Geisinger

To: Marc Williams, MD, and Patricia Deverka, MD, MBE
From: Jennifer K. Wagner, JD, PhD
Date: November 29, 2019
Subject: Relevant Law & Policy Issues for "Stakeholders Assessing Genetics with Employers" (SAGE)

RESEARCH MEMORANDUM

I. Background

This memorandum is the culmination of a narrowly framed law and policy research project to identify and summarize relevant legal and policy issues if employers were to pursue the implementation of a wellness program for employees that incorporated genetic testing. Specifically included are an overview of federal law requirements for wellness programs and state issues related to employers' acquisition and use of genetic testing and genetic information of employees. Standard legal and policy methodologies were used, and research was performed using Westlaw Next. The federal laws summarized here are the exclusive basis for this memorandum. Other federal and state laws that might be relevant and affect wellness program compliance were not reviewed as part of this work.

This research was conducted as part of the "RISE Supplement: Employer Genetic Testing Consortium," a project funded by the National Human Genome Research Institute (NHGRI) Grant No. R01HG009694-03S1 (Peterson, PI). The author is solely responsible for the content. The content is provided as-is and for informational purposes only. Nothing in this memo shall be construed as legal advice or the substitute for a legal opinion on the compliance of any wellness program under development or consideration for implementation. In-line references have been minimized to improve readability.

II. Summary of Federal Laws Affecting the Design and Implementation of Wellness Programs

a. Genetic Information Nondiscrimination Act of 2008 (GINA)

The Genetic Information Nondiscrimination Act (GINA) protects employees from genetic discrimination from employers. Title I relates to health insurance, and Title II relates to employment. Both titles are potentially implicated by employer-sponsored wellness programs. Bradley Areheart and Jessica Roberts (2019) reported that, in the 10+ years of GINA, there have been only 48 unique court cases resolved involving GINA, 30 of which hinged on the application of GINA. Courts faced with deciding alleged GINA violations have stumbled on definitional issues (often getting it wrong). Definitions of particular importance for compliance are *family member*; *family medical history*; *genetic information*; *genetic monitoring*; *genetic services*; *genetic test*; and *manifestation or manifested*. *Family member*, for example, includes not only those related by blood but also those individuals who become related through marriage or adoption.

GINA Title II makes it unlawful for employers to – for any reason and subject to strict liability – acquire genetic information of employees. Contained in this statutory ban on genetic information acquisition, however, were six exceptions, one of which is a wellness program exception providing as follows:

> "Where—
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> (A) health or genetic services are offered by the employer, including such services offered as part of a wellness program;
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> (B) the employee provides prior, knowing, voluntary, and written authorization;
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> (C) only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;"

42 USC 2000ff-1. Sec. 202(b)(2). When the Final Rules for GINA Title II were issued in 2010 by the Equal Employment Opportunity Commission (EEOC), the agency addressed concerns about inducements to participate and considered four different approaches to "voluntariness:"

1. Issue incentive caps similar to those applicable under HIPAA;
2. Issue a rule that combines elements of HIPAA and ADA rules (where a program is voluntary if it does not require participation and does not penalize non-participation along with a determination that incentives below the HIPAA 20% cost of coverage cap would not be considered a penalty);
3. Issue a rule allowing incentives but not indicating whether inducements should have any limitation; and
4. Issue a rule banning incentives for participation in wellness programs that include collection of genetic information (including family medical history inquiries).

Recognizing that employers offering wellness programs have to comply with Title II and the health plans themselves must comply with Title I, EEOC offered examples to illustrate how incentives may be used. The final regulations implementing the wellness program exception in 2010 contained the following verbatim requirements:

(i) This exception applies only where—
(A) The provision of genetic information by the individual is voluntary, meaning the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it;
(B) The individual provides prior knowing, voluntary, and written authorization, which may include authorization in electronic format. This requirement is only met if the covered entity uses an authorization form that:
(1) Is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand it;
(2) Describes the type of genetic information that will be obtained and the general purposes for which it will be used; and
(3) Describes the restrictions on disclosure of genetic information;
(C) Individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace; and
(D) Any individually identifiable genetic information provided under paragraph (b)(2) of this section is only available for purposes of such services and is not disclosed to the covered entity except in aggregate terms that do not disclose the identity of specific individuals (a covered entity will not violate the requirement that it receive information only in aggregate terms if it receives information that, for reasons outside the control of the provider or the covered entity (such as the small number of participants), makes the genetic information of a particular individual readily identifiable with no effort on the covered entity's part).

