

A Response to Proposed Equal Employment Opportunity Commission Regulations on Employer-Sponsored Health, Safety, and Well-Being Initiatives

American College of Occupational and Environmental Medicine, American Council on Exercise, American Heart Association, Bravo Wellness, Health Enhancement Research Organization, HealthFitness, HealthPartners, Healthways, Interactive Health, Johnson & Johnson Services Inc., Optum, Performance pH, Population Health Alliance, StayWell, Truven Health Analytics

Objective: The aim of this study was to identify areas of consensus in response to proposed Equal Employment Opportunity Commission Americans with Disabilities Act of 1990 and Genetic Information Nondiscrimination Act of 2008 regulations on employer-sponsored health, safety, and well-being initiatives. **Methods:** The consensus process included review of existing and proposed regulations, identification of key areas where consensus is needed, and a methodical consensus-building process. **Results:** Stakeholders representing employees, employers, consulting organizations, and wellness providers reached consensus around five areas, including adequate privacy notice on how medical data are collected, used, and protected; effective, equitable use of inducements that influence participation in programs; observance of reasonable alternative standards; what constitutes reasonably designed programs; and the need for greater congruence between federal agency regulations. **Conclusion:** Employee health and well-being initiatives that are in accord with federal regulations are comprehensive, evidence-based, and are construed as voluntary by employees and regulators alike.

For the last 25 years, government regulations and legislation at the state and federal level have addressed individual treatment, data collection, and data handling related to wellness programs and incentives to encourage participation in such programs.^{1–5} The federal regulatory landscape and related court actions have created complicated and often conflicting regulations for those who wish to offer wellness programs, incentives, and health care benefits to employees and/or health plan eligible individuals (Fig. 1).

To further add to the list of conflicting regulations, the Equal Employment Opportunity Commission (EEOC) issued a proposed rule on April 20, 2015, that would amend the regulations and interpretive guidance in Title 1 of the Americans with

Disabilities Act of 1990 (ADA) that relates to employer wellness programs.⁶ By the end of the June 19 comment period, EEOC had received more than 300 comments representing varying degrees of support, concern, and disagreement. Rulemaking is the policy-making process for Executive and Independent agencies of the federal government. Agencies use this process to develop and issue Rules (also referred to as “regulations”). Federal agencies such as the EEOC often propose a regulation, also known as a Notice of Proposed Rulemaking (NPRM). Typically, these proposals are published in the *Federal Register*. During this phase of the rulemaking process, agencies accept public comments. In a typical case, an agency will allow 60 days for public comment. The submitted comments conveyed a lack of consensus on key issues related to employee privacy, accountability, incentives, and discrimination and thus are unlikely to offer clear direction for policy makers.

This document describes a consensus-building process undertaken by 15 organizations—representing the perspectives of employees, employers, occupational medicine, health plans, and wellness program providers—who came together to develop a consensus response to EEOC’s proposed rules relating to the ADA’s wellness provisions. Coincidental to the timeframe of this collaboration process, EEOC on October 30, 2015, issued a proposed rule to the Genetic Information Nondiscrimination Act of 2008 (GINA), as it relates to employer-sponsored wellness programs.⁷ Toward the end of our consensus-building process (December 15, 2015), members of the consensus organizations met with representatives of EEOC and federal legislators to share the results of this collaborative effort.

The goal of this joint statement is to disseminate the results of the consensus effort and to provide the perspectives derived from multisectorial thought leaders for other organizations that develop, deliver, and support employer sponsored health and well-being initiatives. To frame our areas of consensus relating to federal regulations, the discussion is first grounded in the participating organizations’ views on what characterizes a well-designed, evidence-based wellness program. We also

share an overview of the consensus development process as well as the final consensus statements developed as part of this process. It should be noted that this paper was developed during the timeframe in which EEOC was still seeking comments on the proposed GINA rule so the consensus statements that follow were not based on final regulations issued after January 1, 2016. Acknowledging this work represents a foundation for future consensus efforts, the paper ends with a call for additional action needed to inform future research, program design, and federal regulations.

WELLNESS PROGRAMS WITH A REASONABLE CHANCE OF IMPROVING HEALTH

A vital component of the wellness provisions described in the Affordable Care Act (ACA), particularly relating to protecting consumers, is that wellness programs must be “reasonably designed.”⁸ Extensive public comment and expert commentary has been devoted to whether and how the ACA ratified use of financial incentives in wellness programs is effective and/or fair. The recent revisions to ADA guidance from EEOC has spawned further debates about whether “health-contingent incentives” are discriminatory and/or whether “activity-based incentives” are coercive. Such debates seldom focus on whether the wellness programs accompanying incentives are, in total, fair and effective. Moreover, the existing legislation details definitions, rules, requirements, and examples relating to the allowable use of incentives.⁹ In contrast, a “reasonably designed” wellness program is simply defined as a program that “must have a reasonable chance of improving health or preventing disease and not be overly burdensome for individuals.”^{5,9}

If as both the ACA legislation and the EEOC guidance suggest, the use of financial incentives should occur within the context of a reasonably designed program, then it behooves those arguing for or against the use of incentives to provide clear guidance concerning what types of wellness programs do indeed have a “reasonable chance of improving health.”

