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Two separate pieces of recent administrative guidance, both dealing with health risk assessments (HRAs) threaten the viability of certain aspects of wellness initiatives.

Double Whammy – EEOC ADA Opinion Letter and GINA Interim Final Regulations Restrict Health Risk Assessments in Wellness Initiatives

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Questions continue to plague employers regarding the extent to which the Americans With Disabilities Act (ADA) may restrict them from implementing wellness programs and initiatives in connection with the group health plans that they sponsor. The issues surrounding these initiatives have been further clouded by the ADA Amendments Act (ADAAA) and the regulations under the ADAAA that were proposed September 23, 2009 by the EEOC (the "Proposed Regulations"), which substantially expanded the universe of individuals who are protected under the ADA. On August 10, 2009, the EEOC issued an Opinion Letter, recently made publicly available, regarding health risk assessments (HRAs) offered in connection with a health reimbursement arrangement.

In addition, the Departments of Labor, Treasury and HHS have jointly issued interim final regulations under the Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA).[1] These regulations place severe restrictions on an employer's ability to request that plan participants complete an HRA that includes family health history or other "genetic information" as part of a program of wellness incentives under a group health plan.

HRAs as Part of Wellness Programs

Wellness initiatives have continued to emerge as a critical part of group health plan design, as employee wellness has become a key feature of productivity and medical cost containment. It has been estimated that 80% of group health costs are caused by 20% of plan participants with conditions that are preventable with appropriate changes in lifestyle, diet, exercise, and in some cases, medication.[2] US legislators have stated that chronic disease causes 75% of the nation's healthcare costs, with smoking, physical inactivity and obesity, as major contributors to chronic disease and death.[3] It has also been reported that out of the $2 trillion spent by the U.S. on healthcare costs, only 4 cents of every dollar is spent on prevention.

The Health Insurance Portability and Protection Act of 1996 (HIPAA) prohibits discrimination in a group health plan on the basis of a "health factor," but permits an

exception under a program reasonably designed to promote health or prevent disease – in other words, a "wellness program." The HIPAA regulations issued jointly by the DOL, IRS and HHS in 2006, effective in 2007, provide that a wellness program that conditions a plan incentive on a plan participant meeting a standard related to a health factor, such as bringing one's body mass index (BMI), blood pressure, or other health-related measure to within certain limits, would violate the HIPAA nondiscrimination requirements, unless it meets five tests. These tests are: (1) the value of the plan incentive may not exceed 20% of the cost of coverage applicable to the group eligible for the incentive; (2) the program must be reasonably designed to promote health or prevent disease; (3) eligible participants must be permitted to qualify for the incentive at least annually; (4) participants who can demonstrate that it would be dangerous or medically impossible to meet the standard may be offered an alternative standard through an interactive process; and (5) the terms of the program and the availability of a reasonable alternative standard must be disclosed to the participants in writing on an annual basis.[4] The incentive may be a reduction of the applicable deductible, lowered co-pays or co-insurance amounts, a premium rebate or discount, or similar incentive.

The HIPAA wellness regulations stipulate that a wellness program that does not base the plan incentive on a standard related to a health factor is not subject to the five requirements, and automatically qualifies under the regulations, without regard to the level of incentive available for participation in the program. An example of such a program, often termed a "participation-only" program, would be a wellness program in which the participant submits a detailed HRA, to a wellness provider, usually an outside firm that contracts with the plan administrator. On the basis of the HRA results, the wellness provider may refer the participant to a wellness coach, who will contact the participant confidentially, to provide wellness information without the knowledge or involvement of the employer.

