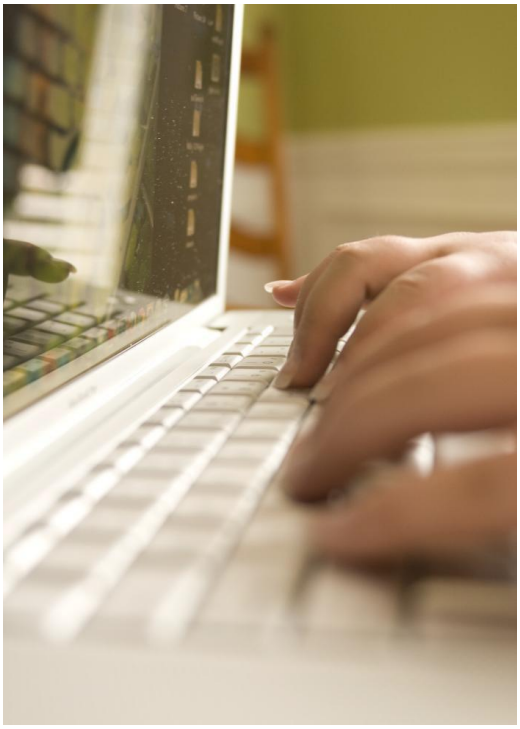


A Consensus Response to EEOC Proposed ADA and GINA Regulations on Employer-Sponsored Wellness Programs

February 5, 2016

Executive Summary

On April 20, 2015, the Equal Employment Opportunity Commission (EEOC) issued a proposed rule on the Americans with Disabilities Act (ADA) as it relates to employer wellness programs, and created an opportunity for the public to comment. Over 300 comments were received, representing varying degrees of support, concern and disagreement expressed by respondents on the proposed rule. Since then numerous organizations—representing the perspectives of consumers, employees, employers, occupational medicine, health plans, and wellness program providers—collaborated to develop a consensus response to the EEOC's proposed rule regarding the ADA, in order to provide clearer feedback to the EEOC to guide development of the final regulations. On October 30, 2015, the EEOC issued a proposed rule on the Genetic Information Nondiscrimination Act (GINA) as it relates to employer wellness programs, inviting comments until December 29, 2015, which was extended until January 28, 2016. This paper was developed, primarily focusing on the ADA proposed rule but recognizes the important relationship between the ADA and GINA proposed rules. Its purpose is to provide policy makers with a consensus-driven point of reference for the agency as it finalizes the proposed regulations in both areas.

A large group of convening individuals and organizations quickly reached consensus on several important areas including:

