

2016

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Recommended Citation

Dumnich, John, "Notice Requirements: Employee Wellness Program" (2016). *Law School Student Scholarship*. 902.
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Notice Requirements: Employee Wellness Program

I. Introduction

Healthcare costs are rising. Currently, employer-sponsored insurance accounts for 57 percent of the population who is insured.¹ Premiums for family coverage increased 73 percent while the median family income rose 16 percent from 2003 to 2013.² These premiums are not cheap. In 2013, the average total premiums for family coverage, including both employer and employee contributions, was \$16,029.³ The average annual premium cost for single-person coverage paid by an employer was \$5,571 in 2013.⁴

In an effort to reduce these healthcare costs and improve employee health, some employers that provide health coverage also offer employee health programs and activities to promote healthier lifestyles or prevent disease.⁵ Commonly referred to as “wellness programs,” a 2013 study conducted by the RAND Health and the Department of Labor found that approximately half of U.S. employers offer some sort of wellness initiative.⁶

Studies indicate that the annual savings produced by wellness programs are around \$ 613 per participant.⁷ For example, wellness programs were estimated to save Johnson & Johnson \$250 million in healthcare costs over ten years.⁸ The company saw a \$2.71 return for every dollar

¹ S.R. COLLINS ET AL., NATIONAL TRENDS IN THE COST OF EMPLOYER HEALTH INSURANCE COVERAGE, 2003-2013, 1 (2014).

² *Id.* at 2.

³ *Id.*

⁴ *Id.* at 3.

⁵ See RAND HEALTH, WORKPLACE WELLNESS PROGRAMS STUDY FINAL REPORT (2013).

⁶ *Id.* at xiv.

⁷ Vedma Collmer, Chase Millea, Nick Wearne, *Guidelines For Improving Workplace Wellness*, HEALTH LAWYER, Aug. 2013

⁸ *Id.*

spent on employee wellness programs.⁹ Some states are taking action with workplace wellness legislation as well.¹⁰ A 2010 study by the National Conference of State Legislatures found four states had passed legislation allowing employers to offer insurance premium discounts, rebates, or incentives for participation in wellness programs.¹¹ Five states adopted legislation supporting the creation of wellness programs for public employees.¹²

Common workplace wellness programs may include nutrition classes, smoking cessation programs, gym memberships, and health coaching.¹³ Some employers also choose to incorporate screening procedures to measure an employee's health risk factors, such as body weight and cholesterol, blood glucose, and blood pressure levels.¹⁴ The screening methods most commonly used by employers are health risk assessments, biometric screening, and self-administered questionnaires on health-related behaviors.¹⁵ Over half of employers who developed workplace wellness programs utilized screening methods.¹⁶

In exchange for program participation, employees may be eligible to receive incentives from their employers.¹⁷ While some programs are designed to offer employees incentives merely for participating in the program, other wellness programs only offer incentives to employees who are able to achieve certain health outcomes.¹⁸ For some employees, these incentives take the form of

⁹ L. L. Berry, A. M. Mirabito, and W. M. Baun, *What's the Hard Return on Employee Wellness Programs?*, HARVARD BUSINESS REVIEW, Dec. 2010.

¹⁰ 2010 Wellness Legislation, <http://www.ncsl.org/research/health/wellness-legislation-2010.aspx> (last visited Dec. 6, 2015).

¹¹ *Id.*

¹² *Id.*

¹³ Berry, Mirabito, & Baun, *supra* note 9.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Amendments to Regulations Under the Americans with Disabilities Act, 29 C.F.R. § 1630, 2160 (2015); RAND HEALTH, *supra* note 6, at xiv.

¹⁸ 29 C.F.R. 1630 at 2160.

a reward.¹⁹ An employee may receive a gift card, cash, or a reduction in healthcare premiums for participating in a wellness program or achieving a specified health goal.²⁰

For other employees, the incentive may take the form of a punishment.²¹ Employees in these wellness programs may be forced to cover a greater portion of their healthcare premium or pay a penalty for failing to meet the requirements of the wellness program.²² 13% of employers utilize some form of penalty in their employee wellness program.²³

As these premium costs rise, employers are asking their employees to make greater contributions to their healthcare to prevent costs from spiraling out of control. Those premiums represent 23 percent of median family income, up from 15 percent in 2003.²⁴ From 2003 to 2013, employees' contributions to their premiums nearly doubled, increasing by 97 percent.²⁵

Workers, however, may be less equipped to handle these additional costs. Wages have remained relatively poor over the last decade.²⁶ Between 2007 and 2014, the bottom 80th percentile of wage earners actually saw their wages decrease.²⁷ At the 50th percentile, median real hourly wages fell four percent.²⁸ Meanwhile, median real hourly wages and compensation increased for earners in the 90th percentile.²⁹ Other studies have found a similar trend: while higher wage jobs have seen an increase in wages over the past decade, lower wage jobs have stalled or decreased in that time period.³⁰

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² RAND HEALTH, *supra* note 6, at xx.

²³ *Id.* at 63.

²⁴ *Id.*

²⁵ COLLINS ET AL., *supra* note 1, at 1.

²⁶ KRISTEN MONACO & BROOKS PIERCE, COMPENSATION INEQUALITY: EVIDENCE FROM THE NATIONAL COMPENSATION SURVEY (2015).

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ David H. Autor, "Skills, education, and the rise of earnings inequality among the 'other 99 percent'," *Science* 344, May 2014, <http://seii.mit.edu/wp-content/uploads/2014/05/Science-2014-Autor-843-51.pdf>.

