January 28, 2016

Ms. Bernadette B. Wilson, Acting Executive Officer
Executive Secretariat
U.S. Equal Employment Opportunity Commission
131 M St., NE
Washington, DC 20507

RE: RIN 3046-AB02, Genetic Information Nondiscrimination Act of 2008

Dear Ms. Wilson:

AARP is a nonprofit, nonpartisan organization representing people age 50 and older, with a membership of nearly 38 million, that helps people turn their goals and dreams into real possibilities, strengthens communities, and fights for the issues that matter most to families such as healthcare, equal employment opportunity, retirement planning, and protection from financial abuse.

We supported passage – and continue to support implementation – of the Patient Protection and Affordable Care Act (ACA). AARP has consistently and actively participated in ACA-related policy discussions and rulemaking proceedings regarding wellness programs. Moreover, because older workers have a tremendous stake in avoiding discrimination on the basis of age, disability, and genetic information, AARP has consistently and actively participated in policy discussions by the EEOC regarding the application of the civil rights laws to wellness programs, including by filing extensive comments in response to the EEOC’s recently proposed regulations changing the treatment of wellness programs under the Americans with Disabilities Act (ADA). 1

Now, the EEOC is proposing substantial changes in its treatment of wellness programs under the Genetic Information Nondiscrimination Act of 2008 (GINA). 2 AARP appreciates this opportunity to offer our comments on this important issue.

Introduction

AARP supports promising, evidence-based strategies to promote wellness as a means of promoting health and reducing health care costs. However, the design and operation of wellness programs must meet well-established civil rights principles and statutory mandates.

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Both the ADA and GINA contain strong prohibitions against allowing employers to demand or request that their employees turn over their medical/disability/genetic information because, quite simply, the record of both the ADA and GINA show that when employers obtain this information, it often leads to discrimination in the provision of health insurance or in other terms and conditions of employment. However, GINA was predicated less on a body of case law and more on a desire to be proactive in allaying the public’s fears about getting genetic tests and services, and that information making its way to employers and insurers. Both laws make an exception for voluntary workplace wellness programs, but even then, important safeguards and privacy protections apply. Voluntariness is the statutory touchstone of lawfulness with regard to common wellness program practices such as health risk assessments and biometric screening exams that seek to collect medical, disability, or genetic information on employees and their family members.

The EEOC recently proposed to depart from statutory standards and longstanding administrative interpretations under the ADA to redefine “voluntary” to allow employees to be penalized for refusing to answer medical inquiries or take medical exams. AARP ardently opposed these proposals, concluding that, because there was “no sound foundation for the EEOC’s redefinition of voluntary,” the rule should be “withdrawn and rewritten in accord with the approach taken in the GINA regulations.” The EEOC now proposes to do the same thing to those GINA regulations: in essence to redefine “voluntary” to permit employers to impose even greater financial pressure on employees to reveal their genetic information.

Summary of Comments

This rulemaking has virtually all of the same legal and policy shortcomings and would permit all of the same harm as the EEOC’s ADA rulemaking, but in many respects this proposed GINA rule is quantitatively and qualitatively worse. Quantitatively, it greatly expands the penalties and thus the coercion that may be used to induce workers to surrender their civil rights; it threatens to make health insurance far less affordable; and it significantly expands the opportunities for data-mining of health information and consequent risks of breaches of privacy and discrimination. Qualitatively, the proposed rule creates a loophole to allow employers, insurers, and a myriad of other businesses to obtain one’s most personal, and sensitive, genetic information, and thereby undermines trust and perhaps individuals’ willingness to get genetic tests, volunteer for genetic research, or even to seek out medical treatment.

The proposed rule is contrary to the statute, it is arbitrary and capricious, and it will give an enormous booster shot to the health data-mining industry that feeds on the largely unfettered

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6 Although the EEOC does not propose an explicit redefinition of “voluntary” in the regulations as it did in the ADA rulemaking, it has accomplished the same kind of redefinition by virtue of permitting employers to penalize one particular family member to provide one particular form of genetic information.
collection and disclosure of medical and genetic information. In doing so, it will make employment discrimination much more likely and potentially discourage individuals from seeking genetic services from which they may benefit, all in the service of a wellness industry that has yet to demonstrate evidence-based health outcomes or significant progress in reducing health care costs. The EEOC should withdraw this proposed rule and instead preserve and retain the EEOC’s current, well-designed GINA regulations. At a minimum, it needs to do much more to help mitigate the inevitable harms created by this rule.

I. The Proposed Rule is Contrary to Law in Several Key Respects

A. The Proposed Rule Vitiates GINA’s Requirement that the Provision of Genetic Information Must Be Voluntary

Under GINA’s express terms, it is an unlawful employment practice for an employer to “request, require, or purchase genetic information with respect to an employee or a family member of the employee,” with few exceptions. One of those exceptions is that employers may request genetic information from an employee or family member as part of a voluntary workplace wellness program – the employee must provide “prior, knowing, voluntary, and written authorization” for the provision of the genetic information. As is the case with the wellness program exception under the ADA, voluntariness is the touchstone of lawfulness for wellness program inquiries and exams that request genetic information.

The EEOC’s recently issued regulations to implement GINA also make clear that the provision of genetic information by an employee must be “voluntary, meaning that the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it.” Furthermore, those regulations state that employers may only offer inducements to answer HRAs that include questions about genetic information provided the questionnaire flags the questions that ask for genetic information and make clear that the inducement will be given regardless of whether or not those questions are answered.

The EEOC is now proposing an about-face on the meaning of “voluntary.” If an employee’s spouse is covered by the employer’s group health plan, the EEOC proposes to revise its regulations to permit employers to financially penalize that spouse for refusing to provide her or his medical information – which is considered family medical history and therefore genetic information of the employee – to the employer. The allowance of any penalties to be imposed for refusal to provide genetic information to an employer’s wellness program violates the plain language of the statute and the EEOC’s own recently issued regulations.

