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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

REG-114084-00

RIN 1545-AY34

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2590

RIN 1210-AA77

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

45 CFR Part 146

RIN 0938-AK19

Notice of Proposed Rulemaking for Bona Fide Wellness Programs

AGENCIES: Internal Revenue Service, Department of the Treasury; Pension and Welfare Benefits Administration, Department of Labor; Health Care Financing Administration, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: This proposed rule would implement and clarify the term “bona fide wellness

program” as it relates to regulations implementing the nondiscrimination provisions of the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act, as added by the Health Insurance Portability and Accountability Act of 1996.

DATES: Written comments on this notice of proposed rulemaking are invited and must be received by the Departments on or before April 9, 2001.

ADDRESSES: Written comments should be submitted with a signed original and three copies (except for electronic submissions to the Internal Revenue Service (IRS) or Department of Labor) to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments.

Comments to the IRS can be addressed to:

CC:M&SP:RU (REG-114084-00)
Room 5226
Internal Revenue Service
POB 7604, Ben Franklin Station
Washington, DC 20044

In the alternative, comments may be hand-delivered between the hours of 8 a.m. and 5 p.m. to:

CC:M&SP:RU (REG-114084-00)
Courier’s Desk
Internal Revenue Service
1111 Constitution Avenue, NW.
Washington DC 20224

Alternatively, comments may be transmitted electronically via the IRS Internet site at:

http://www.irs.gov/tax_regs/reglist.html.

Comments to the Department of Labor can be addressed to:

U.S. Department of Labor
Pension and Welfare Benefits Administration
200 Constitution Avenue NW., Room C-5331

Washington, DC 20210
Attention: Wellness Program Comments

Alternatively, comments may be hand-delivered between the hours of 9 a.m. and 5 p.m. to the same address. Comments may also be transmitted by e-mail to: Wellness@pwba.dol.gov.

Comments to HHS can be addressed to:

Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-2078-P
P.O. Box 26688
Baltimore, MD 21207

In the alternative, comments may be hand-delivered between the hours of 8:30 a.m. and 5 p.m. to either:

Room 443-G
Hubert Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

or

Room C5-14-03
7500 Security Boulevard
Baltimore, MD 21244-1850

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

All submissions to the Department of Labor will be open to public inspection and copying in the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-1513, 200 Constitution Avenue, NW., Washington, DC from 8:30 a.m. to 5:30 p.m.

All submissions to HHS will be open to public inspection and copying in room 309-G of

the Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC from 8:30 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Amy J. Turner, Pension and Welfare Benefits Administration, Department of Labor, at (202) 219-4377; or Ruth A. Bradford, Health Care Financing Administration, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining additional information on HIPAA's nondiscrimination rules may request a copy of the Department of Labor's booklet entitled "Questions and Answers: Recent Changes in Health Care Law" by calling the PWBA Toll-Free Publication Hotline at 1-800-998-7542 or may request a copy of the Health Care Financing Administration's new publication entitled "Protecting Your Health Insurance Coverage" by calling (410) 786-1565. Information on HIPAA's nondiscrimination rules and other recent health care laws is also available on the Department of Labor's website (<http://www.dol.gov/dol/pwba>) and the Department of Health and Human Services' website (<http://hipaa.hcfa.gov>).

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, 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. However, 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. Interim final rules implementing the HIPAA provisions were first made available to the public on April 1, 1997 (published in the **Federal Register** on April 8, 1997, 62 FR 16894) (April 1997 interim rules).

In the preamble to the April 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 that they intend to issue further regulations on the nondiscrimination rules 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 additional guidance is provided. The new interim regulations relating to the HIPAA nondiscrimination rules (published elsewhere in this issue of the **Federal Register**) do not include provisions relating to bona fide wellness programs. Accordingly, the period for good faith compliance continues with respect to those provisions until further guidance is issued. Compliance with the provisions of these proposed regulations constitutes good faith compliance with the statutory provisions relating to wellness programs.

II. Overview of the Proposed Regulations

The HIPAA nondiscrimination provisions generally prohibit a plan or issuer from charging similarly situated individuals different premiums or contributions based on a health factor. In addition, under the interim regulations published elsewhere in this issue of the **Federal Register**,

cost-sharing mechanisms such as deductibles, copayments, and coinsurance are considered restrictions on benefits. Thus, they are subject to the same rules as are other restrictions on benefits; that is, they 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. 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. The April 1997 interim rules, the interim regulations published elsewhere in this issue of the **Federal Register**, and these proposed regulations refer to programs of health promotion and disease prevention allowed under this exception as “bona fide wellness programs.” In order to prevent the exception to the nondiscrimination requirements for bona fide wellness programs from eviscerating the general rule contained in the HIPAA nondiscrimination provisions, these proposed regulations impose certain requirements on wellness programs providing rewards that would otherwise discriminate based on a health factor.

A wide range of wellness programs exist to promote health and prevent disease. However, many of these programs are not subject to the bona fide wellness program requirements. The requirements for bona fide wellness programs apply only to a wellness program that provides a reward based on the ability of an individual to meet a standard that is related to a health factor, such as a reward conditioned on the outcome of a cholesterol test.

Therefore, without having to comply with the requirements for a bona fide wellness program, a wellness program could --

- Provide voluntary testing of enrollees for specific health problems and make recommendations to address health problems identified, if the program did not base any reward on the outcome of the health assessment;
- Encourage preventive care through the waiver of the copayment or deductible requirement for the costs of well-baby visits;
- Reimburse employees for the cost of health club memberships, without regard to any health factors relating to the employees; or
- Reimburse employees for the costs of smoking cessation programs, without regard to whether the employee quits smoking.

