of Health and Human Services

Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated techniques.

Department regulations in 45 CFR 146.121(i)(4) require that if coverage has been denied to

any individual because the sponsor of a self-funded nonfederal governmental plan has elected under 45 CFR Part 146 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance, the plan must: notify the individual that the plan will be coming into compliance; afford the individual an opportunity to enroll that continues for at least 30 days, specify the effective date of compliance; and inform the individual regarding any enrollment restrictions that may apply once the plan is in compliance.

The burden associated with this requirement was approved by The Office of Management and Budget (OMB) under OMB control number 0938-0827, with a current expiration date of April 30, 2009.

In addition, CMS-2078-P, published in the Federal Register on January 8, 2001 (66 FR 1421) describes the bona fide wellness programs and specifies their criteria. Section 146.121(f)(1)(iv) further stipulates that the plan or issuer disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard to qualify for the reward under a wellness program. However, in plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required.

The burden associated with this requirement was approved by OMB control number 0938-0819, with a current expiration date of April 30, 2009.

Special Analyses -- Department of the Treasury

Notwithstanding the determinations of the Departments of Labor and of Health and Human Services, for purposes of the Department of the Treasury it has been determined that this Treasury decision is not a significant regulatory action. Therefore, a regulatory assessment is not required. It has

also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Congressional Review Act

These final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and have been transmitted to Congress and the Comptroller General for review. These regulations, however, constitute a “major rule,” as that term is defined in 5 U.S.C. 804, because they are likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), as well as Executive Order 12875, these final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor does it include mandates which may impose an annual burden of \$100 million or more on the private sector.

Federalism Statement – Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments’ view, these final regulations have federalism implications, because they have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments’ view, the federalism implications of these final regulations are substantially mitigated because, with respect to health insurance issuers, the vast majority of States have enacted laws, which meet or exceed the federal HIPAA standards prohibiting discrimination based on health factors.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting State requirements for group health insurance coverage. With respect to the HIPAA nondiscrimination provisions, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the portability, access, and renewability requirements

of HIPAA, which include HIPAA's nondiscrimination requirements provisions that are the subject of this rulemaking.

In enacting these new preemption provisions, Congress intended to preempt State insurance requirements only to the extent that those requirements prevent the application of the basic protections set forth in HIPAA. HIPAA's Conference Report states that the conferees intended the narrowest preemption of State laws with regard to health insurance issuers. H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205 (1996). State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of" the HIPAA nondiscrimination provisions, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997. (62 FR 16904) and on December 30, 2004 (62 FR 78720). These final regulations clarify and implement the statute's minimum standards and do not significantly reduce the discretion given the States by the statute. Moreover, the Departments understand that the vast majority of States have requirements that meet or exceed the minimum requirements of the HIPAA nondiscrimination provisions.

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. To date, HHS has had occasion to enforce the HIPAA nondiscrimination provisions in only two States and currently enforces the nondiscrimination provisions in only one State in accordance with that State's specific request to do so. When exercising its responsibility to enforce

provisions of HIPAA, HHS works cooperatively with the State for the purpose of addressing the State's concerns and avoiding conflicts with the exercise of State authority.⁸ HHS has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HHS's procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HHS. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, DOL and HHS have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

For example, the Departments sought and received input from State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and the four U.S. territories. In most States the Insurance Commissioner is appointed by the Governor, in approximately 14 States the insurance commissioner is an elected official. Among other activities, it provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss, and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas, and in-depth consideration of insurance issues by regulators, industry

⁸ This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer).

representatives, and consumers. CMS and Department of Labor staff have attended the quarterly meetings consistently to listen to the concerns of the State Insurance Departments regarding HIPAA issues, including the nondiscrimination provisions. In addition to the general discussions, committee meetings and task groups, the NAIC sponsors the standing CMS/DOL meeting on HIPAA issues for members during the quarterly conferences. This meeting provides CMS and the Department of Labor with the opportunity to provide updates on regulations, bulletins, enforcement actions and outreach efforts regarding HIPAA.

In addition, the Departments specifically consulted with the NAIC in developing these final regulations. Through the NAIC, the Departments sought and received the input of State insurance departments regarding certain insurance rating practices and late enrollment issues. The Departments employed the States' insights on insurance rating practices in developing the provisions prohibiting "list-billing," and their experience with late enrollment in crafting the regulatory provision clarifying the relationship between the nondiscrimination provisions and late enrollment. Specifically, the regulations clarify that while late enrollment, if offered by a plan, must be available to all similarly situated individuals regardless of any health factor, an individual's status as a late enrollee is not itself within the scope of any health factor.

The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information on HIPAA is shared among federal regulators, State regulators, and the regulated community. In particular, the Department of Labor has established a Health Benefits Education Campaign with more than 70 partners, including CMS, the NAIC and many business and consumer groups. CMS has sponsored conferences with the States - the Consumer Outreach and

Advocacy conferences in March 1999 and June 2000 and the Implementation and Enforcement of HIPAA National State-federal Conferences in August 1999, 2000, 2001, 2002, and 2003.

Furthermore, both the Department of Labor and CMS Web sites offer links to important State Web sites and other resources, facilitating coordination between the State and federal regulators and the regulated community.

Throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress's intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached final regulation, Final Rules for Nondiscrimination in Health Coverage in the Group Market (RIN 1210-AA77 and RIN 0938-AI08), in a meaningful and timely manner.

Unified Analysis of Costs and Benefits

1. Introduction

HIPAA's nondiscrimination provisions generally prohibit group health plans and group health insurance issuers from discriminating against individuals on the basis of health factors. The primary effect and intent of the provision is to increase access to affordable group health coverage for individuals

with health problems. This effect, and the economic costs and benefits attendant to it, primarily flows from the statutory provisions of HIPAA that this regulation implements. However, the statute alone leaves room for varying interpretations of exactly which practices are prohibited or permitted at the margin. These regulations draw on the Departments' authority to clarify and interpret HIPAA's statutory nondiscrimination provisions in order to secure the protections intended by Congress for plan participants and beneficiaries. The Departments crafted them to satisfy this mandate in as economically efficient a manner as possible, and believe that the economic benefits of the regulations justify their costs. The analysis underlying this conclusion takes into account both the effect of the statute and the impact of the discretion exercised in the regulations.

The nondiscrimination provisions of the HIPAA statute and of these regulations generally apply to both group health plans and group health insurance issuers. Economic theory predicts that issuers will pass their costs of compliance back to plans, and that plans may pass some or all of issuers' and their own costs of compliance to participants. This analysis is carried out in light of this prediction.