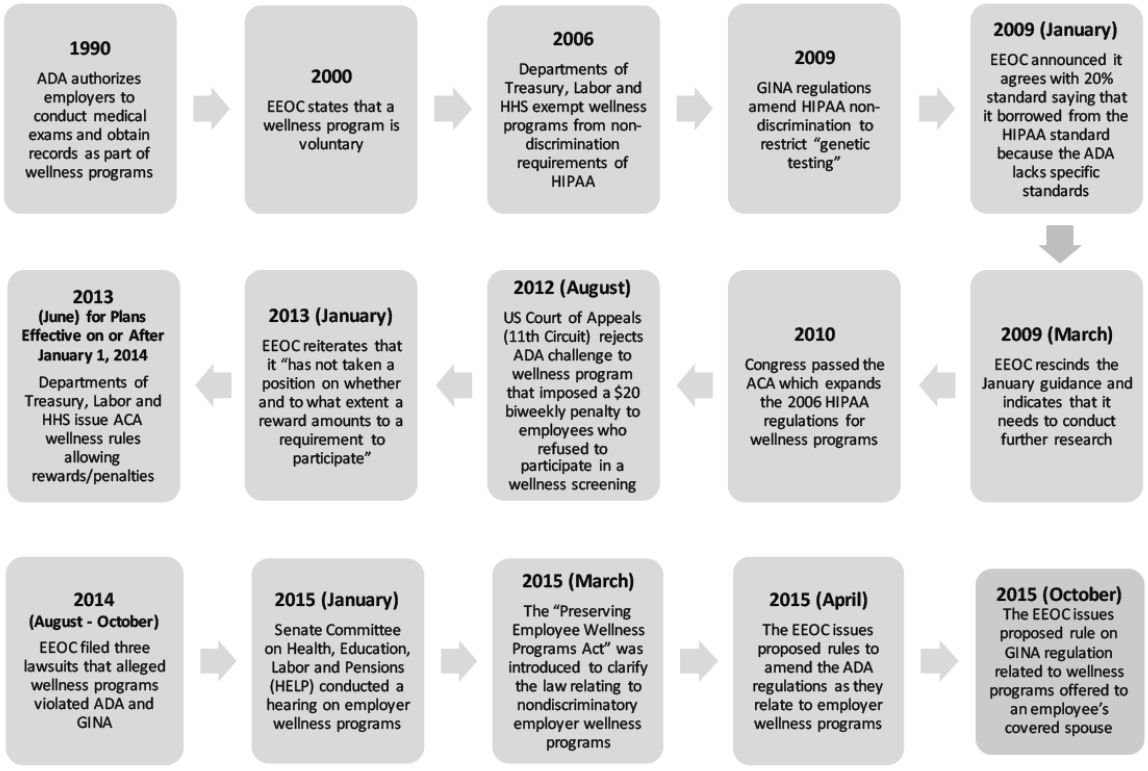
1. Recognition that formal guidance from the EEOC regarding wellness and incentive programs as they relate to the ADA and GINA is needed and appreciated, but that such guidance should be consistent with other regulations (e.g., Tri-Agency regulations) wherever possible;
2. Agreement that retaliation or adverse action against non-participants, including denial of coverage, termination of employment, or requiring 100% of the medical care premium to be paid by non-participants in the wellness program should be prohibited;
3. Agreement that clear notice is needed that programs are voluntary and 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; rather, a reasonable time period is needed for employers and health plans to modify program designs; and
6. Agreement that final regulations from the EEOC on the ADA and GINA should be consistent to create common standards for wellness programs and incentives.

After these initial areas of consensus were identified, five workgroups were formed to address each of the respective key areas identified above. This paper describes the consensus development process and provides consensus statements developed by the five workgroups, and subsequently, reviewed and approved by the larger group of stakeholders.

Introduction

Over the last 25 years, government regulation and legislation at both the state and federal level have addressed individual treatment, data collection, and data handling related to wellness programs and incentives permitted to encourage participation in such programs.[1-5] As characterized in Figure 1, the federal regulatory landscape and related court actions have created complicated and sometimes conflicting regulations for those seeking to offer wellness programs, incentives, and health care benefits to employees and/or health plan eligible individuals.

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



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) related to employer wellness programs.[6] The public was invited to comment by June 19 and more than 300 comments representing varying degrees of support, concern, and disagreement were received. These 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.

Since the close of the comment period on the ADA proposed rule, numerous organizations—representing the perspectives of consumers, employees, employers, occupational medicine, health plans, and wellness program providers—collaborated to develop a consensus response to the EEOC's proposed rule on ADA in order to provider clearer guidance to the EEOC. During this collaboration process, on October 30, 2015, the EEOC issued a proposed rule to the Genetic Information Nondiscrimination Act of 2008 (GINA) as it relates to employer sponsored wellness programs.[7] Comments on this proposed rule were due by December 29, 2015, but the comment period has recently been extended to accept comments by January 28, 2016.

This paper was developed, primarily focusing on the ADA proposed rule but recognizes the important relationship between the ADA and GINA proposed rules. Its purpose is to provide policy makers with a consensus-driven point of reference for the agency as it finalizes the proposed regulations in both areas.

Process for Developing Consensus

The complexity of the regulatory landscape necessitated organizations coming together in order to provide guidance to employers on how to design wellness programs and associated incentives in a way that comply with regulations while advancing the important goals of protecting employees and furthering employee health and well-being. For example, in July 2012, several organizations, including the Health Enhancement Research Organization (HERO), the American College of Occupational and Environmental Medicine (ACOEM), the American Heart Association (AHA), the American Cancer Society Cancer Action Network (ACSCAN), and the American Diabetes Association (ADA) collaborated to provide guidance to employers on the appropriate use of outcomes-based incentives as part of a reasonably designed wellness program, including defining the elements of a well-designed wellness program.[8]

Building on similar past collaborations[9-10] and seeking to provide a consensus point of view, the HERO, the Population Health Alliance (PHA), and the 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. The convening organizations include member groups that represent employers who sponsor wellness programs, along with providers of wellness programs. The goals of the meeting and the subsequent collaboration were intended to provide policy makers with a consensus-driven point of reference as they evaluate the comments submitted to date. Understanding on which issues credible organizations that represent a wide range of perspectives have reached consensus should help inform the final regulations or future legislation and guidance. This consensus-based approach was intended to represent the perspectives of a range of 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.