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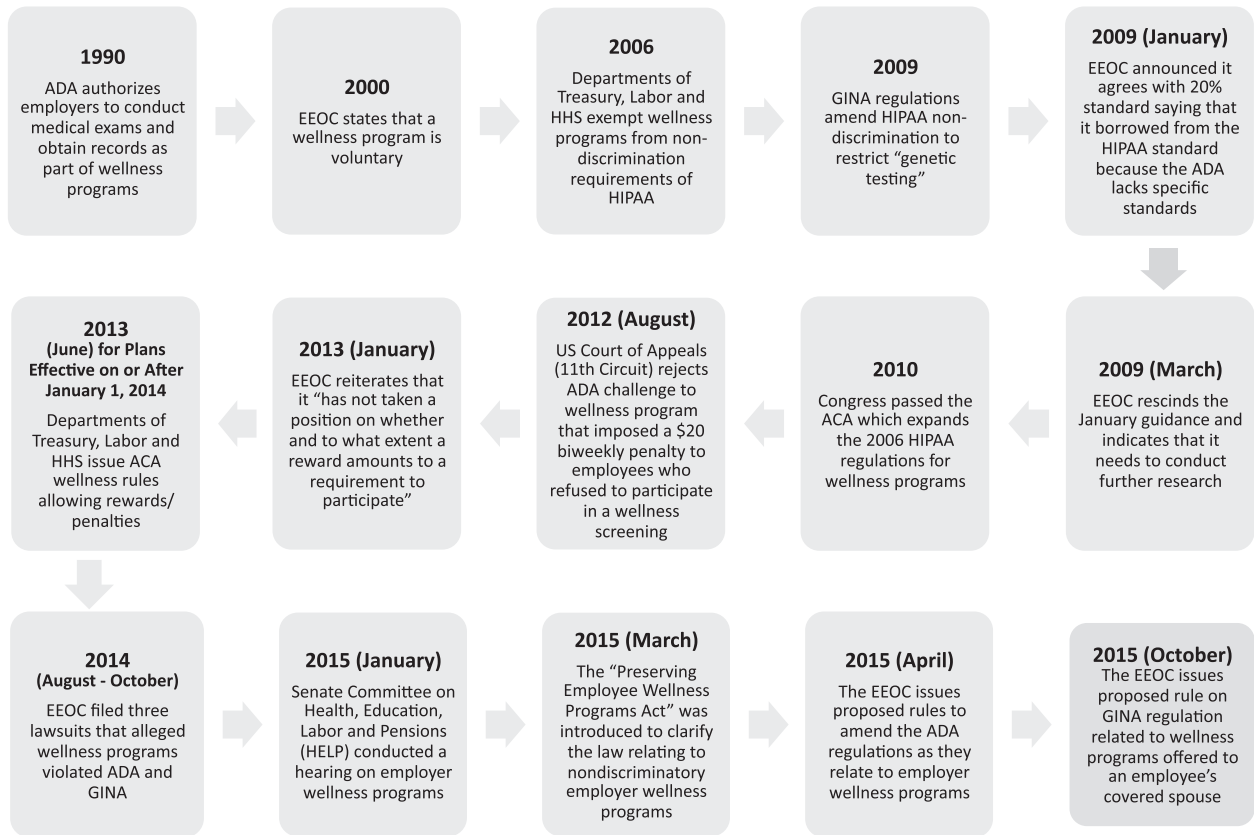


FIGURE 1. Regulations related to the provision of wellness programs by employers and group health plan providers.