Additionally, employees are finding they must fork over more money before their health insurance kicks in.³¹ In 2003, 52% of workers were enrolled in a health plan with a deductible.³² In 2013, the percentage of employees whose health plan included a deductible climbed to 81%.³³ During that time period, health insurance deductibles doubled.³⁴ While employees' wages have flat lined, health insurance premiums and deductibles have continued to take larger and larger bites out of paychecks. If employees are being asked to pay more for their health insurance with less pay, the threat of a penalty further increasing their costs may be enough to motivate these employees to participate.

Although employee wellness programs were first contemplated in the Health Insurance Portability and Accountability Act ("HIPAA"), recent tensions have focused upon the prohibition placed upon employers from requiring employees to submit to the health screenings and medical examinations employers to avoid a financial penalty under Title I of the Americans with Disabilities Act ("ADA").³⁵ An exception exists, however, for employers who conduct "voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site."³⁶ Whether or not the aforementioned incentives or penalties make wellness program "voluntary" with respect to the ADA has been a concern for the Equal Employment Opportunity Commission ("EEOC"). Previously, the EEOC has stated that wellness programs are considered voluntary if "an

³¹ COLLINS ET AL., *supra* note 1, at 4-5.

³² *Id.* at 5.

³³ *Id.*

³⁴ *Id.*

³⁵ Health Insurance Portability and Accountability Act, Pub. L. No. 104—191, 110 Stat. 1936 (1996); Americans with Disabilities Act, 42 U.S.C. § 12112(d)(4)(A) (2015) (a covered entity "shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job related and consistent with business necessity.').

³⁶ 42 U.S.C. 12112(d)(4)(B) (2015).

employer neither requires participation nor penalizes employees who do not participate.”³⁷ On April 20, 2015, the EEOC released a notice of proposed rulemaking regarding amendments to the regulations concerning when an employee wellness program is considered “voluntary for the purpose of complying with Title I of the ADA.”³⁸

In this Note, I will first describe the current statutory and regulatory requirements employers must meet to ensure their employee wellness programs do not run afoul of HIPAA’s anti-discrimination provision. Second, I will outline the privacy concerns wellness programs create for employees when they are not provided with adequate notice. Third, I will discuss the EEOC’s most recent proposed regulations concerning employee wellness programs, emphasizing the EEOC’s solicitation of comments concerning whether medical informed consent or the HIPAA authorization form would be useful in creating notice requirements for employers. Fourth, I will explain various models of medical informed consent. Fifth, I will critique these models and explain how, for the most part, medical informed consent is a poor analog for employee wellness programs. Sixth, I will discuss the requirements of the HIPAA authorization form, and how these requirements more closely align with the EEOC’s goals in providing notice and protecting privacy.

A description of the different wellness programs

The Patient Protection and Affordable Care Act (“ACA”) defines a wellness program as “a program offered by an employer that is designed to promote health or prevent disease.”³⁹

Wellness programs were contemplated by Congress well before the ACA, however. Although HIPAA amended the Internal Revenue Code, the Employee Retirement Income Security Act,

³⁷ U.S. Equal Emp. Opportunity Comm’n, ENFORCEMENT GUIDANCE ON DISABILITY-RELATED INQUIRIES AND MEDICAL EXAMINATIONS OF EMPLOYEES UNDER THE AMERICANS WITH DISABILITIES ACT, Q&A 1 (2000).

³⁸ Amendments to the Regulations Under the ADA.

³⁹ 42 U.S.C. § 300gg-4(j) (2015).

and the Public Health Service Act to include non-discrimination provisions, HIPAA also included an exception to this requirement that appears in each statute, explaining these provision “do not prevent a group health plan and a health insurance issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.”⁴⁰ On December 13, 2006, the Departments of Labor, Treasury, and Health and Human Services issued joint final regulations on the nondiscrimination provisions of HIPAA that provide a framework for structuring wellness programs.⁴¹ The regulations explain that a group health plan or health insurance issuer may vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the requirements of a wellness program that satisfies various requirements.⁴²

Employee wellness programs fall into two categories: participatory and health contingent.⁴³ If the conditions for obtaining an award are not contingent upon an employee satisfying a standard based upon a health factor, the employee wellness program is participatory.⁴⁴ The regulations provide examples of these types of programs, including wellness plans that reimburse all or part of the cost for memberships in a fitness center or reimburse employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.⁴⁵ Participatory wellness programs comply with the HIPAA non-discrimination provisions as long as the benefits derived from these programs are available to all similarly situated employees.⁴⁶

⁴⁰ 29 U.S.C. § 1182(b)(2)(B) (2015); 42 USC 300gg-1(b)(2)(B) (2015); 26 U.S.C. § 9802(b)(2)(B) (2015).

⁴¹ Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ 29 C.F.R. § 2590.702(f)(1)(i-v) (2015).

⁴⁶ 29 C.F.R. § 2590.702(f)(1) (2015).