75 Fed. Reg. 68935. (See also 75 Fed. Reg. 68922-68924; §1635.8(b)(2)). The regulatory provisions continue with an explanation that financial incentives cannot be used to induce employees to provide genetic information; that financial incentives may be used to help employees who have voluntarily disclosed genetic

information to meet health outcome goals only if those incentives are also provided to employees whose lifestyle choices (rather than genetic information) put them at risk for the same identified conditions; and that GINA does not relax the employers' obligations to comply with ADA and HIPAA nondiscrimination requirements, which include making reasonable accommodations to enable similar situated individuals to enjoy equal benefits and privileges of employment (by adjusting the plan) or allowing a reasonable alternative to or waiver of the specific program requirements. 75 Fed. Reg. 68935-68936. Regulatory updates were issued in 2016, but the challenged portions have since been vacated (see infra). The EEOC website contains additional information (such as FAQs, webcasts, etc.); however, caution is warranted in light of the removal of the 2016 rules.

In sum, to comply with GINA the wellness program must be reasonably designed to promote health or prevent disease; the provision of information must be voluntary (i.e., genetic testing cannot be mandatory and people cannot be penalized for not participating in those components); prior knowing, voluntary, and written authorization is required; the disclosures must be limited (individual-level raw data and interpretation only to the licensed professionals and individual employee; employers can at most gain access to aggregated information); and the information cannot be used for *any* purpose other than the wellness program. Incentives can be coercive and undue influences, making a wellness program lose its voluntariness.

b. Americans with Disabilities Act (ADA)

Title I of the Americans with Disabilities Act (ADA) protects qualified individuals from discrimination by employers on the basis of a disability with regard to hiring, promotions, firing, compensation, training, and other terms, conditions, and privileges of employment. *Disability* has a specific meaning and can refer to whether a person

(1) has a physical or mental impairment that substantially limits one or more major life activities;
(2) has a record of such an impairment, or
(3) is regarded as having such an impairment (perceived to be impaired).

The ADA, an anti-discrimination statute based in non-subordination theory rather than mere anti-classification theory (which underlies GINA) not only requires non-discrimination but also use of affirmative action measures known as "reasonable accommodations" when necessary. To protect employees, ADA generally prohibits disability-related inquiries and examinations unless it is "job-related and consistent with business necessity." There is an exception for "voluntary" medical examinations and inquiries that are part of a health program available to employees. (See Sec. 102 (c)(4)).

The ADA requires that wellness programs be "reasonably designed to promote health or prevent disease." A program satisfies this standard if the following conditions are met: (1) it has a "reasonable chance of improving the health of, or preventing disease in, participating employees," and (2) "it is not overly burdensome"; (3) it is "not a subterfuge for violating the ADA or other laws prohibiting employment discrimination;" and (4) it "is not highly suspect in the method chosen to promote health and prevent disease." 29 C.F.R. §1630.14. The Under the ADA, employers cannot require employees "to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by this part to carry out specific activities related to the wellness program)." Voluntariness of the wellness program is critical, and programs will be considered voluntary so long as they meet the following requirements:

1. Employees are not required to participate;
2. Employees who do not participate cannot be denied coverage under any of the health plans or benefits;
3. Employers do not take any adverse actions against employees (i.e., do not retaliate against, "coerce, intimidate, or threaten");
4. Employers provide notice that is written such that it is reasonably likely the employee will understand it and describing not only the type of information to be collected, purpose for its collection, and specific uses of it once collected but also the restrictions on disclosures.

Like GINA, ADA does not permit employers to have access beyond potential aggregated data that is not reasonably likely to disclose the employees' identities. As with resources on GINA, the EEOC website contains

additional information (such as FAQs, webcasts, etc.); however, caution is warranted in light of the removal of the 2016 rules. Disability and genetic rights advocates (such as Erin Oliphant and Sharon Terry) have expressed concern that wellness programs are merely "data mining operations" and that employers have disingenuously turned to "sharing" data with business partners to evade the ADA's restriction against forcing employees to agree to sale or transfer of their otherwise protected health information.

c. Health Information Portability and Accountability Act (HIPAA) as amended by the Patient Protection and Affordable Care Act (ACA)

If a wellness program is itself a group health plan or part of a group health plan, the terms must comply with HIPAA, including its privacy and security rules. Business associate agreements (BAAs) would be appropriate and necessary when interacting with third-party wellness program providers.