The EEOC’s same reversal in its previous ADA rulemaking – which would permit employers to impose a penalty of up to 30% of the total employer-employee cost of employee-only coverage if an employee refuses to submit to medical inquiries and exams – was problematic enough. By virtue of the fact the EEOC now proposes to allow employers to use the total employer-employee cost of the family policy in which the employee is enrolled as the base against which the 30% penalty is calculated, this GINA NPRM proposes to allow employers to impose very large financial penalties on employees and their families, in the form of dramatically higher insurance premiums and cost-sharing burdens.

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8 Id., at § 2000ff–1(b)(2)(B).
9 29 C.F.R. § 1635.8(b)(2)(i)(A) (emphasis added).
10 Id., at § 1635.8(b)(2)(ii).
To illustrate, the average cost of employee-only coverage in 2015 was $6,251.\textsuperscript{11} Under the EEOC’s ADA rulemaking, the maximum allowable penalty for exercising one’s rights not to submit to medical inquiries and exams was 30% of employee-only coverage, or in this case about $1,875. This is on top of the average amount employees already contribute to their health insurance; for employee-only coverage, that’s about 18% of the premium, or about $1,125.\textsuperscript{12} Thus, the ADA rulemaking was already proposing to allow employers to make employees pay $3,000 on average, or about two-thirds more for their health insurance than an employee who involuntarily capitulates to the wellness program’s demands for their medical/disability information.

The GINA NPRM proposes to greatly enlarge the denominator in the penalty calculation to the total cost of family health insurance coverage. The average total premium for family coverage in 2015 was $17,545.\textsuperscript{13} A 30% penalty assessed against that premium amount, due to a spouse’s refusal to hand over her or his genetic information, means that this family would be paying a whopping $5,264 more for their health insurance, and that is on top of the average of 29% of the premium, or $5,088, they already contribute toward their coverage.\textsuperscript{14} In this example, a family could be charged a penalty of more than double the already hefty cost of their family coverage, just because the spouse wishes to exercise her or his civil rights not to relinquish their genetic information to the employee’s workplace wellness program! The EEOC offers no rationale or explanation for supersizing the denominator, and under no reading of GINA’s statutory language could such self-evident and excessive financial coercion be considered voluntary. Statutory civil rights protections against involuntary disclosure of medical/genetic information are fundamentally incompatible with heavy penalties on their exercise.

In addition, it is not even clear that this is the limit on wellness penalties. For instance, in the case of small employers, insurers are permitted to age-rate premiums for a small group health plan by up to 3:1.\textsuperscript{15} There appears to be nothing in this rulemaking that would prevent older employees of small employers from being charged up to a 30% penalty on that tripled premium amount if they choose to exercise their civil rights. If this were to occur, older workers would be disproportionately coerced/burdened (depending on whether they succumbed or refused to provide the information). Also, it is not clear that the penalties allowable by the EEOC under the ADA and GINA establish the ceiling for all allowable wellness-related penalties. The ACA allows unlimited penalties, for instance, for failure to participate in participatory wellness programs. At times, the NPRM seems to be saying that its penalties only relate to the ADA and GINA provisions relevant to health risk assessments and medical exams, and that employers remain free to impose additional penalties on nonparticipation in other wellness program activities or requirements.\textsuperscript{16} On the other hand, the NPRM’s example regarding the apportionment of penalties between an employee and spouse appears to imply that only the amount remaining, after subtracting the penalties assessed for withholding medical/genetic information from the


\textsuperscript{12} Id.

\textsuperscript{13} Id.

\textsuperscript{14} Id.

\textsuperscript{15} Patient Protection and Affordable Care Act, 42 U.S.C. § 300gg(a)(1)(A)(iii).

total 30% penalty, may be imposed to induce participation in other wellness program activities.\textsuperscript{17} The final rule should make clear in the regulation itself (not only in an example) the relationship of the penalties it is allowing under the civil rights laws to the penalties permitted under the ACA.

B. The Proposed Rule Selectively Ignores Statutory Definitions of “Family Members” and “Genetic Information"

The proposed rule also selectively redefines central concepts in GINA’s statutory framework in order to create new exceptions to the statute’s protections from involuntary wellness programs. The NPRM recognizes that spouses are indeed family members under 1) the statutory definition,\textsuperscript{18} which covers dependents without regard to blood relationship, and 2) the GINA regulations previously issued by the EEOC, which specify that persons who are dependents “as a result of marriage” are family members.\textsuperscript{19} The NPRM also concedes that family medical history (“the manifestation of a disease or disorder in family members of such individual”) is considered “genetic information” under the statute.\textsuperscript{20} For instance, the NPRM states that:

[w]hen an employer seeks information from a spouse (who is a family member under GINA…) about his or her current or past health status, the employer is also treated under GINA as requesting genetic information about the employee. This is because GINA defines the term “genetic information” broadly to include information about a family member’s (including a spouse’s) current or past health status [aka “family medical history”].\textsuperscript{21}

However, the EEOC appears to invent out of whole cloth two new “exceptions” to GINA’s statutory definitions: one to the definition of “genetic information” and another to the definition of covered family members. First, the EEOC makes a new distinction in the definition of genetic information. It deems it defensible for an employer to coerce a spouse to submit her or his own medical information – which GINA expressly treats as family medical history/genetic info of the employee – because the EEOC no longer considers this as true genetic information of the employee. (By contrast, the NPRM retains the ban on penalizing refusal to provide the results of genetic tests of the employee or family members.\textsuperscript{22}) Second, and similarly, the NPRM makes an exception to the definition of family members. It creates and justifies an exception for coercing spouses (unlike other “family members”) to provide their own medical information because the spouse’s medical information doesn’t really disclose the genetic make-up of the employee. “There is minimal, if any, chance of eliciting information about an employee’s own genetic make-up or predisposition for disease from the information about current or past health status of the employee’s spouse.”\textsuperscript{23} The NPRM would retain the ban on penalizing refusal to provide medical information about the employee’s children, because the EEOC considers this to be real genetic information.