Health contingent wellness programs come in two varieties: activity-only programs and outcome-based programs.⁴⁷ For activity-only programs, employees must participate in an activity related to a health factor to obtain an award.⁴⁸ An example of this type of program could include attending a health coaching session.⁴⁹ In contrast, outcome-based wellness programs are identical to activity-only programs but additionally require employees to achieve a health-based outcome.⁵⁰ Common forms of outcome-based wellness programs include having employees meet a certain step-count or reducing blood pressure through exercise.⁵¹

Health-contingent wellness programs are also permissible, assuming certain requirements are fulfilled.⁵² First, “the reward for the wellness program . . . shall not exceed 30 percent of the cost of employee-only coverage under the plan.”⁵³ Wellness programs aimed at curbing tobacco use were approved to include rewards of up to 50%.⁵⁴

Second, the program must be “reasonably designed to promote health or prevent disease.” The Department of Labor, The Department of the Treasury, and the Department of Health and Human Services envisioned the “reasonably designed” standard to be “an easy standard to satisfy.”⁵⁵ Programs that are overly burdensome, encourage illegal activity to obtain a benefit, are designed as a subterfuge for discriminating based on a health factor, or are highly suspect in the method chosen to promote health or prevent disease may not be considered “reasonably

⁴⁷ Regulations to Implement the Equal Employment Provisions of the Americans with Disabilities Act, 29 C.F.R. § 1630 (2015).

⁴⁸ *Id.*

⁴⁹ RAND HEALTH, *supra* note 6, at 22.

⁵⁰ 29 C.F.R. § 1630.

⁵¹ RAND HEALTH, *supra* note 6, at 22.

⁵² 29 C.F.R. § 2590.702(f)(2).

⁵³ 29 C.F.R. § 2590.702(f)(2)(i).

⁵⁴ 29 C.F.R. § 1630.

⁵⁵ 71 Fed. Reg. 75014.

designed” to promote health or prevent disease.⁵⁶ However, no scientific record need exist linking the methodology of the wellness program to the promotion of health or prevention of disease.⁵⁷ The Departments wish to encourage experimentation in new ways of promoting wellness with these programs.⁵⁸

Third, the employer must give individuals eligible to participate in an employee wellness program the opportunity to qualify for the reward under the program at least once per year.⁵⁹ Fourth, the program reward must be available to all similarly situated individuals.⁶⁰ An employee wellness program is not “available to all similarly situated individuals” unless a reasonable alternative standard for obtaining a reward is made available to any employee for whom it is “unreasonably difficult” or “medically inadvisable” due to a medical condition to satisfy the program requirements.⁶¹ Employers may also satisfy this requirement by waiving the otherwise that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the standard.⁶² Fifth, all employee wellness program materials must describe the terms of the program and the availability of a waiver or reasonable alternative standard.⁶³

II. Privacy Problem

a. Privacy Defined

One popular conceptualization of privacy defines the term as the amount of control one has over their information. Alan Westin defined privacy as “the claim of individuals, groups, or

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ 29 C.F.R. § 2590.702(f)(2)(iii).

⁶⁰ 29 C.F.R. § 2590.702(f)(2)(i)(B).

⁶¹ 29 C.F.R. § 2590.702(f)(2)(iv)(A)(1).

⁶² 29 C.F.R. § 2590.702(f)(2)(iv)(A)(2).

⁶³ 29 C.F.R. § 2590.702(f)(2)(v)(A).

institutions to determine for themselves when, how, and to what extent information about them is communicated to others.”⁶⁴ The ability of people or institutions to *determine* what information is shared with others is a key distinction between Westin’s conceptualization of privacy and general notions of secrecy.⁶⁵ Rather, an individual’s control over their information-- what types of information shared with others, the depth of the information, and the particular audiences with whom that information is shared-- more accurately captures our concerns with privacy.⁶⁶

This ability of people to control what information about themselves is shared with others reveals another important truth: in society, some of level of social participation and interaction with others is necessary.⁶⁷ Therefore, privacy is a balancing act. The movement of individuals from privacy to full social participation is not only seen in human societies; animals exhibit such a preference as well.⁶⁸ The survival of animals can be jeopardized when private spaces are impinged upon.⁶⁹ Animals may lose their ability to court, smell, or be free from defensive posturing.⁷⁰

Alan Westin starts from the premise that people are aware that there is a “gap” that exists because of our privacy.⁷¹ This gap is a measure of the information individuals share about themselves with the outside world, and the information individuals choose to keep to their private self.⁷² For some people, this gap may be quite large.⁷³ The version of our self that is known to the world is the self that individuals feel most comfortable with sharing. It is the self

⁶⁴ ALAN F. WESTIN, *PRIVACY AND FREEDOM*, 7 (1970).

⁶⁵ *Id.* at 7, 31.

⁶⁶ *Id.* at 42.

⁶⁷ *Id.* at 7, 42.

⁶⁸ *Id.* at 8-9.

⁶⁹ *Id.* at 9.

⁷⁰ ALAN F. WESTIN, *PRIVACY AND FREEDOM*, 33 (1970).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

that an individual has chosen to represent them in context of society.⁷⁴ But a more complicated, holistic self exists for each individual too. This self is the most personal, and individuals may feel uncomfortable sharing this conception of self out of fear of judgment or scrutiny.⁷⁵ Indeed, Westin admits that even an individual's private, inner self is not fully known to the individual.⁷⁶ Rather, an individual may be exploring aspects of their own psyche overtime.⁷⁷

When an individual's "self" is thrust into the light of day, the experience may be very painful.⁷⁸ A great deal of control is expended limiting certain portions of ourselves to others.⁷⁹ Individuals may become embarrassed, or guilty, or otherwise self-conscious when the most private portions of their cognitive and biological processes are laid to bare for the world to see.⁸⁰ The ability to control how much of our "self" or what portions of our "self" is available to others is fundamental to the development of identity and the notions of individual autonomy.⁸¹

Privacy performs a great function in allowing ourselves to limit our roles with others depending on the information that we share.⁸² It allows an individual to walk into one room as a CEO, take the subway as just another commuter, and relax into their role as husband or father at home. The ability to control our information allows us to temper expectations and demands from others in certain settings.⁸³

b. Wellness Program Worries

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ ALAN F. WESTIN, *PRIVACY AND FREEDOM*, 33 (1970).

