of small premium increases or benefit cuts.

The second requirement provides that wellness programs must be reasonably designed to promote health or prevent disease. Comments received by the Departments and available literature on employee wellness programs suggest that existing wellness programs generally satisfy this requirement. The requirement therefore is not expected to compel small plans to modify existing wellness programs.

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

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

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

In addition to the costs associated with new participants qualifying for discounts through alternative standards, small plans may also incur new economic costs by simply providing alternative standards. However, plans can satisfy this requirement by providing inexpensive alternative standards and have the flexibility to select whatever reasonable alternative standard is most desirable or cost effective. Plans not wishing to provide alternative standards also have the option of eliminating health status-based variation in employee premiums or waiving standards for individuals for whom the program standard is unreasonably difficult due to a medical condition or medically inadvisable to meet. The Departments expect that the economic cost to provide alternatives combined with the associated cost of granting discounts or waiving surcharges will not exceed the cost associated with granting discounts or waiving surcharges for all participants who qualify for an alternative. Those costs are estimated here at $0.5 million to $2 million, or about $160 to $650 per affected plan. Plans have the flexibility to pass back some or all of this cost to all participants in the form of small premium increases or benefit cuts.

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

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

The 2001 interim rules included an information collection request (ICR) related to the notice of the opportunity to enroll in a plan where coverage had been denied based on a health factor before the effective date of HIPAA. That ICR was approved under OMB control numbers 1210–0120 and 1545–1728, and was subsequently withdrawn from OMB inventory because the notice, if applicable, was to have been provided only once.

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

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

Finally, although neither the proposed or final regulations include a new information collection request, the regulations might have been interpreted to require a revision to an existing collection of information. Administrators of group health plans covered under Title I of ERISA are generally required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description (SPD) or Summary of Material Modifications (SMM) pursuant to sections 101(a) and 102(a) of ERISA and related regulations. The ICR related to the SPD and SMM is currently approved under OMB control number 1210–0039. While these materials may in some cases require revisions to comply with the final regulations, the associated burden is expected to be negligible, and is in fact already accounted for in connection with the SPD and SMM ICR by a burden estimation methodology that anticipates ongoing revisions. Therefore, any change to the existing information collection request arising from these final regulations is not substantive or material. Accordingly, no application for approval of a revision to the existing ICR has been made to OMB in connection with these final regulations.

Paperwork Reduction Act—Department of Health and Human Services

Collection of Information Requirements

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

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

Department regulations in 45 CFR 146.121(i)(4) require that if coverage has been denied to any individual because the sponsor of a self-funded nonfederal governmental plan has elected under 45 CFR Part 146 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance, the plan must: notify the individual that the plan will be coming into compliance; afford the individual an opportunity to enroll that continues for at least 30 days, specify the effective date of compliance; and inform the individual regarding any enrollment restrictions that may apply once the plan is in compliance.

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

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

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

Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Departments of Labor and of Health and Human Services, for purposes of the Department of the Treasury it has been determined that this Treasury decision is not a significant regulatory action. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Congressional Review Act

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

Unfunded Mandates Reform Act

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

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

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

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

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

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

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

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

HIPAA nondiscrimination provisions, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the portability, access, and renewability requirements of HIPAA, which include HIPAA's nondiscrimination requirements provisions that are the subject of this rulemaking.

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

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

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. To date, HHS has had occasion to enforce the HIPAA nondiscrimination provisions in only two States and currently enforces the nondiscrimination provisions in only one State in accordance with that State's specific request to do so. When exercising its responsibility to enforce provisions of HIPAA, HHS works cooperatively with the State for the purpose of addressing the State's concerns and avoiding conflicts with the exercise of State authority.[8] HHS has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HHS's procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HHS. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, DOL and HHS have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

For example, the Departments sought and received input from State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and the four U.S. territories. In most States the Insurance Commissioner is appointed by the Governor, in approximately 14 States the insurance commissioner is an elected official. Among other activities, it provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss, and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas, and in-depth consideration of insurance issues by regulators, industry representatives, and consumers. CMS and Department of Labor staff have attended the quarterly meetings consistently to listen to the concerns of the State Insurance Departments regarding HIPAA issues, including the nondiscrimination provisions. In addition to the general discussions, committee meetings and task groups, the NAIC sponsors the standing CMS/DOL meeting on HIPAA issues for members during the quarterly conferences. This meeting provides CMS and the Department of Labor with the opportunity to provide updates on regulations, bulletins, enforcement actions and outreach efforts regarding HIPAA.

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

The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information on HIPAA is shared among federal regulators, State regulators, and the regulated community. In particular, the Department of Labor has established a Health Benefits Education Campaign with more than 70 partners, including CMS, the NAIC and many business and consumer groups. CMS has sponsored conferences with the States—the Consumer Outreach and Advocacy conferences in March 1999 and June 2000 and the Implementation and Enforcement of HIPAA National State-federal Conferences in August 1999, 2000, 2001, 2002, and 2003. Furthermore, both the Department of Labor and CMS Web sites offer links to important State Web sites and other resources, facilitating coordination between the State and federal regulators and the regulated community.