ACA generally prohibited discrimination on the basis of health status or pre-existing conditions but included a carve out exception to encourage participation in wellness programs that meet certain specifications. The relevant sections of ACA are §1001 (reporting requirements), §1201 (prohibition on discrimination on the basis of health status), §4303 (technical assistance for employer-sponsored wellness programs), and §10408 (workplace wellness grants). Specifically, ACA §1201 codified the HIPAA wellness program regulations—29 CFR §2590.702(b)(1)(ii), 45 CFR §146.121(b)(1)(ii), and 26 CFR §54.9802.1(b)(1)(ii)—that prohibit discrimination on the basis of health status. These regulations notably distinguish between "Participatory" wellness programs and "Health-contingent" wellness programs (with the latter consisting of two types: "Activity-only" or "Outcome-based") and set different standards for each. There is no cap on financial incentives for "participatory" wellness programs. The cap on financial incentives for health-contingent wellness programs set by HIPAA (i.e., before the ACA) was 20% of the cost of coverage; however, with the passage of the ACA, this cap was increased to 30% and further expanded to allow for an additional 20% incentive if the program involves tobacco prevention and cessation (i.e., a cap of 50% in those situations).

For a health-contingent wellness program to be lawful under HIPAA/ACA, it must be (1) "reasonably designed to promote health or prevent disease" (i.e., that "it is not overly burdensome" or "a subterfuge for discriminating"); (2) all individuals must have at least one opportunity each year to qualify; (3) the size of the award must be below the applicable cap (i.e., which is based on the total amount of employer and employee contributes towards the cost of coverage for which the employee and any dependents are enrolled); and (4) the program's full reward must be available to "all similarly situated individuals" (i.e., if an individual does not meet an initial measurement, test, or screening standard, there must be a reasonable alternative standard and/or opportunity for a waiver). The ACA does allow for employer-sponsored wellness programs to treat individuals with adverse health factors *more* favorably (e.g., if a plan allows participation of dependent children until age 26 but extends participation eligibility to dependent children with disabilities beyond age 26).

In essence, GINA stipulates when employer-sponsored wellness programs may incorporate genetic testing or information without being unlawfully discriminatory, and the ACA stipulates what financial incentives are available to employers to encourage participation in wellness programs. The Congressional Research Service has concluded that it is possible for employers to comply with both GINA and ACA wellness program requirements and that these provisions are complementary rather than in conflict with one another (See Sarata, Jones, and Staman 2011, Pp 6-7). Scholars concluded similarly, with Hudson and Pollitz likening one set of rules as speed limits and the other set of rules as stop-for-pedestrian signs, both of which drivers can and must obey.

Type of Wellness Program	Definition	Non-Discrimination Requirements
Participatory Wellness Program	"If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program." 26 CFR §54.9802.1(f)(1)(ii)	So long as the program "is made available to all similarly situated individuals, regardless of health status" it is considered not discriminatory. 26 CFR §54.9802.1(f)(2)
Health-Contingent Wellness Program – Activity-Only	"An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome." 26 CFR §54.9802.1(f)(1)(iv)	In order to be non-discriminatory, the program must meet requirements for the frequency of opportunities to qualify; the size of the reward/incentive; a reasonable design to promote health or prevent disease; and allow the full reward to all similarly situated individuals (through offering of reasonable alternative standards or waiver options). 26 CFR §54.9802.1(f)(3)
Health-Contingent Wellness Program – Outcome-Based	"An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward..." 26 CFR §54.9802.1(f)(1)(v)	In order to be non-discriminatory, the program must meet requirements for the frequency of opportunities to qualify; the size of the reward/incentive; a reasonable design to promote health or prevent disease; and allow the full reward to all similarly situated individuals (through offering of reasonable alternative standards or waiver options). 26 CFR §54.9802.1(f)(4)

d. Unsettled regulatory issues

The implementation of GINA and the ACA has been plagued with controversy, as the EEOC faced fierce criticism and opposition to its proposed and final rules from professional genetic societies as well as advocacy and business groups. When the rules were issued, they were immediately challenged by the AARP, which initiated litigation in the D.C. District Court.

