Workplace Wellness Programs: How Regulatory Flexibility Might Undermine Success

The Patient Protection and Affordable Care Act revised the law related to workplace wellness programs, which have become part of the nation’s broader health strategy. Health-contingent programs are required to be reasonably designed. However, the regulatory requirements are lax and might undermine program efficacy in terms of both health gains and financial return. I propose a method for the government to support a best-practices approach by considering an accreditation or certification process. Additionally I discuss the need for program evaluation and the potential for employers to be subject to litigation if programs are not carefully implemented. (Am J Public Health. 2014;104:2052–2056. doi:10.2105/AJPH.2014.302149)

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AS PART OF THE PATIENT

Protection and Affordable Care Act (ACA), Congress revised the law related to workplace wellness programs. The government supports these programs as a method to promote healthy behaviors, improve employees’ health knowledge and skills, and help employees get necessary health screenings, immunizations, and follow-up care. But there is a growing consensus that workplace health promotion programs could more widely prevent and control chronic disease and health care costs. Employer health initiatives are now considered part of the nation’s broader health strategy, but much debate ensues regarding efficacy, ethics, and costs. A directly related but thus far largely unexamined issue in this context is the requirement that health-contingent wellness programs must be “reasonably designed to promote health or prevent disease.” The government sought to provide employers flexibility by enacting this permissive standard rather than requiring a more rigorous approach, but this authorization could undermine the health and financial goals of health-contingent programs.

Work sites represent a targeted location to reach a large population of working-age adults within a potentially supportive setting. Employers typically expect health promotion programs to counteract trends of increasing health care costs and declining productivity, but they may also seek to improve worker satisfaction and reduce turnover and absenteeism. However, commentators expressed concern that workplace health programs focus on behavior change through a personal responsibility framework, with the potential to discriminate against employees based on health factors. To alleviate these concerns, I urge the adoption of workplace health programs that are practice- or evidence-based, equitably promote health or prevent disease, and are cost-effective. The focus of such a program goes beyond “wellness” to seek actual health gains to encourage the allocation of resources to benefit both employers and employees.

Congress delegated authority to 3 administrative agencies, the Departments of Treasury, Labor, and Health and Human Services (HHS; collectively “the Departments”), to pass regulations to carry out the intent of the legislation. In June 2013, the Departments finalized regulations that provided exceptions to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for nondiscriminatory wellness programs in group health coverage. This revised the 2006 regulations on the same topic and amended the agencies’ respective regulations on Pension Excise Taxes, the Employee Retirement Income Security Act (ERISA), and the Public Health Services Act. The regulations pertain to programs operated by group health plans, as well as group health insurance coverage beginning January 2014.

Workplace wellness programs are divided into 2 categories. First, “participatory wellness programs,” which make up the majority of programs, do not offer a reward or do not require an individual to satisfy a health-related standard to qualify for a reward. Examples of such programs include providing incentives to employees for attending health seminars or reimbursing employees for gym membership fees.

The second type is “health-contingent wellness programs.” These programs require an individual to satisfy a health-related standard to obtain a reward and can be activity-only or outcome-based. The reward in this context may be a positive incentive or negative penalty. Activity-only programs require the performance of an activity related to a health factor, such as walking or dieting, but do not require the achievement of a specific health outcome to obtain a reward. Outcome-based programs require the individual to attain or maintain a specific health outcome, such as not smoking or maintaining a healthy body mass index, to obtain a reward. Health-contingent programs must satisfy 5 distinct requirements to be lawful. The requirement analyzed herein is that they must be “reasonably designed to promote health or prevent disease.”

The Departments sought to clarify regulatory standards through the revised regulations. However, as explored here, the permissive reasonable design standard is not compatible with addressing the nation’s critical
health problems and increasing health care costs, and is additionally counter to businesses’ expectation to realize a cost savings by investing in them.\textsuperscript{16} The government’s role in this context could be better served by fostering a best-practices approach.\textsuperscript{9,17}

In this article, I evaluate outstanding issues related to a lack of a best practice requirement and argue for a more robust approach. Given that the Departments acknowledge that future modification to the regulations or subregulatory guidance may be necessary,\textsuperscript{3} I propose a method for the Departments to better support optimal programs by utilizing a certification or accreditation method to foster practice- and evidence-based programs. I discuss the need for program evaluation and potential for employers to be subject to litigation if programs are not carefully implemented.