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 34-35.

⁸¹ *Id.*

⁸² ALAN F. WESTIN, *PRIVACY AND FREEDOM*, 34-35 (1970).

⁸³ *Id.* at 35-36.

By collecting sensitive data about employees that is not typically available in the workplace, employers who implement wellness programs with biometric screenings or health risk assessments threaten the privacy of their employees in a number of ways. First, employees who choose to participate in a wellness program and hand over private health information may lose the ability to control their role in the workplace. An individual may be transformed from an accountant in the auditing department to the middle-aged man who is borderline obese and at risk for heart disease. With this knowledge, individuals may treat employees differently. An employee may be expected to perform roles and engage in behaviors with others that is consistent with the information the individual has learned about them. That role – the role of an unhealthy, sickly person – may be a role the employee wished to limit in the employment sphere. Furthermore, this may even be a role the individual wished to limit even from close family and friends.

Second, employees may not adequately be able to exercise control over their information if employees do not know to whom their information is being provided. A Kaiser Health News report from October of 2015 recounted how city employees in Houston were required to report numerous pieces of health information to an online wellness company or pay a \$300 fine.⁸⁴ The authorization form provided by the wellness company raised concerns among some employees; the wellness company reserved the right to pass the data on to “third party vendors acting on [the company’s] behalf,” and informed the employees the data may be posted in places “reviewable to the public.”⁸⁵ The president of the city’s police union noted the employees were uncomfortable

⁸⁴ Jay Hancock, *Workplace Wellness Program Puts Employee Privacy at Risk*, KAISER HEALTH NEWS (Oct. 1, 2015, 4:30 PM) <http://khn.org/news/workplace-wellness-programs-put-employee-privacy-at-risk/>.

⁸⁵ *Id.*

with providing a vendor with a “carte blanche” to do whatever they wished with the employee’s sensitive health information.⁸⁶

The scenario above illustrates how employees may be given little indication of how their information is going to be used or to whom their information is being given. To truly have privacy, an individual needs to be able to make an informed choice as to who should be able to access their information. Employees may not understand the impact of handing over their information. Although the issue was clear to city employees in Houston, employees may be unaware of what parties may have access to their health information.⁸⁷ To appropriately exercise their right to privacy, an employee needs to know where their information may end up.

Third, employee wellness programs present the potential for employees to lose control over their information. Cybersecurity data breaches present a specific risk for employees who hand their health information over to their employers. The recent rash of high profile data breaches show that no industry is immune.⁸⁸ Federal Bureau of Investigation Director James Comey was reported as saying, “[t]here are two kinds of big companies in the United States. There are those who’ve been hacked...and those who don’t know they’ve been hacked.”⁸⁹ A survey conducted by PricewaterhouseCoopers of 9,700 security, IT, and business executives in 154 countries found that 42.8 million information security incidents were detected worldwide in 2014.⁹⁰ That

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ RILEY WALTERS, *CYBER ATTACKS ON U.S. COMPANIES* (2014).

⁸⁹ James Cook, *FBI Director: China Has Hacked Every Big US Company*, BUSINESS INSIDER, October 6, 2014, <http://www.businessinsider.com/fbi-director-china-has-hacked-every-big-us-company-2014-10> (accessed December 3, 2015).

⁹⁰ PRICEWATERHOUSECOOPER, *MANAGING CYBER RISKS IN AN INTERCONNECTED WORLD: KEY FINDINGS FROM THE GLOBAL STATE OF INFORMATION SECURITY SURVEY 10* (2015).

staggering number is the equivalent of 117,393 information security incidents occurring per day.⁹¹

Given the prevalence of cybersecurity incidents, an employee's decision to hand over their personal information to their employer to participate in a wellness program does more than simply allow their employer or a third party vendor to have access to private information. These employees are also exposing themselves to cybercriminals and identity thieves looking to bypass company security measures to access the treasure trove of information being collected. With roughly half of employee wellness programs require some form of biometric screening or health risk assessment, the risk to employees to lose their information is great.

Third, depending on the structure of a wellness program, employees may not have a real "choice" in whether or not they should participate. For individuals who might not otherwise be able to afford health insurance if they are requested to pay a greater share of their premiums or additional penalties, choice is an illusion.⁹² The "decision" makes itself. Following Westin's interpretation of privacy, employers who implement wellness programs such as these impinge upon the right to privacy of their employees by robbing them of the ability to control their own information.

Some individuals may argue that employees are not being forced into wellness programs. Each individual employee can make the choice of whether or not they would like to participate, and that choice will be informed by the value each employee places upon controlling their information. These arguments ring hollow for a number of reasons means. Employees of limited means may not have a "choice." An employee's decision to subject themselves to a biometric

⁹¹ *Id.*

⁹² *See infra* Part I for a discussion of the increasing cost passed on to employees for health insurance.

screening might be the difference between that employee having health insurance or not depending upon the severity of the financial penalty at stake. Additionally, without adequate knowledge, employees cannot accurately decide whether or not to share their information with another person or institution.

