Recommendations Regarding the Voluntariness Standard in Employer Wellness Programs Regulated by the Equal Employment Opportunity Commission

Background:

An overview of the current state of national health in the United States provides essential context when considering the role and appropriate regulation of wellness programs. Certainly, wellness programs can play a role in improving our national health and slowing the growth of national health care expenditures. Despite more than 30 years of efforts by employers, health plans, government, and other stakeholders to control rising health care costs, expenditures now exceed $3.3 trillion\(^1\) and have grown from 10.3 percent of GDP in 1986 to 17.9 percent in 2016.\(^2\) Under current law, these expenditures are expected to grow at an average rate of 5.5 percent annually and reach $5.7 trillion, or 19.7 percent of GDP, by 2026.\(^3\) While health care expenditures are spiraling upward, so are rates of chronic disease and chronic disease risk factors such as diabetes, high blood pressure and obesity. More than 100 million Americans have diabetes or prediabetes, 103 million adults have high blood pressure,\(^4\) and almost 40 percent of the US adult population is obese. Distressingly, for the first time in recent decades, previously decreasing death rates for heart disease and stroke have flattened and even worsened for our most vulnerable populations.\(^5\) The burden of lifestyle-related and other health conditions like cardiovascular disease and cancer is growing faster than our ability to ease it, putting an increasing strain on the US health care system, national health care costs and productivity, and individual well-being.\(^6\) Unfortunately, there is a disproportionate burden of these diseases and risk factors in certain racial and ethnic populations (i.e., blacks, Hispanics, Asian Pacific, American Indian), those with lower income and educational attainment, those living in certain geographies, sex and gender orientations, and those who are experiencing mental illness or suffering from addiction.\(^7\) Life expectancy for men in the US in the lowest

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income group is 14.6 years lower than men in the highest income group, and for women the difference across income groups is 10.1 years.\textsuperscript{8} These health and well-being disparities are often driven by the social determinants of health, \textit{the conditions in the social, physical, and economic environments where people are born, live, work, and age including housing, access to care, crime, education, and wages}.\textsuperscript{9} Wellness programs can be a meaningful way to address risk factors, encourage behaviors that promote health and perhaps ultimately improve overall health and reduce costs.

There is evidence that financial rewards or penalties (commonly referred to as incentives or inducements), including monetary and non-material rewards such as philanthropic participation) can elicit increased rates of simple, time-limited behaviors such as participating in health assessments or obtaining preventive screenings.\textsuperscript{10,11} There is also some evidence that financial inducements can be effective in eliciting short-term behavior changes (i.e., 6-12 months) across a range of health behaviors including tobacco use, physical activity and weight loss.\textsuperscript{12,13} It is less clear to what extent these behavior changes are sustained after interventions end and incentives are removed, since little well-designed research is yet available on long-term effects.\textsuperscript{14,15} Fortunately, the field of behavioral economics is rapidly increasing our understanding of the psychology of economic decision-making, which may help in identifying more sustainable and cost-effective financial models than the most common current approaches.\textsuperscript{16,17} While more research to determine optimal incentive design is needed, these studies are helpful steps in that analysis.

The issue of voluntariness has important behavioral relevance for effective incentive design, since the need for autonomy is a fundamental human motive.\(^{18}\) If only one behavioral option is available to earn a financial inducement (e.g., complete a health assessment), individuals will feel increasingly coerced as the amount of the financial penalty increases.\(^{19}\) This feeling of coercion may be substantially ameliorated by offering individuals choices for how the inducement can be earned (e.g., health assessment or daily walking or health coaching) and by tying relatively modest financial amounts to any single behavior. This concern may be further ameliorated by providing adequate programmatic, environmental and cultural support, which makes healthy choices easier and more normative.\(^{20}\) How to assure voluntariness therefore deserves thoughtful consideration in the design of any wellness program.\(^{21}\)