A wellness program that provides a reward based on the ability of an individual to meet a standard related to a health factor violates the interim regulations published elsewhere in this issue of the **Federal Register** unless it is a bona fide wellness program. Under these proposed regulations, a wellness program must meet four requirements to be a bona fide wellness program.

First, 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, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge. 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.

The proposed regulations specify three alternative percentages: 10, 15, and 20. The Departments welcome comments on the appropriate level for the percentage. Comments will be taken into account in determining the standard for the final regulations.

Several commenters on the April 1997 regulations suggested that the amount of a reward should be permitted if it is actuarially determined based on the costs associated with the health factor measured under the wellness program. However, in some cases, the resulting reward (or penalty) might be so large as to have the effect of denying coverage to certain individuals. The percentage limitation in the proposed regulations is designed to avoid this result. The percentage limitation also avoids the additional administrative costs of a reward based on actuarial cost.

The Departments recognize that there may be some programs that currently offer rewards, individually or in the aggregate, that exceed the specified percentage. However, as noted below in the economic analysis, data is scarce regarding practices of wellness programs. Thus, the Departments specifically request comments on the appropriateness of the specified percentage of the cost of employee-only coverage under a plan as the maximum reward for a bona fide wellness program, including whether a larger amount should be allowed for wellness programs that include participation by family members (i.e., the specified percentage of the cost of family coverage). Note also that, as stated above, the period for good faith compliance continues with respect to whether wellness programs satisfy the statutory requirements. While compliance with these proposed regulations constitutes good faith compliance with the statutory provisions, it is possible that, based on all the facts and circumstances, a plan's wellness program that provides a reward in

excess of the specified range of percentages of the cost of employee-only coverage may also be found to meet the good faith compliance standard.

Under these proposed regulations, the second requirement to be a bona fide wellness program is that the program must be reasonably designed to promote good health or prevent disease for individuals in the program. This requirement prevents a program from being a subterfuge for merely imposing higher costs on individuals based on a health factor by requiring a reasonable connection between the standard required under the program and the promotion of good health and disease prevention. Among other things, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year. In contrast, a program that imposes a reward or penalty for the duration of the individual's participation in the plan based solely on health factors present when an individual first enrolls in a plan is not reasonably designed to promote health or prevent disease (because, if the individual cannot qualify for the reward by adopting healthier behavior after initial enrollment, the program does not have any connection to improving health).

The third requirement to be a bona fide wellness program under these proposed regulations is that the reward under the program must be available to all similarly situated individuals. The April 1997 interim rules provided that if, under the design of the wellness program, enrollees might not be able to achieve a program standard due to a health factor, the program would not be a bona fide wellness program. These proposed regulations increase flexibility for plans by allowing plans to make individualized adjustments to their wellness programs to address the health factors of the particular individuals for whom it is unreasonably

difficult to qualify for the benefits under the program. Specifically, the program must allow any individual for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to satisfy the initial program standard an opportunity to satisfy a reasonable alternative standard. The examples clarify that a reasonable alternative standard must take into account the relevant health factor of the individual who needs the alternative. A program does not need to establish the specific reasonable alternative standard before the program commences. To satisfy this third requirement for being a bona fide wellness program, 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.

Many commenters asked how the bona fide wellness program requirements apply to programs that provide a reward for not smoking. An example in the proposed regulations clarifies that if it is unreasonably difficult for an individual to stop smoking due to an addiction to nicotine¹, the individual must be provided a reasonable alternative standard to obtain the reward.

The fourth requirement to be a bona fide wellness program under the proposed regulations is that all plan materials describing the terms of the program must disclose the availability of a reasonable alternative standard. The proposed regulations include model language that can be used to satisfy this requirement; examples also illustrate substantially similar language that would

¹ Under the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, American Psychiatric Association, 1994 (DSM IV), nicotine addiction is a medical condition. See also Rev. Rul. 99-28, 1999-25 I.R.B. 6 (June 21, 1999), citing a report of the Surgeon General stating that scientists in the field of drug addiction agree that nicotine, a substance common to all forms of tobacco, is a powerfully addictive drug.

satisfy the requirement.

The proposed regulations contain two clarifications of this fourth 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.

III. Economic Impact and Paperwork Burden

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

Under the proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health status factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs. It (1) limits the permissible amount of variation in employee premium or benefit levels; (2) requires that programs be reasonably designed to promote health or prevent disease; (3) requires programs to permit plan participants who for medical reasons would incur unreasonable difficulty to satisfy the programs' initial wellness standards to satisfy reasonable alternative standards instead; and (4) requires certain plan materials to disclose the availability of such alternative standards. The Departments carefully considered the costs and benefits attendant to these requirements. The Departments believe that the benefits of these requirements exceed their costs.

The Departments anticipate that the proposed regulation will result in transfers of cost

among plan sponsors and participants and in new economic costs and benefits.

Economic benefits will flow from plan sponsors' efforts to maintain wellness programs' effectiveness where discounts or surcharges are reduced and from plans sponsors' provision of reasonable alternative standards that help improve affected plan participants' health habits and health. The result will be fewer instances where wellness programs merely shift costs to high risk individuals and more instances where they succeed at improving such individuals' health habits and health.

Transfers will arise because the size of some discounts and surcharges will be reduced, and because some plan participants who did not satisfy wellness programs' initial standards will satisfy alternative standards. These transfers are estimated to total between \$18 million and \$46 million annually. (The latter figure is an upper bound, reflecting the case in which all eligible participants pursue and satisfy alternative standards.)