These final regulations are needed to clarify and interpret the HIPAA nondiscrimination provisions under section 702 of ERISA, section 2702 of the PHS Act, and section 9802 of the Code, and to ensure that group health plans and group health insurance issuers do not discriminate against individual participants or beneficiaries based on any health factors with respect to health care coverage and premiums. The 2001 interim rules provided additional guidance to explain the application of the statute to benefits, to clarify the relationship between the HIPAA nondiscrimination provisions and the HIPAA preexisting condition exclusion limitations, to explain the applications of these provisions to premiums, to describe similarly situated individuals, to explain the application of the provisions to

actively-at-work and nonconfinement clauses, to clarify that more favorable treatment of individuals with medical needs generally is permitted, and to describe plans' and issuers' obligations with respect to plan amendments.⁹ These final regulations clarify the relationship between the source-of-injury rules and the timing of a diagnosis of a medical condition and add an example to illustrate how the benefits rules apply to the carryover feature of HRAs.

The proposed rules on wellness programs were issued in order to ensure that the exception for wellness programs would not contravene HIPAA's nondiscrimination provisions. With respect to wellness programs, these final regulations clarify some ambiguities in the proposed rules, make some changes in terminology and organization, and add a description of wellness programs not required to satisfy additional standards. The final rules also set the maximum reward for wellness programs that require satisfaction of a standard at 20 percent of the cost of single coverage (with additional provisions related to rewards that apply also to classes of dependents), where the proposed rules had stated the limit in terms of a range of percentages.

Because the 2001 interim rules and proposed regulations on wellness programs were originally issued as separate rulemaking actions, the Departments estimated their economic impacts separately.

The costs and benefits of the statutory nondiscrimination provisions and the 2001 interim rules are again

⁹ The Departments' estimate of the economic impact of the 2001 interim final regulations was published at 66 FR 1393 (January 8, 2001). These one-time costs were already absorbed by plans and issuers and are not discussed in this analysis. In fact, the only notice requirement in the 2001 interim final regulations was deleted from the final regulations because the time period for compliance has passed, with one small exception. Certain self-insured, nonfederal governmental plans that had opted out of the HIPAA nondiscrimination provisions under Section 2721 (b)(2) of the PHS Act and that have since decided to opt back in may be required to send a notice to individuals previously denied coverage due to a health factor. However, to date, only approximately 550 such plans have notified CMS that they are opting-out of the HIPAA nondiscrimination provisions and CMS does not receive information regarding a plan's decision to opt back in. The Departments estimate that the number of plans having done this is very small and, therefore, estimate that the impact of the notice provision on such plans is too small to

described separately from the wellness program provisions here, due to both differing baselines for the measurement of impact, and to reliance on different types of information and assumptions in the analyses.

2. Costs and Benefits of HIPAA's Nondiscrimination Provisions

The Departments have evaluated the impacts of HIPAA's nondiscrimination provisions. The nondiscrimination provisions of the 2001 interim final rules were estimated to result in costs of about \$20 million to amend plans, revise plan informational materials, and notify employees previously denied coverage on the basis of a health factor of enrollment opportunities. Because these costs were associated with one-time activities that were required to be completed by the applicability date of the 2001 interim rules, these costs have been fully defrayed.

calculate.

The primary statutory economic benefits associated with the HIPAA nondiscrimination provisions derive from increased access to affordable group health plan coverage for individuals whose health factors had previously restricted their participation in such plans. Expanding access entails both benefits and costs. Newly-covered individuals, who previously had to purchase similar services out-of-pocket, reap a simple and direct financial gain. In addition, these individuals may be induced to consume more (or different) health care services, reaping a benefit which has financial value, and which in some cases will produce additional indirect benefits both to the individual (improved health) and possibly to the economy at large.¹⁰

¹⁰ Individuals without health insurance are less likely to get preventive care and less likely to have a regular source of care. A lack of health insurance generally increases the likelihood that needed medical treatment will be forgone or delayed. Forgoing or delaying care increases the risk of adverse health outcomes. These adverse outcomes in turn generate higher medical costs, which are often shifted to public funding sources (and therefore to taxpayers) or to other payers. They also erode productivity and the quality of life. Improved access to affordable group health coverage for individuals with health problems under HIPAA's nondiscrimination provisions will lead to more insurance coverage, timelier and fuller medical care, better health outcomes, and improved productivity and quality of life. This is especially true for the individuals most affected by HIPAA's nondiscrimination provisions - those with adverse health conditions. Denied insurance, individuals in poorer health are more likely to suffer economic hardship, to forgo badly needed care for financial reasons, and to suffer adverse health outcomes as a result. For them, gaining insurance is more likely to mean gaining economic security, receiving timely, quality care, and living healthier, more productive lives. For an extensive discussion of the consequences of uninsurance, see: "The Uninsured and their Access to Health Care" (2004). *The Kaiser Commission on Medicaid and the Uninsured*, November; "Insuring America's Health", (2004). *Institute of Medicine*; "Health Policy and the Uninsured" (2004) edited by Catherine G. McLaughlin. Washington, DC: Urban Institute Press; Miller, Wilhelmine et al (2004)

“Covering the Uninsured: What is it Worth,” *Health Affairs*, March: w157-w167.

Inclusion of these newly-covered individuals, though, will increase both premiums and claims costs incurred by group health plans. Economic theory predicts that these costs will ultimately be shifted to all plan participants or employees, either through an increased share of insurance costs, or lowered compensation.¹¹ If the number of newly-covered individuals is small relative to the total number of plan participants and costs are distributed evenly, then the increased burden for each individual should be minimal. However, it is unclear how previously-covered individuals will respond to subsequent changes in their benefits package and if their response will have unforeseen economic costs.¹² The HIPAA nondiscrimination cost is estimated to be substantial. Annual group health plan costs average

¹¹ The voluntary nature of the employment-based health benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. It is likely that 80% to 100% of the cost of employee benefits is borne by workers through reduced wages (see for example Jonathan Gruber and Alan B. Krueger, "The Incidence of Mandated Employer-Provided Insurance: Lessons from Workers Compensation Insurance," *Tax Policy and Economy* (1991); Jonathan Gruber, "The Incidence of Mandated Maternity Benefits," *American Economic Review*, Vol. 84 (June 1994), pp. 622-641; Lawrence H. Summers, "Some Simple Economics of Mandated Benefits," *American Economic Review*, Vol. 79, No. 2 (May 1989); Louise Sheiner, "Health Care Costs, Wages, and Aging," Federal Reserve Board of Governors working paper, April 1999; and Edward Montgomery, Kathryn Shaw, and Mary Ellen Benedict, "Pensions and Wages: An Hedonic Price Theory Approach," *International Economic Review*, Vol. 33 No. 1, Feb. 1992.). The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits they will discount their value to adjust for this risk. This discount drives a wedge in the compensation negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. The extent to which workers perceive a federal regulation supported by enforcement authority to improve the security and quality of benefits, the differential between the employers costs and workers willingness to accept wage offsets is minimized.