The HIPAA wellness regulations further provide that the incentive for participation in such a participation-only wellness program is not limited (as it would be if the incentive were based on a health factor), and that an employee who does not participate in the wellness program may be barred from participating in the health plan altogether without violating HIPAA.[5]

HRAs as Part of a Wellness Initiative Under the ADA

HRAs that are included in a wellness initiative as part of a group health plan under HIPAA may violate the Americans with Disabilities Act even if they comply with HIPAA. The ADA, as amended by the ADAAA, prohibits discrimination in employment "against a qualified individual on the basis of disability in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment."[6] Further, the ADA prohibits employers from requiring employees to undergo medical examinations or inquiries, except under specific exclusions. Generally, the examination or inquiry must be made on a post-offer basis for employment and either be "job-related and consistent with business necessity,"[7] or a voluntary medical examination, as "part of an employee health program available to employees at that work site."[8]

These enforcement provisions of the ADA, and the "benefit plan exception," described below, were not amended by the ADAAA. Therefore, the concerns relating to violations of the ADA arising out of HRAs or medical examinations as part of a HIPAA-compliant group health plan wellness program have not been affected by the ADAAA, other than to bring the issues into greater focus. Note that the ADA's prohibition on medical examinations and inquiries is not dependent on the employee or applicant's status as a "qualified individual." The prohibition applies to all applicants and employees.

The position of the EEOC with respect to HRAs or medical examinations as part of a wellness program has evolved slowly over the past two years, and has been revealed mainly through informal pronouncements to professional groups and private Opinion Letters issued to individual employers. However, at the national level, the EEOC has not taken an official position or published any guidance regarding the extent to which such HRAs or examinations will violate or be permitted under the ADA.

In May 2008, the EEOC staff responded to questions posed by the Joint Committee on Employee Benefits, a working group of the American Bar Association.[9] One question raised the issue of whether an HRA conducted as part of a wellness program would come within the "benefit plan exception" under section 12201(c) of the ADA.[10] The "benefit plan exception" provides that the ADA shall not be

construed to prohibit or restrict an employer from "establishing, sponsoring, observing or administering the terms of a bona fide benefit plan," which are: "(1) based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law" (that is, a fully insured plan); or (2) where the plan is not subject to state law (that is, a self-insured employee benefit plan, in which case state law is preempted by ERISA). In either case, the plan provision may not be a "subterfuge for avoiding the purposes" of the ADA.[11]

The EEOC staff answered only that the EEOC National Office did not have an official position on the question of mandatory HRAs administered as part of a wellness program under a group health plan, but they expressed "some concern about requiring an HRA as a condition for receiving health insurance." The EEOC did not elaborate, but presumably, the "concern" was with regard to the question of whether the HRA was voluntary, since it would be unlikely that a general HRA would be job-related and consistent with business necessity.

In March 2009, the EEOC issued an Opinion Letter[12] withdrawing a previous letter in which Peggy Mastroianni, Associate Counsel for the EEOC, opined that requiring employees to take an HRA, which included disability-based questions and medical examinations as a condition for participation in the employer's group health plan was not a job-related medical inquiry and therefore violated the ADA's prohibition on medical examinations and inquiries that are not job related or based on business necessity.[13] The EEOC rules state that unless these exceptions apply, post-employment medical examinations or medical inquiries are prohibited by the ADA unless they are voluntary.

The withdrawn Opinion Letter had stated that an HRA administered as part of a wellness program meeting the requirements of the HIPAA wellness regulations, in that the plan incentive or penalty did not exceed 20% of the total cost of plan coverage pertaining to the participant, would be deemed "voluntary" and would not violate the ADA. This portion of the prior ruling letter was withdrawn because it was not raised in the facts in the opinion letter request.

In 2009, the EEOC again responded to a question from the Joint Committee on Employee Benefits regarding whether HRAs that rewarded participation with a plan incentive violate the ADA. The EEOC's answer evidenced a hardening of its position is hardening on the subject of HRAs. This time, the EEOC responded by noting that an opinion letter had recently been issued holding that an employer violated the ADA by requiring an HRA as a condition for enrollment in its group health plan, but reiterated that it "had not taken a position as to what level of inducement would make an [HRA] involuntary."[14]

On August 10, 2009, the EEOC issued a second Opinion Letter with respect to an HRA,[15] also authored by Ms. Mastroianni, and recently made publicly available, dealing with an employer that conditioned reimbursements under a health reimbursement arrangement on whether the employee completed an HRA. The HRA in this case included questions on the employee's family health history, self care, personal health, nutrition, physical activity, alcohol and tobacco use, safety, and health changes. The Opinion Letter noted that some innocuous questions, such as how often the employee exercised and ate fruit and vegetables, and whether the employee had a family doctor, were not "disability-based" because the questions would not elicit a response that would be disability related. These questions would also be unlikely to yield useful information regarding the state of the individual's health and whether wellness services should be offered, and would render the HRA effectively useless from the standpoint of a wellness program.