At "central issue" was the balancing of the nondiscrimination rights afforded under GINA and ADA and the promotion of health via wellness programs under ACA, a task of reconciliation that is/was ultimately the EEOC's responsibility. A key question was whether incentives under ACA were permissible when the wellness programs implicate GINA or ADA and what is "voluntary" (an element neither defined by the GINA nor ADA statutes but a prerequisite to lawfulness). AARP argued that provision of incentives involving disclosures of GINA- and ADA-protected information would render wellness program involuntary. In the initial rules issued (see EEOC enforcement guidance 2000 on ADA and EEOC 2010 regulations on GINA), the EEOC had taken the position that incentives could not be tied to the employee's disclosure of GINA- or ADA-protected information, but the new rules issued in 2016 reversed this position. Additionally, the new incentive limits were applied to both participatory and health-contingent wellness programs (whereas the prior 2013 HIPAA regulations only capped health-contingent wellness programs). AARP argued that the EEOC changed its

position and also set the 30% cap on incentives arbitrarily without sufficient explanation that such incentives would not render the plan coercive and involuntary. AARP further argued the EEOC had not adequately addressed the public comments in opposition to the proposed rules and that the rules were internally inconsistent (changing the definition of "genetic information" and distinguishing different types of genetic information when it indicated it would allow collection of an employee's spouse's medical information, which is *by statutory definition* included as the employee's genetic information).

In August 2017 the Court had found that the EEOC did not provide any reasonable explanation for its issuance of rules that would allow employer-sponsored wellness programs to provide discounts (or penalties) of up to 30% of the health coverage costs for providing (or refusing to provide) certain medical information and alter the meaning of "voluntary." In December 2017, the Court was unmoved by the EEOC's suggestion that it planned to issue final rules in October 2019 and, instead, decided to vacate the challenged portion of the rules given its concerns about the "potentially widespread disruption and confusion" that could ensue and its concurrent belief that by vacating the rules effective January 1, 2019 the 2019 wellness program plans could be developed without "substantial disruptive effects." The Court warned the EEOC,

> "Because the Court issued its summary judgment decision in August 2017, EEOC will thus have over sixteen months to come up with interim or new permanent rules by the time the vacatur takes place. The Court will also hold EEOC to its intended deadline of August 2018 for the issuance of a proposed rulemaking. But an agency process that will not generate applicable rules until 2021 is unacceptable. Therefore, EEOC is strongly encouraged to move up its deadline for issuing the notice of proposed rulemaking, and to engage in any other measures necessary to ensure that its new rules can be applied well before the current estimate of sometime in 2021." (292 F. Supp. 3d at 245, internal citations omitted).

Despite its assertion to the D.C. District Court that final rules would issue in October 2019, the EEOC has shown little urgency to replace the vacated rules on wellness programs under GINA and the ADA. However, the EEOC has placed the item on their regulatory agenda for Fall 2019, and proposed rules could be expected as early as January 2020. As of the date of this memo, no proposed text for interim or final rules has yet been released to the public. The statutory protections remain in place despite the regulatory uncertainty following the vacation of the challenged portions of the rules on wellness programs set by GINA and ACA. At least for now, wellness programs involving disability-related inquiries or medical examinations (health risk assessments, biometric screenings, etc.) can be considered "voluntary" so long as (1) employees are not required to participate; (2) the employer does not deny coverage or limit benefits to those employees who don't participate; (3) the employer does not take any retaliatory actions (adverse employment decisions or interference, coercion, intimidation, etc.); and (4) the employer provides a detailed confidentiality notice that meets specifications. What remains unclear is whether incentives tied to the GINA- or ADA-protected activities (e.g., genetic testing or genetic information requests or disability-related inquiries, respectively) would be permitted.

e. Notable Caselaw

A few cases brought by the EEOC to enforce nondiscrimination in employer-sponsored wellness programs caught employers' attention prior to the issuance of the now vacated 2016 rules. These include EEOC v. Flambeau, Inc.; EEOC v. Orion Energy Systems; and EEOC v. Honeywell Int'l Inc.. In Flambeau, Inc., the Western District of Wisconsin considered actions of an employer who offered a self-insured health plan (with coverage a benefit but not a requirement of employment) and launched a wellness program involving a health risk assessment (HRA) consisting of a questionnaire and blood analysis. Flaumbeau offered a $600 incentive to employees participating and completing the HRA. The company later changed the program, discontinuing the $600 incentive and instead only offering health insurance coverage to those who participate in the wellness program (i.e., making the wellness program mandatory). The Court held that the ADA safe harbor provision could apply to employer-sponsored wellness programs and further ruled that the specifications of this particular wellness program was not subterfuge to deny employees their right to disability-related informational privacy. In Orion, at issue was whether an employer could require employees who refused to complete a health risk