**HEALTH CONTINGENT PROGRAMS AND REASONABLE DESIGN**

In the ACA, Congress defined the “reasonable design” requirement to mean that

the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a substitute for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.\textsuperscript{3}

The Departments’ regulations repeat this definition and add that the determination of whether a program is reasonably designed is “based on all the relevant facts and circumstances.”\textsuperscript{15} In accordance with the 2006 regulations, the Departments continued to support a flexible standard for the “reasonable design” requirement with the goal of fostering employer-based programs. However, health-contingent programs are still reported to be the least utilized type of incentive scheme so the flexible approach might not have been sufficient to encourage employers to invest in such programs.\textsuperscript{4}

Based solely on the language of the law, it is not immediately apparent what is required of employers or program providers to satisfy the reasonable design requirement.\textsuperscript{13,18} The law utilizes the same word, “reasonable,” to define the expectation of the requirement, as in that it must have a “reasonable chance” of improving health or preventing disease.\textsuperscript{15} Furthermore, the regulations provide examples of permissible outcomes to be achieved, such as maintaining a healthy body mass index, or achieving a total cholesterol count of 200 milligrams per deciliter, but they do not explain how to design the program reasonably to achieve these outcomes.\textsuperscript{4} Rather, the examples restate the definition, explaining that an appropriate plan

requires participation at a time and place that is not unreasonable, burdensome or impractical for participants and that is otherwise reasonably designed based on all the relevant facts and circumstances.\textsuperscript{4}

Although generally a low standard, the term “reasonable” is not self-explanatory because it is found in multiple areas in the law and has a different meanings in each context.\textsuperscript{19,20}

Because the regulatory language is not self-explanatory, the Departments’ construction can be determined from the preamble, or the language preceding the regulation, which states the basis and purpose of the regulation.\textsuperscript{21} The preamble is not binding law like the regulation itself,\textsuperscript{22} but it reveals how agencies perceive their regulations. The Departments explained that health-contingent wellness programs are “not required to be accredited or based on particular evidence-based standards.”\textsuperscript{4} Rather, employers are “encouraged” to consider best practices, but the underlying goal of the reasonable design standard is “to provide plans and issuers flexibility and encourage innovation.”\textsuperscript{4} The Departments then refer back to the original regulation and quote the 2006 preamble, stating the reasonable design standard was “intended to be an easy standard to satisfy,” and that there “does not need to be a scientific record that the method promotes wellness to satisfy this standard.”\textsuperscript{4} The Departments emphasized that experimentation and innovation were the goals of this standard.

The unquoted language from the portion of the 2006 preamble explaining the reasonable design standard is noteworthy. This states that the reasonable design requirement “prohibits bizarre, extreme, or illegal requirements in a wellness program,” and provides the example that “a plan or issuer could satisfy this standard by providing rewards to individuals who participated in a course of aromatherapy.”\textsuperscript{18} This statement is puzzling because obtaining a reward for the act of completing a class is a participatory wellness program, not a health-contingent program, and therefore does not need to abide by the reasonable design requirement. Putting that aside, aromatherapy is the use of essential oils for a diverse range of purposes, including alleviating stress, clearing sinuses, enhancing massage, and relieving nausea. Without disputing the benefits of aromatherapy itself, or that utilizing it may reduce stress, which contributes to poor health, there is no evidence to support the investment in aromatherapy classes for a workforce to meet the ACA’s goal of improving health or preventing disease. Nor would such a class seem to further the national objective of controlling chronic disease and health care spending.

The loose standard seems to indicate a tension between the need for effective solutions to the US health care crisis and the government’s interest in fostering employer implementation while not deterring employee participation. However, the goal of providing flexibility might undermine the potential for effective health-contingent programs. Perhaps recognizing this, state legislators have passed laws to encourage a more evidenced-based approach. For example, in New York, if a wellness program offers certain incentives, the program provider must be able to demonstrate that the “program can reasonably be expected to result in the overall good health and well being of the group” based on actuarial science.\textsuperscript{23} In Colorado, state law requires health-contingent programs to be “consistent with evidence-based research and best practices,” and that each plan must be accredited by a nationally recognized nonprofit accrediting entity.\textsuperscript{24}

As states continue to enact diverse requirements for workplace health programs, national employers and program providers will have to abide by different requirements. Federal floor requirements that foster best practices are preferable to meet the demands associated with preventable chronic disease throughout the whole country. Moving toward a practice- and evidence-based approach aligns with the goal of poignantly addressing
true health care issues rather than simply encouraging "wellness."