III. The EEOC guidelines

The latest proposed regulations by the EEOC were spurred by a call from industry to adequately clarify its position on when employee wellness programs are considered “voluntary.”⁹³ The EEOC challenged the wellness programs of a number of companies.⁹⁴ In the Flambeau case, the company cancelled the medical insurance of an employee who refused to submit to a biometric test and health risk assessment.⁹⁵ The employee was then forced to pay all of his health insurance premium cost, while employees who submitted to the testing and assessment were only asked to cover 25% of premium costs.⁹⁶ At Honeywell, employees alleged they faced up to \$4,000 in penalties for refusing to submit to blood and medical tests that screened for smoking, diabetes, and heart conditions.⁹⁷ Employees or spouses who refused to submit to testing lost a \$1,500 company contribution to a health savings account, and were billed for medical plan and tobacco surcharges.⁹⁸

The proposed rule explains what an employee health program is, what it means for an employee health program to be voluntary, what incentives employers may offer as part of a

⁹³ Regulations to Implement the Equal Employment Provisions of the Americans with Disabilities Act, 29 C.F.R. § 1630 (2015).

⁹⁴ EEOC v. Honeywell Int'l, Inc., 2014 U.S. Dist. LEXIS 157945 (D. Minn. Nov. 6, 2014); EEOC v. Orion Energy Systems, Inc., Case No. 14-1019 (E.D. Wis. filed Aug. 20, 2014); EEOC v. Flambeau Inc., Case No. 14-638 (W.D. Wis. filed Sept. 30, 2014).

⁹⁵ Press Release, U.S. Equal Emp. Opportunity Comm'n, EEOC Lawsuit Challenges Flambeau Over Wellness Programs (Oct. 1, 2014).

⁹⁶ *Id.*

⁹⁷ Honeywell, 2014 U.S. Dist. LEXIS 157945 at *3-5.

⁹⁸ *Id.* at *4-5.

voluntary employee health program, and what requirements apply concerning notice and confidentiality of medical information obtained as part of voluntary employee health programs.⁹⁹ Wellness program may be offered as part of a group health plan or an employer may choose to offer a wellness program outside of a group health plan.¹⁰⁰ The EEOC's proposed rule regarding notice requirements and changes to interpretive guidance only apply to wellness programs that are "part of or provided by a group health plan or by a health insurance issuer offering group health insurance in connection with a group health plan."¹⁰¹

The EEOC requested information on a number of elements of the proposed rule.¹⁰² One such area concerned the notice of disclosure requirements set forth in the proposed regulations.¹⁰³ The EEOC regulations propose employers must "provide notice that clearly explains what medical information will be obtained, who will receive the medical information, how the medical information will be used, the restrictions on its disclosure, and methods the covered entity will employ to prevent improper disclosure of the medical information."¹⁰⁴

More specifically, the EEOC solicited comments on a number of queries related to the proposed notice requirement.¹⁰⁵ The EEOC sought comments on whether the proposed notice requirement under this rule should require that employees provide prior, written and knowing confirmation that their participation in the employee wellness program was voluntary.¹⁰⁶ If so, the EEOC wished to obtain comments on whether or not medical informed consent could inform

⁹⁹ 29 C.F.R. § 1630 (2015).

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ 29 C.F.R. § 1630.

¹⁰⁶ *Id.*

the notice process.¹⁰⁷ In the alternative, the EEOC solicited comments on whether or not the HIPAA authorization form may provide a useful standard for notice as well.¹⁰⁸

IV. Relevant informed consent models.

The Department of Health and Human Services (“HHS”) has explained that the informed consent process is comprised of three elements: (1) disseminating information to inform the individual, (2) ensuring that decisions are voluntary, and (3) facilitating comprehension of the information conveyed to the individual.¹⁰⁹ In essence, informed consent is a process whereby individuals are able to determine what happens to them.¹¹⁰ The information provided should be sufficient for the individual to make a decision regarding treatment or participation.¹¹¹ The manner in which the information is presented is also key to the informed consent process: maturity and intellectual functioning will dictate the best manner in which to present information to a particular individual.¹¹² Any decision made by the individual should be free of coercion or any undue influence.¹¹³

While most informed consent models follow the basic tenets discussed above, differences exist between how much importance various models place on different components of the informed consent process. This next part details three popular informed consent models, describing their underlying philosophies and goals.

I. Event Model of Informed Consent

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ U.S. Dep’ of Health & Human Servs., WHAT IS INFORMED CONSENT AND WHEN, WHY, AND HOW MUST IT BE OBTAINED, FAQ 1 (2009).

¹¹⁰ KENNETH J. RYAN ET AL., ETHICAL PRINCIPLES AND GUIDELINES FOR PROTECTION OF HUMAN SUBJECTS RESEARCH (1979).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

The model of informed consent that most readily dominates the field of medicine is the event model of informed consent.¹¹⁴ Through this approach, informed consent is a discrete act. It will occur only once during the treatment process.¹¹⁵ After a patient has presented a problem to the physician, the medical professional will provide an explanation of the patient's condition along with recommendations for a proper course of treatment.¹¹⁶ The physician will disclose the risk of any available treatment options as well as suggest alternatives.¹¹⁷ After hearing all of this information, the patient is tasked with evaluating their options and communicating to the physician how they would like to proceed.¹¹⁸

This model of informed consent conforms neatly with the legal obligations placed upon physicians and healthcare organizations.¹¹⁹ The “hallmark” of the event model, the consent form, provides a specific point in time where the healthcare provider's obligation to the patient has been fulfilled and documented.¹²⁰ This model of informed consent places less of an emphasis on the ability of the patient to understand the information being presented to them.¹²¹ Rather, the focus is upon the physician providing the patient with the information necessary to make a choice regarding their treatment.¹²²

¹¹⁴ Informed Consent and the Clinician-Client Relationship, <http://www.umassmed.edu/globalassets/center-for-mental-health-services-research/documents/products-publications/issue-briefs/human-rights/informed-consent-and-the-clinician-client-relationship.pdf> (last visited Dec. 6, 2015).