assessment to pay 100% of their monthly premium for the self-insured plan. Orion (employer) argued that its wellness program was either within the ADA safe harbor or it was voluntary (and, either way, therefore lawful). The wellness program consisted of an attestation that the employee is not a smoker, agreement to exercise 16 time per month at Orion's fitness center, and completion of a health risk assessment, which included a questionnaire and blood analysis. The Eastern District of Wisconsin ruled that the safe harbor did not apply (agreeing with the EEOC that ADA safe harbor was not intended to apply to wellness programs that require involuntary medical exams and inquiries) but also ruled that the wellness program was voluntary. In Honeywell, the EEOC sought a preliminary injunction against Honeywell's issuance of penalties (in the form of reduced contributions to employee Health Savings Accounts) against employees who refuse biometric testing as part of their employer-sponsored wellness program. The program used Quest Diagnostics to perform blood testing, the results of which Quest relay to a third-party actuarial firm and subsequently provides aggregated data to Honeywell directly. Honeywell successfully defended the suit by arguing its plan fell into the ADA safe harbor provision in 42 U.S.C. §12201(c)(2) or, in the alternative, was voluntary. This case also illustrates courts interpreting GINA contrary to its own definitions, as Honeywell argued that the use of a blood test for an employee spouse was not a *genetic test* (overlooking the specific definition of protected *genetic information* set by GINA, which is broader than *genetic tests*). The District of Minnesota Court lamented, "great uncertainty persists in regard to how the ACA, ADA, and other federal statutes such as GINA are intended to interact." (at 5).

There have not been many reported court decisions involving employer-sponsored wellness programs in recent years, but there have been some notable exceptions. As previously mentioned, AARP initiated a lawsuit that ultimately resulted in the final regulations for GINA and the ADA regarding employer-sponsored wellness programs to be vacated and removed. At least four other lawsuits have been on point. Two cases in the Seventh Circuit involving the same plaintiff-employee who alleged that the employer-sponsored wellness program violated his rights by charging him a surcharge after he refused, because of privacy concerns, to complete a medical screening and questionnaire. The defendants were ACS Human Services LLC (employer), Xerox Corporation (an affiliate of the employer with significant input into employee-related health insurance decisions), and Quest Diagnostics, Inc. (vendor authorized by the employer to administer the health benefits and online access to health information). The case against ACS and Xerox was dismissed, and the plaintiff-employee was compelled to resolve his dispute via arbitration (per the terms of the employment contract). The case against Quest failed, as it was unsuccessfully based upon the argument that Quest was an "employer" for purposes of the statutory violations through its control of a portion of the plaintiff-employee's wages. The other two cases involved the employer-sponsored wellness program of the Fire Department for the City of San Antonio, Texas. An employee (Ortiz) alleged the mandatory wellness program violated GINA (the plaintiff separately alleged violations of Title VII of the Civil Rights Act) and that the employer engaged in retaliation by placing him on alternate duty (which cost him potential overtime wages) for his refusal to engage in a GINA-protected activity (i.e., participation in the wellness program). The program was adopted for the stated purpose "to provide early detection of serious medical conditions and encourage better health, thereby allowing ... employees to do their job more safely and effectively" and included a job-related medical evaluation that included a medical history, complete physical exam, blood and urine tests, and hearing, vision, and lung capacity tests. Summary judgment was awarded to the City, as (1) there was nothing in the record to indicate that genetic testing or information was requested or required as part of the mandatory wellness program or that the employee was discriminated against on the basis of any genetic information and (2) the City provided a legitimate unrelated business reason for the alternate duty. The Fifth Circuit Court of Appeals upheld the decision to grant summary judgment for the City. A second employee sued shortly thereafter alleging that the City's fire department violated GINA by requiring him to provide personal health information without a voluntary and written authorization and by retaliating against his failure to comply with the mandatory wellness program. The court rejected claims that the mandatory wellness program violated GINA because there was no evidence on the record indicating that the blood tests within the wellness program involved analysis of DNA, RNA, chromosomes, proteins, metabolites, genotypes, mutations, or chromosomal changes. The court also did not find any evidence that there was a requirement to provide genetic information or family medical history as part of the mandatory wellness program. The court similarly granted summary judgment on the retaliation

claim, finding that he had not been engaged in a GINA-protected activity (as the court deemed relevant that the employee's initial objections to the mandatory wellness program noted privacy concerns without explicitly mentioning GINA).