**Legislative and Regulatory Landscape:**

Responding to concerns about the millions of Americans who did not have health insurance as well as rapidly escalating health care expenditures, Congress enacted the Affordable Care Act (ACA) in 2010. A fundamental goal of this legislation was to shift the US health care system from its historic focus on sickness and disease to a system focused on prevention and wellness.\(^{22}\) Wellness programs had a standing history as a valued component of employee benefit design, and the ACA expanded the flexibility for health plan incentives in employment-based wellness programs. The ACA built on the framework established in 1996 with the passage of the Health Insurance Portability and Accountability Act (HIPAA), which included nondiscrimination provisions with specific provisions addressing wellness programs.\(^{23}\) The ACA statutorily codified provisions under which employers, through a group health plan, could offer financial inducements for employees, spouses and dependents to engage in wellness programs by participating in preventive screenings and health promotion activities, such as walking programs, or by making improvements in health indicators such as achieving a healthy body

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\(^{23}\) See Public Health Service Act (PHSA) Section 2702 (later amended and moved to PHSA Section 2705); ERISA Section 702 and Internal Revenue Code Section 9802.
mass index. The ACA amendments also allowed greater flexibility in incentives to promote cessation of tobacco use.

HIPAA and the ACA are not the only laws applicable to employment-based wellness programs. Employers must comply with a range of laws and regulations when implementing wellness programs. Notably, in addition to the HIPAA and ACA wellness program rules, Title I of the Genetic Information Nondiscrimination Act (GINA) applies to wellness programs offered through employer group health plans. These laws are administered by the Departments of Health and Human Services (HHS), Labor (DOL) and the Treasury. In addition, the Americans with Disabilities Act (ADA), and Title II of GINA, both administered by the EEOC, apply to employer-sponsored wellness programs regardless of whether or not such programs are provided through a group health plan. In addition, HIPAA’s nondiscrimination provisions generally prohibit a group health plan from discriminating against individual participants and beneficiaries with respect to eligibility, benefits or premiums based on a health factor. However, the HIPAA nondiscrimination and ACA regulations include an exception for wellness programs allowing them to vary premiums, benefits or contribution rates as long as the program meets certain requirements. The requirements differ depending on whether the wellness program is participatory or health-contingent. Health-contingent programs — activity-only and outcome-based — require an individual to satisfy a standard related to a health factor to obtain a reward and must comply with five requirements: the opportunity to qualify for the reward, limits on the size of the inducement, reasonable wellness program design, uniform availability, reasonable alternative standard, and notice of the alternative standard. These requirements have a more stringent application for outcome-based programs. Under HIPAA and the ACA, participatory programs are not subject to the compliance requirements applicable to health-contingent programs, most notably the limitations on incentives and disincentives.

In 2016, the EEOC issued final rules for wellness programs under both the ADA and GINA. The ADA generally prohibits employers from requiring employees to undergo a medical examination that could divulge protected information about a disability (e.g., biometric screenings) and from inquiring about either the existence of, or the nature or severity of, an employee’s disability (e.g., health risk assessment, or HRA) unless the requirement or inquiry is job-related or part of either a “bona fide benefit plan” or a “voluntary employee health program.” GINA prohibits group health plans, insurers and employers from discriminating on the basis of an individual’s “genetic information.” Among other things, it prohibits employers from requesting, requiring or

See Public Health Service Act Section 2705, incorporated by reference into ERISA Section 715(a)(1) and Internal Revenue Code Section 9815(a)(1).

See PHSA Section 2702 (later amended and moved to PHSA Section 2705); ERISA Section 702 and Internal Revenue Code Section 9802.

See PHSA Act 2705(j). See also 26 CFR 54.9815-2705; 29 CFR 2590.715-2705; 45 CFR 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); and 4 CFR 146.121(f).
purchasing information about the current or past health status of a spouse or other family member. Under Title II of GINA, information about the medical conditions of an employee’s spouse is considered genetic information of the employee (even though the employee and spouse do not share any genetic material).