\textsuperscript{17} GINA Wellness NPRM, supra n. 2, at 66858.
\textsuperscript{19} See 29 C.F.R. § 1635.3(a)(1).
\textsuperscript{21} GINA Wellness NPRM, supra n. 2, at 66855.
\textsuperscript{22} The NPRM sometimes uses “genetic information” to refer to the more complete statutory definition, and sometimes uses the phrase to refer to its new, narrower definition. See e.g., GINA Wellness NPRM, supra n. 2, at 66856: “while the proposal allows inducements in return for a spouse’s current and past health status, it does not allow inducements in return for the spouse providing his or her own genetic information, including the results of his or her genetic tests.”
\textsuperscript{23} GINA Wellness NPRM, supra n. 2, at 66856.
In both of these cases, the EEOC has drawn distinctions in statutory definitions and invented new exceptions to the statutory requirements in contradiction to the plain language of GINA. Congress could have limited GINA’s protections to blood relatives, but it didn’t. It expressly included dependents in the definition of family members, in addition to blood relatives. Presumably, this was because a chief rationale for these provisions of GINA was to give employees a mechanism for self-protection from discrimination, which Congress recognized would occur against employees whether the dependents on their health policies were blood relatives or not. Likewise, Congress could have limited its definition of “genetic information” to genetic test results, but it didn’t. The EEOC’s new “narrow exception” to allow penalties for failure to disclose family medical history creates a hole in GINA’s protections that are expressly addressed and disallowed by the statute. In both of these cases, the EEOC has read important definitions and fundamental protections completely out of the statute.

II. The Proposed Rule is Arbitrary and Capricious

The interpretation of the voluntariness standard in this rulemaking is directly opposite to the one taken by the Commission in its GINA regulations issued only five years ago. It is also inconsistent with an informal discussion letter issued four years ago.24 Bewilderingly, given this recent history, the Commission states in conclusory terms that allowing penalties of thousands of dollars on spouses who don’t want to turn over their medical information to a wellness program “promotes GINA’s interest in limiting access to genetic information and ensuring that inducements are not so high as to be coercive, and thus prohibited.”25 In other words, the Commission takes a position on coercion in direct conflict with recent regulations, yet offers no real rationale or supporting evidence for this ipse dixit U-turn.

In the preamble, the Commission seems to imply that the justification for its change of regulatory direction is the need to clarify some unidentified vagueness in the prior regulations. The EEOC states that it has received “questions” from the business community since the publication of the final GINA regulations about GINA’s application to wellness programs,26 as if they were a new development justifying another set of regulations so soon after the last ones. The preamble goes on to say that, “read one way,” conditioning any part of a wellness penalty on the provision of genetic information would violate GINA, and that these proposed regulations would “clarify” that GINA does not prohibit limited penalties.27

There has been and remains only one way to read the EEOC’s current GINA regulations: they ban employers from financially coercing (via penalties or inducements) the disclosure of genetic information. This rulemaking doesn’t “clarify” anything; rather, it is a straightforward, clear reversal of this previous, statutorily based regulation with no further rationale offered other than “the business community raised questions.”

The NPRM preamble also alludes to its newly created exceptions as striking the “appropriate balance”28 between GINA’s goal of protecting employees from employment discrimination and the ACA’s goal of promoting participation in wellness programs. As a supporter of the ACA,

24 See EEOC Office of Legal Counsel, ADA & GINA: Incentives for Workplace Wellness Programs (June 24, 2011), available at http://www.eeoc.gov/eeoc/foia/letters/2011/ada_gina_incentives.html (“the final rule makes clear that covered entities may not offer financial inducements for individuals to provide genetic information as part of a wellness program.”)
25 GINA Wellness NPRM, supra n. 2, at 66857-58.
26 Id., at 66855.
27 Id.
28 GINA Wellness NPRM, supra n. 2, at 66856.
AARP notes that two other even higher priority goals of the ACA were to end health status discrimination and make health insurance more affordable, goals that this rulemaking directly undermines. To the extent this balance argument is a restatement or extension of its earlier ADA rulemaking rationale of a need to resolve any conflicts between the civil rights laws and the ACA, that argument is no more convincing here than it was there.\textsuperscript{30} In fact, it is far less convincing here. The EEOC already deliberated on and expressly struck the right balance the first time in its 2010 GINA regulations, which were \textit{unanimously} issued by the Commission, \textit{after} the passage of the ACA. The ACA was not a later-enacted statute vis-à-vis the GINA regulations. When the EEOC proposed those regulations, it specifically asked for comments on wellness program inducements.\textsuperscript{31} Business groups urged an approach deferring to HIPAA/ACA, and the EEOC rejected it. The EEOC then stated it had “balanced” the goals and approaches of the two statutes, and it decided to accept a more protective, \textit{balanced} approach that allowed employers to ask about genetic information, but didn’t penalize the worker/family member if they didn’t answer.\textsuperscript{32} That was the right balance; this is not.

Having ruled out any rationale for this proposal based on new legal developments or a lack of clarity, there is also no factual record supporting such a significant departure from the Commission’s prior statutory interpretation. The weight of the research on wellness programs,\textsuperscript{33}
which continues to build,\textsuperscript{34} finds these programs largely ineffective in improving employee health or bringing down health care costs (except perhaps through the immediate cost-shift to employees who refuse to disclose medical/genetic information to their employers).

\section*{III. The Proposed Rule Greatly Expands the Potential for Discrimination and Invasion of Privacy}