However, the EEOC found that questions regarding whether an individual ever felt depressed, was knowledgeable about certain health conditions such as asthma, heart disease or diabetes, how much alcohol they drank, and what prescription medications they took regularly, were directed at specific disabilities. Further, the Opinion Letter noted that the questions were not job related or based on business necessity because all employees were required to answer them in order to obtain reimbursement under the employer's health reimbursement arrangement.

Additionally, the Opinion Letter stated that the "family medical history" questions would, as of November 21, 2009, violate the Genetic Information Nondiscrimination Act (GINA), which prohibits employers from obtaining genetic information from applicants or employees,

including family medical history, except under very limited circumstances, such as part of a "voluntary" wellness program.[16] The Opinion Letter concluded that a wellness program is not voluntary when it penalizes an employee who does not complete a health risk assessment by making him or her ineligible to receive reimbursement for health expenses.

Thus, the EEOC's position is that HRAs required as part of HIPAA-compliant wellness plans are prohibited under the ADA's "no medical exams or inquiries" provision unless they are voluntary. On this basis, the level of inducement, or more specifically, the value of the incentive for taking the HRA, forms the basis of the EEOC's view of what is a "voluntary" medical examination or inquiry.

A prior EEOC Opinion Letter that was withdrawn by the EEOC on account of the positions taken in the March 2009 Opinion Letter had taken the position that if value of the HRA did not exceed 20% of the cost of medical coverage under the group health plan, and therefore complied with the HIPAA requirement for a "health factor-based" wellness program, it would be considered voluntary under the ADA. Since that Opinion Letter was withdrawn, the EEOC has not broached the subject of what level of incentive would suffice to pass muster under the "voluntary" analysis.

Meanwhile, lost in the EEOC's analysis is the question first posed to the EEOC staff by the Joint Committee on Employee Benefits in 2008 as to whether an HRA required as part of a wellness program under an employer's group health plan would be excluded under the "benefit plan exclusion."

As noted above, section 12201(c) of the ADA generally exempts insured and self-insured group health plans that make a disability-based distinction, as long as that distinction is not a "subterfuge for avoiding the purposes" of the ADA. In 1993, the EEOC issued "interim guidance" on the "subterfuge" standard in the context of health plan exclusions and limitations. The interim guidance stated that a disability-based distinction in a health plan is permitted if the plan can present actuarial or other underwriting-based evidence that unless the disability-based distinction is made, the plan would be threatened with insolvency.

There is no definitive case law at this time shedding light on how the "benefit plan exception" to the ADA operates in the case of an HRA required as part of a wellness program. However, the courts have not gone so far as the EEOC in holding that the exception requires the plan sponsor to demonstrate that the plan would effectively be bankrupted were it not for the disability-based distinction.[17]

Several points are notable in the evolution of the EEOC's position regarding incentive/penalty-based HRAs in wellness programs.

First, the EEOC appears to be leaning toward a position where disability-based inquiries and medical examinations may be permitted if the incentive/penalty does not exceed the 20% of total cost of coverage under the HIPAA standard for wellness programs that impose a standard based on a health factor. However, until there is an official pronouncement from the EEOC on this point, employers proceed at their own risk in implementing such programs. What is known is that basing plan eligibility on completion of an HRA or obtaining a medical examination could draw a challenge from the EEOC. Employers intent on proceeding should be aware of this and prepare accordingly.

Second, the employer would be well advised to obtain actuarial (in the case of a self-insured plan) or underwriting-based (in the case of an insured plan) documentation of the cost to the plan of not addressing health costs that could be mitigated through a mandatory wellness program. At least in theory, if the employer can place the plan in a position where the "bona fide employee benefit plan" exception to the ADA applies, the mandatory wellness program would arguably pass muster under the ADA even if it exceeded the 20% standard.