¹² Research shows that while the share of employers offering insurance is generally stable and eligibility rates have only declined slightly over time, the overall increase in uninsured workers is due to the decline in worker take-up rates, which workers primarily attribute to cost. Research on elasticity of coverage, however, has focused on getting uninsured workers to adopt coverage (which appears to require large subsidies) rather than covered workers opting out of coverage. This makes it difficult to ascertain the loss in coverage that would result from a marginal increase in costs. (See, for example, David M. Cutler "Employee Costs and the Decline in Health Insurance Coverage" NBER Working Paper #9036. July 2002; Gruber, Jonathon and Ebonya Washington. "Subsidies to Employee Health Insurance Premiums and the Health Insurance Market" NBER Working Paper #9567. March 2003; and Cooper, PF and J. Vistnes. "Workers' Decisions to Take-up Offered Insurance Coverage: Assessing the Importance of Out-of-Pocket Costs" *Med Care* 2003, 41(7 Suppl): III35-43.) Finally, economic discussions on elasticity of insurance tend to view coverage as a discrete concept and does not consider that the value of coverage may have also changed.

approximately \$7,100 per-participant,¹³ and it is likely that average costs would be higher for individuals who had been denied coverage due to health factors. Prior to HIPAA's enactment, less than one-tenth of one percent of employees, or roughly 120,000 in today's labor market, were denied employment-based coverage annually because of health factors.¹⁴ A simple assessment suggests that the total cost of coverage for such employees could be \$850 million. However, this estimated statutory transfer is small relative to the overall cost of employment-based health coverage. Group health plans will spend over \$620 billion this year to cover approximately 174 million employees and their dependents.¹⁵ Estimated costs under HIPAA's nondiscrimination provisions represent a very small fraction of one percent of

¹³ Departments' tabulations using the 2005 Kaiser Family Foundation's Employer Health Benefits Annual Survey. Average employee premium is a weighted average of premiums for single, family, and employee-plus-one health plans. The estimate for Employee-Plus-One health premiums was derived using the 2003 MEPS-IC, as was the share of employees in each type of plans. Participants are defined as the workers or primary policy holders.

¹⁴ Departments' tabulations off the February 1997 Current Population Survey (CPS), Contingent Worker Supplement. The estimate was projected to reflect current labor market conditions by assuming the same share of the employed, civilian force would be affected and using the 2004 CPS table, "Employment status of the civilian noninstitutional population, 1940 to date."

¹⁵ The Departments' estimate is based on the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) projected measure of total personal health expenditures by private health insurance in 2005. This total (\$707.0 billion) is then multiplied by the share of privately insured individuals covered by employer-sponsored health insurance in 2004 as estimated by the 2005 March CPS (88 percent).

total group health plan expenditures.

3. Costs and Benefits of Finalizing the 2001 Interim Rules

Prohibiting Discrimination

Many of the provisions of these regulations serve to specify more precisely than the statute alone exactly what practices are prohibited by HIPAA as unlawful discrimination in eligibility or employee premiums among similarly situated employees. For example, under the regulations, eligibility generally may not be restricted based on an individual's participation in risky activities, confinement to an institution, or absence from work on an individual's enrollment date due to illness. The regulations provide that various plan features including waiting periods and eligibility for certain benefits constitute rules for eligibility which may not vary across similarly situated individuals based on health factors. They also provide that plans may not reclassify employees based on health factors in order to create separate groups of similarly situated individuals among which discrimination would be permitted.

All of these provisions have the effect of clarifying and ensuring certain participants' right to freedom from discrimination in eligibility and premium amounts, thereby securing their access to affordable group health plan coverage. The costs and benefits attributable to these provisions resemble those attendant to HIPAA's statutory nondiscrimination provisions. Securing participants' access to affordable group coverage provides economic benefits by reducing the numbers of uninsured and thereby improving health outcomes. The regulations entail a shifting of costs from the employees whose rights are secured (and/or from other parties who would otherwise pay for their health care) to plan sponsors (or to other plan participants if sponsors pass those costs back to them).

The Departments lack any basis on which to distinguish these benefits and costs from those of

the statute itself. It is unclear how many plans were engaging in the discriminatory practices targeted for prohibition by these regulatory provisions. Because these provisions operate largely at the margin of the statutory requirements, it is likely that the effects of these provisions were far smaller than the similar statutory effects. The Departments are confident, however, that by securing employees' access to affordable coverage at the margin, the regulations, like the statute, have yielded benefits that justify costs.

Clarifying Requirements

Additional economic benefits derive directly from the improved clarity provided by the regulations. The regulation provides clarity through both its provisions and its examples of how those provisions apply in various circumstances. By clarifying employees' rights and plan sponsors' obligations under HIPAA's nondiscrimination provisions, the regulations reduce uncertainty and costly disputes over these rights and obligations. Greater clarity promotes employers' and employees' common understanding of the value of group health plan benefits and confidence in the security and predictability of those benefits, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans by employers.

Impact of the Final Rules

As noted earlier in this preamble, the Departments have not modified the 2001 interim rules in any way that would impact the original cost estimates or the magnitude of the statutory transfers. Accordingly, no impact is attributable to these final regulations when measured against the baseline of the interim final rules. The provisions of the 2001 interim rules offer the appropriate baseline for this measurement because these rules were generally applicable for plan years beginning on or after July 1,

2001.

4. Costs and Benefits of the Rules Applicable to Wellness Programs

By contrast with the nondiscrimination regulatory provisions issued as interim final rules, the provisions relating to wellness programs were issued as proposed rules. This final regulation will not become effective until its applicability date.

Under the final regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on a health factor only in connection with wellness programs. The final regulation establishes five requirements for wellness programs that vary premiums or benefits based on participation in the program and condition a reward involving premiums or benefits on satisfaction of a standard related to a health factor. These requirements will, therefore, apply to only a subset of all wellness programs.

Available literature, together with comments received by the Departments, demonstrate that well-designed wellness programs can deliver benefits well in excess of their costs. For example, the U.S. Centers for Disease Control and Prevention estimate that implementing proven clinical smoking cessation interventions can save one year of life for each \$2,587 invested.¹⁶ In addition to reduced mortality, benefits of effective wellness programs can include reduced absenteeism, improved productivity, and reduced medical costs.¹⁷ The requirements of the final regulation were crafted to

16 Cromwell, J., W. J. Bartosch, M. C. Fiore, V. Hasselblad and T. Baker . “Cost-Effectiveness of the Clinical Practice Recommendations in the AHCPR Guideline for Smoking Cessation.” *Journal of the American Medical Association*, vol. 278 (December 3, 1997): 1759-66.