Health “data is the new money,” according one recent article on the collection and compilation of “patient-generated” data.\textsuperscript{35} Insurance companies, retail pharmacy chains, wellness program vendors, health system software companies, wearable fitness device companies, and health care providers, among others, are collecting and sharing “big data” on the health status, risks, and needs of significant portions of the population. While some of the data is contributing to health care research or helping some individuals become healthier, the objective of many wellness programs is to acquire massive quantities of health data from multiple sources, to compile it into big data, and then to sell or “share” it for a profit.\textsuperscript{36} Such large-scale collection and sharing of information greatly magnifies the risks that it will be used to discriminate against an employee or other insured person,\textsuperscript{37} or that it will be misused for marketing purposes or even stolen by criminals.\textsuperscript{38}

\begin{quotation}
\textsuperscript{34} See e.g., \textit{Premium-based Financial Incentives Did Not Motivate Obese Employees to Lose Weight, Penn Study Finds} (Penn Medicine News Release, Jan. 5, 2016), available at \url{http://www.uphs.upenn.edu/news/News_Releases/2016/01/patel/}.
\textsuperscript{36} According to Kaiser Family Foundation, the wellness industry produces revenues of $7-8 billion/year industry, K. Pollitz & M. Rae, \textit{Workplace Wellness Programs Characteristics and Requirements} 8 (Kaiser Family Fdn., Issue Brief, Jan. 4, 2016), available at \url{https://kaiserfamilyfoundation.files.wordpress.com/2016/01/8742-02-workplace-wellness-programs-characteristics-and-requirements.pdf} [hereinafter \textit{Kaiser Report}]. However, the industry is fragmented with few barriers to entry, \textit{id.}, and estimates vary, as there is little consensus on how to define or measure this unregulated industry.
\textsuperscript{37} There is little doubt these data will make their way back to employers. In fact, many employers are making health data collection on their workforce a public affair. “Several giants of global industry” recently signed up for an initiative to gather and publish health information on their employees. I. Swetlitz, “Should companies publicly report employees’ weight and stress levels?” \textit{Stat} (Jan. 22, 2016), at \url{http://www.statnews.com/2016/01/22/publicizing-employee-health-data/}. This article doesn’t say so expressly, but it’s clear that the mechanism by which an employer would collect this information is through the employer’s (likely coercive) wellness program. The organizer of the initiative stated “he is confident that existing laws are strong enough to prevent companies from firing employees for being unhealthy.” \textit{Id}. The article does not address whether safeguards on the data are strong enough to prevent the employer from finding out who is unhealthy.
There are several features of the NPRM that enable wellness programs to expand their health data collection and disclosure operations. The first and main problem here is the hollowness of the “reasonably designed” requirement. As it did in its ADA rulemaking, the Commission again imports the ultimately unenforceable version of that concept from the ACA regulations, which defined “reasonably designed” in a way that was “intentionally vague and flexible and requires no scientific evidence of efficacy, only the sponsor’s claim that it has a reasonable chance of promoting health. [The ACA regulations also state that the standard was] intended to be easy to satisfy ...." Under this standard, a wellness program need not do anything that has been proven effective in improving health. In the interpretive guidance to its ADA wellness rulemaking, the EEOC declared that all a wellness program needs to do to satisfy this “reasonable chance at health promotion” standard is to conduct an “HRA and/or a biometric screening of employees for the purpose of alerting them to health risks of which they may have been unaware,” or when collecting medical information on a health questionnaire, to provide follow-up information or advice on health risk factors. In other words, it is perfectly legal under this standard for a wellness program to consist solely of collecting health data for the purpose of alerting employees to what the data collection found, along with perhaps some general information about how to lower health risks or a product to try. And that is what they do: roughly half do little more than screen.

Unfortunately, the other elements of the “reasonably designed” standard imported from the ACA provide little help in offsetting this emphasis on data collection. A wellness program “must not be overly burdensome, a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. ... The program is also not reasonably designed if it exists merely to shift costs from the covered entity to targeted employees based on their health.”

Yet, there are no standards for what constitutes a “highly suspect method.” A wellness firm called Newtopia is offering free genetic testing for “genetic markers associated with metabolism, weight gain and overeating,” and then claiming to offer personalized diet and exercise coaching based on the genetic results. There does not appear to be any scientific evidence to back up this approach. Not coincidentally, employees who answer Newtopia’s HR questionnaires are offered the chance to purchase Newtopia’s nutritional supplements and vitamins, an approach that appears “highly suspect.”

40 Id., at n. 18. The ACA’s reasonably designed requirements apply to health-contingent wellness programs.
41 ADA Wellness NPRM, supra n. 1, at 21668 (emphasis added).
43 GINA Wellness NPRM, supra n. 2, at 66857.
With no requirement that the program be evidence-based, how would this prohibition be enforced? Nor does the ACA’s “reasonably designed” requirement obligate employers to conduct any evaluation or collect any data on the effectiveness of its wellness program in improving health, or even in bringing down health care costs over and above the money saved by being able to penalize employees and their families for withholding their genetic information from the employer. Without such data, it will be next to impossible to enforce the “subterfuge” and “cost-shifting” aspects of the definition.

Second, having adopted a “reasonably designed” standard that allows wellness programs to gather data and do little else, the EEOC now proposes to sanction employers to coerce employees and their families to provide their own medical and genetic information. Wellness programs may have been data-mining operations before, but at least employees had the right to opt out and were protected from involuntary surrender of their health information under the ADA and GINA. In this rulemaking, the EEOC compounds the invasion of privacy permitted in its ADA rulemaking by now enabling the collection of data on more family members, and enabling genetic information to be added to the mix, making the data collected and compiled even more valuable to the health data market.

Third, wellness program vendors routinely and electronically obtain employees’ passive consent to waive their confidentiality rights and authorize the vendor to disclose their medical data to others. For instance, Healthmine makes blanket consent for it to collect and share one’s medical information from and to all sources, and to “seamlessly integrate” it with any health insurance carrier or employer-sponsored plan, automatically bringing together “comprehensive clinical data.” Zensey, another major wellness provider, makes use of its website tantamount to a wholesale authorization to gather your personal health insurance from health care providers, insurers, others on your physical and mental health, diagnoses, prescriptions, health care treatments, test results, etc. and “share personal information with its partners, subsidiaries, and third party vendors.” These passively and well-hidden authorizations allow the wellness program to seek out addition information from the employee’s health care providers, insurer, and others, and to then widely “share” that information with business partners. Neither employers nor many wellness vendors are covered by HIPAA, which protects personal health information. However, even if these programs were protected by HIPAA, this would not be adequate protection: HIPAA has many exceptions. Moreover, there is no private right of action for an aggrieved individual, and reports indicate that the federal agency on which harmed individuals must rely to take action needs to be much more vigorous in enforcing the law.