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

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

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

Unified Analysis of Costs and Benefits

1. Introduction

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

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

These final regulations are needed to clarify and interpret the HIPAA nondiscrimination provisions under section 702 of ERISA, section 2702 of the PHS Act, and section 9802 of the Code, and to ensure that group health plans and group health insurance issuers do not discriminate against individual participants or beneficiaries based on any health factors with respect to health care coverage and premiums. The 2001 interim rules provided additional guidance to explain the application of the statute to benefits, to clarify the relationship between the HIPAA nondiscrimination provisions and the HIPAA preexisting condition exclusion limitations, to explain the applications of these provisions to premiums, to describe similarly situated individuals, to explain the application of the provisions to actively-at-work and nonconfinement clauses, to clarify that more favorable treatment of individuals with medical needs generally is permitted, and to describe plans' and issuers' obligations with respect to plan amendments.[9] These final regulations clarify the relationship between the source-of-injury rules and the timing of a diagnosis of a medical condition and add an example to illustrate how the benefits rules apply to the carryover feature of HRAs.

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

Because the 2001 interim rules and proposed regulations on wellness programs were originally issued as separate rulemaking actions, the Departments estimated their economic impacts separately. The costs and benefits of the statutory nondiscrimination provisions and the 2001 interim rules are again described separately from the wellness program provisions here, due to both differing baselines for the measurement of impact, and to reliance on different types of information and assumptions in the analyses.

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

2. Costs and Benefits of HIPAA's Nondiscrimination Provisions

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

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

[10] Individuals without health insurance are less likely to get preventive care and less likely to have a regular source of care. A lack of health insurance generally increases the likelihood that needed medical treatment will be forgone or delayed. Forgoing or delaying care increases the risk of adverse health outcomes. These adverse outcomes in turn generate higher medical costs, which are often shifted to public funding sources (and therefore to taxpayers) or to other payers. They also erode productivity and the quality of life. Improved access to affordable group health coverage for individuals with health problems under HIPAA's nondiscrimination provisions will lead to more insurance coverage, timelier and fuller medical care, better health outcomes, and improved productivity and quality of life. This is especially true for the individuals most affected by HIPAA's nondiscrimination provisions—those with adverse health conditions. Denied insurance, individuals in poorer health are more likely to suffer economic hardship, to forgo badly needed care for financial reasons, and to suffer adverse health outcomes as a result. For them, gaining insurance is more likely to mean gaining economic security, receiving timely, quality care, and living healthier, more productive lives. For an extensive discussion of the consequences of uninsurance, see: "The Uninsured and their Access to Health Care" (2004). *The Kaiser Commission on Medicaid and the Uninsured*, November; "Insuring America's Health", (2004). *Institute of Medicine*; "Health Policy and the Uninsured" (2004) edited by Catherine G. McLaughlin. Washington, DC: Urban Institute Press; Miller, Wilhelmine et al (2004) "Covering the Uninsured: What is it Worth," *Health Affairs*, March: w157–w167.

Inclusion of these newly-covered individuals, though, will increase both premiums and claims costs incurred by group health plans. Economic theory predicts that these costs will ultimately be shifted to all plan participants or employees, either through an increased share of insurance costs, or lowered compensation.[11] If the number of newly-covered individuals is small relative to the total number of plan participants and costs are distributed evenly, then the increased burden for each individual should be minimal. However, it is unclear how previously-covered individuals will respond to subsequent changes in their benefits package and if their response will have unforeseen economic costs.[12] The HIPAA nondiscrimination cost is estimated to be substantial. Annual group health plan costs average approximately $7,100 per-participant,[13] and it is likely that average costs would be higher for individuals who had been denied coverage due to health factors. Prior to HIPAA's enactment, less than one-tenth of one percent of employees, or roughly 120,000 in today's labor market, were denied employment-based coverage annually because of health factors.[14] A simple assessment suggests that the total cost of coverage for such employees could be $850 million. However, this estimated statutory transfer is small relative to the overall cost of employment-based health coverage. Group health plans will spend over $620 billion this year to cover approximately 174 million employees and their dependents.[15] Estimated costs under HIPAA's nondiscrimination provisions represent a very small fraction of one percent of total group health plan expenditures.

3. Costs and Benefits of Finalizing the 2001 Interim Rules

Prohibiting Discrimination

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

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

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

Clarifying Requirements

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

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

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

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

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

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

standards (assuming participation in the program is made available to all similarly situated individuals). Such programs are those under which none of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor or under which no reward is offered. The final regulations include the following list to illustrate the wide range of programs that would not have to satisfy any additional standards to comply with the nondiscrimination requirements:

- A program that reimburses all or part of the cost for memberships in a fitness center.
- A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.
- A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits.
- A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.
- A program that provides a reward to employees for attending a monthly health education seminar.

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

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

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

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

Reasonably-designed and at-least-once-per-year requirements. In the 2001 proposed rules, the second of four requirements was that the program must be reasonably designed to promote good health or prevent disease. The regulations also provided that a program did not meet this standard unless it gave individuals eligible for the program the opportunity to qualify for the reward at least once per year.

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

Comments also expressed other concerns about the "reasonably designed" requirement. While acknowledging that this standard provides significant flexibility, these comments were concerned that this flexible approach might also require substantial resources in evaluating all the facts and circumstances of a proposed program to determine whether it was reasonable in its design.

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