Third, given the enormous pressure on employers to provide wellness programs to encourage healthy behavior, improve employee health and prevent disease, and control health costs, without helpful guidance from the EEOC setting forth a reasonable framework in which wellness initiatives can operate without violating the ADA, discrimination charges and subsequent litigation appear to be inevitable, barring legislative relief from the EEOC's restrictive reading of the ADA. Employers should review their wellness initiatives and programs to ensure that they are in the best position possible in relation to the ADA as amended by the ADAAA.

HRAs, Wellness Initiatives, and GINA

In addition to the tightening of restrictions on the use of HRAs in employer-sponsored wellness programs, on October 7, 2009, the DOL, Treasury and HHS issued interim final regulations under Title I of GINA, which address GINA's amendments relating to group health plans and health insurers to be effective as of the first plan year of a plan following December 7, 2009. In general, GINA prohibits employers from requesting, requiring or purchasing genetic information from its employees except in very narrow circumstances.[18] In connection with any group health plan or health insurer, GINA prohibits the covered entity from: (1) increasing the group premium or contribution amounts based on genetic information; (2) requesting or requiring an individual or family member to undergo a genetic test; and (3) requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for "underwriting purposes." In the context of GINA, "underwriting" does not refer to overall rate-setting, but the establishment of cost-sharing features as between the employer and covered employees through incentives or penalties for participation or non-participation in the wellness program.

The "underwriting" exclusion is very broad in scope, and restricts requesting, requiring or collecting genetic information in connection with any incentive, whether a cash payment, premium discount or rebate, reduction in co-pays or deductibles, or any other incentive, in return for activities such as completing an HRA or participating in a wellness program. The preamble to the GINA regulations specifically notes that such a program violates GINA, even if it does not base the incentive on any medical outcome, and would therefore conform to the HIPAA wellness regulations as a "participation only" wellness program.

The interim final regulations further restrict, and in most cases prohibit, the use of an HRA in connection with a wellness program, whether as part of a group health plan or separately from the plan, for "underwriting purposes," if "genetic information" is requested or required ("collected") as part of the HRA.

Under GINA and the regulations, "genetic information" includes results of genetic testing of the individual, information regarding medical conditions of family members as remote as great-great grandparents and children of second cousins, and can include individuals who are not related by blood if they are dependents of the individual.

Under the GINA interim regulations, genetic information may be obtained only by a medical provider in connection with providing medical services or treatment to the individual, or if the collection of the genetic information is voluntary or voluntarily requested by the individual with full knowledge and disclosure.

The interim regulations under GINA are effective for group health plans whether insured or uninsured, for the first plan year beginning on or after December 7, 2009. Therefore, group health plans which include a wellness program, and employers who offer wellness programs outside the health plan context, must review these wellness plans, particularly those that offer financial incentives for participating in HRAs that request genetic information, and make necessary changes before GINA's effective date.

There are some strategies made available by the GINA interim regulations that may permit employers and group health plan administrators to offer incentives for HRAs and remain in compliance with the GINA rules. For example, the regulations specify that the wellness program could offer two HRAs after and unrelated to enrollment, one that does not request genetic information, and which qualifies the participant for the incentive, and a second HRA which the participant may voluntarily agree to take, which requests (but does not require) genetic information, but which is not required to qualify for the incentive. There are strict technical requirements in designing these programs, including specific disclosures that must be provided, therefore, extreme caution is advised in structuring a wellness program around an HRA that will comply with the new GINA regulations by requesting a genetic information on a voluntary basis.

One particularly troubling issue that has arisen given the fact that the GINA regulations were issued so late in the year, is that many group health plans have already administered non-compliant HRAs as part of a plan, where a plan incentive will be offered as of the start of the next plan year. The GINA regulations are effective for plans administered on a calendar plan year basis as of January 1, 2010. Therefore, even though GINA was not applicable at the time the non-conforming HRA was administered, GINA will be effective when the

plan incentive (or penalty) will be applied in the 2010 plan year. The question is, does GINA apply to the application of the incentive or penalty where GINA did not apply at the time the HRA was administered?

The preamble to the GINA regulations provide that if the HRA, which requires genetic information, is administered during 2009, at a time when GINA does not apply to the plan, but the genetic information collected as part of the HRA is used by the insurer or plan administrator to adjust overall group rates, then GINA will be violated. Neither the preamble nor the regulations explain what the result would be if an HRA that includes genetic information is administered before the GINA effective date, and used for "underwriting purposes" after GINA's effective date.