The convening meeting was organized by HERO staff in collaboration with representatives from PHA and AHA. 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 (see Table 1 for a list of participants). These invited groups represented a balance of those focused on consumer/employee protection, science, corporations and for-profit businesses, insurance, and providers.

Table 1. National convening meeting participants

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

The convening meeting began with an overview of the EEOC regulations and proposed rule along with a review of the public comments that were submitted to the EEOC on the proposed rule. A summary of key issues provided an organizing framework for this initial meeting.

The group identified five key areas of discussion regarding the proposed rule including:

1. Whether consumers are receiving adequate privacy notice about how medical data are collected, used, and protected;

2. How the use of rewards or penalties influences employee perceptions about the voluntary nature of wellness programs;
3. What are “reasonable alternative standards;”
4. What constitutes a “reasonably designed program;” and
5. Whether or not there is adequate congruence between EEOC regulations compared to regulations developed by the Departments of Health and Human Services, Labor, and the Treasury (hereafter referred to as the Tri-Agencies).

With the goal of identifying consensus points within each of these areas, five workgroups were formed with diverse representation from each of the stakeholder groups, with the goal of developing an initial consensus statement draft. The draft statements from each of the five workgroups were consolidated into a single document and were circulated amongst all workgroup members until they reached agreement on a final set of statements. 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 the paper. Table 2 lists the organizations who agreed to be listed as endorsers of this work.

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

Immediate Areas of Consensus

In addition to establishing an organizing framework for consensus development workgroups, a facilitated discussion occurred during the initial July 20 meeting with the aim of identifying those issues of ready agreement versus those that generated greater dissonance within the group. The group reached consensus in this first session on several important areas, including many on which organizations agreed with proposed EEOC regulations.

Areas where participants quickly came to consensus included:

1. Recognition that formal guidance from the 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 (e.g., Tri-Agency regulations) wherever possible;
2. Agreement that retaliation or adverse action against non-participants, including denial of coverage, termination of employment, or requiring 100% of the medical care premium to be paid by non-participants in the wellness program 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 rather, a reasonable time period for employers and health plans to modify program designs is needed; and
6. Agreement that final regulations from the EEOC on the ADA and GINA should be consistent to create common standards for wellness programs and incentives.

In the initial meeting consensus was reached with respect to several other general aspects of the proposed EEOC regulations outlined below.

- Employer wellness programs have the potential to benefit employees and employers when programs are designed according to best practice design dimensions and evidence-based standards (see the workgroup section on *reasonably designed programs* for more information).
- Regulations should clarify the rules without making it difficult or burdensome for employees and their family members (if applicable) to participate in, and benefit from, 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 Congruence with Tri-Agency Regulations

As previously noted, the EEOC has issued proposed rules on the ADA[6] and GINA.[7] The consensus groups agree that the EEOC has a statutory responsibility to protect employees through both the ADA and GINA.

However, it is confusing when there are inconsistencies across the federal agencies. Jurisdictional inconsistencies between the ADA, GINA, and the tri-agency guidance complicate the opportunity to deliver wellness programs in a way that is best for both employees and employers. The consensus groups agree that the ADA and GINA final regulations should 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.

Some areas of concern related to potential regulatory inconsistencies include:

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 groups felt that concern for low wage workers is addressed through various provisions of the Affordable Care Act (ACA)[5]—including the 30%/50% limitation on incentive amounts, the 9.56 percent affordability rule, and provisions related to reasonable alternative standards—and therefore does not require further intervention by the EEOC.

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 the EEOC, there is little doubt that clearer definition concerning voluntariness for wellness programs would be a welcome contribution. Consensus groups are 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 organizations reached agreement in several important areas.