New economic costs may be incurred if reductions in discounts or surcharges reduce wellness programs' effectiveness, but this effect is expected to be very small because reductions will be small and relatively few plans and participants will be affected. Other new economic costs will be incurred by plan sponsors to make available reasonable alternative standards where required. The Departments were unable to estimate these costs but are confident that these costs in combination with the transfers referenced above will not exceed the estimate of the transfers alone. Affected plan sponsors can satisfy the proposed regulation's third requirement by making available any reasonable standard they choose, including low cost alternatives. It is unlikely that plan sponsors would choose alternative standards whose cost, in combination with costs transferred from participants who satisfy them, would exceed the cost of providing discounts or

waiving surcharges for all eligible participants.

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, it has been determined that this action raises novel policy issues arising out of legal mandates. Therefore, this notice is “significant” and subject to OMB review under Section 3(f)(4) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this regulatory action. The Departments’ assessment, and the analysis underlying that assessment, is detailed below. The Departments performed a comprehensive, unified analysis to estimate the costs and benefits attributable to the interim regulation for purposes of compliance with Executive Order 12866, the

Regulatory Flexibility Act, and the Paperwork Reduction Act.

Statement of Need for Proposed Action

These interim regulations are needed to clarify and interpret the HIPAA nondiscrimination provisions (Prohibiting Discrimination Against Individual Participants and Beneficiaries Based on Health Status) under Section 702 of the Employee Retirement Income Security Act of 1974 (ERISA), Section 2702 of the Public Health Service Act, and Section 9802 of the Internal Revenue Code of 1986. The provisions are needed to ensure that group health plans and group health insurers and issuers do not discriminate against individuals, participants, and beneficiaries based on any health factors with respect to health care premiums. Additional guidance was required to define bona fide wellness programs.

Costs and Benefits

The Departments anticipate that the proposed regulation will result in transfers of cost among plans sponsors and participants and in new economic costs and benefits. The economic benefits of the regulation will include a reduction in instances where wellness programs merely shift costs to high risk individuals and an increase in instances where they succeed at improving such individuals' health habits and health. Transfers are estimated to total between \$18 million and \$46 million annually. The Departments were unable to estimate new economic costs but are confident that these costs in combination with the transfers referenced above will not exceed the estimate of the transfers alone. The Departments believe that the regulation's benefits will exceed its costs. Their unified analysis of the regulation's costs and benefits is detailed later in this preamble.

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 which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis (IRFA) at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of analysis under the RFA, PWBA proposes to continue to 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 the Employee Retirement Income Security Act of 1974 (ERISA), which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department of Labor has previously issued at 29 C.F.R. §§ 2520.104-20, 2520.104-21, 2520.104-41, 2520.104-46 and 2520.104b-10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans covering fewer than 100 participants and which satisfy certain other requirements.

Further, while some large employers may have small plans, in general most small plans are

maintained by small employers. Thus, PWBA believes that assessing the impact of this proposed rule on small plans is an appropriate substitute for evaluating the effect on small entities. For purposes of their unified IFRA, the Departments adhered to PWBA's proposed definition of small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business which is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 et seq.). The Departments therefore request comments on the appropriateness of the size standard used in evaluating the impact of this proposed rule on small entities.

Under this proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs.

The Departments estimate that 36,000 plans with fewer than 100 participants vary employee premium contributions or benefit levels across similarly situated individuals based on health factors. While this represents just 1 percent of all small plans, the Departments nonetheless believe that it represents a substantial number of small entities. The Departments also note that at least some premium discounts or surcharges may be large. Premium discounts associated with wellness programs are believed to range as high as \$560 per affected participant per year. Therefore, the Departments believe that the impact of this regulation on at least some small entities may be significant. Having reached these conclusions, the Departments carried out an IRFA as part of their unified analysis of the costs and benefits of the regulation. The reasoning and assumptions underlying the Departments' unified analysis of the regulation's costs and

benefits are detailed later in this preamble.

The regulation's first requirement caps maximum allowable variation in employee premium contribution and benefit levels. The Departments estimate that 9,300 small plans will be affected by the cap. These plans can comply with this requirement by reducing premiums (or increasing benefits) by \$1.1 million on aggregate for those participants whose premiums are higher (or whose benefits are lower) due to health factors. This would constitute an ongoing, annual transfer of cost of \$1.1 million, or \$122 on average per affected plan. The regulation does not limit small plans' flexibility to transfer this cost back evenly to all participants in the form of small premium increases or benefit cuts.

The regulation's 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 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. It is not expected to entail economic costs nor to prompt transfers.

The third requirement provides that rewards under wellness programs must be available to all similarly situated individuals. In particular, programs must allow individuals for whom it would be unreasonably difficult due to a medical condition to satisfy initial program standards an opportunity to satisfy reasonable alternative standards. The Departments believe that some small plans' wellness programs do not currently satisfy this requirement and will have to be modified.

The Departments estimate that 21,000 small plans' wellness programs include initial standards that may be unreasonably difficult for some participants to meet. These plans are

estimated to include 18,000 participants for whom the standard is in fact unreasonably difficult to meet. (Many small plans are very small, having fewer than 10 participants, and many will include no participant for whom the initial standard is unreasonable difficult to meet for a medical reason.) Satisfaction of alternative standards by these participants will result in transfers of cost as they qualify for discounts or escape surcharges. If all of these participants request and then satisfy an alternative standard, the transfer would amount to \$5 million annually. If one-half request alternative standards and one-half of those meet them, the transfer would amount to \$1 million.

