EMPLOYER-SPONSORED HEALTH PLANS UNDER NON-PRIVACY HEALTH PLAN PROVISIONS OF HIPAA

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I. **OVERVIEW.** This outline covers the Health Insurance Portability and Accountability Act of 1996, enacted August 21, 1996 ("HIPAA"), plus the following statutory amendments and Departmental guidance:

A. Final regulations issued on December 30, 2004, sometimes referred to as the "2004 Final HIPAA Regulations" (replacing temporary, proposed and interim final regulations issued on April 3, 1997 and clarified on December 29, 1997, sometimes collectively referred to as the "1997 HIPAA Regulations," "as they relate to individuals who were denied coverage before the effective date of HIPAA on the basis of any health factor");

B. Proposed regulations also issued on December 30, 2004, sometimes referred to as the "2004 Proposed HIPAA Regulations";

C. A "Request for Information on Benefit-Specific Waiting Periods Under HIPAA Titles I & IV," published in the Federal Register on December 30, 2004, beginning on page 78825;

D. Final regulations issued on December 13, 2006, sometimes referred to as the "2006 HIPAA Regulations" (replacing the 1997 HIPAA Regulations; and also replacing three sets of temporary, proposed and interim final rules issued on January 8, 2001, one set of which was generally applicable to HIPAA's non-discrimination rules, one set applicable to an exemption from such rules for "certain grandfathered church plans," and one set of proposed regulations dealing with wellness programs (sometimes collectively referred to as the "2001 Proposed HIPAA Regulations");

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E. Final regulations issued on January 8, 2001;

F. The Newborns' and Mothers' Health Protection Act of 1996, enacted September 26, 1996 ("NMHPA");

G. Temporary, proposed and interim final regulations issued under the NMHPA on October 27, 1998 (sometimes referred to as the "NMHPA Regulations");

H. The Mental Health Parity Act of 1996, enacted September 26, 1996 ("MHPA"), followed by the addition of corresponding provisions to the Internal Revenue Code in the Taxpayer Relief Act of 1997 ("TRA 1997");

I. Temporary, proposed and interim final regulations issued under the MHPA on December 22, 1997, sometimes referred to as the "MHPA Regulations";

J. Various amendments to MHPA extending its sunset date (collectively, the "MHPA Amendments");

K. Interim final DOL regulations implementing the MHPA extensions (the "MHPA Extension Regulations");

L. The Womens' Health and Cancer Rights Act of 1998, enacted on October 21, 1998 (the "WHCRA"); and

M. Department of Labor ("DOL") guidance issued on October 18,1998 and October 20,1999 under the WCHPA (sometimes referred to as the "WHCRA Guidance"); and

N. The Genetic Nondiscrimination Information Nondiscrimination Act of 2008 ("GINA"), enacted May 21, 2008.

II. APPLICABILITY OF HIPAA AND EXEMPTIONS.

A. APPLICABLE TO GROUP HEALTH PLANS AND THEIR INSURERS. In general, the requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") are applicable to any group health plan (an "employee welfare benefit plan to the extent that the plan provides medical care… to employees or their dependents… directly or through insurance, reimbursement, or otherwise.") The requirements are also applicable to the issuer of a policy or contract utilized by a group health plan (sometimes referred to in this outline as an "insurer").

1. Medical Care Defined. Medical care includes "items and services paid for as medical care," and means amounts paid for:

a. "The diagnosis, cure, mitigation, treatment, or prevention of disease,"

b. "The purpose of affecting any structure or function of the body,"

c. "Transportation primarily for and essential to medical care" as defined in a and b, above, or

d. "Insurance covering medical care" as defined in a, b and c, above.

Code §9805(d)(3); ERISA §733(a)(2). The 2004 Final HIPAA Regulations define this term by reference to Section 213(d) of the Code (other than the deductibility cap and the references to long term care insurance).