¹¹⁵ *Id.*

¹¹⁶ JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 168 (2nd ed., 2001).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 168 (2nd ed., 2001).

The event model also offers healthcare providers with significant flexibility in the treatment process.¹²³ Medical professionals can choose to break up a treatment into as many discrete components as they like.¹²⁴ Each component of treatment is accompanied by an informed consent event.¹²⁵ Healthcare providers can take comfort in knowing that, as long as the patient consented to the treatment being provided at an earlier consent event, the physician is cleared to proceed.¹²⁶

Numerous criticisms have been levied against the event model of informed consent. First, critics of the model argue the client's understanding of the treatment process is not improved; the focus is not upon the patient understanding the information, but rather upon the physician transmitting the information.¹²⁷ Second, the event model of informed consent is said to overemphasize the bureaucratic component of process.¹²⁸ The proper focus should be upon the patient's understanding, and not the liability of the physician.¹²⁹ Rather than establishing a process that empowers the patient to take an equal party in their treatment decision, the event model centers around having a single communication that can be checked off the treatment list.¹³⁰

II. Process Model of Informed Consent

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ Informed Consent and the Clinician-Client Relationship, <http://www.umassmed.edu/globalassets/center-for-mental-health-services-research/documents/products-publications/issue-briefs/human-rights/informed-consent-and-the-clinician-client-relationship.pdf> (last visited Dec. 6, 2015).

¹²⁸ BERG, *supra* note 116, at 170.

¹²⁹ *Id.*

¹³⁰ *Id.*

In contrast to the event model of informed consent, the process model involves ongoing communication throughout the treatment process.¹³¹ Both the client and clinicians expectations for treatment will be discussed.¹³² By regularly speaking to the client about their treatment options and current medical condition, the patient can gain a better understanding of their diagnosis and prognosis by becoming an active participant in their care.¹³³

First, the clinician is tasked with establishing responsibility.¹³⁴ This typically refers to the duration for which the physician will oversee the individual's care and the responsibilities the physician has with regard to the patient's medical treatment.¹³⁵ Second, the clinician and patient begin a dialogue so that they can both accurately define and diagnosis the patient's ailment.¹³⁶ The third step in the process involves the selection of the treatment process.¹³⁷ Similar to the diagnostic stage of the physician—patient relationship, the treatment selection process heavily relies upon input from both the patient and physician.¹³⁸ Fourth, after treatment has been selected, the physician implements the selected treatment and follows-up with the patient concerning prognosis.¹³⁹ This follow-up does not mark the end of the informed consent process; rather, informed consent is seen as an ongoing cycle, where the patient and physician are engaged in a continuous dialogue to jointly plan a course of treatment for the individuals.¹⁴⁰

While the event model of informed consent focuses upon the whether or not a physician had transmitted information to the patient, the process model of informed consent places a

¹³¹ NEIL C. MANSON & ONORA O'NEILL, *RETHINKING INFORMED CONSENT IN BIOETHICS* 69 (2007).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Informed Consent, *supra* note 127.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ MANSON & O'NEILL, *supra* note 131, at 69.

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 69-70.

greater concern on what the patient does with the information they have been provided.¹⁴¹

Personal autonomy is key.¹⁴² Information is shared with the patient so that they can weigh the possibilities and make an informed choice regarding their treatment.¹⁴³

III. Waiver Model

A third interpretation of informed consent, the waiver model, views the process as a simple waiver of ethical and legal norms.¹⁴⁴ Proponents of the waiver model argue that medicine, by its very nature, involves the provision of procedures by healthcare professionals that would usually infringe upon the legal rights of the patient.¹⁴⁵ Informed consent is a necessary part of the treatment process because physicians need to obtain permission to perform treatment, actions that would otherwise violate legal and ethical norms.¹⁴⁶ We see this going back to first documented informed consent cases.¹⁴⁷ Consent allows a patient to receive treatment that a physician would otherwise be reluctant to provide because of its illegal nature.¹⁴⁸ Physicians would only want to deliver treatment if a patient gives consent because the consent absolves the medical professional from liability.¹⁴⁹

Simplistic in its construction, the waiver model strikes a balance between the rights of both the physician and patients: while patients are protected from otherwise illegal conduct such as battery and assault, physicians likewise receive immunity from being prosecuted for actions that

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ MANSON & O'NEILL, *supra* note 131, at 69.

¹⁴⁴ Emma Bullock, *Informed Consent as Waiver: The Doctrine Rethought?*, 17 ETHICAL PERSPECTIVES 4, 538 (2010).

¹⁴⁵ *Id.* at 538-39.

¹⁴⁶ *Id.*

¹⁴⁷ *Mohr v. Williams*, 140 N.W. 12 (Minn. 1905).

¹⁴⁸ Bullock, *supra* note 144, at 538-39.

¹⁴⁹ *Id.*

would otherwise be deemed criminal or tortious.¹⁵⁰ Without consent, medical treatment would effectively be impossible; few healthcare providers would agree to treat a patient if the threat of a battery action loomed over interaction.¹⁵¹ Therefore, the waiver model of informed consent views consent in terms of ethical and legal necessity, as opposed to a means of protecting patient autonomy.¹⁵²

V. Critique of Informed Consent Models

At first glance, it would seem that medical informed consent may have much to offer for a discussion of employee notice with regard to wellness programs. One of the chief concerns in the informed consent process is whether or not an individual is fully informed to make a decision with regard to their healthcare. A number of fundamental differences in the context in which each of these communications occur, however, make informed consent models less useful to the EEOC's desired result.