In addition to transfers, small plans will also incur new economic costs to provide 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 efficient. Plans not wishing to provide alternative standards also have the option of abolishing health-status based variation in employee premiums. The Departments expect that the economic cost to provide alternatives combined with the associated transfer cost of granting discounts or waiving surcharges will not exceed the transfer cost associated with granting discounts or waiving surcharges for all participants who qualify for an alternative, estimated here at \$1 million to \$5 million, or about \$55 to \$221 per affected plan. Plans have the flexibility to transfer some or all of this cost evenly to all participants in the form of small premium increases or benefit cuts.

The fourth requirement provides that plan materials describing wellness plan standards must disclose the availability of reasonable alternative standards. This requirement will affect the 36,000 small plans that apply discounts or surcharges. These plans will incur economic costs to revise affected plan materials. The 5,000 to 18,000 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, and the regulation provides model 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.

Special Analyses -- Department of the Treasury

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that this notice of proposed rulemaking does not impose a collection of information on small entities and is not subject to section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5). For these reasons, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply pursuant to 5 U.S.C. section 603(a), which exempts from the Act's requirements certain rules involving the internal revenue laws. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Paperwork Reduction Act

Department of Labor and Department of the Treasury

This Notice of Proposed Rulemaking includes a requirement that if the plan materials describe the standard required to be met in order to qualify for a reward such as a premium

discount or waiver of a cost-sharing requirement, they must also disclose the availability of a reasonable alternative standard. However, plan materials are not required to describe specific reasonable alternatives. The proposal also includes examples of disclosures which would satisfy the requirements of the proposed rule.

Plan administrators of group health plans covered under Title I of ERISA are required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description or Summary of Material Modifications pursuant to sections 101(a) and 102(a) of ERISA. Group health plans and issuers also typically make other informational materials available to participants, either as a result of state and local requirements, or as part of their usual business practices in connection with the offer and promotion of health care coverage to employees.

While this proposal may cause group health plans to modify informational materials pertaining to wellness programs, the Departments conclude that it creates no new information collection requirements, and that the overall impact on existing information collection activities will be negligible. First, as described earlier, it is estimated that the proposed reasonable alternative requirements for bona fide wellness programs will impact a maximum of 22,000 plans and 229,000 participants. These numbers are very small in comparison with the 2.5 million ERISA group health plans that cover 65 million participants, and 175,500 state and local governmental plans that cover 11.5 million participants.

In addition, because model language is provided in the proposal, these modifications are expected to require a minimal amount of effort, such that they fall within the provision of OMB regulations in 5 CFR 1320.3(c)(2). This provision excludes from the definition of collection of

information language which is supplied by the Federal government for disclosure purposes.

Finally, the Department of Labor's methodology in accounting for the burden of the Summary Plan Description (SPD) and Summary of Material Modifications (SMM), as currently approved under OMB control number 1210-0039, incorporates an assumption concerning a constant rate of revision in these disclosure materials which is based on plans' actual reporting on the annual report/return (Form 5500) of their rates of modification. This occurrence of SPD revisions is generally more frequent than the minimum time frames described in section 104(b) and related regulations. The annual hour and cost burdens of the SMM/SPD information collection request is currently estimated at 576,000 hours and \$97 million. Because the burden of modifying a wellness program's disclosures is expected to be negligible, and readily incorporated in other revisions made to plan materials on an ongoing basis, the methodology used already accounts for this type of change. Therefore, the Department concludes that the modification described in this proposal to the information collection request is neither substantive nor material, and accordingly it attributes no burden to this regulation.

Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day 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 collection techniques.

Section 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(f) Bona fide wellness programs Paragraph (1)(iv) requires the plan or issuer to disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. However, in plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required. This requirement will affect the estimated 1,300 nonfederal governmental plans that apply premium discounts or surcharges. The development of the materials is expected to take 100 hours for nonfederal governmental plans. The corresponding burden performed by service providers is estimated to be \$38,000.

We have submitted a copy of this rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration,
Office of Information Services,
Information Technology Investment Management Group,

Division of HCFA Enterprise Standards,
Room C2-26-17, 7500 Security Boulevard,
Baltimore, MD 21244-1850,
Attn: John Burke HCFA-2078-P,

and

Office of Information and Regulatory Affairs,
Office of Management and Budget,
Room 10235, New Executive Office Building,
Washington, DC 20503,
Attn.: Allison Herron Eydt, HCFA-2078-P.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and, if finalized, will be transmitted to Congress and the Comptroller General for review. The rule is not a “major rule” as that term is defined in 5 U.S.C. 804, because it is not 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 (Public Law 104-4), as well as Executive Order 12875, this proposed rule does 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 (August 4, 1999) 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. 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 proposed regulations do not have federalism implications, because they do not 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. This is largely because, with respect to health insurance issuers, the vast majority of States have enacted laws which meet or exceed the federal standards in HIPAA prohibiting discrimination based on health factors. Therefore, the regulations are not likely to require substantial additional oversight of States by the Department of Health and Human Services.

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) preserving the applicability of State laws establishing requirements for issuers of group health insurance coverage, except to the extent that these requirements prevent the application of the portability, access, and renewability requirements of HIPAA. The nondiscrimination provisions that are the subject of this rulemaking are included among those requirements.

In enacting these new preemption provisions, Congress indicated its intent to establish a preemption of 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). Consequently, under the statute and the Conference Report, State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of" the HIPAA nondiscrimination provisions.

Accordingly, States are given significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law. In many cases, the federal law imposes minimum requirements which States are free to exceed. Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 and these regulations do not reduce the discretion given to the States by the statute. It is the Departments' understanding that the vast majority of States have in fact implemented provisions which meet or exceed the minimum requirements of the HIPAA non-discrimination 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. When exercising its responsibility to enforce the provisions of

HIPAA, HCFA works cooperatively with the States for the purpose of addressing State concerns and avoiding conflicts with the exercise of State authority.² HCFA 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. HCFA'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 HCFA. To date, HCFA has had occasion to enforce the HIPAA non-discrimination provisions in only two States.