Both the ADA and GINA provide exceptions for voluntary wellness programs, and regulations relating to both laws outline requirements for wellness programs to be considered voluntary. Under the EEOC’s rules, programs that involve a medical exam and/or disability-related or genetic inquiry had generally been considered voluntary if, among other things, the inducement is limited to 30 percent of the cost of self-only coverage.

In October 2016, AARP filed suit against the EEOC on behalf of its members, alleging that the 30 percent inducement permitted under the ADA and GINA regulations is “arbitrary, capricious, an abuse of discretion and contrary to the law.” The court found that the EEOC had not provided an adequate basis (i.e., justification) in its regulations for concluding that the 30 percent inducement limit is a reasonable interpretation of voluntariness (as required by the statute), and instructed the EEOC to review and revise its regulations. However, it did not vacate (i.e., throw out) the challenged rules at that time because of concerns that doing so would be too disruptive. Proposing a schedule for its review of the existing regulations, the court also directed the EEOC to file a status report. In September 2017, the EEOC told the court that it expected to issue a proposed rule by August 2018 and a final rule by October 2019 (with the expectation that the final rule would not be applicable until the beginning of 2021).

In late December 2017, AARP filed a motion asking the court to modify its earlier judgment and to either vacate the regulations as of January 1, 2018, or enjoin the EEOC from enforcing them as of that date. The judge ordered the EEOC to provide status reports on the progress of the regulatory review process and said that the court would hold the EEOC to its intended deadline of August 2018 for issuing proposed rules. The court was displeased that new regulations might not be applicable until 2021 and “strongly encouraged” the EEOC to move up its deadline. The court ordered that, barring new proposed or final regulations, the current regulations would be vacated as of January 1, 2019.

The EEOC pushed back with a motion asking the court to reconsider, arguing that the agency should not be subject to a set schedule for issuing regulations. The court agreed with the EEOC that it could not require the agency to adhere to a set schedule, but maintained that the current regulations would be nullified as of January 1, 2019.

In its initial ruling, the court rejected the EEOC’s argument of harmonizing its regulations with HIPAA, stating that HIPAA does not contain a voluntary requirement, which is statutorily mandated in the ADA and GINA, and that HIPAA’s directive — prohibiting health coverage
discrimination — differs from the protections of the ADA and GINA. It appears that the court hoped Congress\textsuperscript{27} would provide a legislative fix, referencing the HIPAA statute. Such legislation has been introduced, but it has made little progress.

With the nullification of its regulation, employers are left with uncertainty regarding the permissible amount of inducements tied to certain types of employer wellness programs to comply with the voluntariness standard of the ADA and GINA. The EEOC has yet to reissue the same regulations with a justification for the 30 percent inducement or to issue new regulations. It is important to note that the order only vacated the portions of the ADA and GINA regulations that relate to the amount of the inducement. Other requirements, such as the notice requirement, appear to remain in effect and be required for programs that contain health risk assessments or biometric screenings, even in the absence of related rewards or penalties. Most recently, the EEOC indicated that it is now developing a response to the court’s ruling with plans to provide a Notice of Proposed Rule Making (NPRM) by December 2019.

**Discussion:**

While the current EEOC regulations use some concepts from the HIPAA and ACA wellness regulations, they also contain differences. Some differences are driven by the fact that HIPAA and the ACA regulate programs offered under an employer-sponsored group health plan (and thereby generally limit the size of inducements to 30 percent of the cost of coverage in which the employee is enrolled), while the ADA regulations limit financial inducement amounts of all employer-sponsored wellness programs, including programs that are not tied to enrollment (and therefore coverage costs) of a group health plan; other differences simply reflect an alternative interpretive approach chosen by the EEOC. Some experts suggest that the EEOC could issue regulations that more closely align with the HIPAA/ACA wellness regulations while better explaining how this meets a voluntary standard.