By expanding opportunities for disclosure and sharing of such sensitive data, this rulemaking severely undermines the two intertwined goals of GINA: to protect civil rights; and thereby to encourage participation in and the development of genetic medicine. In the findings section of the Act, Congress stated: “Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.”\(^5^0\) GINA’s provision on wellness programs directly supported this legislative purpose. By prohibiting employers from being able to demand or coerce employees and their families from involuntarily having to provide their genetic information to a wellness program, individuals could seek genetic tests, genetic counseling, and participate in genetic research and medicine without fear that their genetic information would fall into the hands of their insurer or employer. Now, however, it is quite possible that the greatly expanded opportunities for breach of privacy and discrimination will make individuals unwilling to seek genetic services or volunteer for initiatives such as NIH’s Precision Medicine Initiative.\(^5^1\)

IV. In the Face of Such a Substantial Weakening of Statutory Protections, Other Safeguards Need to Be Strengthened

As noted above, in its final GINA regulations, the EEOC already carefully balanced the ACA’s objective to encourage workplace wellness programs with the ADA and GINA’s objectives to prevent discrimination and invasions of medical privacy as well as, in GINA’s case, to promote genetic medicine. By putting the power to withhold information in the hands of employees, the “voluntary” standard has been the linchpin to enforcing GINA’s antidiscrimination and privacy provisions. By undermining that standard, as proposed here, the EEOC creates a need to adopt a whole host of new protections to plug the holes its initial proposal would create. Consequently, AARP strongly urges the EEOC to walk back from this NPRM and retain its current regulations, unmodified. In the event, however, that the Commission decides to go forward, there are several measures it should adopt to mitigate the damage.

A. Some Needed Protections Included in the EEOC’s ADA Wellness Rulemaking Should Be Included Here

As deeply concerned as AARP is with the EEOC’s ADA rulemaking, that proposal did contain a few very important protections that are inexplicably missing here. First, there is no express prohibition here on requiring an employee’s spouse to capitulate to requests to turn over medical/genetic information to the wellness program, or making surrender of genetic information a condition for enrolling in health insurance coverage. Nor is there any ban on employers making access to certain tiers, elements, or package of benefits contingent on agreeing to turn over medical/genetic information to the wellness program. Especially in light of the recent decision in \textit{EEOC v. Flambeau, Inc.}^5^3 (a decision AARP urges the Commission to appeal), an

\(^{50}\) GINA Findings, supra n. 3, at Sec. 2(5).


\(^{52}\) NIH, About the Precision Medicine Initiative Cohort Program, at https://www.nih.gov/precision-medicine-initiative-cohort-program.

\(^{53}\) Civil Action No. 3:14-cv-638-bbc (W.D. Wis., Dec. 30, 2015). Clearly, in light of the \textit{Flambeau} decision, the EEOC’s final rule in the ADA rulemaking needs to make absolutely clear that for purposes of the
ADA wellness case in which a court upheld an employer’s ability to make enrollment in its health insurance plan contingent on answering an HRA and submitting to biometric screenings, it is critically important that the EEOC do here what it did in the ADA rulemaking. This proposed rule needs to include explicit prohibitions on 1) outright requiring an employee’s family members to disclose past and current medical information to the employer’s wellness program, and 2) making such submissions a condition of access to participation in the health plan, or access to any tier or package of benefits, for the employee or any family member of the employee.

A second important protection that was included in the ADA rulemaking but is missing here is an absolute prohibition on retaliating against the employee for a spouse’s refusal to submit her or his medical information to the wellness program. Before, this type of protection may not have been necessary, because the provision of genetic information had to be voluntary; thus, retaliation against an employee whose spouse refused to provide it would have been a violation of the voluntariness requirement. But now that the EEOC has proposed allowing employers to demand this information involuntarily, it is important for there to be a new, separate provision in the regulations that explicitly prohibits taking any action that retaliates against, interferes with, coerces (in a non-wellness-penalty sort of way), intimidates, or threatens an employee whose spouse refuses to provide medical information, or for that matter an employee who refuses to provide their own family medical history. The EEOC’s pending case against Orion Energy for firing an employee who refused to provide previously ADA-protected medical information underscores the need to include such a provision here too.

B. The Protections That Are Included Here to Mitigate the Damage Done by the Proposed Rule Are Inadequate

The Commission spotlights several elements of its proposal that either limit the forfeitures being proposed or establish new safeguards against the new opportunities for injury. AARP agrees that all of these limits and safeguards are appropriate – the Commission certainly should not weaken them any further – but they are insufficient and need to be significantly strengthened. The mitigation proposals include:

- The rule only permits penalties on family medical history, not genetic test results

AARP appreciates that the EEOC is not requiring the covered spouses of employees to hand over the results of their genetic tests in order to avoid huge financial penalties. But, given how few individuals have undergone genetic testing, and how much discrimination has occurred based on family medical history, family medical history is a core element of genetic information, as statutorily defined, and must be a core focus of GINA’s protections. The loss of protection likely under the new “voluntary” standard is a substantial reduction in the scope of rights provided by GINA. Unfortunately, the only way to fix this is to preserve the current rules, which would allow a wellness program to ask the covered spouse about medical conditions and allow the spouse not to answer those questions without being penalized.

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ADA’s safe harbor for bona fide insurance plans, wellness programs do not qualify, regardless of whether an employer claims they are using the wellness program for underwriting purposes and regardless of whether the wellness program is part of the group health plan. A footnote disfavoring the Seff and Flambeau approaches will not suffice; there needs to be a strong regulation.

• The rule only permits financial coercion of medical information from spouses, not children

AARP appreciates that the EEOC still prohibits wellness plans from separately penalizing employees who do not provide medical information on and screenings of their children. The EEOC declined to go this far because that information would reveal too much genetic information about the employee. However, it is not quite accurate to say that the EEOC is not allowing wellness programs to penalize employees for providing medical/genetic information on their children. First, to the extent an employee pays more for family coverage that includes children, and to the extent that the EEOC is permitting employers to base the size of their penalties on the size of the family premium, the penalty does include the children. The employer may not be separately penalizing them, but the new family premium denominator includes them. Second, the EEOC’s proposal does permit employers to coerce employees to provide genetic information on their children, by virtue of having coerced medical information from the parents. The medical information of the parents is family medical history, hence genetic information, of the children.