Although the Departments conclude that these proposed regulations do not have federalism implications, in keeping with the spirit of the Executive Order that agencies closely examine any policies that may have federalism implications or limit the policy making discretion of the States, the Department of Labor and HCFA have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

For example, the Departments were aware that some States commented on the way the federal provisions should be interpreted. Therefore, the Departments have 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, that among other things provides

² 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). For additional information relating to the application of these nondiscrimination rules to church plans, see the preamble to regulations being proposed elsewhere in this issue of the **Federal Register** regarding section 9802(c) of the Code relating to church plans.

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 representatives, and consumers. HCFA 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 following two standing HIPAA meetings for members during the quarterly conferences:

- HCFA/DOL Meeting on HIPAA Issues (This meeting provides HCFA and Labor the opportunity to provide updates on regulations, bulletins, enforcement actions and outreach efforts regarding HIPAA.)
- The NAIC/HCFA Liaison Meeting (This meeting provides HCFA and the NAIC the opportunity to discuss HIPAA and other health care programs.)

In their comments on the 1997 interim rules, the NAIC suggested that the permissible standards for determining bona fide wellness programs ensure that such programs are not used as a proxy for discrimination based on a health factor. The NAIC also commented that the nondiscrimination provisions of HIPAA “are especially significant in their impact on small groups, and particularly in small groups, where there is a great potential for adverse selection and gaming.” One State asked that the Departments' final nondiscrimination provisions be as consumer-protective as possible. Finally, another State described already-existing State regulation of issuers offering wellness programs in that State and asked that standards for bona fide wellness programs be left to the States.

The Departments considered these views very carefully when formulating the wellness program proposal. While allowing plans a great deal of flexibility in determining what kinds of incentives best encourage the plan's own participants and beneficiaries to pursue a healthier lifestyle, the Departments proposal ensures that individuals have an opportunity to qualify for the premium discount or other reward. If an individual is unable to satisfy a wellness program standard due to a health factor, plans are required to make a reasonable alternative standard available to the individual. In addition, the Departments reiterate their position that State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of" the federal law and therefore are saved from preemption. Therefore, these more protective State laws continue to apply for individuals receiving health insurance coverage in connection with a group health plan.

The Departments welcome further comment on these issues from the States in response to this proposal.

The Departments also cooperate 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 HCFA, NAIC and many business and consumer groups. HCFA has sponsored four conferences with the States - the Consumer Outreach and Advocacy conferences in March 1999 and June 2000, the Implementation and Enforcement of HIPAA National State-Federal Conferences in August 1999 and 2000. Furthermore, both the Department of Labor and HCFA websites offer links to important State websites and other resources, facilitating coordination between the State and

federal regulators and the regulated community.

In conclusion, 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 plans and health insurance issuers, and the rights of those individuals that Congress intended to protect through the enactment of HIPAA.

Unified Analysis of Costs and Benefits - Department of Labor and Department of Health and Human Services

Introduction

Under the proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs.

A large body of 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. In addition to reduced mortality, benefits of effective wellness programs can include reduced absenteeism, improved productivity, and reduced medical costs. The requirements contained in the proposed 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.

Detailed Estimates

Estimation of the economic impacts of the four 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 undertook to consider the impacts fully and to develop estimates based on reasonable assumptions.

Based on a 1993 survey of employers by the Robert Wood Johnson Foundation, 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 and will be subject to the four requirements for bona fide wellness programs. This amounts to 32,000 plans covering 1.2 million participants. According to an industry survey by Hewitt Associates, just more than one-third as many plans vary benefit levels across similarly situated individuals as vary premiums. This amounts to 11,000 plans covering 415,000 participants. The Departments separately considered the effect of each of the four 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 1.4 million participants will be subject to the four requirements for bona fide wellness programs.

Limit on Dollar Amount -- Under the first requirement, any discount or surcharge, whether applicable to employee premiums or benefit levels, must not exceed a specified percentage of the total premium for employee-only coverage under the plan. The proposed regulations specify three alternative percentages: 10, 15, and 20. For purposes of this discussion, the Departments examine the midpoint of the three alternative percentages, 15 percent.

The Departments lack representative data on the magnitude of the discounts and

surcharges applied by affected plans today. One leading consultant practicing in this area believes that wellness incentive premium discounts ranged from about \$60 to about \$480 annually in 1998, averaging about \$240 that year. Expressed as a percentage of average total premium for employee-only coverage that year, this amounts to a range of about 3 percent to 23 percent and an average of about 11 percent. 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 discounts or surcharges they apply. It appears likely, however, that a sizeable minority of plans -- perhaps a few thousand plans covering a few hundred thousand participants -- will need to reduce the size of their discounts or surcharges in order to comply with the first requirement. The table below summarizes the Departments' assumptions regarding the size of discounts and surcharges at year 2000 levels, expressed in annual amounts.

The Departments considered the potential economic effects of requiring these plans to reduce the size of their discounts or surcharges. These effects are likely to include transfers of costs among plan sponsors and participants, as well as new economic costs and benefits.