While interactions among HIPAA, ADA and GINA create some challenges for employer-provided wellness programs, the now-vacated ADA and GINA rules provided specific guidance about acceptable inducement limits. Without such guidance, employers are concerned about increased litigation risk if they offer programs previously compliant with the law. Some employers are rethinking how best to use financial incentives in their overall wellness program designs. Others may simply reduce or eliminate the use of incentives in their wellness programs due to concerns about litigation risk. This reaction may decrease utilization of these programs and diminish positive employee health outcomes and/or affect morale. Yet, others may carry

\textsuperscript{27} *Preserving Employee Wellness Programs Act. 2017-2018 (115th*) H.R. 1313.
on as they have been by including inducements and program designs currently compliant with the lapsed ADA and GINA rules.

**Recommended Guidance**

*It is the consensus opinion of the working group authoring this paper that an interim enforcement safe harbor should be issued to support the ability of employers to continue to use inducements as a part of their overall worksite health promotion strategies. This safe harbor should be issued expeditiously with an applicability date retroactive to January 1, 2019.*

**Suggested Interim Enforcement Safe Harbor**

Pending the applicability of new rules, we encourage the EEOC to issue an enforcement safe harbor. The issuance of a safe harbor in the instance of vacated regulatory provisions would be consistent with the approach of other Federal departments in similar circumstances. For example, certain provisions of a DOL regulation regarding Association Health Plan were found to be unlawful resulting in the rule being remanded to DOL for reconsideration. In response to this, the Department very quickly issued a statement regarding its approach to enforcement pending the issuance of additional guidance. Specifically, this working group recommends that the enforcement safe harbor provide that:

- Enforcement action will not be taken by the EEOC with respect to any wellness program using a financial incentives approach designed in good faith compliance with the ADA or GINA Title II. For purposes of this safe harbor, incentive program designs relating to wellness programs that comply with the EEOC regulations as written will be considered to be operating in good faith compliance.

**Suggested Regulatory Guidance**

*It is the consensus opinion of this working group that the following recommendations regarding the “voluntariness standard,” if set forth in the EEOC regulatory guidance regarding the use of financial inducements in wellness programs, would reflect standards that employers could satisfy.*

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29 See https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv1747-79

For wellness programs offered as part of a group health plan: This working group supports the requirements set forth in the ACA and HIPAA related to inducements used in support of wellness programs.

- The EEOC could deem all programs subject to inducement limits under HIPAA and the ACA as compliant with the voluntary standard under the EEOC rules to the extent the program is compliant with the HIPAA/ACA rules. This approach would eliminate the burden and confusion of dual and conflicting oversight, generally leaving the EEOC to regulate employer practices in the use of rewards or penalties used as part of wellness programs that are either unregulated by HIPAA/the ACA or offered outside of employer group health plans.
- Alternatively, the EEOC could expressly adopt provisions parallel to the HIPAA/ACA.
- When the ADA and Title II of GINA are applicable (for example, in the case of incentivized health risk assessment completion), the EEOC could continue to regulate these inducements, which are generally not subject to limits under the HIPAA/ACA rules; when these assessments are connected to a group health plan, we recommend that the incentive limit track the otherwise applicable HIPAA/ACA limits.

For the reasons described below, in meeting the HIPAA/ACA standards, we believe employment-based group health plan programs, which are already subject to minimum coverage and limitation requirements regardless of wellness program inducement impacts, are adequately protected by safeguards from burden and punitive cost implications that might otherwise render the programs in effect involuntary.

Rationale: Wellness programs offered as part of a group health plan are subject to numerous laws and regulations to protect against health status discrimination, guard member privacy, assure data security, limit the scope of data collected, assure minimum levels of coverage including preventive care, and assure fairness and consistency in program design. These laws also include strict enforcement guidelines and penalties (in some cases criminal as well as civil). This working group believes that these programs are generally competently regulated by the agencies historically tasked with their oversight. The legal protections applicable through these programs are thorough and, while they do not use the term “voluntary,” these programs incorporate standards that protect against discrimination and coercion, thereby making the programs voluntary.