The EEOC could fix the first problem by keeping the penalty denominator proposed in its ADA rulemaking (employee-only coverage), or at least limit the penalty denominator to the cost of employee+1 coverage in the event an employee is covering a spouse on policy (if covering employee plus a nonspouse dependent, should base it on employee-only). In any case, however, the EEOC should make clear that the limitation on coercing the medical information of covered children applies whether they are dependents or not, and without regard to their age. The only way for the EEOC to fix the second problem is to withdraw this proposed rule.

• The rule maintains a penalty limit of 30%

AARP appreciates that that the EEOC is requiring the new family-sized 30% penalty to be apportioned among family members rather than permitting a separate 30% penalty to be assessed against each covered family member. However, if the EEOC was concerned about the impact that its ADA rulemaking would have on the affordability of health insurance, it should be triply concerned here: the cost of family health coverage is, on average, almost triple the cost of the employee-only coverage the EEOC used as the basis for penalty calculations under the ADA. The size of these penalties will be indisputably huge – the equivalent to 10% of median household income in 2014 – and coercive. It is disheartening that the EEOC does not raise or address the real-life impact of its proposal on the affordability of health insurance and the extreme coercive effect that its proposal will have.

If the EEOC is not going to retain its current regulations prohibiting penalties altogether, at a minimum it should revise its proposal regarding the appropriate base on which the penalty is calculated. The denominator for permissible penalties on refusals to provide medical/genetic information should be restricted to the employee-only coverage proposed in its ADA rulemaking, regardless of whether a spouse or other dependents are covered by the plan. In addition and better yet, as we urged in the ADA rulemaking, the base against which penalties are calculated should be the employee’s contribution toward health coverage (or here, the employee’s contribution to family coverage), rather than including the employer’s contribution as well. Such penalties would still be highly coercive, but they might not put the price of health


56 AARP ADA Wellness Comments, supra n. 5, at 14.
insurance totally out of reach for those who object to sharing such information. Finally, the EEOC should also specify that penalties may not be computed using a premium amount that has been age-rated or inflated by any other legal factor; in this case, the appropriate benchmark would be the cost absent the effect of the rating factor.

- The rule still requires prior, knowing, voluntary, written authorization

This authorization is a statutory requirement. In reality, though, with the substance gone, the EEOC is proposing that employers and employees/spouses go through the motions of a voluntary authorization. It makes little sense to pretend that an employee or spouse is providing “voluntary” authorization to provide their medical/genetic information to the employer, when in fact they have been coerced into doing so by the threat of enormous fines in the form of much higher health insurance costs.

It would be helpful for an employee and spouse, before they are told to turn over their medical/genetic information, to receive advance notice, written in language designed to ensure that the recipients will understand it. However, one of two types of changes is needed: either the form 1) should be altered to honestly reflect whether the authorization was made under duress or was genuinely voluntary, or 2) it should be transformed into a mere notice/disclosure. Because the “voluntariness” of the authorization has already been compromised, the authorization/notice requirements need to be much more specific and accurately reflect the new circumstances under which they are being provided.

The first option would involve the inclusion of a two-part, check-the-box designation, indicating that the individual’s provision of the genetic information is either “truly voluntary” or “under financial compulsion.” No employee or covered family member should be required to state they are voluntarily authorizing the disclosure of their medical/genetic information to the wellness program when the authorization is not voluntary. The second option would require advance notice (not authorization) describing the type of genetic information to be obtained, the specific purposes for which it will be used, the confidentiality restrictions that apply and to whom the wellness provider may or plans to disclose it. In both cases, the form should provide notice of the “choice” the individual is being asked to make, and the nature and size of any penalties/rewards that are contingent on providing the information. In addition, contrary to the proposal in the NPRM, the employee should also be required to separately authorize the provision of the spouse’s medical information; after all, under GINA, the spouse’s medical information is the employee’s genetic information. Moreover, given the well-documented practices of wellness vendors who obtain passive consent to collection and disclosure of health information in the terms of use on their website, the EEOC should retract its permission for wellness programs to obtain authorizations through electronic consent, and instead insist in the regulations on “written” consent to acquire genetic information or to disclose it to others.

- The rule requires programs to be “reasonably designed”

Insisting that wellness programs be reasonably designed is appropriate. However as discussed above, the ACA’s definition, requiring only that a program have a “reasonable chance” at health promotion, requires little. As AARP argued in our comments on the ADA rulemaking, the civil rights laws demand a more exacting standard, because when civil rights are being infringed, employers are required to show a close relationship between a practice (acquiring

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58 See material cited at notes 46 and 47, supra.
medical/genetic information) and the objective sought (health promotion). The rule’s “reasonably designed” requirement could be strengthened in a number of ways. Rather than echoing an ineffectual standard, the EEOC should require that wellness programs offer services and programs of real benefit and proven to improve health – be evidence-based. Employers should also be required to collect data on and evaluate their wellness programs for effectiveness, including documenting the type and amount of incentives/penalties imposed, the impact of penalties on cost of health coverage for employees and their families compared to the impact on employer costs, the “take-up” rate on succumbing to penalties, and any improvement in health outcomes and health care costs (over and above reductions attributable to cost-shifting). Unless the rule requires evidence-based programs with documented results, many programs will remain largely unadorned data-mining operations.

- The rule includes new privacy protections

Protecting confidentiality is an important objective, not only to protect medical privacy, but also to help prevent employers from acquiring genetic information they can use to discriminate. That is the goal of the entire framework of Title II. To its credit, the EEOC has taken notice of the aggressive practices of an unregulated wellness industry that has built a business model on masking waivers of confidentiality and engaging in widespread data-sharing for profit. And it has proposed two additional safeguards to address them. These are a good start, but they need to be much stronger, and more extensive.