Given the tenor of the comments by those who argue that the use of incentives is discriminatory or unfair, perhaps it should not go without saying: an incentive program is not a wellness program. There is scant evidence to suggest that the use of financial incentives alone provide a “reasonable chance of improving health.”¹⁰ However, there is considerable agreement that incentives are but one aspect of what constitutes a reasonably designed worksite wellness program.^{11–16}

Although the ACA and EEOC are virtually silent on the elements and components of a reasonably designed wellness program, there are several consensus papers and panels to draw from that are derived from evidence-based perspectives.^{13–15} Such programs are comprehensive and strategic, well aligned with an organization’s vision, and authentically supported by organizational leaders. Effective programs include health education, a supportive environment, continuous monitoring, and evaluation, and are integrated with related support services and resources.¹⁴ And, effective wellness programs sometimes include incentives, albeit using an integrated approach and rarely as a stand-alone behavior change strategy.¹⁰ In the context of the use of financial incentives, it may be as

important to describe what a reasonably designed wellness program is not. As Goetzel and colleagues¹² note, “random acts of wellness” are not effective in evoking and sustaining behavior changes. Similarly, off-the-shelf programs unassociated with a culture of health, intermittent screenings without tailored follow-up, or web-based strategies that lack a social component, while not uncommon, are also not generally considered effective.^{11,12}

The goals of reasonably designed programs that measurably improve health and prevent disease are, for nearly all organizations, directed at their whole population, not only individuals already ready to improve their health. Accordingly, reasonably designed programs traditionally follow a systematic process for determining population-wide goals and reviewing and revising strategies as needed.¹⁷ Specifically, Loeppke and colleagues outline five components of a program: planning, assessment, implementation, monitoring, and review.¹³ Within these design constructs, integration of strategy with organizational vision, evaluation of the current health status of the organization, gauging progress, and taking corrective action are the primary methods driving well-designed programs. Relative to these systematic

methods, the use of incentives is tactical within, and subordinate to, program design. This paper offers some consensus-based definitions relating to reasonably designed wellness programs. However, given the predominant focus on the equitable use of incentives by the EEOC, most of this paper addresses the consensus process used to respond to related issues such as privacy, voluntariness, and reasonable alternatives relating to incentives.

PROCESS FOR DEVELOPING CONSENSUS

Building on past collaborations^{13,18,19} and seeking to provide a consensus point of view, the Health Enhancement Research Organization (HERO), the Population Health Alliance (PHA), and the American Heart Association (AHA) convened a meeting on July 20, 2015, to determine where there is common ground on issues related to privacy notices and the issue of voluntariness for wellness programs. Representatives from the American College of Occupational and Environmental Medicine (ACOEM) participated as a member of the Consensus Group along with member companies from HERO, PHA, and the AHA’s CEO Roundtable (Table 1). The convening organizations represented the perspectives of a range of

TABLE 1. National Convening Meeting Participants

Individual	Organization
David Anderson [‡]	StayWell, HERO
Blaine Bos [‡]	Optum, HERO, PHA
Catherine Bresler [‡]	HealthFitness, HERO, PHA
Wayne Burton	American Express, ACOEM, HERO
Chris Calitz [†]	American Heart Association
Ralph Colao	HERO member
Michael Dermer [†]	Welltok, PHA
Shane Doucet	Williams & Jensen, PHA
Ed Framar [‡]	HealthFitness, HERO, PHA
Ron Goetzel	Truven Health Analytics, HERO
Jessica Grossmeier*	Health Enhancement Research Organization
John Harris [†]	Performance pH, HERO
Kurt Hobbs	Mayo Clinic, HERO, PHA
Warner Hudson	University of California—Los Angeles, ACOEM
Pamela Hymel [‡]	Disney, ACOEM
Fikry Isaac	Johnson & Johnson, HERO
Rebecca Kelly	University of Alabama, HERO
Lisa Langas	American Heart Association
Ron Loeppke [‡]	US Preventive Medicine, ACOEM
Robert McLellan	ACOEM member
Karen Moseley*	Health Enhancement Research Organization
Jerry Noyce*	Health Enhancement Research Organization
LaVaughn Palma-Davis	University of Michigan, HERO
Danielle Pere	American College of Preventive Medicine
Erica Pham	Kaiser Permanente, HERO
Nico Pronk [‡]	HealthPartners, HERO
Jim Pshock [†]	Bravo Wellness, HERO, PHA
Prad Prasoon	American Heart Association
Kyu Rhee [‡]	IBM Corporation, HERO
Tom Richards [‡]	American Council on Exercise/National Coalition for Promoting Physical Activity, HERO
Jane Ruppert [‡]	Interactive Health, HERO
Victoria Shapiro [‡]	UnitedHealth Group, PHA
Vicki Shepard*	Healthways, HERO, PHA
Tami Simon	Buck Consultants a Xerox Company
Laura Sol	American Heart Association
Alan Spiro	Accolade, HERO
Jay Sweeney [‡]	
James Tacci [‡]	Rochester Regional, ACOEM
Paul Terry*	Health Enhancement Research Organization
Joni Troester [‡]	University of Iowa, HERO
Michele Voss [‡]	Interactive Health, HERO
Laurie Whitsel* [†]	American Heart Association
Shelly Wolff [‡]	Towers Watson, HERO
Lilly Wyttenbach	Goldman Sachs, HERO
Charles Yarborough	CY Health Associates, ACOEM

ACOEM, American College of Occupational and Environmental Medicine; HERO, Health Enhancement Research Organization; PHA, Population Health Alliance.