2. Health Insurance Coverage Defined. Health insurance coverage includes "items and services paid for as medical care," and "means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise. . .) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer." Code §9805(b)(1); ERISA §733(b)(1). The 2004 Final HIPAA Regulations make clear that benefits that are always excepted (accident (including accidental death and dismemberment), disability, liability (including general liability insurance and automobile liability insurance) and supplemental liability, workers' compensation or similar coverage, automobile medical payment, credit-only, and on-site medical clinic coverages) are NOT considered health insurance.

3. Health Insurance Issuer Defined.

a. Under the statutory provisions, health insurance issuer "means an insurance company, insurance service, or insurance organization (including a health maintenance organization. . .) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of [ERISA]). Such term does not include a group health plan." Code §9805(b)(2).

b. The 2004 Final HIPAA Regulations further define a health insurance issuer to include an entity (as listed immediately above) that is "required to be licensed to engage in the business of insurance in a State."

4. Health Maintenance Organization Defined. A health maintenance organization means an organization recognized as such under State or Federal law, or a similar organization "regulated under State law for solvency

in the same manner and to the same extent as such a health maintenance organization." Code §9805(b)(3); ERISA §733(b)(3).

5. Group Health Insurance Coverage Defined. Group health insurance coverage "means, in connection with a group health plan, health insurance coverage offered in connection with such plan." ERISA §733(b)(4).

6. Group Health Insurance Plan Defined.

a. A group health plan is an insured or self-insured plan "of, or contributed to by, an employer (including a self-employed person) or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families." Treas. Reg. §54.9831-1(a).[2] The effect of this definition, among other things, is that independent contractors who are covered by an employer's health plan will be entitled to HIPAA's protections.

b. Determination as to Number of Plans. An employer (or, in the case of a multiemployer plan, its joint board of trustees), will have all its "health care benefits… constitute one group health plan," except that:

(1) If it "is clear from the instruments governing the arrangement or arrangements to provide health care benefits that the benefits are being provided under separate plans," and if the "arrangement or arrangements are operated pursuant to such instruments as separate plans," then the arrangements may be treated as separate plans. Prop. Treas. Reg. §54.9831-1(b)(i).

(2) A multiemployer plan and a non-multiemployer plan are always treated as separate plans. Prop. Treas. Reg. §54.9831-1(b)(ii).

(3) "If a principal purpose of establishing separate plans is to evade any requirement of law, then the separate plans will be considered a single plan to the extent necessary to prevent the evasion." Prop. Treas. Reg. §54.9831-1(b)(iii).

B. PARTNERSHIP PLANS AND SELF-EMPLOYED PERSONS COVERED.

[2] Parallel citations to DOL and HHS regulations are generally not included.

1. Rule.

a. A plan covering only partners is NOT exempted, and is as fully subject to the requirements as if the entity were incorporated. All self-employed persons (and their dependents) covered (or eligible to be covered) by any plan are entitled to the same protections as any other participants and beneficiaries. ERISA §732(d).

b. The 2004 Final HIPAA Regulations provide that "a plan providing medical care, maintained by a partnership, and usually not treated as an employee welfare benefit plan under ERISA" will nevertheless be treated as a group health plan for purposes of HIPAA. Treas. Reg.§54.9831-1(d)(1).

2. Operation.

a. The partnership is treated as the "employer" with respect to the partners. ERISA §732(d)(2). The 2004 Final HIPAA Regulations state that the partnership will be the employer "in relation to any bona fide partner." Treas. Reg.§54.9831-1(d)(2).

b. The partners covered by a plan maintained by a partnership are treated as participants, and self-employed persons covered by any employer plan are treated as participants, to the same extent as employees of any other employer. ERISA §732(d)(3). The 2004 Final HIPAA Regulations state that "any bona fide partner" will be treated as an employee. "Whether or not an individual is a bona fide partner is determined based on all the relevant facts and circumstances, including whether the individual performs services on behalf of the partnership." Treas. Reg. §54.9831-1(d)(2).

c. A bona fide partner or self-employed individual will be considered a "participant" "if the individual is, or may become, eligible to receive a benefit under the plan or the individual's beneficiaries may be eligible to receive any such benefit." Treas. Reg.§54.9831-1(d)(3).