However, in recent days, DOL representatives have informally stated that such a procedure would violate GINA, and that each application of a plan incentive would constitute a separate violation of GINA. In these cases, the plan administrator may either: (1) apply the incentive prior to GINA's effective date with respect to the plan; (2) not apply the incentive; or (3) apply the incentive to all plan participants whether or not they complied with the HRA requirement.

Consequences of HRA or Wellness Plan Violations of ADA or GINA

The consequences of violating the ADA may be a suit by the EEOC or the affected employees for damages, including compensatory damages, emotional pain, suffering, inconvenience, mental anguish, punitive damages, and other non-monetary losses.[19] Damages under the ADA are limited by the damage caps under Title VII.[20] However, these damages caps apply on a per plaintiff basis. Therefore, violations of the ADA in the case of a group health plan that effectively applies to all of the company's employees is potentially catastrophic.

In the case of a private employer, the potential liability for violations of the group health plan restrictions under GINA arise under GINA's amendments to ERISA and the Internal Revenue Code.[21] Under ERISA, GINA could result in an action by a participant, beneficiary or a plan fiduciary for declaratory judgment, injunction and other equitable relief.[22] Generally, damage remedies are not available under ERISA's general enforcement provision, sometimes called the "catch-all" provision, under which a GINA enforcement action would be brought.[23]

However, GINA added a new civil penalty to ERISA's existing enforcement provision. Under this new provision, the Secretary of Labor may bring an action for a civil penalty against the plan sponsor or insurer for a violation of Title I of GINA in an amount that tracks the excise tax discussed below.[24] Attorneys' fees and costs are available at the discretion of the court in ERISA enforcement actions.[25]

In addition, violations of GINA's group health plan rules may result in the imposition of an excise tax under the Code in an amount equal to $100 per day per violation, up to the lesser of 10% of the amount spent by the taxpayer during the previous year for group health care, or $500,000.[26] The minimum penalty is $2,500, but if it is more than de minimis, then the minimum penalty is $15,000.

Generally, small employers, defined as an employer with 2 to 50 employees on average for the preceding year, are exempt from the excise tax. Also, the penalty will not apply if it was not due to willful neglect, and is corrected within 30 days of discovery, or the date on which it could have been known with reasonable diligence. Finally, the IRS has the discretion to waive the penalty if it is shown that the taxpayer did not know, and in the exercise of reasonable diligence, could not have known of the violation, and the IRS determines that the penalty would be excessive relative to the violation in question.

In addition to the excise tax requirement itself, the Treasury Department on October 13, 2009, promulgated final regulations requiring taxpayers to self-report excise taxes arising under Code Sections 4980B (failure to comply with COBRA continuation coverage), and 4980D (violations of HIPAA and GINA), among other benefits-related excise tax provisions. The excise taxes are reportable on IRS Form 8928 not later than the last day of the seventh month after the close of the plan year, effective with the first plan year beginning on or after January 1, 2010.[27] Failure to file the return will result in additional interest and penalties.

The effective date of both the ERISA civil penalty and Internal Revenue Code excise tax provisions of GINA are effective as of the first

day of the plan year beginning after one year following the date of enactment of GINA.[28] GINA was enacted on May 21, 2008. Therefore, in the case of a calendar year group health plan, the effective date of the excise tax and civil penalty provisions will be January 1, 2010.

There is nothing in either the excise tax or the ERISA civil penalty provision to indicate that either remedy is exclusive to the other. Therefore, the total combined maximum civil penalty and excise tax under the ERISA and the Code enforcement provisions of Title I of GINA could be up to $1,000,000.

What to Do Now

Sponsors of group health plans that currently include, or are considering incentive-based HRAs as part of their HIPAA-compliant wellness program, should consider the following:

1. Partner with legal counsel to perform an objective review of your current wellness program.
   - Does it reflect your organization's business model?
   - Does it comply with GINA and the ADA as amended?
   - What steps should your organization take to bring the HRA program into compliance with GINA and the ADA?
2. Communicate with legal counsel regularly to remain "on top" of the latest developments with respect to guidance from federal agencies with respect to wellness programs and HRAs.
3. If an HRA is utilized as part of your wellness program, does it contain questions about genetic information? Determine whether or not to abandon all inquiries with respect to genetic information or design an alternative voluntary HRA that will comply with GINA's requirements for protection of genetic information.
4. Enlist your service providers to assist you with development of HRAs, employee communications and plan design features that will comply with GINA and the ADA, and continue to contain the cost of health care and promote the general health of your employee population.