On waivers of confidentiality, the Commission proposes that a workplace wellness program can use penalties to coerce the provision of the spouse’s medical information, but it would not be permitted to use penalties to coerce the spouse into agreeing to allow the wellness program to disclose that information. AARP agrees, but it appears the Commission is only addressing disclosure of the information, as indicated by the cross-reference to the confidentiality protections of § 1635.9 in proposed § 1635.8(b)(2)(vi).

The Commission has neglected to address two of the bigger problems here: the ubiquitous practice of obtaining passive consent to waive the individual’s confidentiality rights, and the fact these programs are using those waivers not only to disclose information but to collect more of it from other sources. To fix these problems, the Commission needs to add several more protections that should apply to wellness programs that collect any type of medical/genetic information from the employee or family, with or without penalties. First, the proposed rule currently only covers disclosure. All waiver protections should also apply to the collection or acquisition of any medical/genetic information on the employee or family member from other sources, however obtained. Second, the rule needs to ban the use of any form of passive consent in this context for any purpose, and require any waiver or authorization to collect or disclose information to be express (not a hidden or automatic term of use of the website), clearly and prominently communicated (not buried in a mountain of legalese in fine print), and it should be separately administered (separate from the completion of the HRA) and in written form (not electronic). In addition, no penalty or reward should be permitted for the provision of a waiver/authorization to collect any medical/genetic information from other sources or to disclose it to others. Authorizations to collect outside information or to disclose it to a third party should be treated as a separate, truly voluntary transaction – separate from the completion of HRAs or biometric screenings. Finally, employers themselves should never have access to any health/genetic information in any form that discloses the identity of the individual participants. There should always be a firewall between the employer and whoever is collecting the genetic information. These protections would help limit unfettered data-mining and increase the odds that any waivers of confidentiality are knowing and voluntary.
The Commission also rightly prohibits a wellness program from using penalties to coerce employees and family members to agree to the sale of their medical/genetic information. However, this proposal, too, falls short in several respects and needs to be strengthened.

First, the EEOC should prohibit the sale of this information outright, with or without penalties. A wellness program that is supplying health or genetic services to employees should not profit off of the sale of medical information – especially medical information that was likely obtained through financial coercion.

Second, the Commission needs to expand this prohibition to any “sharing” or disclosure of the information, not just the sale of it. “Sharing” is the way the wellness industry operates; it seeks your permission to “share” or disclose your information with “business partners” and others, and to “use” your information to provide “services,” which may amount to as little as receiving an ad that Weight Watchers (the business partner) has a new app available. The Commission should include “sharing” in the prohibition – it should be a violation to condition receipt of a reward or avoidance of a penalty on agreeing to allow the program to sell genetic information (including the health information of a family member) or to “share” it with anyone, including “business partners.” In addition, even if no penalties are involved, wellness programs should not be permitted to “share” genetic information with business partners without express authorization as suggested above with regard to waivers. Moreover, they should be required to reveal the identity of any partners, and to describe the explicit purpose for which it is disclosing the genetic information to that particular partner.

A third problem here is that, even with the strongest restrictions on data-mining and disclosures, the wellness industry is largely unregulated. With all of the information-“sharing” and subcontracting by employers and vendors, data can be broadly disclosed, and hacked into, with no legal accountability or adequate redress for employees and their family members. No confidentiality protection is as strong as self-help – preserving the power of employees and family members to withhold their genetic information at the outset. Prevention is the best enforcement mechanism here. Failing that, however, the EEOC has not proposed any new penalties or remedies for unauthorized disclosure of the genetic information it is now allowing to be coerced. Instead, EEOC should add two more provisions to its strengthening of § 1635.8(b)(2)(vi). First, harm should be presumed from any unauthorized disclosure, or any outside breach/access to the data due to hacking. Second, the employer should be made strictly liable to the employee and/or family member for that harm, notwithstanding any contract provision imposing liability on the wellness vendor or its subcontractors/partners. Employers should not be able to set up these programs and then outsource the liability for harm they create. Imposing strict liability on the employer will make them more diligent about who they hire, and what procedural safeguards they have in place to ensure knowing waivers of confidentiality, careful subcontracting, and protection of the data from outside hackers.


60 Not surprisingly, wellness vendors typically disclaim any liability for any breaches or violations, and as part of the terms and conditions of using their websites, they require any disputes to be resolved by forced arbitration. In addition to the recommendation here that the EEOC employers be held strictly liable for any misuse or breach, the EEOC should consider prohibiting any wellness program or subcontractor from including a predispute, mandatory arbitration agreement in its user agreements, at least as they regard any charge or claim under the ADA, GINA, the ADEA, or the other civil rights laws the EEOC enforces.
Finally, all of these privacy protections in their strengthened form should be included in the ADA wellness rulemaking as well. In our comments on that rulemaking, we pointed out that “these wellness programs are built on enabling the sharing of personal medical information, ‘voluntarily authorized’ by the employee.”\textsuperscript{61} There, the Commission focused on the aggregation of data and preventing the employer from finding out personalized medical/disability information on their employees. However, employees are vulnerable to all of the same concerns regarding data-mining and privacy vis-à-vis that information as with genetic information. The EEOC should ensure that employees are protected from all of these practices under the ADA as well.

V. Specific Issues on which Comments Were Requested

In addition to comments on its specific proposals, the Commission invites comment on some particular questions and issues.

1. Medical certification alternative – Of course, AARP would prefer that the EEOC retain its current, balanced approach of permitting employers to ask for genetic information, but allowing individuals to avoid the penalty/get the inducement regardless. However, if the spouse must now provide the medical information in order to avoid the penalty, it is important that the EEOC provide some alternative that allows the spouse to withhold the information and still avoid the penalty. As AARP recommended in its comments on the ADA rulemaking, it should suffice if the spouse obtains a certification from any medical professional (not necessarily a physician) that any medical conditions or risks the spouse may have are being managed (not necessarily “actively treated”). In addition, the spouse should get to select that medical professional, certification should not disclose any medical or genetic information, and the employer should be prohibited from seeking or requiring verification.\textsuperscript{62}

2. Authorizations needed for de minimis rewards/penalties – In general, AARP has had no objection to wellness programs that offer de minimis rewards such as gift cards or small electronics as an incentive to participate in an HRA, screenings, or other wellness program components. The problem arises when the rewards/penalties are tied to the cost of health insurance and services: charging even a relatively small amount more for premiums or imposing a slightly higher deductible can have a significant effect on affordability, and therefore the coercive power of the penalty, especially for workers who are not highly compensated. To the extent notices/authorizations are required, they should be required for de minimis penalties/rewards as well.