*Convener.

[†]Workgroup leader.

[‡]Workgroup member.

stakeholders, including employees, employers, consulting organizations, and providers of employee wellness services who share the aim of protecting the rights of all employees while providing effective health promotion programs. Participants also represented a balance of those focused on consumer/employee protection, science, corporations and for-profit businesses, insurance, and providers.

The convening meeting began with an overview of the EEOC regulations and proposed rules as well as a summary of the public comments that were submitted to EEOC on the ADA proposed rule.⁶

Five key areas of potential concern were identified:

1. Whether consumers are receiving adequate privacy notice about how medical data are collected, used, and protected⁶ [21659, 21663; Section 1630.14(d)(2)(iv)]
2. How the use of rewards or penalties influences employee perceptions about the voluntary nature of wellness programs⁶ [21659, 21663; Section 1630.14(d)(3)]
3. What are “reasonable alternative standards”⁶ [21659, 21668]

4. What constitutes a “reasonably designed program”⁶ [21659, 21663, 21668] and
5. Whether or not there is adequate congruence between EEOC regulations compared with regulations developed by the Departments of Health and Human Services, Labor, and the Treasury (the Tri-Agencies).

After the meeting, five workgroups formed to continue discussions in these areas and draft initial consensus statements, which were consolidated into a single document and circulated among workgroup

TABLE 2. Organizations Endorsing National Consensus Statement

American College of Occupational and Environmental Medicine
American Council on Exercise
American Heart Association
Bravo Wellness
Health Enhancement Research Organization
HealthFitness, A Trustmark Company
HealthPartners
Healthways
Interactive Health
Johnson & Johnson Services, Inc.
Optum
Performance pH
Population Health Alliance
StayWell
Truven Health Analytics

members until they reached agreement on a final set of statements. Subsequent reviews were provided to all convening meeting participants and additional organizations that expressed interest in the work. During the final rounds of review, we invited organizations to indicate their desire to be listed among the organizations who endorsed the consensus statements in this document (Table 2).

INITIAL AREAS OF CONSENSUS

In addition to establishing an organizing framework for consensus development during its initial convening session, the group also reached consensus on several important areas. Areas where participants quickly came to consensus included:

1. Recognition that formal guidance from EEOC regarding wellness and incentive programs as they relate to the ADA and GINA is needed and appreciated, but that such guidance should be consistent with other regulations (eg, Tri-agency regulations) wherever possible;
2. Agreement that retaliation or adverse action against nonparticipants in wellness programs (including denial of coverage, termination of employment, or requiring 100% payment of medical care premiums) should be prohibited;
3. Agreement that clear notice that programs are voluntary is needed, as well as clear notice regarding what personal health information will be gathered, who will have access to it, how it will be used, and how it will be protected;
4. Agreement that protected health information should not be sold or provided for commercial purposes;
5. Agreement that final ADA and GINA regulations should be released jointly, should not be enforced retroactively,

and a reasonable time period for employers and health plans to modify program designs is needed; and

6. Agreement that final regulations from EEOC regarding ADA and GINA should be consistent to create common standards for wellness programs and incentives.

Consensus was also reached on the following general aspects of the proposed EEOC regulations:

1. When designed according to best practice design dimensions and evidence-based standards (see section on *Consensus on Definition of Reasonably Designed Programs*), employer wellness programs have the potential to benefit employees and their employers.
2. Effective regulations clarify the rules without making it difficult or burdensome for employees and their family members (if applicable) to participate in, and benefit from, wellness programs. At the same time, the delivery of wellness programs must not become so complicated for employers that organizations stop providing programs or significantly limit the wellness benefits offered.

Consensus on Needed Congruence Between EEOC and Tri-Agency Regulations

The Consensus Group agrees that EEOC has a statutory responsibility to protect employees through both the ADA and GINA. However, policy guidance and the attendant rules and regulatory inconsistencies that exist between the ADA, GINA, and the Tri-Agency guidance complicate the ability to deliver wellness programs in a way that benefits employees and employers. The Consensus Group drafted the statements that follow, and met with EEOC commissioners, with the hope that the final ADA and GINA regulations would be addressed and implemented simultaneously in order to provide clear and consistent guidance on whether, when, and how the use of health and/or genetic information is allowable and legal.