1. Participation in a wellness program would be considered voluntary if it complies with the parameters already established by the ACA regulations.[12] That is that any reward must be available to all similarly situated individuals; the program must give eligible individuals the opportunity to qualify for the reward at least once a year; the program must be reasonably designed to promote health and prevent disease whether activity only or outcome-based; the reward must not exceed 30% of the cost of coverage (or 50% for programs designed to prevent or reduce tobacco use); and 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 proposes to limit the valued amount of incentives to 30% of the cost of "employee only coverage" and provides an example of the calculation.[7] The workgroup consensus was that ADA regulations[6] should be consistent with the proposed rule on GINA[7] 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 point above, limiting the cost-of-coverage calculation to only employees could result in (a) employers reducing or eliminating incentives for other family members, or (b) reducing the incentives available to employees if employers wish to provide incentives to other family members and have to allocate budgets accordingly.

4. The EEOC proposes to count non-financial incentives towards limits on the value of incentives. The workgroup is concerned that including the cost of non-financial 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 non-financial

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[†] The latest proposed EEOC rule on GINA uses the term "inducements" instead of "incentives." The authors choose to use the term incentives since it is consistent with the ADA proposed rules

incentives. In addition, the consensus organizations are concerned about the significant administrative burden associated with accounting for the value of non-financial incentives in the calculation since many of these incentives are de-minimus in value. The workgroup consensus is that de minimis incentives such as movie tickets, water bottles, and t-shirts should not be counted towards 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 compared to 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. While 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 like 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 HIPAA 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 allows employers to 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.[12] The EEOC proposes to limit the total value amount of all incentives to 30% if the determination of smoking status is determined by biological testing. Further, the EEOC proposes that the value of participation-based incentives be included towards the financial limit on the amount of incentives, whereas the ACA regulations stipulate incentive limits only for health-contingent incentive designs. These inconsistencies between ACA and the EEOC 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 (i.e., requiring participants to achieve a specific health outcome in order to receive an incentive) and away from participation-based incentive designs.

We did not reach consensus on whether the 50% limit should be applied regarding tobacco use or whether the limit should be capped 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 non-smokers even if that is not the case.

Though 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 cutoff 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 four 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.

One area of consensus among the organizations that were part of this process is, 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 where employees are allowed to go through a cessation program a number of times to overcome their nicotine addiction in accordance with clinical guidelines. This approach to smoking cessation interventions is referenced in Department of Labor guidance[13], and in a recently published consensus paper on e-cigarette policies for employers[9], and by the CDC.[14]

Consensus on Definition of "Reasonable Alternative Standards"

The EEOC-proposed rule on the ADA 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 organizations considered the implications of this regulation on health plan participants and health plan non-participants.

A proposed rule in the ADA[6] 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 organizations reached agreement on the following statement with regard to this proposed rule.

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 requests 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. In response to this call for input, the consensus organizations agree 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 the 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 join in the request for an alternative to any participatory requirement for wellness program incentives. Additionally, the group agreed that alternatives did 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"

Consensus organizations observed that wellness programs can be designed in a number of different ways. The 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."[12] 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 be offered for the individual completing it.[15]

In order for a wellness program design to be considered credible and effective, the program design itself 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.

Based on the level of evidence available during these discussions, the consensus organizations believe that reasonably designed programs are those comprised of all of the following minimum elements or standards. Any one of these elements on its own does not define a reasonably designed program.

- 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. Some examples include programs characterized in a consensus statement offering guidance to employers on reasonably designed, employer-sponsored wellness programs,[8] the Community Guide based on recommendations from the Community Preventive Services Task Force,[16] and the Cochrane Reviews.[17]

Consensus on Privacy Notice

The collaborating organizations also reached consensus related to the use of privacy notices for a medical inquiry, 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.

Collecting health-related information is permitted by ACA and HIPAA. Assuming data privacy is assured and HIPAA protections are invariably utilized for wellness programs delivered within the health plan, consensus organizations believe such data collection should be permitted for both 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. Additionally, there should be 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 organizations also support the requirement of a privacy notice to inform employees about how their personal health information will be used, stored, shared, and protected. The consensus organizations understand 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 organizations believe the following characteristics would generally align with HIPAA and be helpful to participants:

- The privacy notice can be provided electronically or as a hardcopy. A hardcopy version of the privacy notice must be provided if requested by the employee.