C. EXEMPTIONS. The following are exempt from the requirements of HIPAA:

1. Small Plans. The above rules do "not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees." Code §9804(a); ERISA §732(a); Treas. Reg.§54.9831-1(b).

a. No Preemption**.** However, a State may require insured plans covering less than 2 participants to comply with the group health plan requirements.

b. Retiree Plans.

(1) Clearly, retirees covered as part of a health plan covering 2 or more active employees will be fully subject to HIPAA, whether or not Medicare covers them on a primary basis due to their having no coverage due to current employment status.

(2) Plans covering only retirees will be exempt, provided the retiree plan is a totally separate plan, since such a plan would have NO participants who were active employees. However, if two or more retirees are permitted to return to work for the employer, it appears that will make the retiree plan subject to these requirements of HIPAA, even if they work at a level low enough so that they are not entitled to coverage under the plan covering the active employees and thus continue to receive their coverage from the retiree plan.

2. Governmental and Church Plans. Plans maintained by the following employers appear to be the only exemptions based on the type of employer:

a. The Federal government.

b. Non-federal governments electing to be exempt from the portability, non-discrimination, guaranteed availability and guaranteed renewability requirements of HIPAA.

(1) Enrollees must be notified annually and at the time of enrollment of the fact and consequences of such election.

(2) Note that the insurer issuing coverage to a governmental plan electing to be exempt is not necessarily exempt just because the plan itself is exempt).

(3) Such an election does NOT carry with it an exemption from the certification requirements.

(4) Under the Regulations, the notice requirements are an inherent part of the process of electing not to be covered, and any election by a non-federal governmental plan will be invalid if the notice requirements are not complied with.

c. Church Plans.

(1) A general provision exempts all church plans not electing to be covered by ERISA. Note, however, that the insurer issuing coverage to a church plan is not necessarily exempt just because the plan itself is exempt. Public Health Service Act §272(b); 45 CFR §146.143(a).

(2) A specific exemption regarding HIPAA's non-discrimination rules applies to plans meeting certain requirements on July 15, 1997, which require evidence of insurability for certain late enrollees. From the specificity of the conditions for the exemption, one presumes that this exemption was aimed primarily at one particular plan with these provisions. Proposed Regulations issued by the Treasury Department and the Internal Revenue Service define the terms on which they propose to exempt "certain grandfathered church plans" from HIPAA's non-discrimination requirements:

(3) Because insurers of church plans are not exempt from HIPAA's requirements, this exemption will only apply to self-insured plans.

(4) The proposed regulation limits the exemption to plans covering self-funded individuals (many ministers are treated for tax and sometimes other purposes as self-funded individuals) and employers of 10 or fewer employees, and only applies to plans for whom both categories of individuals have been continuously required to provide evidence of insurability since July 15, 1997. Because it is generally only large plans that can self-insure, and because most employers of 10 or fewer employees could not self-insure a single-employer plan, the proposed regulation will presumably be limited primarily to multiple employer plans.

(5) The exemption in the proposed regulation is only available if the plan provides that a person enrolling after the first 90 days of eligibility must provide evidence of insurability. A longer or shorter period before the medical underwriting requirement is triggered will disqualify the plan from the exemption.

3. Excepted Benefits. The following benefits are always exempt from the above requirements:

a. "Coverage only for accident (including accidental death and dismemberment)."

b. Disability income insurance.

c. "Liability insurance, including general liability insurance and automobile liability insurance."

d. "Coverage issued as a supplement to liability insurance."

e. "Workers' compensation or similar insurance."

f. "Automobile medical payment insurance."

g. "Credit only insurance (for example mortgage insurance)."

h. "Coverage for on-site medical clinics."

i. "Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits."