The double whammy of the EEOC's pronouncements on HRAs under the ADA, and the new interim GINA regulations and its potentially crushing civil penalties and excise tax, make it critical that all group health plan sponsors offering wellness programs that include HRAs review their wellness plan for legal compliance, and make necessary changes to meet the emerging challenges posed by the ADA and GINA.

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[1] The Genetic Information Nondiscrimination Act, Title I, Genetic Nondiscrimination in Health Insurance, Pub. Law No. 110–233, May 21, 2008 (GINA).

[2] *See*, Littler Report: *Employer Mandated Wellness Initiatives: The Continuum from Voluntary to Mandatory Plans*, April 2008.

[3] *See generally, Reform that Reduces Chronic Disease and Health Care Costs, November 4, 2009, Democratic Policy Committee*, http://dpc.senate.gov/dpcdoc.cfm?doc_name=fs-111-1-142, accessed Nov. 17, 2009.

[4] Labor Reg. Sec. 2590.702(f)(2).

[5] See DOL Field Assistance Bulletin 2008-02, Feb. 14, 2008, Wellness Program Analysis, Item D, Example 2.

[6] 42 U.S.C. § 42112(a).

[7] 42 U.S.C. § 42112(d)(4)(A).

[8] 42 U.S.C. § 42112(d)(4)(B).

[9] Questions for the EEOC Staff for the 2008 Joint Committee of Employee Benefits Technical Session, May 8, 2008

[10] 42 U.S.C. § 12201(c).

[11] *Id*.

[12] EEOC Opinion Letter, Mar. 6, 2009.

[13] 42 U.S.C. § 21112(d). Under the business necessity exception, a disability-based inquiry may be permitted only if the employer reasonably believes, based on objective evidence, that (1) the employee's ability to perform the essential functions of the position will be impaired by the limitation; or (2) the employee will pose a direct threat to other employees or the public due to the medical condition. See, EEOC Enforcement Guidance on Disability-Based Inquiries and Medical Examinations Under the ADA.

[14] Questions for the EEOC Staff for the 2009 Joint Committee of Employee Benefits Technical Session, May 6, 2009.

[15] EEOC Opinion Letter, Aug. 10, 2009.

[16] In fact, the GINA regulations under Part I of GINA are effective with respect to group health plans beginning with the first day of the first plan year beginning on or after December 7, 2009. For calendar year plans, that date will generally be January 1, 2010.

[17] *See, e.g., Krauel v. Iowa Methodist Med. Center*, 95 F.3d 674, 678 (8th Cir. 1996).

[18] *See*, Littler ASAP, *Genetic Antidiscrimination Law Creates New Compliance Challenges For Employers*, May 2008.

[19] 42 U.S.C. § 1981a(a)(2). Punitive damages are generally available only if the defendant is shown to have acted with "malice or reckless indifference" to the rights of the plaintiff. However, the act need not be "egregious," and punitive damages will be available if the defendant acted with knowledge of a perceived risk that its actions would contravene the ADA. *Kolstad v. American Dental Ass'n*, 527 U.S. 526 1697 (1999).

[20] 42 U.S.C. § 1981a(b)(3).

[21] Internal Revenue Code of 1986, as amended, hereafter, the "Code."

[22] ERISA § 702(b), 29 U.S.C. § 1182(b), as enforced through ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3).

[23] ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3).

[24] ERISA § 502(a)(9), 29 U.S.C. § 1132(a)(9).

[25] ERISA § 502(g), 29 U.S.C. § 1132(g).

[26] Code § 4980D, 26 U.S.C. 4980D.

[27] Treas. Reg. § 54.4980D-1.

[28] GINA, § 102(f), 29 U.S.C. 1132, note; GINA § 103(f), 26 U.S.C. § 9802, note.