Single employee total premium		\$2,448
Discount or Surcharge		
low	3%	\$70
average	11%	\$280
high	23%	\$560
Cap on discount or surcharge	15%	\$367

Transfers will arise as plans reduce discounts and surcharges. Plan sponsors can exercise substantial control over the size and direction of these transfers. Limiting the size of discounts and surcharges restricts only the differential treatment of participants who satisfy wellness

program standards and those who do not. It does not, for example, restrict plans sponsors' flexibility to determine the respective employer and employee shares of base premiums. Possible outcomes include a transfer 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 transfers that might derive from this requirement. The Departments' estimate assumes that (1) all discounts and surcharges 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. This implies that just more than one-fourth of plans with discounts or surcharges will be impacted by the cap, and that these plans' current discounts and surcharges exceed the cap by \$86 on average. The 9,600 affected plans could satisfy this requirement by reducing premiums for the 106,000 participants who do not qualify by \$86 annually, for an aggregate, ongoing annual transfer of approximately \$9 million. The Departments solicit comments on their assumptions and estimate, and would welcome information supportive of better estimates.

New economic costs and benefits may arise if changes in the size of discounts or surcharges 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 a discount of between \$368 and \$560 annually will not take part to obtain a discount of \$367. This might represent a net loss of economic welfare. This effect is expected to be negligible, however. Based on the assumptions specified above, just 248,000 participants now qualifying for discounts would be affected. Reductions in discounts are likely to average about \$86 annually, which amounts to \$7 per month or \$3 per biweekly pay period. Employee premiums are often deducted from pay pre-tax, so the after tax value of these discounts may be even smaller. Moreover, the proposed regulation caps only discounts and surcharges applied to similarly situated individuals in the context of a group health plans. It does not restrict plan sponsors from employing other motivational tools to encourage participation in wellness programs. According to the Hewitt survey, among 408 employers that offered incentives for participation in wellness programs, 24 percent offered awards or gifts and 62 percent varied life insurance premiums, while just 14 percent varied medical 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. Consider a plan that provides a very large discount for non-smokers. The very high employee premiums charged to smokers might discourage some from enrolling in the plan at all, and some of these might be uninsured as a result. It seems unlikely that the plan sponsor would respond to the first requirement of the proposed regulation by raising premiums drastically for all non-smokers, driving many out of the plan. Instead, the plan sponsor would reduce premiums for smokers, and more smokers would enroll. This would result in transfers to newly enrolled smokers from the plan sponsor (and

possibly from non-smokers if the plan sponsor makes other changes to compensation). But it would also result in net gains in economic welfare from reduced uninsurance.

The Departments believe that the net economic gains from prohibiting discounts and surcharges so large that they could discourage enrollment based on health factors outweigh any net losses that might derive from the negligible reduction of some employees' incentive to participate in wellness programs. Comments are solicited on the magnitude of these and any other effects and on the attendant costs and benefits.

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 transfer costs from plan sponsors to targeted individuals based on health factors. This requirement therefore is not expected to impose economic costs but might prompt transfers of costs from otherwise targeted individuals to their plans' sponsors (or to other participants in their plans if plan sponsors elect to pass these costs back evenly to all participants). Comments received by the Departments and available literature on employee wellness programs, however, suggest that existing wellness programs generally satisfy this requirement. The requirement therefore is not expected to compel plans to modify existing wellness programs. It is not expected to entail economic costs nor to prompt transfers. The Departments would appreciate comments on this conclusion and information on the types of existing wellness programs (if any) that would not satisfy requirement.

Uniform Availability -- The third requirement provides that rewards under the program must be available to all similarly situated individuals. In particular, the program must allow any individual for whom it would be unreasonably difficult due to a medical condition to satisfy the

initial program standard an 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. Based on the Hewitt survey, the Departments estimate that among employers that provide incentives for employees to participate in wellness programs, 18 percent require employees to achieve a low risk behavior to qualify for the incentive, 79 percent require a pledge of compliance, and 38 percent require participation in a program. (These numbers sum to more than 100 percent because wellness programs may apply more than one criterion.) Depending on the nature of the wellness program, it might be unreasonably difficult due to a medical condition 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 the third 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 transferred from individuals who would fail to satisfy programs' initial standards, but who will satisfy reasonable alternative standards once available (and thereby qualify for associated discounts), to plan sponsors (or to other participants in their plans if plan sponsors elect to pass these costs back evenly to all participants).

The Departments note that some plans that apply different discounts or surcharges to similarly situated individuals 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 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. The Departments reviewed Hewitt survey data on wellness program standards and criteria. Based on their review they estimate that 20,000 of the 35,000 potentially affected plans have initial wellness program standards that might be unreasonably difficult for some participants to satisfy due to a medical condition. Moreover, because alternatives need not be made available until they are sought by qualified plan participants, it might be possible for some these plans to go for years or even indefinitely without needing to make available an alternative standard. This could be particularly likely for small plans. The most common standards for wellness programs pertain to smoking, blood pressure, and cholesterol levels, according to the Hewitt Survey. Based on U.S. Centers for Disease Control and Management data on the incidence of certain health habits and conditions in the general population, the Departments estimate that among companies with 5 employees, about one-fourth probably employ no smokers, and about one-third probably employ no one with high blood pressure or cholesterol. Approximately 96 percent of all plans with potentially difficult initial wellness program standards have fewer than 100 participants.