17 The benefits of employer wellness programs are well documented. One study found the annual per participant savings to be \$613 while private companies have reported returns of as much as \$4.50 in lowered medical expenses

accommodate and not impair such beneficial programs, while combating discrimination in eligibility and premiums for similarly situated individuals as intended by Congress.

Estimation of the economic impacts of the requirements is difficult because data on affected plans' current practices are incomplete, and because plans' approaches to compliance with the requirements and the effects of those approaches will vary and cannot be predicted. Nonetheless, the Departments endeavored to consider the impacts fully and to develop estimates based on reasonable assumptions.

The Departments estimate that 1.6 percent of large plans and 1.2 percent of small plans currently vary employee premium contributions across similarly situated individuals due to participation in a wellness program that provides rewards based on satisfaction of a standard related to a health factor.¹⁸ This amounts to 30,000 plans covering 1.1 million participants. According to survey data reported by Hewitt Associates,¹⁹ just less than one-half as many plans vary benefit levels across similarly situated individuals as vary premiums. This amounts to 13,000 plans covering 460,000 participants. The Departments considered the effect of each of the five requirements on these plans.

for every dollar spent on health programs. (See for example, Gregg M. State et al, "Quantifiable Impact of the Contract for Health Wellness: Health Behaviors, Health Care Costs, Disability and Workers' Compensation," *Journal of Occupational and Environmental Medicine* (2003), vol. 45 (2):109-117; Morgan O'Rourke & Laura Sullivan, "A Health Return on Employee Investment" *Risk Management* (2003), vol. 50 (11): 34-38; American Association of Health Plans and Health Insurance Association of America "The Cost Savings of Disease Management Programs: Report on a Study of Health Plans," November, 2003; Rachel Christensen, "Employment-Based Health Promotion and Wellness Programs" EBRI Notes (2001), vol. 22 (7): 1-6; and Steven G. Aldana "Financial Impact of Wellness Programs: A Comprehensive Review of the Literature," *American Journal of Health Promotions* (2001), vol. 15 (5): 296-320.)

¹⁸ Estimates are based on a 1993 survey of employers by the Robert Wood Johnson Foundation. More recent estimates are unavailable.

¹⁹ Hewitt Associates, July 2003.

For purposes of its estimates, the Departments assumed that one-half of the plans in the latter group are also included in the former, thereby estimating that 37,000 plans covering 1.3 million participants will be subject to the five requirements for wellness programs.

Limit on Reward

Under the first requirement, any reward, whether applicable to employee premiums or benefit levels, must not exceed 20 percent of the total premium for employee-only coverage under the plan (with additional provisions related to rewards that apply also to classes of dependents). This percentage is the highest of the three alternative percentages suggested in the proposed rule, and the award limit used for purposes of the analysis of the proposed rule, which was 15 percent - the midpoint of the three alternative percentages suggested in the proposal. The estimates here also reflect increases in average annual premiums and the numbers of plans and participants since publication of the proposed rules.

The Departments lack representative data on the magnitude of the rewards applied by affected plans today. One consultant practicing in this area suggested that wellness incentive premium discounts ranged from about 3 percent to 23 percent, with an average of about 11 percent.²⁰ This suggests that most affected plans, including some whose discounts are somewhat larger than average, already comply with the first requirement and will not need to reduce the size of the rewards they apply. It appears likely, however, that perhaps a few thousand plans covering approximately one hundred thousand

²⁰ This estimate was made in 1998, shortly after the 1997 interim final rule was published. Since then, it appears that wellness programs advocates have been advising health plans to offer premium discounts in the range of 5 to 11 percent, well below the proposed ceiling. For a full discussion, see Larry Chapman's, "Increasing Participation in Wellness Programs," *National Wellness Institute Members 'Ask the Expert,'* July/August 2004.

participants will need to reduce the size of their rewards in order to comply with the first requirement.

The Departments considered the potential economic effects of requiring these plans to reduce the size of their rewards. These effects are likely to include a shifting of costs between plan sponsors and participants, as well as new economic costs and benefits. Shifts in costs will arise as plans reduce rewards where necessary. Plan sponsors can exercise substantial control over the size and direction of these shifts. Limiting the size of rewards restricts only the differential treatment between participants who satisfy wellness program standards and those who do not. It does not, for example, restrict plan sponsors' flexibility to determine the overall respective employer and employee shares of base premiums. Possible outcomes include a shifting of costs to plan sponsors from participants who satisfy wellness program standards, from plan sponsors to participants who do not satisfy the standards, from participants who satisfy the standards to those who do not, or some combination of these.

The Departments developed a very rough estimate of the total amount of costs that might derive from this requirement. The Departments' estimate assumes that (1) all rewards take the form of employee premium discounts; (2) discounts are distributed evenly within both the low-to-average range and the average-to-high range, and are distributed across these ranges such that their mean equals the assumed average; and (3) 70 percent of participants qualify for the discount. The 4,000 affected plans could satisfy this requirement by reducing the premium discount for the 100,000 participants who successfully complete a certified wellness program. When applied to the 2005 average annual employee-only premium of \$4,024,²¹ discounts range from \$115 to \$920, with an average of \$460.

²¹ Average based on the Kaiser Family Foundation/Health Research and Education Trust *Survey of Employer-Sponsored Health Benefits, 2005*.

The maximum allowable discount based on 20 percent of current premium is \$805. Reducing all discounts greater than \$805 to that amount will result in an average annual reduction of about \$57. Applying this reduction to the 100,000 participants assumed to be covered by 4,000 plans affected by the limit results in an estimate of the aggregate cost at \$6 million.

New economic costs and benefits may arise if changes in the size of rewards result in changes in participant behavior. Net economic welfare might be lost if some wellness programs' effectiveness is eroded, but the magnitude and incidence of such effects is expected to be negligible. Consider a wellness program that discounts premiums for participants who take part in an exercise program. It is plausible that, at the margin, a few participants who would take part in order to obtain an existing discount will not take part to obtain a somewhat lower discount. This effect is expected to be negligible, however. Reductions in discounts are likely to average about \$57 annually, which is very small when spread over biweekly pay periods. Moreover, the final regulation limits only rewards applied to similarly situated individuals in the context of a group health plan. It does not restrict plan sponsors from encouraging healthy lifestyles in other ways, such as by varying life insurance premiums.

On the other hand, net economic welfare likely will be gained in instances where large premium differentials would otherwise have served to discourage enrollment in health plans by employees who did not satisfy wellness program requirements.