In particular, under HIPAA and the ACA:

1. **Health-status discrimination protections.** Wellness programs offered as part of a group health plan should continue to be required to follow all of the requirements set forth in HIPAA and ACA wellness program rules. This includes standards such as uniform availability and availability of reasonable alternative standards to prevent discrimination in cost and access to benefits. It also includes notice requirements that ensure that
individuals are aware of and can exercise (or choose not to exercise) their right to an alternative means of obtaining an incentive.

2. **Inducement limits.** Inducements offered as part of wellness programs within a group health plan should continue to comply with the regulatory requirements set forth under the ACA and HIPAA, including the prohibition to exceed the maximums specified by the law and regulations. Employers carry a significant burden of health care costs (both in premium payments and, in the case of self-funded group health plans, the direct cost of care). Empowering employees to play a role in managing their behaviors that put their health at risk to help manage costs with appropriate, evidence-based behavior change programs can be supported by inducements that would be considered to render a program involuntary. As noted above, since individual behaviors play a significant role in health and well-being, it is reasonable to have laws that give employers flexibility to design programs that incent plan participants to address their unhealthy behaviors. Meanwhile, the importance of balancing this interest against the need for access to care and protection from discriminatory practices against individuals with adverse health factors calls for inducement limitations. The HIPAA nondiscrimination rules took this into account, limiting incentives to 20 percent. Congress reviewed this limit and worked with a broad range of stakeholders before codifying the HIPAA nondiscrimination rules into the ACA with an increase to 30 percent (50 percent for tobacco reduction programs). The HIPAA/ACA wellness regulation adopted additional consumer protections, such as standards giving deference to attending providers in outcome-based programs and reasonable alternative standards. While an individual may forfeit the inducement by choosing not to participate in the wellness program, the reward is not punitive to such degree that the program is considered “involuntary” because the individual will still be covered with comprehensive health coverage, and there are significant consumer protections in place.

3. **Reasonable design.** The incorporation of the HIPAA/ACA standards ensuring reasonable design of a wellness program provides protections that programs will not be overly burdensome or a subterfuge for discrimination and will be aimed at health promotion and disease prevention. This group has written previously that reasonably designed programs adhere to “best practices” that, depending on the facts and circumstances of each employer’s situation, could include leadership support, comprehensive program offerings, strategic planning, a supportive culture and environment, and clear communications.31 These standards mitigate the potential for a wellness program to be burdensome to such a degree as to render it involuntary.

For wellness programs offered outside of a group health plan: This working group recommends that, consistent with current research, employers should be permitted to offer

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reasonably designed wellness programs that include the limited use of financial inducements outside of a group health plan.

- In general, the HIPAA/ACA wellness exception standards including uniform availability, reasonable alternative standards, reasonable design, and notice should be adopted under EEOC guidance as a measure to ensure the voluntary nature of the program, as supported in our discussion above. The incorporation of the HIPAA/ACA standards related to reasonable design is a vital step in balancing burden and protecting against discrimination in an effort to ensure the voluntary nature of the program. As noted above, a reasonably designed wellness program that adheres to current best practices offers tools and resources to support the attainment of health goals.

Whether a program is “reasonably designed” depends on the facts and circumstances. The following protections should generally be self-implementing through compliance with the HIPAA/ACA standards of reasonable design, however, the EEOC may consider adding express language to emphasize important components of reasonable design. Ensuring that programs follow evidence-based health research, do not increase inequities and incorporate flexibility to avoid barriers to participation supports the voluntary, nondiscriminatory nature of a program. Specifically:

- Programs that include financial inducements associated with participation in an exam or the completion of health questionnaires that may reveal a disability should be based on population health needs. EEOC may consider adding language to ensure that an employer is sponsoring and promoting a program that is considered relevant based on evidence-based research. For instance, it could include regular evaluation of a program to ensure it is consistent with current health recommendations. The EEOC could solicit recommendations or comments regarding a reasonable timeframe for periodic assessment of program effectiveness.