Code §9805(c)(1); ERISA §733(c); Public Health Service Act §2791(c); Treas. Reg. §54.9831-1(c)(2).

4. Excepted Benefits if Offered Separately.

a. The following benefits are exempt from the above requirements if offered under a separate policy and otherwise are not an integrated with the plan:

(1) Limited scope dental or vision benefits (not including treatment for injuries or diseases of the mouth or eyes).

(2) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(3) Such similar benefits as may be specified in regulations.

Code §§9805(c)(2) and 9804(c)(1); ERISA §§732(c)(1) and §§733(c)(2); Public Health Service Act §§2721(d)(1) and §§2791(c)(2).

b. The 2004 Final HIPAA Regulations provide that, to be excepted, they must be "provided under a separate policy, certificate, or contract of insurance," or else they must otherwise not be "an integral part" of plan that is subject to these rules. Treas. Reg. §54.9831-1(c)(3)(i). Benefits are deemed to be "integral" only if participants have the right to elect not to receive them, AND participants electing to receive them must pay "an additional premium or contribution for that coverage." Treas. Reg. §54.9831-1(c)(2)(ii).

c. Limited Scope Dental and Vision Benefits**.** "Limited scope dental or vision benefits" were limited in the 1997 HIPAA Regulations, to those "sold under a separate policy or rider," and also "to a narrow range or type of benefits that are generally excluded from hospital/medical/surgical benefit packages." Treas. Reg. §54.9804-1T(b)(3)(iii). The 2004 Final HIPAA Regulations, however, dropped these limitations and simply defined:

(1) "limited scope dental benefits" as "benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth)," and

(2) "limited scope vision benefits" as "benefits substantially all of which are for treatment of the eye."

Treas. Reg. §54.9831-1(c)(2)(iii). The reason for this change is that the Departments learned that true stand-alone dental and vision policies tended to cover many services that are also commonly covered under major medical plans.

d. Long Term Care Benefits**.** Limited scope long term care benefits include those that are qualified under Section 7702B of the Code, subject to State long term care insurance laws, **or** based on "cognitive impairment or a loss of functional capacity that is expected to be chronic." Treas. Reg. §54.9831-1(c)(2)(iv).

e. Health Flexible Spending Accounts.

(1) "Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2)" of the Code are excepted for a class of participants only if:

(a) "Other group health plan coverage, not limited to excepted benefits, is made available for the year to the

class of participants by reason of their employment"; and

(b) "The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement)."

Treas. Reg. §54.9831-1(c)(2)(iv).

(2) It is fortunate that health flexible spending accounts have been exempted in this way, because the application of HIPAA to a typical health flexible spending account would be a greater burden than most regular health insurance programs, because people may go in and out of the flexible spending account from year to year at times that employers would find difficult to monitor. Presumably, the mere cessation of health flexible spending account contributions would trigger a need for a certificate of creditable coverage if the flexible spending account is subject to HIPAA, even if the employee is still be working for the employer and is still be covered by the employer's major medical plan, and thus had no need either to receive the certificate of creditable coverage or to be accumulating additional creditable coverage at the same time as the creditable coverage being accumulated in the regular health plan.

(3) A typical health flexible spending account doesn't normally impose pre-existing condition exclusions anyway, nor does it discriminate on the basis of health conditions, so the major prohibitions of HIPAA are not needed.

(4) It is possible, however, for a health flexible spending account not to meet the requirements for exemption as a supplemental plan.

(a) This would clearly occur if it were funded primarily from employer contributions in excess of $500 per year.

(b) It could also happen, even if the health flexible spending account is funded entirely by elective employee contributions, if only employees are allowed to be covered under the regular health insurance program, but the uninsured medical expenses of the employees' dependents are allowed to be paid from the health flexible spending account.

f. Excepted benefits will still be treated as creditable coverage, and must be certified as such, if the plan to which the individual transfers uses the "alternative" method of counting creditable coverage.