The Departments believe that the net economic gains from prohibiting rewards so large that they could discourage enrollment based on health factors justify any net losses that might derive from the negligible reduction of some employees' incentive to participate in wellness programs.

Reasonable Design

Under the second requirement, the program must be reasonably designed to promote health or prevent disease. The Departments believe that a program that is not so designed would not provide economic benefits, but would serve merely to shift costs from plan sponsors to targeted individuals based on health factors. Comments received by the Departments and available literature on employee wellness programs, however, suggest that existing wellness programs generally satisfy this requirement. As was stated in the analysis of the proposed rule, this requirement therefore is not expected to compel plans to modify existing wellness programs or entail additional economic costs.

Annual Opportunity to Qualify

Although this requirement was included in the proposal within the requirement for reasonable design, it has been reorganized as a separate provision in these final regulations. At the time of the proposal, the Departments assumed that most plans satisfied the requirements for reasonable design, such that they would not be required to modify existing programs. Accordingly, no cost was attributed to the reasonable design requirements when taken together. The Departments did request comments on this assumption, but received no additional information in response. Accordingly, the Departments have not attributed a cost to this provision of the final regulations.

Uniform Availability

The fourth requirement provides that where rewards are conditioned on satisfaction of a standard related to a health factor, rewards must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals unless the program allows for a reasonable

alternative standard if the otherwise applicable initial standard is unreasonably difficult to achieve due to a medical condition or medically inadvisable for the individual to meet. In particular, the program must offer any such individual the opportunity to satisfy a reasonable alternative standard. Comments received by the Departments and available literature on employee wellness programs suggest that some wellness programs do not currently satisfy this requirement and will have to be modified. The Departments estimate that among employers that provide incentives for employees to participate in wellness programs, nine percent require employees to achieve a low risk behavior to qualify for the incentive, 53 percent require a pledge of compliance, and 55 percent require participation in a program.²² Depending on the nature of the wellness program, it might be unreasonably difficult due to a medical condition or medically inadvisable for at least some plan participants to achieve the behavior or to comply with or participate in the program.

The Departments identified three broad types of economic impact that might arise from this requirement. First, affected plans will incur some economic cost to make available reasonable alternative standards. Second, additional economic costs and benefits may arise depending on the nature of alternatives provided, individuals' use of these alternatives, and any changes in the affected individuals' behavioral and health outcomes. Third, some costs may be shifted from individuals who would fail to satisfy programs' initial standards, but who will satisfy reasonable alternative standards once available (and thereby qualify for associated rewards), to plan sponsors (or to other participants in their plans if plan sponsors elect to pass these costs back to all participants).

²² Hewitt Associates, July, 2003. The sum of these shares exceeds 100 percent due to some employers using multiple criteria to determine compliance.

The Departments note that some plans that offer rewards to similarly situated individuals based on their ability to meet a standard related to a health factor (and are therefore subject to the requirement) may not need to provide alternative standards. The requirement provides that alternative standards need not be specified or provided until a participant for whom it is unreasonably difficult due to a medical condition or medically inadvisable to satisfy the initial standard seeks such an alternative. Some wellness programs' initial standards may be such that no participant would ever find them unreasonably difficult to satisfy due to a medical condition or medically inadvisable to attempt. The Departments estimate that 3,000 potentially affected plans have initial wellness program standards that might be unreasonably difficult for some participants to satisfy due to a medical condition or medically inadvisable to attempt.²³ Moreover, because alternatives need not be made available until they are sought by qualified plan participants, it might be possible for some plans to go for years without needing to make available an alternative standard. This could be particularly likely for small plans.²⁴

The Departments estimate that as many as 27 percent of participants in plans with rewards that are based on meeting a standard related to a health factor, or 344,000 individuals, might fail to satisfy wellness programs' initial standards because they are unreasonably difficult due to a medical condition

23 Estimate is based on both the share of plans in the 2003-04 Hewitt survey stating that certain health factors or lifestyle choices affect employees' benefit coverage and the share of employers requiring employees to achieve a lower-risk behavior to earn incentives. These measures are then combined with the number of workers in the civilian labor force (from 2003 estimates of the Bureau of Labor Statistics (BLS) suffering from these maladies (as provided by the Centers for Disease Control (CDC) 2004 *Health* and the National Center for Statistics and Analysis (NCSA) 2004 estimates of seatbelt use), by demographic group.

24 The most common standards that would be implemented by this provision of the wellness program rules pertain to smoking, blood pressure, and cholesterol levels, according to the Hewitt survey. Based on data from the CDC, NCSA and BLS, the Departments estimate that among plans with five participants, about one-fourth will not contain any smokers, one-third will not contain participants with high blood pressure and two-fifths will not contain any with high cholesterol. Approximately 97 percent of all plans with potentially difficult initial wellness program standards

or medically inadvisable to meet.²⁵ Of these, only about 30,000 are in the 3,000 plans assumed to apply standards that might be unreasonably difficult due to a medical condition or medically inadvisable for some plan participants to satisfy. The standards would in fact be unreasonably difficult or medically inadvisable to satisfy for some subset of these individuals — roughly two-thirds, or 19,000 by the Departments’ estimate.²⁶ Of these, it is assumed that between 5,000 and 19,000 of those individuals that seek alternative standards are able to satisfy them.²⁷

The cost associated with establishing alternative standards is unknown. However, the regulation does not prescribe a particular type of alternative standard that must be provided. Instead, it permits plan sponsors flexibility to provide any reasonable alternative, or to waive the standard, for individuals for whom the initial standard is unreasonably difficult due to a medical condition or medically inadvisable

have fewer than 100 participants.

²⁵ This estimate is considerably lower than that offered in the proposal due to a difference in the format of the data reported in the 2001 and 2003 Hewitt surveys, and the Departments’ original adjustment for data reported in the 2001 survey as, “not provided.” The Departments believe in light of the 2003 data that the adjustments thought to be appropriate at the time overestimated the number of plans with standards that might be unreasonably difficult or medically inadvisable to meet, resulting in more instances in which alternative standards might be established and met, and greater magnitudes of transfers for individuals who would newly attain rewards. The Departments have revised their assumptions to account for a smaller number of plans with standards unreasonably difficult or medically inadvisable to meet, and a correspondingly larger number of participants who will already have been satisfying these standards. Accordingly, this results in a reduction of the estimates of transfers in connection with establishing reasonable alternative standards.

²⁶ Having previously determined the share of the working class population suffering from various maladies using CDC, NCSA and BLS estimates and how, according to the Hewitt survey, these conditions are factored into wellness programs, the Departments were able to estimate that 26.8 percent of plan participants may initially fail to satisfy program standards. Since the Hewitt study went on to state that 9 percent of employers surveyed required participants to meet the standard in order to receive premium discounts, it was then concluded that 2.3 percent *may* have difficulty meeting the standards and 1.5 percent *will* have difficulty meeting the standards.