How many participants might qualify for, seek, and ultimately satisfy alternative standards? The Departments lack sufficient data to estimate these counts with confidence. Rough estimates were developed as follows. The Departments examined the Hewitt survey of wellness program provisions and U.S. Centers for Disease Control and Prevention statistics on the incidence of certain health habits and conditions in the general population in order to discern how

wellness programs' initial standards might interact with plan participants' health habits and health status. Based on these data, it appears that as many as 29 percent of participants in plans with discounts or surcharges, or 394,000 individuals, might fail to satisfy wellness programs' initial standards. Of these, approximately 229,000 are in the 22,000 plans which apply standards that might be unreasonably difficult due to a medical condition for some plan participants to satisfy, the Departments estimate. The standards would in fact be unreasonably difficult to satisfy for some subset of these individuals -- 148,000 by the Departments' estimate. The Departments lack any basis to estimate how many of these will avail themselves of an alternative standard, or how many that do will succeed in satisfying that standard. To estimate the potential impact of this requirement, the Departments considered two assumptions: an upper bound assumption under which all 148,000 individuals seek and satisfy alternative standards, and an alternative assumption under which one-half (or 74,000) seek an alternative and one-half of those (37,000) satisfy it.

Where plans are required to make available reasonable alternative standards, what direct costs will they incur? 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. The Departments expect that plans sponsors will select alternatives that entail the minimum net costs (or, stated differently, the maximum net benefits) that are 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. The Departments also note that the number of plans with initial wellness program standards that might be unreasonably difficult for some participants to satisfy is probably small (having been estimated at 22,000, or 1 percent of all plans), as is the number of individuals who would take advantage of alternative standards (estimated at between 74,000 and 148,00, or between 0.1 percent and 0.2 percent of all participants).

It seems reasonable to presume that the net cost plan sponsors will incur in the provision of alternatives, including transfers as well as new economic costs and benefits, will not exceed the transfer cost of providing discounts (or waiving surcharges) for all plan participants who qualify for alternatives, which is estimated below at between \$9 million and \$37 million. 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 much smaller than this. The Departments have no basis for estimating the magnitude of the cost of providing alternative standards or of potential offsetting benefits, however, and therefore solicit comments from the public on this question.

What other economic costs and benefits might arise where alternative standards are made available? A large number of outcomes are possible. Consider a program that provides premium discounts for non-smokers.

It is possible that some individuals who would have quit smoking in order to qualify for a discount will nonetheless find it unreasonably difficult to quit and will obtain the discount while continuing to smoke by satisfying an alternative standard. This would represent a net loss of economic welfare from increased smoking.

On the other hand, consider individuals who, in the context of the initial program, are unable or unwilling to quit smoking. It seems likely that some of these individuals could quit with

appropriate assistance, and that some alternative standards provided by plan sponsors will provide such assistance. In such cases, a program which had the effect of shifting premium costs to smokers would be transformed into one that successfully reduced smoking. This would represent a net gain of economic welfare.

Which scenario is more likely? The Departments have no concrete basis for answering this question, and therefore solicit comments on it. However, the Departments note that plan sponsors will have strong motivation to identify and provide alternative standards that have positive net economic effects. They will be disinclined to provide alternatives that undermine their overall wellness program and 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 outweigh 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 high risk individuals improve their health habits and health.

What transfers of costs might derive from the availability of (and participants' satisfaction of) alternative standards? The transfers arising from this requirement may take the form of transfers to participants who satisfy new alternative wellness program standards from plan sponsors, to such participants from other participants, or some combination of these. The Departments estimated potential transfers as follows. Assuming average annual total premiums

for employee-only coverage of \$2,448,³ the maximum allowable discount of 15 percent amounts to \$367 per year. As noted earlier, discounts under existing wellness programs appear to average about 11 percent (or \$280 per year for a plan costing \$2,448), ranging from 3 percent (\$70) to 23 percent (\$560). Reducing all discounts greater than \$367 per year to that amount will reduce the average, perhaps to about \$251. Assuming that the 37,000 to 148,000 participants who satisfy alternative standards would not have satisfied the wellness programs' initial standards, the transfers attributable to their discounts and hence to this requirement would amount to between \$9 million and \$37 million. The Departments solicit comments on their assumptions and estimates regarding transfers that may derive from this requirement.

Disclosure of Alternatives' Availability -- The fourth requirement provides that plan materials describing wellness plan standards must disclose the availability of reasonable alternative standards. This requirement will affect the 37,000 plans that apply discounts or surcharges. These plans will incur economic costs to revise affected plan materials. The 37,000 to 148,000 participants who will succeed at satisfying these alternative standards will benefit from these disclosures. The disclosures need not specify what alternatives are available, and the regulation provides model language that can be used to satisfy this requirement. 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.

³Average level based on the Kaiser Family Foundation/Health Research and Education Trust *Survey of Employer-Sponsored Health benefits, 1999*, projected by the Departments to 2000 levels.

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

Employee benefit plans, Employee Retirement Income Security Act, Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 146

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

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54 -- PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

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

Par. 2. Section 54.9802-1 is amended by adding text to paragraph (f) to read as follows:

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

* * * * *

(f) Bona fide wellness programs -- (1) Definition. A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(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 [10/15/20] percent of the cost of employee-only coverage under the plan. For this purpose, 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. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or prevent disease.

For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

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

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

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

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: “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 4, 5, and 6 of paragraph (f)(2) of this section.

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

Example 1. (i) Facts. A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) Conclusion. In this Example 1, the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is \$2,400 (of which the employer pays \$1,800 per year and the employee pays \$600 per year). The plan implements a wellness program that offers a \$240 rebate on premiums to program enrollees.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, \$240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [\$240/\$360/\$480]. ($\$2,400 \times [10/15/20]\% = [\$240/\$360/\$480]$.)

Example 3. (i) Facts. A group health plan gives an annual premium discount of [10/15/20] 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 3, the program is not a bona fide wellness program. 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 for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative 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 4. (i) Facts. Same facts as Example 3, except 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), 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 is unable to achieve a cholesterol count under 200. The plan accommodates D by making the discount available to D, but only if D complies with a low-cholesterol diet.