5. Excepted Benefits if Offered as Independent, Non-coordinated Benefits.

a. The following benefits are exempt from the above requirements if offered as independent, noncoordinated benefits:

(1) Coverage limited to a single disease or illness.

(2) "Hospital indemnity or other fixed indemnity insurance."

Code §9805(c)(3); ERISA §733(c)(3); Public Service Health Act §2791(c)(3); Treas. Reg. §54.9831-1(c)(4)(i).

b. To be exempted:

(1) The benefits must be provided under a separate policy, certificate, or contract of insurance.

(2) There must be no coordination between such benefits and any exclusion of benefits under any covered group health plan maintained by the same plan sponsor.

(3) The benefits must be paid with respect to an event without regard to whether benefits are provided with respect to such an event under any covered group health plan maintained by the same plan sponsor.

Code §9804(c)(2); ERISA §732(c)(2); Public Health Service Act §2721(d)(2); Treas. Reg. §54.9831-1(c)(4)(ii).

c. To constitute "hospital indemnity or other fixed indemnity insurance, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred." Treas. Reg. §54.9831-1(c)(4)(i). An example is given of a policy paying "a fixed percentage of hospital expenses up to a maximum of $100 a day." Such a policy is NOT exempt from HIPAA's requirements, "even if, in practice, the policy pays the maximum of $100 for every day of hospitalization." Treas. Reg. §54.9831-1(c)(4)(iii).

6. Medicare and Other Supplements.

a. Medicare supplements are exempt if offered "under a separate policy, certificate, or contract of insurance." Code §§9804(c)(3) and 9805(c)(4); ERISA §§ 732(c)(3) and 733(c)(4); Public Health Service Act §2721(d)(3) and 2791(c)(4).

(1) The 2004 Final HIPAA Regulations identify this coverage as including "Medigap or MedSupp insurance." Treas. Reg. §54.9831-1(c)(5)(i)(A).

(2) Retirees covered by an employer's group health plan on a Medicare-primary basis are NOT treated as having only a Medicare Supplement, and are fully subject to HIPAA. Treas. Reg. §54.9831-1(c)(5)(ii). (Of course, a separate retiree-only health plan would be exempt if it does not have two or more participants who are active employees.)

b. The 2004 Final HIPAA Regulations provide a similar exemption for coverage supplemental to CHAMPUS. Treas. Reg. §54.9831-1(c)(5)(i)(B).

c. Similar programs specifically designed as supplements to a group health plan are exempt on the same basis. Treas. Reg. §54.9831-1(c)(5)(i)(C):

(1) This category includes programs designed to reimburse for deductibles and expenses not covered under the main plan, and specifically does not include any program with coverage that duplicates the coverage offered under the main plan.

(2) "Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination-of-benefits provision."

(3) The agencies have established a safe harbor, compliance with which will render a supplemental health insurance plan or coverage "excepted benefits." Coverage that does not meet the safe harbor may still qualify as an excepted benefit based on further analysis, but the agencies note that such coverage "may be subject to enforcement action by the Department." To qualify, four requirements must be met:

(a) The supplemental coverage must be issued by a different entity than the entity providing primary coverage. Entities in the same controlled group are considered the same entity for this purpose.

(b) The coverage must be specifically designed to fill gaps in the primary coverage, such as coinsurance and deductibles, and not merely coordinate with the underlying policy.

(c) The cost of the supplemental coverage must not exceed fifteen percent (15%) of the cost of the primary coverage. The applicable COBRA premium is used for determining the cost of the policy.

(d) The supplemental coverage may not differentiate among individuals based on eligibility, benefits, or premiums based on a health factor.[3] Note that this requirement appears to be a flat prohibition on discrimination without reference to exceptions for benign discrimination or for wellness plans, meaning that a supplemental coverage that discriminates at all on the basis of a health factor may not qualify for the safe harbor.