²⁷ No independent estimates of the those satisfying alternative standards were available, so the Departments created an upper bound which assumes all individuals for whom the standards are unreasonably difficult seek and satisfy an alternative standard, and a lower bound which assumes half of those for whom the standards are unreasonably difficult seek an alternative, and half of those are able to satisfy it.

to meet. The Departments expect that plan sponsors will select alternatives that entail the minimum net costs possible. Plan sponsors may select low-cost alternatives, such as requiring an individual for whom it would be unreasonably difficult to quit smoking (and thereby qualify for a non-smoker discount) to attend a smoking cessation program that is available at little or no cost in the community, or to watch educational videos or review educational literature. Plan sponsors presumably will select higher-cost alternatives only if they thereby derive offsetting benefits, such as a higher smoking cessation success rate.

Although there is considerable uncertainty in these estimates, it seems reasonable to assume that the net cost sponsors will incur in the provision of alternatives, including new economic costs and benefits, will not exceed the cost of providing discounts (or waiving surcharges) for all plan participants who qualify for alternatives, which is estimated at between \$2 million and \$9 million.²⁸ Other economic costs and benefits might arise where alternative standards are made available. For example, some individuals might receive a discount for satisfying alternative standards that turn out to be less beneficial to overall health than the initial standard might have been, resulting in a net loss of economic welfare. In other cases, the satisfaction of an alternative standard might produce the desired health improvement, which would represent a net gain in economic welfare.

Although outcomes are uncertain, the Departments note that plan sponsors have strong motivation to identify and provide alternative standards that have positive net economic effects. They will be disinclined to provide alternatives that worsen behavioral and health outcomes, or that make

²⁸ These estimates are the product of the range of numbers of individuals who might newly attain rewards and the average premium reward. It is likely that many plan sponsors will find more cost effective ways to satisfy this

financial rewards available absent meaningful efforts by participants to improve their health habits and health. Instead they will be inclined to provide alternatives that sustain or reinforce plan participants' incentive to improve their health habits and health, and/or that help participants make such improvements. It therefore seems likely that gains in economic welfare from this requirement will equal or justify losses. The Departments anticipate that the requirement to provide reasonable alternative standards will reduce instances where wellness programs serve only to shift costs to higher risk individuals and increase instances where programs succeed at helping individuals with higher health risks improve their health habits and health.

Disclosure Regarding Reasonable Alternative Standards

The fifth requirement provides that plan materials describing wellness program standards that are related to a health factor must disclose the availability of reasonable alternative standards. Under some wellness programs, an individual must satisfy a standard related to a health factor in order to qualify for the reward.

Plans offering wellness programs under which an individual must satisfy a standard related to a health factor in order to qualify for the reward must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard. The regulations provide sample language for this disclosure. An actual description of the alternative standard is not required in such materials. In plan materials that merely mention that a wellness program is available but do not describe its terms, this disclosure of the availability of an alternative standard is not required. The Departments generally

requirement, and that the true net cost to them will therefore be smaller than this.

account elsewhere for plans' cost of updating such materials to reflect changes in plan provisions as required under various disclosure requirements and as is part of usual business practice. This particular requirement is expected to represent a negligible fraction of the ongoing cost of updating plans' materials, and is not separately accounted for here.

Statutory Authority

The Department of the Treasury final rule is adopted pursuant to the authority contained in sections 7805 and 9833 of the Code (26 U.S.C. 7805, 9833).

The Department of Labor final rule is adopted pursuant to the authority contained in sections 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c, sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); Secretary of Labor's Order 1-2003, 68 FR 5374 (Feb. 3, 2003).

The Department of Health and Human Services final rule is adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as added by HIPAA (Public Law 104-191, 110 Stat. 1936), and amended by the Mental Health Parity Act (MHPA) and the Newborns' and Mothers' Health Protection Act (NMHPA) (Public Law 104-204, 110 Stat. 2935), and the Women's Health and Cancer Rights Act (WHCRA) (Public Law 105-277, 112 Stat. 2681-436).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping

requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Adoption of Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR Part 54 is amended as follows:

PART 54 -- PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by removing the citation for §54.9802-1T to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§54.9802-1T [Removed]

Par. 2. Section 54.9802-1T is removed.

Par. 3. Section 54.9802-1 is revised to read as follows:

§54.9802-1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) **Health factors.** (1) The term **health factor** means, in relation to an individual, any of the following health status-related factors:

- (i) Health status;
- (ii) Medical condition (including both physical and mental illnesses), as defined in §54.9801-2;
- (iii) Claims experience;
- (iv) Receipt of health care;
- (v) Medical history;
- (vi) Genetic information, as defined in §54.9801-2 of this chapter;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes --

(i) Conditions arising out of acts of domestic violence; and

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under §54.9801-6, a plan must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) Prohibited discrimination in rules for eligibility -- (1) In general. (i) A group health plan may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to

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- (A) Enrollment;
- (B) The effective date of coverage;
- (C) Waiting (or affiliation) periods;
- (D) Late and special enrollment;
- (E) Eligibility for benefit packages (including rules for individuals to change their selection

among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b)(2) and (3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) Conclusion. In this Example 1, the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. (i) Facts. Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) Conclusion. In this Example 2, the requirement to provide evidence of good health in order

to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) Facts. Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) Conclusion. In this Example 3, excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one more health factors and thus violates this paragraph (b)(1).

Example 4. (i) Facts. A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual A is an employee of the employer maintaining the plan. A and A's dependents have a history of high health claims. Based on the information about A and A's dependents, the issuer excludes A and A's dependents from the group policy it offers to the employer.

(ii) Conclusion. See Example 4 in 29 CFR 2590.702(b)(1) and 45 CFR 146.121(b)(1) for a conclusion that the exclusion by the issuer of A and A's dependents from coverage is a rule for eligibility that discriminates based on one or more health factors and violates rules under 29 CFR 2590.702(b)(1) and 45 CFR 146.121(b)(1) similar to the rules under this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for A and A's dependents through other means, the plan violates this paragraph (b)(1).

(2) Application to benefits -- (i) General rule. (A) Under this section, a group health plan is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual

participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under ERISA, the Americans with Disabilities Act, or any other law, whether State or Federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan applies a \$500,000 lifetime limit on all benefits to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 1, the limit does not violate this paragraph (b)(2)(i) because \$500,000 of benefits are available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) Facts. A group health plan has a \$2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant B files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a \$10,000 lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) Conclusion. The facts of this Example 2 strongly suggest that the plan modification is directed at B based on B's claim. Absent outweighing evidence to the contrary, the plan violates this paragraph (b)(2)(i).