These emerging cases illustrate the importance of a clear employer-employee relationship and potential insulation from liability that the vendors of wellness programs might have if mere business partners. The cases also illustrate the scope of GINA-protected activities for which retaliation by employers is forbidden, underscoring that disputes will be fact-intensive inquiries and that courts likely will give plaintiffs more favorable treatment if evidence clearly indicates the wellness program included DNA testing or genetic information, thereby making per se violations and retaliation claims under GINA viable. Moreover, as the punitive damages awarded in the infamous case of the "devious defecator"—Lowe v. Atlas Logistics Group Retail Servs. Atlanta, LLC, 102 F. Supp. 3d 1360 (N.D. Ga. 2015)—signaled, employers must be cautious whenever contemplating genetic information or testing, as strict liability is imposed unless the conditions for an exception (such as a wellness program) are plainly satisfied.

f. Other Applicable Laws not covered in this memorandum

When an employee receives something "of value" from the employer, it is generally taxable as income. So designing an employer-sponsored wellness program should include a compliance check not only with GINA, ADA, and HIPAA/ACA but also with the Internal Revenue Code. Zimmer and Wakefield (2019) have indicated that some incentives (such as water bottles, t-shirts, etc) would not be taxable (as merely de minimus fringe benefits) but cash and cash equivalents (such as gift cards) would be taxable income. They note that generally the IRC does not consider discounts on health plan contributions, deductibles, co-pays, and co-insurance; health savings accounts; or health flexible spending accounts to be taxable.

Additionally, the design should be reviewed for compliance with the Fair Labor Standards Act. According to the Department of Labor (DOL) website, the FLSA does not require employers to provide a wellness program. However, wellness programs that contain activities outside of working hours (such as exercising a certain amount of time, attending health fairs, or completing biometric screenings) invite the question as to whether the employee is "on the clock" or doing job-related work for which he/she/they are entitled to be compensated. The DOL issued an opinion letter (FLSA2018-20) in 2018 on this very issue, and the DOL has issued proposed rules that would add an example to §778.224 clarifying that the costs of wellness programs (i.e., likening wellness programs to on-the-site medical care and recreational facilities that are conveniences to employees) may be excluded from an employee's regular rate of pay (See 84 Fed. Reg. 11896). Nevertheless, wellness programs that are mandatory or involve various trainings (e.g., nutritional classes, tobacco cessation classes, etc.) during work hours could potentially run afoul of FLSA or worker's compensation laws.

III. Summary of State Issues Regarding Genetic Testing and Employers

Two landmark 50-state surveys have been performed to detail the state variation in laws related to genetic testing. First and foremost was the National Conference of State Legislatures (NCSL) work done prior to GINA's passage which, unfortunately, has not been updated since GINA's passage. The second is that performed by Anya Prince that was published in 2013. The appendix is particularly the most useful part of the publication, which reviews state legislation on provisions covering employment or health insurance; covering other insurance; providing a property right; and providing privacy right. A related update regarding reporting of genetic results was performed as part of the *All of Us*[SM] Research Program by Megan Doerr and colleagues in the development of their uniform consent process. That provides as its Appendix A, a review of the state and territorial laws on age of majority, patient's bill of rights, primary consent, HIPAA authorization, and return of genomic results. A comprehensive 56 jurisdiction (50 states, District of Columbia, and five territories) would require far more effort than what has been budgeted in this supplement, so I direct you to those resources. The variation of state laws regarding biometrics more broadly (i.e., not in the narrow context of wellness programs but, rather, in the context of data privacy and security considerations within precision health) has been proposed as part of an R01 application submitted to NHGRI on October 7, 2019.

IV. Relevant ELSI/Policy Concerns

The design of any wellness program integrating population genetic testing must, in addition to ensuring legal and regulatory compliance, anticipate skepticism from the scientific and bioethics community regarding voluntariness of the program. Issues of coercion, duress, and undue influence, for example, might be particularly problematic for wellness programs that seek to include individuals residing in rural areas or individuals with lower educational attainment who might, as a result of those circumstances, have limited employment options and/or limited accessibility to affordable health coverage.