Areas of concern that relate to potential regulatory inconsistencies included:

1. Protection for low-income employees: In the proposed rule on the ADA, the EEOC requested comments on whether additional protections are needed for low-income employees.⁶ The Consensus Group feels that concern for low-wage workers is already addressed through various provisions of the Affordable Care Act (ACA)⁵—including the 30%/50% limitation on

incentive amounts, the 9.56% affordability rule, and provisions related to reasonable alternative standards. Therefore, further intervention by the EEOC is not required.

2. Inducements to participate in programs: The EEOC should avoid contributing to a fragmented regulatory environment that could ultimately harm employees if administratively complex and costly regulations result in organizations that sponsor wellness programs reducing or eliminating access to wellness benefits.

Consensus on Influence of Incentives on the Voluntary Nature of Programs

Consistent with the guidance language already issued by EEOC, a clearer definition concerning voluntariness for wellness programs would be a welcome contribution (The latest proposed EEOC rule on GINA uses the term “inducements” instead of “incentives.” The authors choose to use the term incentives, as it is consistent with the ADA-proposed rules.). The Consensus Group is receptive to EEOC guidance that clearly defines a voluntariness standard within the context of EEOC regulations.

With regard to EEOC regulations about the voluntary nature of programs, the Consensus Group reached agreement in several important areas:

1. Participation in a wellness program is considered voluntary if it complies with the parameters already established by ACA regulations,⁹ which state that (1) any reward must be available to all similarly situated individuals; (2) the program must give eligible individuals the opportunity to qualify for the reward at least once a year; (3) the program must be reasonably designed to promote health and prevent disease whether activity only or outcome-based; (4) the reward must not exceed 30% of the cost of coverage (or 50% for programs designed to prevent or reduce tobacco use); and (5) the program must provide a reasonable alternative standard to an individual who informs the plan that it is unreasonably difficult or medically inadvisable for him or her to achieve the standard for health reasons. Health contingent inducements must provide an alternative standard even in the absence of a medical issue.
2. The EEOC proposed rule limits the valued amount of incentives to 30% of the cost of “employee-only coverage” and provides an example of the calculation.⁶ The Consensus Group believes that ADA regulations⁶ should be consistent with the proposed rule on GINA⁷ by limiting the total inducement

to the employee and spouse to 30% of the total annual cost of coverage for the plan in which the employee and any dependents are enrolled, as long as the spouse is eligible to participate in the wellness program.

3. Related to the statement above, limiting the cost-of-coverage calculation to only employees could result in (1) employers reducing or eliminating incentives for other family members; or (2) reducing the incentives available to employees if employers wish to provide incentives to other family members and have to allocate budgets accordingly.
4. EEOC proposes to count nonfinancial incentives toward limits on the value of incentives.⁶ The Consensus Group is concerned that including the cost of nonfinancial incentives in the legal limit could cause employers to reduce or eliminate their use. These types of incentives are often valuable in establishing a culture of health and including them in the calculation could undermine that effort if employers decide not to use nonfinancial incentives. In addition, the Consensus Group is concerned about the significant administrative burden associated with accounting for the value of nonfinancial incentives in the calculation, as many of these incentives are de minimis in value. It is the opinion of the Consensus Group that de minimis incentives, such as movie tickets, water bottles, etc, should not be counted toward the value limit when calculating the legally permitted value of incentives.
5. Another concern related to voluntariness is how the proposed regulations create different opportunities and disadvantages for employees who are part of an employer-sponsored health plan versus those who are provided wellness programs outside a health plan. More specifically:
 - Under ACA, health-contingent incentive limits are in place for employees in a wellness program that is part of an employer-sponsored health plan, with limits capped at 30% and 50% of the cost of a single health plan or if the spouse is included in the wellness program, 30% and 50% of an employee/spouse or family plan.⁹ Although health-contingent incentives are not common outside an employer-sponsored health plan, they do exist. For example, some programs allow individuals to earn points by completing various health challenges and activities or by entering their recent biometric screening results. These points can then be used for things

such as purchasing merchandise in an online reward mall. Such limits are not in place for programs that are solely participation-based or for employees who are not in an employer-sponsored health plan, and because they do not have coverage, there is nothing on which to base the calculation of 30% and 50%.

- EEOC regulations should clarify that employers will not be accused of wage discrimination when incentive designs comply with established Health Information Portability and Accountability Act (HIPAA)² and ACA rules. This allows, but does not require, employees outside of an employer-sponsored health plan to receive incentives similar to employees inside an employer-sponsored health plan, and employers may provide these incentives while complying with existing laws.