**Best Practices**

The Departments’ continued emphasis on experimentation might undermine efficacy because of a lack of focus on best practices and evaluation. In the preamble to the 2013 regulations, the Departments only “encouraged” the use of best practices to increase the likelihood of success and recommended the Guide to Community Preventive Services (Guide) by the Community Preventive Service Task Force (Task Force). The Task Force was established by HHS and is an independent panel, which is funded and administered by the Centers for Disease Control and Prevention.

The Guide provides evidence-based recommendations on community-based preventive services, programs, and policies. To develop each recommendation, a coordinated team systematically reviews scientific studies to determine efficacy and evaluates costs, cost-effectiveness, and applicability to various settings.

The Task Force recommended workplace wellness programs related to obesity, tobacco use, physical activity, and utilizing health risk assessments. For example, the Task Force recommends tobacco cessation programs that offer financial incentives in conjunction with cessation interventions such as support groups, self-help materials, telephone support, or workplace smoke-free policies.

The government’s role would be better served by establishing protocols to strengthen the requirements for employers and program operators to utilize practice- and evidenced-based programs. The federal government could require government certification, third-party accreditation, or offer incentives. These could be coupled with a provision to grandfather-in existing programs to minimize disruption and employer and provider opposition to the requirement. The increased requirements should be assessed from both a health outcome and financial perspective. This additional guidance could foster implementation by employers that lack knowledge of the evidence base by increasing confidence in efficacy from both perspectives.

First, the government could take advantage of the existing infrastructure and expertise of the Task Force and create a certification program for wellness programs. Congress could support a continuous systematic evaluation of programs by the Task Force to assemble a compilation of certified best practices from which employers and plan operators can choose. If it took this route, Congress would need to ensure a stable funding stream for the Task Force so it can continuously capture a new knowledge base to develop additional reviews and update existing recommendations. The Task Force could also be charged with providing technical assistance to providers. Strengthening this existing infrastructure to accelerate the use of best practices would build on established protocols and minimize the potential for duplicative efforts.

Second, the government could establish a third-party accreditation requirement for wellness programs. For example, 2 entities, the Utilization Review Accreditation Commission (URAC) and the National Committee for Quality Assurance (NCQA) are nationally recognized independent nonprofit organizations that promote health care quality through accreditation. They require providers to abide by certain standards, including employing evidence-based practices, to obtain accreditation of their workplace wellness programs. This evidence base is made up of a mix of best practices, scientific evidence, professional standards, and industry leader or expert opinion, depending on the program. Unlike the Task Force, however, URAC and NCQA do not evaluate program outcomes. This counsels in favor of the government still increasing support for the Task Force even if it chooses an accreditation method.

Third, businesses might urge government to alternatively offer incentives for the use of best practices or to work with the government on compliance with best practice protocols. Such incentives might take the form of tax deals that result in reduced income for the government but provide no additional guarantee of a successful outcome to warrant such a measure. Ultimately, the initial cost of implementing wellness programs should continue to be borne by businesses. Plan providers can compete in the marketplace for employers’ business by establishing the required accreditation or certification standards and by offering programs that can provide a return on an employer’s investment. This should protect employees by requiring a best-practices approach, but also motivate providers to create programs that produce a cost savings. Encouraging provider competition within a regulated marketplace would not be a new concept for the ACA, as it is one of the goals underlying the health insurance exchange.

**Evaluation**

Even if a wellness plan is based on identified best practices, this does not guarantee implementation, participation, or effectiveness of the intervention at a particular work site. There is no evaluation component built into the regulations and this would not result simply from requiring certification or accreditation, although the government could include some sort of evaluation standard within any new requirements. Regardless, it is in employers’ best interest to require the health plans that implement their wellness programs to evaluate them.

Program evaluation is considered an essential tool of public health to determine whether a program is implemented according to protocol, the extent the program reaches its goals, and the effectiveness of the strategies utilized. Evaluation would similarly benefit employers to determine the financial benefits of investing in such a program (e.g., changes in absenteeism, productivity, and performance) and to hold the plan operator accountable.