With regard to the event model, the same criticism that are applicable to the medical context are similarly applicable to the employment context. If notice of how a wellness plan will treat an individual employees sensitive information is viewed as an item on a list—something that needs to be given with only a simple acknowledgement form the employee that the notice occurred—the wellness program could hardly be considered to give the employee “notice.” Such a simple communication may be insufficient to adequately inform an employee of what sensitive information will be collected, how it will be used, and who it will see this information. If the employee is not appropriately informed of the consequences of their decision, they can hardly be

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 538.

¹⁵² *Id.*

considered to be exercising control over their information. Therefore, a notice procedure based upon the event model of informed consent fails to adequately protect employee privacy.

The process model of informed consent seems ill-suited to inform the notice process of employee wellness programs as well. First, the continuing dialogue the model praises would be onerous for employers to implement. The defining feature of the process model is the view that informed consent is not a “one—and—done,” but rather is a series of ongoing, collaborative communication. An ongoing collaborative notice process for employee wellness programs seems both cumbersome and impractical. Employees will likely not have much input, if any, into the type of wellness program an employer is offering. Additionally, unlike the medical context, wellness programs are typically not tailored to an individual employee, and employers do not need to take special consideration as to the specific beliefs and feelings of employees when designing programs. Rather, an employer develops a wellness program for its entire staff, and employees can choose whether or not to participate.

Second, the process model is effective in the medical context because the course of treatment for individual is likely to change overtime. Physicians would need to communicate these changes to patients to allow the patient to effectively make decisions regarding their treatment. In contrast, wellness programs are static. The information concerning a wellness program is unlikely to change throughout the course of the program.

Third, critics of the process model have cited the impossible standard which the rule attempts to create as a reason for dismissing the model as a real solution to issues of informed consent.¹⁵³ The focus upon autonomy is cited as the process models biggest weakness.¹⁵⁴ For those

¹⁵³ Bullock, *supra* note 144, at 535-36.

¹⁵⁴ *Id.*

individuals embracing “minimal autonomy,” a patient need only be supplied with information so they can make some choice.¹⁵⁵ Any choice that the patient makes is desirable simply by virtue of being a choice made by the patient.¹⁵⁶ In contrast, in a “full autonomy” approach, an incredible amount of pressure is placed on a practitioner to disclose information in such a way that the patient can make a fully informed decision.¹⁵⁷ Given the cognitive capabilities of the patient, that may be impossible for a practitioner to actually accomplish.

Another shortcoming present in numerous models is the difference between receiving information to obtain medical treatment and receiving information to determine how you wish to control your private information. In the medical context, the patient is highly motivated to share information with the physician: their very life could depend on it. In the wellness program context, however, the decision to share private health information is one motivated by finances. Additionally, employees do not have the trusting relationship with their employer or a third-party wellness plan vendor as they do their own physician. In short, most forms of informed consent have little to offer the EEOC in terms of informing the notice process of employee wellness programs.

The event model of informed consent can be considered a noteworthy exception. This model sheds the onerous communication requirements of the process model, and instead favors a course of conduct which involves obtaining consent for treatments and procedures as they arise. The event model also places an emphasis on providing the patient with information for the purpose of having the patient decide how they would like to proceed; in contrast, the waiver model views the informed consent process as a means for physicians to absolve themselves from liability.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 536.

¹⁵⁷ *Id.*

Lastly, most adherents to the event model focus upon the use of an authorization form to document the informed consent experience, thereby providing healthcare professionals with clear evidence of a patient's choice. In relation to employee wellness programs, having evidence that an employee was supplied with information and consented to the provisions of the program would be valuable to the EEOC's goal of providing notice to employees. One aspect of the notice process the event model does not adequately address, however, is the types of information about the wellness program that should be provided to the employee.

VI. HIPAA Authorization Form

The HIPAA authorization form requirements pick up where the event model of informed consent leaves off; while the event model provides employers with the structure of the interaction between employees and employers, the HIPAA authorization form requirements provide employers with the information employers should communicate to their employees. A covered entity must obtain the individual's written authorization for any use or disclosure of protected health information that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.¹⁵⁸ The authorization form must be written in "plain language."¹⁵⁹ Covered entities must provide a signed copy of the authorization form to individuals whenever they seek authorization to use or disclose private health information of the individual.¹⁶⁰

Authorization forms supplied by covered entities must contain at least six core elements.¹⁶¹

First the form must provide "a description of the information to be used or disclosed that

¹⁵⁸ *Id.*

¹⁵⁹ Uses and Disclosures for Which an Authorization is Required, 45 C.F.R. 165.508(c)(3) (2015).

¹⁶⁰ 45 C.F.R. 165.508(c)(4).