3. Procedural safeguards against cost-shifting – The Commission asks how to ensure that employer-sponsored wellness programs are designed to promote health and prevent disease rather than operating to “shift costs to employees who have health impairments or stigmatized conditions.”\textsuperscript{63} The best way to do this would be to adopt a meaningful definition of “reasonably designed” rather than importing the ACA definition. The program would also need to collect data on its operations. Both of these issues are discussed at greater length in sections III and IV above. At a minimum, however, the employer should have to track its overall health insurance costs, the amounts contributed by employees and employers with and without penalties imposed, and

\textsuperscript{61} AARP ADA Wellness Comments, supra n. 5, at 19.

\textsuperscript{62} Id., at 16.

\textsuperscript{63} GINA Wellness NPRM, supra n. 2, at 66859.
measure whether there was any health improvement as a result of having supplied the medical information and having participated in the program. If there is no improvement in health by virtue of “participation” then the penalty only acted to shift costs. And given the overwhelming body of evidence that many of these wellness programs do not improve health, in the context of a charge, the burden of proof for proving reasonable design should be on the employer who is sponsoring the program and who is benefitting from the cost shift.

4. Treatment/confidentiality of electronically stored personnel records and Treatment/confidentiality of spouse’s health information - The EEOC’s concerns about hacking and breaches of electronic record systems are well-founded. Again, of course, the best protection in this context is self-help. But even in cases in which employees and family members provide medical/genetic information voluntarily, the confidentiality protections of electronic records is a large concern. There are several measures that the EEOC could require, many of which have already been discussed, i.e., restrictions on the collection of information, restrictions on the disclosure of information, a meaningful requirement to be reasonably designed in a meaningful sense, and the imposition of strict liability on employers for breaches of the data, whomever is storing it. In addition, as per # 6 below, the EEOC should restrict any permissible data collection to that minimally necessary to support the provision of real, evidence-based wellness services. Finally, while AARP is no expert in data encryption and security procedures, the data could be encrypted and stored securely. Perhaps the EEOC should consult with NIH on what procedures it is using for the Precision Medicine Initiative to protect their genetic information data, and then require employers, their vendors, and their business partners to store the data with similar levels of protection.

5. Restrict data collected to minimum necessary – The minimum necessary should be the requirement, both with regard to the collection of HRA and screening data from the spouse and the collection of any data on the spouse from other sources. The EEOC should include a definition of “necessary” that requires any information to be directly related to and necessary to the offering of the specific wellness activities, interventions, and advice provided through the program. In section IV(B) above, AARP does not go so far as to suggest that wellness programs should be absolutely prohibited from collecting or accessing genetic information from other sources such as claims or physician records. However, strong protections are needed. First and foremost, no penalty or reward should be permitted to provide the authorization to collect any medical/genetic information from other sources. There would also need to be protections in the form of reasonably designed requirements; true, separate, written, voluntary consent procedures; disclosure restrictions; etc. Without such protections, collection from outside sources should indeed be prohibited. Furthermore, employers themselves should never be permitted to seek or access individual information from other sources.

6. Penalties/rewards on spouses when the wellness program is not part of a group health plan – As we discussed in our comments on the ADA wellness rulemaking, many if not most employers that offer wellness programs with “incentives” do so outside of the group health plan. In that rulemaking, the EEOC explicitly proposed changing the definition of “voluntary” only for HRAs and screenings that were offered as “part of” the group health plan, and asked what it should do about those offered outside GHPs. There, AARP noted that the EEOC had not defined what it meant by “part of” a GHP. We also noted

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64 AARP ADA Wellness Comments, supra n. 5, at 12-13.
that whether an employer practice occurred in or out of a GHP had no relevance under the civil rights laws. But, if it meant that fewer employees would be subjected to financial coercion, the EEOC should not apply its new definition to HRAs/screenings conducted outside of group health plans.

In this rulemaking, the EEOC has not proposed any differentiation in regulatory treatment between information requests made as part of or outside of a GHP. Perhaps this is because the spouse is reached by coercive wellness penalties only if she or he is covered by that group health plan? In any case, the Commission specifically seeks comment on whether GINA should now permit rewards/penalties on spouses who refuse to submit their medical information to an outside-the-plan wellness program. AARP gives the same answer here. The ADA and GINA prohibit employers from requiring or penalizing employees and their family members from having to disclose medical/disability/genetic information to a workplace wellness program. The EEOC still has not defined what it means to be “part of” a group health plan, but to the extent that this new rule does not apply to “outside” programs, and the EEOC continues to ban coercive inducements/penalties for those, that would be a good thing for the employees and covered spouses who do not wish to turn over genetic information to the employer.

Conclusion

With this proposal to permit employers to exact huge financial penalties on employees and their spouses if they should deign to exercise their rights under GINA – combined with the EEOC’s troubling proposal last year to negate the “voluntary” standard for wellness programs under the ADA – the EEOC has effectively proposed making the exercise of one’s statutory civil rights the exclusive domain of workers with salaries high enough to afford an enormous financial penalty to withhold their and their family’s medical/genetic information. This is not only contrary to law, it is contrary to the spirit of both of these civil rights laws. Accordingly, the Commission should withdraw this proposed rule and reissue a rule that preserves the balanced approach taken in the current GINA regulations. In the absence of corrective action to reinstate a meaningful voluntary standard, the EEOC should take further steps as outlined here to more effectively protect employees and their families from the harms these proposals will cause.

Thank you for the opportunity to comment and your consideration of our recommendations. If you have any questions, please contact Deborah Chalfie in our Government Affairs Department at 202-434-3723.

Sincerely,

David Certner
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Government Affairs