While not specific to wellness programs, the ELSI research community is increasingly critical of employer-based data collection efforts and bioethical vulnerabilities of employees (among others) related to data-exposures and never-ending data surveillance. With regard to genetic privacy specifically, there is a growing concern about law enforcement and third-party access to genomic databases. Moreover, there is limited recognition of the HIPAA Privacy Rule exception allowing law enforcement access to some information (including name and address) without the patient's authorization (See 45 C.F.R. 164.512(F)(1)(ii)) and similarly low awareness that the NIH Certificates of Confidentiality, even in their expanded form pursuant to the 21st Century Cures Act, do not shield identifiable information or non-research data effectively. The data privacy, security, and confidentiality issues should be of utmost priority, and examination of emerging state laws (including but not limited to CA's Consumer Privacy Act of 2018, AB-375, signed into law on 6/28/2018; SB-822 signed into law on 9/30/2018; and CalGINA, SB-559, signed into law on 10/9/2011, and VT's Data Broker Law, Act 171 of 2018) will be necessary to ensure that employer-sponsored wellness programs that are not conducted in-house but involve relationships with vendors have responsible, equitable data stewardship policies in addition to their business associate agreements.

Equitable data practices for wellness programs would relate to what level of information is actually given to the participating employee (e.g., raw data, only interpretative summaries, both) and what permissible uses for the generated/collected data relating to the employees the vendor providing the population genetic testing has (e.g., use for research). Moreover, participant engagement (in this context, employer engagement) and corporate culture will be critical components for evaluating wellness programs, employee buy-in, and ultimately success.

Finally, there are scant empirical data to support employer-sponsored wellness programs effectiveness in improving health and wellness, which will continue to draw criticism regarding the reasonable collection of these "sensitive" data (not only genetic data but geolocation data imbedded in data generated by wearables/fitness trackers) by employers. Trustworthiness (i.e., a factor that focuses on the employer or wellness program vendor's actions) will be a substantial area for future ELSI work, as it relates to willingness of employees to participate, cost/benefit tradeoffs made in those decisions, and evaluation of appropriate financial incentives for the actual benefits and risks involved.

V. Conclusion

A foundational question when evaluating the legal compliance of a specific wellness program is first whether the program is a group health plan or part of a group health plan (i.e., if it provides medical care or if participation in the program affects cost-sharing for group health plan), in which case ACA and other mandates on group health plans (e.g., ERISA and COBRA) are applicable. If the wellness program is not providing medical care or part of a group health plan, the wellness program must still comply with the non-ACA non-discrimination mandates of GINA, ADA, ADEA, Title VII of the Civil Rights Act of 1964, and the Fair Labor Standards Act. GINA Title I and Title II compliance should be considered separately. However, because of the current regulatory uncertainty, designers of employer-sponsored wellness programs would be wise to avoid tying *any* rewards intended to encourage participation (whether in the form of discounts or surcharges) to the GINA-protected or ADA-protected activities, which would involve any type of population genetic testing, health risk assessment that is likely to elicit genetic information (as broadly defined statutorily by GINA as opposed to the more narrow common understanding) or disability-related inquiry or exam. Design of wellness programs must take care to ensure that those activities are genuinely voluntary, that firewalls be established and data aggregation practices imposed to prevent employers from having any possible temptation to use the

information pertaining to any specific individual in an employment decision and to protect the confidentiality of the employees' (and employees' dependents) participation and resulting information.

For purposes of this NHGRI-funded work, it would be useful to use the opportunity provided by key informant interviews to examine the extent to which these compliance-related issues influence employer preliminary interests in integrating population genetic testing in their current or future wellness programs and subsequent design decisions. One could anticipate a wide range of perspectives given sizes of employers (e.g., GINA's mandates do not apply to private employers with fewer than 15 employees) and given the geographic range of employees (e.g., GINA did not preempt more stringent state laws, which could affect compliance costs and complexity of wellness program designs for employers with multi-state business locations or employees located in different states). Wellness programs have, potentially, dual benefits: (1) health promotional benefits to the participating employees and their dependents and (2) cost-saving benefits to the employers. It could be useful to examine the extent to which an employer's outlook emphasizes one or the other, as it might be a predictor of mistakes or obstacles to successful implementation of a sustainable wellness program.

If additional information or resources would be useful to you in further development of your project, please let me know.

VI. Appendix: Relevant Resources

a. Primary Sources

i. Cases

1. AARP v. United States Equal Employment Opportunity Commission, 292 F. Supp. 3d 238 (D. D.C., 2017)
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