ADDITIONAL CONSIDERATIONS RELATING TO VOLUNTARINESS STANDARDS

ACA regulations allow the total value amount of incentives to reach 50% of the total cost of coverage if the program is directed at tobacco use.⁵ EEOC proposes to limit the total value amount of all incentives to 30% if the determination of smoking status is determined by biological testing.⁶ Further, EEOC proposes that the value of participation-based incentives be included toward the financial limit on the amount of incentives, whereas ACA regulations stipulate incentive limits only for health-contingent incentive designs. These inconsistencies between ACA and EEOC's proposed rule on incentive limits raise a concern that the inclusion of participatory programs in the cost-of-coverage calculation could cause employers to shift more of their incentive dollars to health-contingent programs (ie, requiring participants to achieve a specific health outcome in order to receive an incentive) and away from participation-based incentive designs.

There was not consensus regarding application of the 50% limit to tobacco use or capping the limit at 30%. Some employers use biological testing to determine smoking status. These employers maintain that enabling individuals to earn incentives based on self-reporting of smoking status without any attestation may encourage employees to state they are nonsmokers even if that is not the case.

Although there will likely always be variation between companies concerning the best method for determining employee smoking status, to date, most

employers use personal attestation and some indicate that a falsified statement may be subject to disciplinary action. For some, this relates to the weaknesses with biomarker testing. Specifically, if the cut-off level for a positive test is not set high enough, employees exposed to environmental tobacco smoke might test positive. For some tobacco product users, a negative test can occur if they abstain from using the product for more than 4 days. Similarly, a biomarker test cannot distinguish between a cigarette smoker, an e-cigarette user, or someone who is using other tobacco products or FDA-approved nicotine replacement therapy.

There was consensus that if a 50% incentive limit is applied, it should be complemented with robust smoking cessation tools, a tobacco-free environment at the workplace, and a comprehensive cessation program wherein employees are allowed to go through a cessation program numerous times to overcome their nicotine addiction in accordance with clinical guidelines. This approach to smoking cessation interventions is referenced in Department of Labor guidance,²⁰ in a recently published consensus paper on e-cigarette policies for employers,¹⁸ and by the CDC.²¹

Consensus on Definition of "Reasonable Alternative Standards"

The EEOC-proposed rule on the ADA⁶ requires an alternative way to qualify for incentives that is based on health-contingent or participatory goals, even in the absence of a medical issue. The Consensus Group considered the implications of this regulation on health plan participants and health plan nonparticipants.

A proposed rule in the ADA⁶ extends the reasonable alternative standards that currently exist under the ACA for health-contingent incentives to also be required for participatory incentives that impact premium contributions and/or benefit plan design. The Consensus Group agrees on the following statements with regard to this proposal:

1. Participatory incentives already require alternatives when participation would be medically inadvisable or unreasonably difficult due to a medical issue. It is also already necessary to offer alternatives when the participation requirement for an incentive is overly burdensome for an individual to complete. Examples include group exercise classes with inflexible hours or screening requirements to close a "gap in care" without giving a reasonable amount of time to do so.

2. Program providers should not be required to provide unlimited time for participants to request an alternative or to complete the alternative.
3. Alternatives to alternatives should be required when an individual's personal physician supports the request for one, and if an employee's medical status changes during the course of the program year, they should be allowed to switch to an alternative standard.
4. Providers should allow a reasonable amount of time to request an alternative and adequate time to complete the alternative offered.
5. Employers that satisfy the existing ACA regulations on the reasonable alternative standard should be considered compliant with EEOC nondiscrimination rules, regardless of whether or not the individual is participating in an employer-sponsored health plan. However, an employer should not have to pay for an individual's medical visit in order to receive an alternative standard if an individual is not a member of the health plan.
 - The EEOC-proposed rule on the ADA requested input regarding a proposal to allow anyone "under the care of a health professional" to earn all potential incentives by providing a waiver from a health care provider, whether or not an individual participates in the employer-sponsored health plan.⁶ The Consensus Group believes that an individual should not be able to receive all possible incentives simply because he or she is under the care of a medical professional. However, as required by ACA regulations, an individual's personal physician should always be able to determine when a specific health-contingent goal should be waived or modified for the patient. The personal physician should also be able to request an alternative to any participatory requirement for wellness program incentives. In addition, the Consensus Group agrees that alternatives do not need to be provided for small or de minimus incentives (such as t-shirts and water bottles) that are offered.

Consensus on Definition of "Reasonably Designed Programs"

The Consensus Group observed that wellness programs could be designed in a number of different ways. ACA defines reasonably designed programs as those that "have a reasonable chance of improving health or preventing disease in participating individuals, are not overly burdensome, are not a subterfuge for discrimination based on

a health factor, and are not highly suspect in the method chosen to promote health or prevent disease."⁹ An ACA FAQ document, issued in April 2015, further defined minimum requirements for a reasonably designed program to include offering a health assessment with a summary of health risks and an action plan for the individual completing it.²²

In order for a wellness program design to be considered credible and effective, it must be informed by evidence of effectiveness. Program design must be guided by the most current level of scientific research available concerning best practices while also allowing space for employers to experiment or innovate with new strategies that support employee health and access to affordable health care, furthering our understanding of what works best.

