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 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 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 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 plans 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.

[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 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.

[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.

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. 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).

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

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

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

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 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 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 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 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.

[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 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.

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

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 (Pub. L. 104–191, 110 Stat. 1936), and amended by the Mental Health Parity Act (MHPA) and the Newborns' and Mothers' Health Protection Act (NMHPA) (Pub. L. 104–204, 110 Stat. 2935), and the Women's Health and Cancer Rights Act (WHCRA) (Pub. L. 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;

(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—

(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