III. LIMITATIONS ON PRE-EXISTING CONDITION EXCLUSIONS.

A. MAXIMUM PRE-EXISTING CONDITION LIMITATION OR EXCLUSION PERIOD.

3 Dept. of Labor Field Assistance Bulletin No. 2007-04 (Dec. 7, 2007).

1. Scope. This rule applies to limitations or exclusions based on physical or mental conditions, and applies regardless of the cause of the condition. Code §9801(a); ERISA §701(a); Public Health Service Act §2701(a).

2. Pre-existing Conditions Exclusion Defined. The 2004 Final HIPAA Regulations added a definition of the term "pre-existing condition exclusion." The definition encompasses both permissible and impermissible pre-existing condition exclusions. The Departments felt the need to define the term before they then set forth rules specifying permitted exclusions.

   a. In General**.** Basically, a pre-existing condition exclusion is "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the effective date of coverage." Treas. Reg. §54.9801-3(a)(i).

      (1) This definition applies "whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day." (Note that the definition of a pre-existing condition that may be excluded is much narrower. But in terms of determining whether a plan provision IS OR IS NOT a pre-existing condition exclusion, this broad definition will be used.)

      (2) A pre-existing condition exclusion "includes any exclusion applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage."

         (a) Information uncovered through "a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period" will all be considered to be a "condition" for purposes of this definition, such that any limitations placed under the plan as a result of that information will be tested to determine whether the exclusion or limitation complies with HIPAA's requirements.

         (b) Information obtained through other sources will also create a pre-existing condition exclusion if used to limit coverage. For example, imposing a rider on an individual's coverage excluding a condition that the issuer learns the individual has had in the past would constitute an impermissible pre-existing condition

exclusion. Treas. Reg. §54.9801-3(a)(i)(C), Example 3.

b. Examples. The 2004 Final HIPAA Regulations provide examples that help to identify several plan provisions that would be considered "pre-existing condition exclusions" under this definition. Since these exclusions do not comply with HIPAA's requirements, these examples would be prohibited:

(1) An employer switches to a new insurer, which "excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy."

(2) Coverage is provided for cosmetic surgery for accidental injury, "but only if the injury occurred while the individual was covered under the plan."

(3) A plan has a lifetime cap for a specific condition, and counts treatments received under a prior plan towards that limit. The regulation explains that this practice "operates to limit benefits for a condition based on the fact that the condition was present before the effective date of coverage."

(4) A plan generally covers diabetes without any dollar limitation. However, coverage for diabetes is capped at $10,000 "if an individual was diagnosed with diabetes before the effective date of coverage under the plan."

(5) A plan excludes benefits for pregnancy "until the individual has been covered under the plan for 12 months."

(a) This provision is considered "a subterfuge for a pre-existing condition exclusion because it is designed to exclude benefits for a condition (pregnancy) that arose before the effective date of coverage."

(b) The example notes that no pre-existing condition exclusion may be applied to pregnancy, so "the plan provision is prohibited."

(c) The example goes on to note that the problem is not just that a limitation is imposed on pregnancy. Rather, the problem is that it is a limitation imposed on pre-coverage pregnancies. The regulation states

that "if the plan provision included an exception for women who were pregnant before the effective date of coverage under the plan (so that the provision applied only to women who became pregnant on or after the effective date of coverage) the plan provision would not be a pre-existing condition exclusion (and would not be prohibited by paragraph (b)(5) of this section)." Thus, presumably, HIPAA's limitations on pre-existing conditions wouldn't prevent a plan from penalizing a woman who "became pregnant" in the first few weeks of coverage. This author suggests that a plan not try to adopt such a provision, however, since it would surely violate the Pregnancy Discrimination Act of 1978, which requires that pregnancy be treated as any other medical condition.

(6) A plan that generally covers heart conditions excludes congenital heart conditions.