Several studies, including a comprehensive survey and case study conducted by the Rand Corporation at the request of HHS, found positive results in the programs evaluated. However, HHS warned that the literature “should be interpreted with caution as many of these programs were not evaluated with a rigorous approach.” In fact, Rand found that despite broad employer satisfaction, none of the 4 case studies and about half of employers with wellness programs formally evaluated the program impact. Employers should consider requiring providers to include an evaluation component to their programs as a practical tool to support and protect their financial investment.

**Enforcement**

The regulations explained that the determination of whether a
program is reasonably designed is “based on all the relevant facts and circumstances.” Which entity makes this determination and at what intervals, are questions pertaining to enforcement. There are several methods to enforce the workplace wellness provisions because the Departments and the states share enforcement authority. Although the Department of Treasury has the power to assess an excise tax on a taxpayer who fails to comply with the provisions, more likely methods stem from the other entities’ authority. The Departments anticipate state enforcement because states are the primary regulators of health insurance, and both HIPAA and the Public Health Services Act provide the states the authority to enforce the federal requirements. If, however, a state fails to enforce these laws or notifies HHS that it cannot or will not enforce federal law, HHS must act. In these circumstances, HHS works cooperatively with the state.

ERISA provides a final source of enforcement. The US Department of Labor has the authority to bring civil actions to enforce ERISA so it can enforce the wellness program provision through this authority. ERISA also provides a private right of action; it is thus important to note the possibility of litigation. This might not come to fruition but the law does permit participants and beneficiaries to sue both plans and issuers to enforce their rights under ERISA. ERISA fiduciaries are required to act solely in the interest of plan participants and beneficiaries for the purpose of providing benefits to them. Under ERISA, a participant or beneficiary may bring a civil action for administrator failures or to obtain equitable relief if an action violates ERISA or the plan. If a wellness program is challenged by a participant, courts will look to determine whether the provider acted in accordance with ERISA requirements, including the workplace wellness provisions. To date there has not been litigation over health-contingent programs; however, there has been litigation over participatory programs and attorneys warn that the ACA in general “may increase employers’ exposure to high-stakes ERISA class action litigation.” If this turns out to be accurate in the context of health-contingent programs, employers would want to minimize vulnerability during a lawsuit.

The preamble to the regulations specifically condones innovation through flexibility and experimentation, and Congress did not explicitly strengthen the “reasonable design” definition in response to the 2006 regulations. Furthermore, the preamble does not inherently conflict with the enabling legislation or the regulation so the Departments’ interpretation are generally entitled to deference by a court. In this case, the lenient reasonable design standard could be considered protective if litigation ensues because it would be easy for an employer to assert that the program had a reasonable chance to have some sort of health outcome, even if none is found. However, the revisions to the workplace wellness law were enacted into law as part of the ACA, which comprehensively reformed the national market for health care. The ACA also specifically states that workplace programs must “not be overly burdensome” or use “highly suspect” methods to attain goals. As employers are permitted to incentivize employees using penalties for nonparticipation in a health-contingent wellness program, an employee who has to pay a penalty might challenge a potentially suspect program in court, as has occurred for participatory programs. Reasonable minds could differ on what constitutes a “highly suspect” program if not based on proven methods to improve health or prevent disease. Therefore, it would be in an employer’s interest to rely on a best practice model both to ensure there are standards in place for the program and to minimize questions about the program’s design if litigation ensued.

Because of the risk of litigation, if the government utilizes an accreditation or certification process, it might consider providing a presumption against an ERISA violation if the employer and program operator abide by the accredited or certified program protocols. This might additionally assist in encouraging employers to adopt such plans.

CONCLUSIONS

Employers in the United States offer health insurance to their workforce through historical accident. Now that this is the largest source of health insurance for people in the United States, strategies to optimize this relationship are pivotal. Effective workplace wellness programs have the potential to improve worker health and reduce health care costs. Investment in a program that does not realize one of these outcomes is not only a waste of resources but also a missed opportunity.

The ACA’s focus on workplace health promotion programs might have revitalized interest in implementation, but without stronger legal requirements, it is a missed chance to ensure efficacy from both a health and financial perspective. Congress or the Departments should address the overly flexible standard especially in light of the fact that it did not prove to increase uptake of health-contingent plans. Reliance on best practices nurtures the investment made into worker health by utilizing effective programming.


13. 45 CRF 146.121(f).


15. 45 CRF 146.121(f).

16. 45 CFR 150.201.


37. 45 CFR 150.201.

38. 29 USC § 1132(a).


44. 42 USC § 300gg-4(c)(A).