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual C is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about C's adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that C has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for C for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) Conclusion. See Example 3 in 29 CFR 2590.702(b)(2)(i) and 45 CFR 146.121(b)(2)(i) for a conclusion that the issuer violates rules under 29 CFR 2590.702(b)(2)(i) and 45 CFR 146.121(b)(2)(i) similar to the rules under this paragraph (b)(2)(i) because benefits for C's condition are available to other individuals in the group of similarly situated individuals that includes C but are not available to C. Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates the rules under 29 CFR 2590.702(b)(2)(i) and 45 CFR 146.121(b)(2)(i). If the plan provides coverage through this policy and does not provide equivalent coverage for C through other means, the plan violates this paragraph (b)(2)(i).

Example 4. (i) Facts. A group health plan has a \$2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 4, the limit does not violate this paragraph (b)(2)(i) because \$2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries. . (This example does not address whether the plan provision is permissible under the Americans with Disabilities Act or any other applicable law.)

Example 5. (i) Facts. A group health plan applies a \$2 million lifetime limit on all benefits. However, the \$2 million lifetime limit is reduced to \$10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) Conclusion. In this Example 5, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) Facts. A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 6, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) Facts. Under a group health plan, doctor visits are generally subject to a \$250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 7, imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 8. (i) Facts. An employer sponsors a group health plan that is available to all current employees. Under the plan, the medical care expenses of each employee (and the employee's dependents) are reimbursed up to an annual maximum amount. The maximum reimbursement amount

with respect to an employee for a year is \$1500 multiplied by the number of years the employee has participated in the plan, reduced by the total reimbursements for prior years.

(ii) Conclusion. In this Example 8, the variable annual limit does not violate this paragraph (b)(2)(i). Although the maximum reimbursement amount for a year varies among employees within the same group of similarly situated individuals based on prior claims experience, employees who have participated in the plan for the same length of time are eligible for the same total benefit over that length of time (and the restriction on the maximum reimbursement amount is not directed at any individual participants or beneficiaries based on any health factor).

(ii) Exception for wellness programs. A group health plan may vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(iii) Specific rule relating to source-of-injury exclusions. (A) If a group health plan generally provides benefits for a type of injury, the plan may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions). This rule applies in the case of an injury resulting from a medical condition even if the condition is not diagnosed before the injury.

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Because of depression, Individual D attempts suicide. As a result, D sustains injuries and is hospitalized for treatment of the injuries. Under the exclusion, the plan denies D benefits for treatment of the injuries.

(ii) Conclusion. In this Example 1, the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of D's injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) Facts. A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant E sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for E's head injury.

(ii) Conclusion. In this Example 2, the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow E to enroll in the plan (or applied different rules for eligibility to E) because E frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(3) Relationship to §54.9801-3. (i) A preexisting condition exclusion is permitted under this section if it --

(A) Complies with §54.9801-3;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

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

Example 1. (i) Facts. A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable

coverage in accordance with §54.9801-3. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 1, even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with §54.9801-3 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) Facts. A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) Conclusion. In this Example 2, the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(c) Prohibited discrimination in premiums or contributions -- (1) In general. (i) A group health plan may not require an individual, as a condition of enrollment or continued enrollment under the plan, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan based on any health factor that relates to the individual or a dependent of the individual.

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) Rules relating to premium rates -- (i) Group rating based on health factors not restricted

under this section. Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan.

(ii) List billing based on a health factor prohibited. However, a group health plan may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

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

Example 1. (i) Facts. An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of F's claims experience.

(ii) Conclusion. See Example 1 in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer does not violate the provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for F than for a similarly situated individual based on F's claims experience.

Example 2. (i) Facts. Same facts as Example 1, except that the issuer quotes the employer a higher premium rate for F, because of F's claims experience, than for a similarly situated individual.

(ii) Conclusion. See Example 2 in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer violates provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for F than for a similarly situated individual, see Example 2 in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer would still violate 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) Exception for wellness programs. Notwithstanding paragraphs (c)(1) and (2) of this section, a plan may vary the amount of premium or contribution it requires similarly situated individuals

to pay based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(d) Similarly situated individuals. The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) Participants. Subject to paragraph (d)(3) of this section, a plan may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on

any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) Beneficiaries. (i) Subject to paragraph (d)(3) of this section, a plan may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (for example, as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.

(3) Discrimination directed at individuals. Notwithstanding paragraphs (d)(1) and (2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be

permitted under this section.

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

Example 1. (i) Facts. An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's usual business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 1, treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) Facts. Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 2, treating spouses and dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) Facts. A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 3, the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) Facts. An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 4, imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) Facts. An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee G has a different job title and different responsibilities. After G files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with G's job title receive a different benefit package that includes a lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) Conclusion. Under the facts of this Example 5, changing the coverage classification for G based on the existing employment classification for G is not permitted under this paragraph (d) because the creation of the new coverage classification for G is directed at G based on one or more health factors.

(e) Nonconfinement and actively-at-work provisions -- (1) Nonconfinement provisions -- (i)

General rule. Under the rules of paragraphs (b) and (c) of this section, a plan may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution.

In addition, under the rules of paragraphs (b) and (c) of this section, a plan may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (3) of this section

(permitting plans, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) Examples. The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) Conclusion. In this Example 1, the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) Facts. In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer M. However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer N. Under Issuer N's policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) Conclusion. See Example 2 in 29 CFR 2590.702(e)(1) and 45 CFR 146.121(e)(1) for a conclusion that Issuer N violates provisions of 29 CFR 2590.702(e)(1) and 45 CFR 146.121(e)(1) similar to the provisions of this paragraph (e)(1) because the group health insurance coverage restricts benefits based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits from a previous issuer. See Example 2 in 29 CFR 2590.702(e)(1) and 45 CFR 146.121(e)(1) for the additional conclusions that under State law Issuer M may also be responsible for providing benefits to such a dependent; and that in a case in which Issuer N has an obligation under 29 CFR 2590.702(e)(1) or 45 CFR 146.121(e)(1) to provide benefits and Issuer M has an obligation under State law to provide benefits, any State laws designed to prevent more than 100% reimbursement, such as State coordination-of-benefits laws, continue to apply.

(2) Actively-at-work and continuous service provisions -- (i) General rule. (A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on

whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) Conclusion. In this Example 1, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) Facts. Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) Conclusion. In this Example 2, the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service.