(7) A plan has a general exclusion for treatment of cleft palate. The regulation notes that such an exclusion is not prohibited since it has nothing to do with whether the condition is present before coverage begins. However, the regulation also gives another example, in which cleft palate is only covered if the individual has been "continuously covered under the plan from the date of birth." Limiting coverage to individuals who are covered from birth would be a pre-existing condition exclusion (and thus prohibited if not limited in accordance with HIPAA's requirements) for those who had the condition but entered the plan after birth.

Treas. Reg. §54.9801-3(a)(ii).

c. Benefit-Specific Waiting Periods**.** As indicated by the above example dealing with pregnancy, the Departments do not intend to tolerate internal plan limits that are proxies for impermissible pre-existing condition exclusions. However, the Departments indicated that comments it had received "do not suggest that it would be impermissible to impose a waiting period for all benefits available under the plan or to impose permanent exclusions on specific benefits (that is, these types of exclusions would not be considered a pre-existing condition exclusion nor would they be considered discrimination based on health status)." Thus, the Departments have

requested "further comments on this issue of benefit-specific waiting periods."

(1) They are particularly "interested in comments reflecting the experience of group health plans, health insurance issuers, states, individuals, and other interested parties with waiting periods on specific benefits such as:

(a) Tonsillectomies.

(b) Hernia Repairs.

(c) Organ Transplants.

(2) "Rules under consideration might also affect plans that cover only emergency services for an initial period."

(3) "One possible standard for determining whether a benefit-specific waiting period is operating as a pre-existing condition exclusion is whether the waiting period is likely to affect principally individuals who had a condition before the first day of any coverage under the plan or health insurance coverage. Several factors affect the application of such a standard to a particular plan's waiting period, including":

(a) The "relevant population considered to determine whether the impact is likely to affect principally individuals who had a condition before the first day of coverage."

(b) The "condition to which a plan's waiting period is applied."

(c) The "length of a plan's waiting period (because, generally, as the waiting period becomes longer, a greater number of individuals affected will not have had the condition before enrolling)."

"The Departments welcome comments on this standard and these factors, and also invite suggestions for alternative standards."

d. Case Law**.** In Hoagland v. AmeriHealth Administrators, 2006 WL 42172 (M.D. Penn.), the court interpreted the rules defining a pre-

existing condition. Ms. Hoagland had a long history of irritable bowel syndrome ("IBS"), an uncomfortable but not life threatening condition and one for which surgery is not an appropriate treatment. On a visit to her doctor on January 2, 2004, her symptoms had worsened and he recommended a colonoscopy to rule out inflammatory bowel disease ("IBD"), a serious and life-threatening condition for which radical treatments are often necessary. Ms. Hoagland did not then have insurance, so she did not follow her doctor's recommendations and did not have the colonoscopy. Ms. Hoagland married on January 10, 2004, and her new husband was able to enroll her as a dependent in his employer's health plan. On January 29, 2004, she presented at an emergency room, was admitted, and on February 2, 2004 had a colonoscopy, whereupon she was diagnosed with Crohn's disease, a form of IBD. The plan denied her claims for treatment of the Crohn's disease, on the ground that she had received medical attention on January 2nd sufficient to cause the condition to be considered a pre-existing condition, subject to the plan's limitations during its permitted pre-existing condition exclusion period. Ms. Hoagland contended that she should be fully covered because she had neither been diagnosed with nor treated for IBD on January 2nd. Applying an arbitrary and capricious standard of review on a motion for summary judgment, the court held that she had received medical services related to her condition, and that the mere fact that she refused to have the tests done that would have allowed the specific diagnosis to be made did not prevent the condition, of which her doctor on that date was clearly concerned, from being treated as a pre-existing condition.

3. Pre-existing Conditions to which Exclusions May Apply.

a. A pre-existing condition to which a plan may apply an exclusion or limitation period is one for which "medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date." Code §9801(b)(1)(A); ERISA §701(b)(1)(A); Public Health Service Act §2701(b)(1)(A).

(1) The 2004 HIPAA Final Regulations call this measuring period a "6-month look-back rule" (although a plan may provide for a shorter look-back period), making clear that the same rules apply whether the condition is physical or mental, and "regardless of the cause of the condition." Treas. Reg. §54.9801-3(a)(2)(i).