On the basis of the level of evidence available during these discussions, the Consensus Group believes that reasonably designed programs are composed of *all* of the following minimum elements or standards:

- An assessment of health risks (whether through a health risk assessment or a biometric screening) with feedback that provides employees with a summary of their health risks and suggested activities to improve their health.
- Provision of innovative health promotion programs, approaches, or initiatives that are informed by relevant expert panels, consensus statements, peer-reviewed research studies, and systematic reviews. This includes programs that are delivered individually, in groups, in person, or enabled by technology. Examples include programs characterized in a consensus statement offering guidance to employers on reasonably designed, employer-sponsored wellness programs,¹³ the Community Guide based on recommendations from the Community Preventive Services Task Force,²³ and the Cochrane Reviews.²⁴
- None of the above elements on their own constitute a reasonably designed program.

Consensus on Privacy Notice

The Consensus Group also reached agreement on the use of privacy notices for a medical inquiry and collection of personal health information within a health risk assessment or biometric screening as part of a wellness program offered, both within and outside of a group health care plan.

ACA and HIPAA regulations permit collection of health-related information. The Consensus Group believes such data collection should be permitted for

employees in wellness programs who are part of an employer-sponsored health plan, as well as for employees who are not part of such a plan, if privacy is assured and HIPAA protections are utilized and as long as there is evidence that the information collected is effective in determining current and future risk and helpful for tailoring wellness programs to the needs of employees.

The Consensus Group also supports the requirement of a privacy notice to inform employees about how their personal health information will be used, stored, shared, and protected. The Consensus Group understands that privacy protections apply to wellness programs outside of the EEOC proposed rules. In particular, HIPAA applies to group health plan wellness programs and requires that the plans send privacy notices to participants. With regard to the privacy notice, and other privacy notices provided by wellness programs, the Consensus Group believes the following characteristics would generally align with HIPAA and be helpful to participants:

1. The privacy notice can be provided electronically or as a hardcopy. A hardcopy version must be provided if requested by the employee.
2. The privacy notice must make a clear, consumer-friendly statement about how the data will be used, shared, sold and/or protected. It should be written at the average reading literacy level for US adults.
3. A privacy notice should be provided in *all* situations wherein personal health information is being collected.
4. EEOC should work in collaboration with other federal agencies, such as the Departments of HHS, Labor, and Treasury, as well as with employers, vendor suppliers, and consumer groups to develop sample privacy notices that are easily understood by employees and can be adopted or adapted by employers, health care plans, and wellness vendors.
5. When electronic communication is used to disclose privacy notices, employees should be asked to actively note that they have read the privacy notice before providing their personal health information.
6. HERO, PHA, and AHA would be willing to work with a multi-stakeholder group, to develop a transparent set of principles and ethical standards for the industry around the use of personal health information within workplace wellness programs that reassures employees about the safety of their data.
7. Consistent with the proposed EEOC rule on GINA,⁷ the Consensus Group

is fundamentally opposed to the selling of personal health information that is collected as part of a biometric screening or health risk assessment within a workplace wellness program. This does not necessarily apply to de-identified or aggregate data that may be used for research or program evaluation purposes.

8. Protecting privacy and preventing de-identified or aggregate data from being errantly or inadvertently re-identified requires quality control of data management and procedural/internal corporate governance. Many large accounting firms, law firms, health care consultants, and IT consultants can provide this, as they specialize in health care information-related audits.
9. The Consensus Group encourages the development of an educational campaign through public/private collaboration to help consumers understand their rights regarding the use and safeguarding of their personal health information.

DISCUSSION

Behavioral economics is an emerging field to the science that has informed public health and worksite health promotion. Evidence to date from behavioral economics researchers indicates that financial incentives can be effective in overcoming the inertia that has so many individuals acquiescing to unhealthy habits. Yet, recent research indicates that incentive design using only modest premium adjustment associated with personal improvement in challenging health issues such as obesity may not be adequate for changing behavior, especially in a sustained way, and that other approaches should be explored.²⁵ According to Kevin Volpp, a leading scientist in the study of use of behavioral economics in health and wellness programs, many cases of how financial incentives are used in wellness programs and recent legislation represents a relatively uncommon example where “policy has run ahead of science” because the policies put in place go beyond what has been adequately tested (e-mail communication between Kevin Volpp and Paul Terry, January 3, 2016). Although it may be true that policy has run ahead of science, the health care community is committed to use of financial incentives as one of the key levers that needs to be pulled to drive behavior change. As a result, it is critical that the health care community is given the opportunity to test the most effective incentive designs for specific health behaviors. Clarity and consistency in the regulations are necessary in order to support the experimentation that is necessary to determine how to optimize financial

incentives. In many respects, the ACA rules ratifying HIPAA protections and enabling greater use of financial incentives have led to a country-wide natural experiment. Nevertheless, answering fundamental questions about the effectiveness as well as the fairness of the use of financial incentives will require a rigorous and systematic scientific approach.