- The design of financial inducements that require an exam or the completion of health questions that may reveal a disability should be such that it ensures health equity by motivating positive behaviors across all employee populations. This includes consideration for incentive structures to assure they incorporate flexibility to avoid barriers to participation and do not increase inequity. For instance, when needed, programs may take into account various work schedules or education levels across a workforce (perhaps providing resources in multiple distribution formats such as in-person, video, podcast, or written). While the reasonable design standard under the HIPAA/ACA rules takes into account factors such as cost and travel time, the EEOC could provide some examples under its regulations under which programs have taken into account time commitments outside of the workplace, nutritional barriers, or availability of public transportation in a manner that results in a program that is reasonably designed and in a manner that does not increase inequity in vulnerable populations.
• For a wellness program outside of a group health plan, inducements should not be the wellness program per se, but should instead be one means of engagement within a broader program incorporating elements that encourage healthy behaviors and disease prevention. This is supported through adoption of the HIPAA/ACA reasonable design standards.

• Inducements should be limited so that, similar to HIPAA/ACA wellness programs rules, they are not punitive to a degree that renders the program involuntary. We offer the following example as an illustration:

➢ Outside of group health plans, inducements should be limited to an amount that motivates but does not compel action. Limited research exists to support a universal “tipping point” for what is or is not voluntary. However, since reasoning by analogy is a common approach taken by government agencies and the judiciary, we believe that consideration of a standard that has already been widely accepted within the employee benefits industry is a reasonable approach. An example is an employer match in 401(k) plans to encourage retirement savings. In the group health plan context, limitation of 30 percent or less of the total cost of coverage is widely accepted as reasonable and has been administered by employers for nearly two decades. For programs outside of the group health plan, pointing to the group health plan or a similar cost basis as a calculation seems comparable to widely accepted practices and appears to be administratively feasible, as evidenced by ongoing employer compliance. Such limits have been broadly supported as reasonable, which suggests that they would not inherently render a program involuntary.

Provide guidance based on evidence-based best practices. As the EEOC considers alternative approaches in drafting its next round of guidance, this working group urges the EEOC to base guidance on well established, evidence-based definitions of a reasonably designed wellness program. Previous guidance about a voluntariness standard has focused almost exclusively on the use of financial inducements, so much so that many lay observers have come to confuse “wellness programs” solely with incentives schemes that are neither effective nor equitable on a stand-alone basis. Instead, guidance should emphasize the way in which a reasonably designed program will mitigate against the perception that, when inducements are used, they are coercive rather than supportive in intent. Such guidance on a voluntariness standard casts inducements as but one tactic in a broader strategic approach to improving and supporting employee health and well-being.

Conclusion:

32 For more information, see: https://www.bls.gov/ore/pdf/ec100020.pdf.
America is facing a healthcare crisis that could be significantly averted if individuals engage in meaningful preventive health and wellness behaviors. Incentives are now commonly used to attempt to increase engagement in these programs and to motivate health improvement, ideally in combination with cultural and environmental support for positive health behaviors. In light of the recent court order, an immediate safe harbor is needed to protect employers operating in good faith as they await clarification.

Inducements are only a minor, tactical component of a much broader population health improvement strategy. Nonetheless, financial inducements must be reasonably designed to promote health and prevent disease. Our suggestions help guide ensuring inducements can be retained as a useful, yet nondiscriminatory, tool to promote wellness. Laws and regulations must be carefully crafted to allow effective financial inducements to play a supporting role within the overarching context of reasonably designed wellness programs as outlined above.