¹⁶¹ 45 C.F.R. 165.508(c).

identifies the information in a specific and meaningful fashion.”¹⁶² Second, the form requires covered entities to provide individuals with the “name, or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.”¹⁶³ Third, covered entities are requested to list to whom the covered entity may make the requested use or disclosure.¹⁶⁴ Fourth, the covered entity must provide a description for each purpose of the requested use or disclosure.¹⁶⁵ Fifth, the covered entity must provide an individual with an “expiration date or event that relates to the individual or the purpose of the use or disclosure.”¹⁶⁶ Sixth, the authorization form is required to have the individual’s signature and date.¹⁶⁷

The HIPAA authorization form also requires a covered entity to include additional statements regarding the individual’s ability to control their health information. The authorization form must include a statement “adequate to place the individual on notice” that the individual has the right to revoke the authorization, and the consequences thereof.¹⁶⁸ Additionally, covered entities are required to include a statement informing individuals of the covered entities ability or inability to condition “treatment, payment, enrollment or eligibility for benefits on the authorization.”¹⁶⁹ Such a statement must also include, if relevant, information concerning the consequences to the individual for choosing not to sign the authorization form.¹⁷⁰ Any potential for disclosure of the individuals protected health information must also be provided in the authorization statement as well.¹⁷¹

¹⁶² 45 C.F.R. 165.508(c)(1)(i).

¹⁶³ 45 C.F.R. 165.508(c)(1)(ii).

¹⁶⁴ 45 C.F.R. 165.508(c)(1)(iii).

¹⁶⁵ 45 C.F.R. 165.508(c)(1)(iv).

¹⁶⁶ 45 C.F.R. 165.508(c)(1)(v).

¹⁶⁷ 45 C.F.R. 165.508(c)(1)(vi).

¹⁶⁸ 45 C.F.R. 165.508(c)(2)(i)(A) and (B).

¹⁶⁹ 45 C.F.R. 165.508(c)(2)(ii).

¹⁷⁰ 45 C.F.R. 165.508(c)(2)(ii)(A) and (B).

¹⁷¹ 45 C.F.R. 165.508(c)(2)(iii).

Clearly, the HIPAA authorization form provides a much better analog than the medical treatment context. The very purpose of the HIPAA authorization form is to provide individuals with adequate notice of how a covered entity intend to use or disclose their personal health information. The requirement to list who will be asking to use and disclose health information and to whom they will be disclosing the health information allows employees to make an informed choice about how to share their information with others. This protects an employee's privacy.

Additionally, if the EEOC were to adopt the signature, plain language, and copy requirements of the HIPAA authorization form, it would ensure the agency is taking great strides to force employers to provide notice to their employees. By requiring a form be written in plain language, the EEOC is maximizing the number of employees who will be able to understand the mechanics of the employee wellness program. The EEOC could adopt similar signature and copy requirements as well. Instead of requiring an authorization form be required for every use or disclosure of health information not otherwise exempted, the EEOC could mandate that employers provide a copy of an authorization form when deciding whether to join the wellness program. Using such a form would ensure the employee is receiving the information and also provide documentation to the employer that the employee was placed on notice regarding the wellness program.

In this way, the HIPAA authorization acts like a form of the event model of informed consent. Similar to the process I have outlined for the EEOC above, the defining feature of the event model is the acquisition of the authorization form for the physician. In both instances, the authorization form serves as a discrete time point where either physicians or employers can look back to determine that an employee gave their consent to participate in an employee wellness

program or treatment. Another similarity the HIPAA authorization form process and the event model of informed consent share is the emphasis placed on continuing communication. While other models of informed consent championed an ongoing communication between a physician and patient, that expectation for communication is not reasonable in the employment context. This is why the event model parallels so well with the HIPAA authorization form; both models understand that consent need only be given once in the process, and a “new consent” must only be obtained when conditions (in either treatment or a wellness program agreement) change.

VII. Conclusion

If the Department of Labor’s recent study of wellness programs in the United States tell us anything, it is that wellness programs are here to stay. While employers should be permitted to take steps to reduce healthcare costs and encourage a more health, active workforce, and any wellness program that is constructed must properly respect employee privacy, or the right to control their information. The EEOC correctly noted in its most recent proposed rule that wellness programs that do not provide adequate notice to participants concerning who is collecting their information, what information is being collected, and how the information will be used may not properly be considered “voluntary” programs: a lack of meaningful information about a wellness program leaves an employee with only the illusion of choice.

The EEOC solicited comments with regard to how models of medical informed consent could possibly inform the notice requirements for wellness programs. However, some informed consent models were ill-suited to meaningfully inform the notice process for wellness programs. First, informed consent is more of a communicative process than a means of providing notice.¹⁷²

¹⁷² Additionally, the event model of informed consent, the one model that does treat the informed consent process as a mere notice requirement, has its own shortcomings in the medical context by not providing patients with enough information to make a fully informed decision on matters of critical importance, such as healthcare.

Requiring employers to have ongoing conversations with their employees regarding wellness programs would be cumbersome. Second, informed consent and notice for wellness programs are targeting different types of problem. For informed consent, the concerns are chiefly whether or not a patient understands the risk a certain physician will expose them to with a given procedure. For a wellness program, employees are not concerned with life or limb. Instead they are concerned with who has access to their information. Third given the sensitive privacy concerns at stake, the notice procedure is more than a waiver of liability for the patient; it involves the dissemination of information to the employee that allows them to adequately exercise autonomy over their health information.

The EEOC also asked whether the HIPAA authorization form could be useful in noting what type of notice should be available for employee wellness programs. The requirements laid out for the authorization form are significantly helpful in protecting the health privacy of employees. The requirements to be contained in the authorization form allow individuals to make informed choices with regard to the sharing of their private health information. Similar concerns are found in the employee wellness programs.

For these reasons, the EEOC should require a similar writing to the HIPAA authorization form for employee wellness programs. Such a clear disclosure of how an employee's health information will be used and collected, and for what purpose will allow employees to make meaningful decisions with regard to how they would like to share their health information with their employer, protecting the employee's personal autonomy and privacy.