(ii) Exception for the first day of work. (A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) Facts. Under the eligibility provision of a group health plan, coverage for new

employees becomes effective on the first day that the employee reports to work. Individual H is scheduled to begin work on August 3. However, H is unable to begin work on that day because of illness. H begins working on August 4, and H's coverage is effective on August 4.

(ii) Conclusion. In this Example 1, the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) Facts. Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual J is scheduled to begin work on March 24. However, J is unable to begin work on March 24 because of illness. J begins working on April 7 and J's coverage is effective May 1.

(ii) Conclusion. In this Example 2, the plan provision does not violate this section. However, as in Example 1, if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) Relationship to plan provisions defining similarly situated individuals. (i) Notwithstanding the rules of paragraphs (e)(1) and (2) of this section, a plan may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other Federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) Conclusion. In this Example 1, the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) Facts. To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) Conclusion. In this Example 2, the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) Facts. Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee B has been covered under the plan. B experiences a disabling illness that prevents B from working. B takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, B terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) Conclusion. In this Example 3, the plan provision terminating B's coverage upon B's termination of employment does not violate this section.

Example 4. (i) Facts. Under a group health plan, coverage of an employee is terminated when

the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee C is laid off for three months. When the layoff begins, C's coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) Conclusion. In this Example 4, the plan provision terminating C's coverage upon the cessation of C's performance of services does not violate this section.

(f) Wellness programs. A wellness program is any program designed to promote health or prevent disease. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f). If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, paragraph (f)(1) of this section clarifies that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program does not violate this section if the requirements of paragraph (f)(2) of this section are met.

(1) Wellness programs not subject to requirements. If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that are related to a health factor (or if a wellness program does not provide a reward), the wellness program does not violate this section, if participation in the program is made available to all similarly situated individuals. Thus, for example, the following programs need not satisfy the requirements of paragraph (f)(2) of this

section, if participation in the program is made available to all similarly situated individuals:

(i) A program that reimburses all or part of the cost for memberships in a fitness center.

(ii) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(iii) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits.

(iv) A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly health education seminar.

(2) Wellness programs subject to requirements. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program does not violate this section if the requirements of this paragraph (f)(2) are met.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed 20 percent of the cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses or spouses and dependent children) may participate in the wellness program, the reward must not exceed 20 percent of the cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(2), the cost of coverage is determined based on the total amount of employer and employee contributions for the

benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.

(ii) The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of or preventing disease in participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease.

(iii) The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iv) The reward under the program must be available to all similarly situated individuals.

(A) A reward is not available to all similarly situated individuals for a period unless the program allows --

(1) A reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(2) A reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) A plan or issuer may seek verification, such as a statement from an individual's physician,

that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(v) (A) The plan must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under paragraph (f)(2)(iv) of this section. However, if plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the requirement of this paragraph (f)(2)(v): “If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.” In addition, other examples of language that would satisfy this requirement are set forth in Examples 3, 4, and 5 of paragraph (f)(3) of this section.

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

Example 1. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is \$3,600 (of which the employer pays \$2,700 per year and the employee pays \$900 per year). The annual premium for family coverage is \$9,000 (of which the employer pays \$4,500 per year and the employee pays \$4,500 per year). The plan offers a wellness program with an annual premium rebate of \$360. The program is available only to employees.

(ii) Conclusion. In this Example 1, the program satisfies the requirements of paragraph (f)(2)(i) of this section because the reward for the wellness program, \$360, does not exceed 20 percent of the total annual cost of employee-only coverage, \$720. ($\$3,600 \times 20\% = \720 .) If any class of dependents is allowed to participate in the program and the employee is enrolled in family coverage, the plan could offer the employee a reward of up to 20 percent of the cost of family coverage, \$1,800.

(\$9,000 x 20% = \$1,800.)

Example 2. (i) Facts. A group health plan gives an annual premium discount of 20 percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) Conclusion. In this Example 2, the program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard or waive the cholesterol standard. (In addition, plan materials describing the program are required to disclose the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) for obtaining the premium discount. Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 3. (i) Facts. Same facts as Example 2, except that the plan provides that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count) within a 60-day period, the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: “If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.” Individual D begins a diet and exercise program but is unable to achieve a cholesterol count under 200 within the prescribed period. D’s doctor determines D requires prescription medication to achieve a medically advisable cholesterol count. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D’s health status. The plan accommodates D by making the discount available to D, but only if D follows the advice of D’s doctor’s regarding medication and blood tests.

(ii) Conclusion. In this Example 3, the program is a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 4. (i) Facts. A group health plan will waive the \$250 annual deductible (which is less than 20 percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable in the burden it imposes and is reasonable taking into consideration the individual's medical situation. All plan materials describing the terms of the wellness program include the following statement: "If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived." Due to a medical condition, Individual E is unable to achieve a BMI of between 19 and 26 and is also unable to follow the walking program. E proposes a program based on the recommendations of E's physician. The plan agrees to make the discount available to E if E follows the physician's recommendations.

(ii) Conclusion. In this Example 4, the program satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 5. (i) Facts. In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is 20 percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: "If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative

standard for you to avoid this surcharge.” It is unreasonably difficult for Individual F to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates F by requiring F to participate in a smoking cessation program to avoid the surcharge. F can avoid the surcharge for as long as F participates in the program, regardless of whether F stops smoking (as long as F continues to be addicted to nicotine).

(ii) Conclusion. In this Example 5, the premium surcharge is permissible as a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

Example 6. (i) Facts. Same facts as Example 5, except the plan accommodates F by requiring F to view, over a period of 12 months, a 12-hour video series on health problems associated with tobacco use. F can avoid the surcharge by complying with this requirement.

(ii) Conclusion. In this Example 6, the requirement to watch the series of video tapes is a reasonable alternative method for avoiding the surcharge.

(g) More favorable treatment of individuals with adverse health factors permitted -- (1) In rules for eligibility. (i) Nothing in this section prevents a group health plan from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) Conclusion. In this Example 1, the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) Facts. An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees \$50 per month for employee-only coverage and \$125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee \$100 per month for employee-only coverage and \$250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) Conclusion. In this Example 2, the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) Facts. To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) Conclusion. In this Example 3, the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) In premiums or contributions. (i) Nothing in this section prevents a group health plan from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) Facts. Under a group health plan, employees are generally required to pay \$50 per month for employee-only coverage and \$125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) Conclusion. In this Example, the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) No effect on other laws. Compliance with this section is not determinative of compliance with any provision of ERISA (including the COBRA continuation provisions) or any other State or Federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other Federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(i) Applicability dates. This section applies for plan years beginning on or after July 1, 2007.

Mark E. Matthews
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved: 22 June 2006

Eric Solomon
Acting Deputy Assistant Secretary of the Treasury (Tax Policy).