Experiential evidence from the past several years, during which the use of financial incentives has increased significantly across the nation, indicates that the context in which incentives are used can dramatically mitigate the receptivity to and effectiveness of incentives. Although considerable evidence shows how incentives can be effectively used in the context of a well-designed wellness program,^{12,26} less is known about environmental, demographic, and situational factors that mitigate the effectiveness of incentives. For example, research into population health disparities offers compelling evidence that susceptibility to disease is associated with race and class. Somewhat related to this, one interesting study of the varying effects of different incentives approaches found that the lottery method was particularly effective in attracting low-income participants.²⁷ More such research is needed to demonstrate whether financial incentives have a differential impact on lower income employees and/or other variables such as generational, ethnic, or geographic differences.

There is consensus among experts that wellness programs need to be tailored according to the goals of an organization and the needs of their employees.¹² More research is needed showing the effects of select wellness program components, including incentives, according to the types of workers and the types of industries in which these components are used. For example, one study showed that older workers were less motivated by incentives and that offering a variety of social supports for wellness programs actually diminished the impact of incentives.¹⁷ It is also likely the social norms within a work group will mitigate the effectiveness of incentives. Incentives that may be considered draconian in one workplace, such as a university, may well be deemed as “par for the course” in another workplace, such as a financial services organization. Studies concerning the role of culture, leadership, and norms are needed, given it is unlikely that there will ever be a uniformly effective approach to the use of incentives in wellness. In addition to the effects that workplace culture can have on the use of incentives, the role a company plays in advancing the health of their communities may also influence the effectiveness of an organization’s wellness strategies.²⁸

How to activate consumers to improve their health and be well informed as health care consumers has been the subject of extensive research.²⁹ Considerably less research is available, however, about what role incentives can effectively play in the ongoing and, for many, arduous process of chronic condition management. ACA and EEOC indicate that a financial incentive ceiling of 30% (and 50% for smokers’) health insurance premium differentials has been set; still, little is known about how these levels may differentially impact lower versus higher wage earners and their readiness, willingness, or ability to change health behaviors or manage a chronic condition. With respect to a related EEOC guidance issue, how should a de minimis incentive methodology be defined and delivered that effectively supports wellness activities? Additional research is needed to understand the differential impacts various levels of rewards, such as t-shirts, mugs, or gift certificates, have on differently situated employees and within the range of health issues they present with.

Outcomes-based incentives, a common term used today, was once labeled “risk rating.” The idea that people with unhealthy lifestyles should bear more responsibility for the cost of health insurance is not new.³⁰ Moreover, that individuals ought to be held more accountable for poor choices regardless of their life circumstances is an idea that will assuredly continue to be proffered for years to come and across a number of ideological perspectives. A core tenet of health promotion is that it is a combination of voluntary actions and learning experiences. Perhaps the most difficult challenge for researchers and policy makers alike is that of garnering empirical evidence that can lucidly inform a “voluntariness standard.” With rigorous research that addresses the questions about the differential effects of incentives raised here, it will be more likely that policy decisions can be as informed by evidence as by ideology.

CONCLUSION

Many organizations representing diverse perspectives worked together to identify points of agreement in response to the proposed EEOC regulations. Through a collaborative series of focused consensus-building dialogs, these groups have identified many areas of common agreement. This consensus represents a significant step forward to provide the EEOC with requested guidance on the final regulations. The organizations eagerly await the final rule and emphasize their desire that ADA and GINA regulations align with existing Tri-Agency regulations, that ADA and GINA final regulations be released simultaneously, and that

final regulations *not* be made effective retroactively. In addition, the collaborating organizations are eager to work with EEOC, as necessary, to clarify these areas of consensus.

It is difficult to discuss various components of the EEOC guidelines in isolation. Therefore, the Consensus Group recommends that more dialogs occur via an objective convening party (eg, National Academy of Medicine, HERO, PHA, AHA, ACOEM, Bipartisan Policy Center, or others) with representation from all parties affected by federal regulations. The intent would be to reach consensus on regulations from the various federal agencies that meet the objectives of consumer advocates, scientists, health care providers, and employers.

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