(ii) Conclusion. In this Example 4, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 5. (i) Facts. A group health plan will waive the \$250 annual deductible (which is less than [10/15/20] 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 a reasonable alternative standard that is tailored to the individual’s 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, such as a dietary regimen.”

(ii) Conclusion. In this Example 5, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 6. (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 [10/15/20] 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 medical condition 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 E to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates E by requiring E to participate in a smoking cessation program to avoid the surcharge. E can avoid the surcharge for as long as E participates in the program, regardless of whether E stops smoking (as long as E continues to be addicted to nicotine).

(ii) Conclusion. In this Example 6, the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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.

* * * * *

Robert E. Wenzel
Deputy Commissioner of Internal Revenue

For the reasons set forth above, 29 CFR Part 2590 is proposed to be amended as follows:

PART 2590 [AMENDED] -- RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority: Secs. 107, 209, 505, 701-703, 711-713, and 731-734 of ERISA (29 U.S.C. 1027, 1059, 1135, 1171-1173, 1181-1183, and 1191-1194), as amended by HIPAA (Public Law 104-191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104-204, 110 Stat. 2935), and WHCRA (Public Law 105-277, 112 Stat. 2681-436), section 101(g)(4) of HIPAA, and Secretary of Labor's Order No. 1-87, 52 FR 13139, April 21, 1987.

2. **Section 2590.702 is proposed to be revised by adding text to paragraph (f) to read as follows:**

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) Bona fide wellness programs -- (1) Definition. A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(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 [10/15/20] percent of the cost of employee-only coverage under the plan. For this purpose, 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. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or prevent disease. For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iii) The reward under the program must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals for a period unless the program allows --

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

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: "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 4, 5, and 6 of paragraph (f)(2) of this section.

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

Example 1. (i) Facts. A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) Conclusion. In this Example 1, the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is \$2,400 (of which the employer pays \$1,800 per year and the employee pays \$600 per year). The plan implements a wellness program that offers a \$240 rebate on premiums to program enrollees.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, \$240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [\$240/\$360/\$480]. (\$2,400 x [10/15/20]% = [\$240/\$360/\$480].)

Example 3. (i) Facts. A group health plan gives an annual premium discount of [10/15/20] 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 3, the program is not a bona fide wellness program. 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 for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative 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 4. (i) Facts. Same facts as Example 3, except 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), 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 is unable to achieve a cholesterol count under 200. The plan accommodates D by making the discount available to D, but only if D complies with a low-cholesterol diet.

(ii) Conclusion. In this Example 4, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 5. (i) Facts. A group health plan will waive the \$250 annual deductible (which is less than [10/15/20] 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 a reasonable alternative standard that is tailored to the individual’s 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, such as a dietary regimen.”

(ii) Conclusion. In this Example 5, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 6. (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 [10/15/20] 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 E to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates E by requiring E to participate in a smoking cessation program to avoid the surcharge. E can avoid the surcharge for as long as E participates in the program, regardless of whether E stops smoking (as long as E continues to be addicted to nicotine).

(ii) Conclusion. In this Example 6, the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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.

* * * * *

Signed at Washington, DC this _____ day of _____, 2000.

Leslie B. Kramerich

*Assistant Secretary, Pension and Welfare Benefits Administration
U.S. Department of Labor*

For the reasons set forth above, we propose to amend 45 CFR Part 146 as follows:

**PART 146 [AMENDED] -- RULES AND REGULATIONS FOR HEALTH INSURANCE
PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS**

1. The authority citation for Part 146 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92 as amended by HIPAA (Public Law 104-191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104-204, 110 Stat. 2935), and WHCRA (Public Law 105-277, 112 Stat. 2681-436), and section 102(c)(4) of HIPAA.

2. We propose to revise § 146.121 by adding text to paragraph (f) to read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) Bona fide wellness programs -- (1) Definition. A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(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 [10/15/20] percent of the cost of employee-only coverage under the plan. For this purpose, 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. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or prevent disease. For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iii) The reward under the program must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals for a period unless the program allows --

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

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: "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 4, 5, and 6 of paragraph (f)(2) of this section.

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

Example 1. (i) Facts. A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) Conclusion. In this Example 1, the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is \$2,400 (of which the employer pays \$1,800 per year and the employee pays \$600 per year). The plan implements a wellness program that offers a \$240 rebate on premiums to program enrollees.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, \$240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [\$240/\$360/\$480]. (\$2,400 x [10/15/20]% = [\$240/\$360/\$480].)

Example 3. (i) Facts. A group health plan gives an annual premium discount of [10/15/20] 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 3, the program is not a bona fide wellness program. 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 for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative 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 4. (i) Facts. Same facts as Example 3, except 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), 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 is unable to achieve a cholesterol count under 200. The plan accommodates D by making the discount available to D, but only if D complies with a low-cholesterol diet.

(ii) Conclusion. In this Example 4, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 5. (i) Facts. A group health plan will waive the \$250 annual deductible (which is less than [10/15/20] 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 a reasonable alternative standard that is tailored to the individual’s 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, such as a dietary regimen.”

(ii) Conclusion. In this Example 5, the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits

on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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 6. (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 [10/15/20] 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 E to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates E by requiring E to participate in a smoking cessation program to avoid the surcharge. E can avoid the surcharge for as long as E participates in the program, regardless of whether E stops smoking (as long as E continues to be addicted to nicotine).

(ii) Conclusion. In this Example 6, the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, 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. Fourth, 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.

* * * * *

Dated: _____

Nancy-Ann Min DeParle,
Administrator, Health Care
Financing Administration.

Approved: _____

Donna E. Shalala,
Secretary.

BILLING CODE 4120-01-P