- The privacy notice must make a clear, consumer-friendly statement about how the data will be used, shared, sold and/or protected, and should be written at the average reading literacy level for adults in the United States.
- A privacy notice should be provided in all situations where personal health information is being collected.
- The 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 vendor suppliers.
- 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.
- 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.
- Consistent with the proposed EEOC rule on GINA,[7] consensus organizations are 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.
- 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.
- Consensus organizations encourage 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.

Conclusion

Many organizations representing diverse perspectives worked together to identify points of agreement in response to proposed EEOC regulations. Through a collaborative series of focused consensus-building dialogues, 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, we recommend that more dialogue occur using an objective convening party (e.g., The National Academy of Medicine, HERO, PHA, AHA, ACOEM, Bipartisan Policy Center, or others) with representation from all parties affected by EEOC regulations, with the intent of reaching consensus on regulations from the various federal agencies that meet the objectives of consumer advocates, scientists, healthcare providers, and employers.

References

2. *Health Insurance Portability and Accountability Act (HIPAA).* 42 U.S.C. 300-gg-1(b)(2)(B).

3. 29 C.F.R. Parts 1630 and 1635.

4. *Genetic Information Nondiscrimination Act (GINA).* 42 U.S.C. 2000ff, et seq.

5. *Patient Protection and Affordable Care Act (PPACA or ACA).* 42 U.S.C. 300gg-4.

6. EEOC Amendments to Regulations Under the Americans with Disabilities Act [Proposed Rule].
Federal Register Vol. 80, No. 75. April 20, 2015;21659, 21662.

7. EEOC Genetic Information Nondiscrimination Act (GINA) [Proposed Rule]. *Federal Register.* Vol. 80, No. 210. October 30, 2015;66853.

8. Guidance for a reasonably designed, employer-sponsored wellness program using outcomes-based incentives: consensus statement of the Health Enhancement Research Organization (HERO), American College of Occupational and Environmental Medicine (ACOEM), American Cancer Society and American Cancer Society Cancer Action Network, American Diabetes Association, and American Heart Association. *J Occup Environ Med.* 2012;54(7):889-
96.

9. Whitsel LP, Benowitz N, Bhatnagar A, et al. Guidance to employers on integrating e-cigarettes/electronic nicotine delivery systems into tobacco worksite policy. *J Occup Environ Med.* 2015;57(3):334-343.

10. Biometric health screening for employers: consensus statement of the Health Enhancement Research Organization, American College of Occupational and Environmental Medicine, and Care Continuum Alliance. *J Occup Environ Med.* 2013;55(10):1244-1251.

11. Stillman NG, Anderson AR. Wellness program falls within ADA safe harbor. *Employee Benefit News*. September 21, 2012. Available at: http://ebn.benefitnews.com/news/wellness-program- falls-within-ada-safe-harbor-2727924-1.html?zkPrintable=true. Accessed November 19, 2015.

12. Departments of Labor, Treasury, and Health and Human Services. Incentives for nondiscriminatory wellness programs in group health plans. *Federal Register.* Vol. 78, No. 106. June 3, 2013;33158, 33167.

13. Department of Labor. FAQs about Affordable Care Act Implementation (Part XIX). Available at: http://www.dol.gov/ebsa/faqs/faq-aca19.html. Accessed on November 18, 2015.

14. Centers for Disease Control and Prevention. Quit smoking. Available at: http://www.cdc.gov/tobacco/quit_smoking/index.htm. Accessed November 18, 2015.

15. Department of Labor. FAQs about Affordable Care Act implementation (Part XXV). Available at: http://www.dol.gov/ebsa/faqs/faq-aca25.html. Accessed November 18, 2015.

16. Community Preventive Services Task Force. The community guide: what works to promote health. Available at: http://www.thecommunityguide.org/index.html. Accessed November 17,
2015.

17. Cochrane. Cochrane Reviews. Available at: http://community.cochrane.org/cochrane- reviews. Accessed November 17, 2015.