(2) The "medical advice, diagnosis, care, or treatment" must be "recommended by, or received from," "an individual licensed or similarly authorized to provide such services under State law and operating within the scope of practice authorized by State law." Treas. Reg. §54.9801-3(a)(2)(i)(A).

(3) The "6-month period ending on the enrollment date begins on the 6-month anniversary date preceding the enrollment date." Under examples in the 2004 Final HIPAA Regulations:

(a) The 6-month period ends the day before the enrollment date. (For example, for an August 1, 1998 enrollment date, the 6-month period ends July 31, 1998.)

(b) The 6-month period is computed based on calendar months, not days. (For example, for an enrollment date of August 30, 1998, the 6-month period begins on February 28, 1998, the closest date in February to the 30th.)

Treas. Reg. §54.9801-3(a)(2)(i)(B).

(4) Under the 2004 Final HIPAA Regulations:

(a) If a person was advised, prior to the 6-month lookback period, to get "medical advice, care, diagnosis or treatment" for a condition during that period and did not, the condition will not be a pre-existing condition. Treas. Reg. §54.9801-3(a)(2)(i)(C), Examples 2 and 3.

i) Thus, HIPAA clearly offers an opportunity for someone who can get through the 6-month look-back period without taking needed medication or keeping needed doctors' appointments can keep a known condition from being a pre-existing condition when coverage finally occurs.

ii) Of course, a person pursuing such a strategy would have to know when an enrollment date was to occur — for example, if the person was getting married 6 months later to a person

whose plan allowed spousal coverage. Most people don't know so precisely the schedules on which they or their family members are going to find new jobs.

(b) Conditions that accompany a pre-existing condition will usually also be pre-existing conditions. However, a separate event, even if made more likely by a pre-existing condition, will often not itself be a pre-existing condition. An example in the 2004 Final HIPAA Regulations is of a diabetic (the diabetes is a pre-existing condition), with poor vision and poor circulation in the extremities (both of which are also considered part of the pre-existing condition). A leg fracture occurring during the pre-existing condition exclusion period would not be a pre-existing condition, even if the diabetic's poor circulation made the fracture more likely to occur. "However, any additional medical services that may be needed because of [the] pre-existing diabetes, poor circulation, or retinal degeneration that would not be needed by another patient with a broken leg who does not have these conditions may be subject to the pre-existing condition exclusion imposed under" the plan. Treas. Reg. §54.9801-3(a)(2)(i)(C), Example 5.

(c) Additional examples are given:

i) If a plan's maximum pre-existing condition exclusion period for an individual has lapsed and the individual changes benefit options under the plan, no pre-existing condition exclusion can be imposed by the issuer of the new option. Treas. Reg. §54.9801-4(a)(3)(iv), Example 2.

ii) If an employer switches policies after an individual who has been covered for at least 12 months has suffered an amputation, the new policy may not restrict coverage prostheses to those whose body parts were lost after the new policy was effective. Such a

proscription would be prohibited for two reasons:

a) In the example, the individual's amputation occurred after he was covered by the employer's prior policy. Therefore, no medical advice, diagnosis, care, or treatment was recommended or received during the applicable look-back period (even though care was provided during the 6-month period preceding the effective date of the new policy).

b) Even if the injury had occurred during the look-back period, the individual's maximum pre-existing condition exclusion period ended before the switch in policies, and no new pre-existing condition exclusion period can be imposed on him by the new insurer.

Treas. Reg. §54.9801-3(a)(3)(iv), Example 3.

4. Genetic Information. Genetic information can never be treated as a pre-existing condition. Code §9801(b)(1)(B); ERISA §701(b)(1)(B); Public Health Service Act § 2701(b)(1)(B). Under the 2004 Final HIPAA Regulations:

a. A pre-existing condition exclusion may not be imposed "relating to a condition based solely on genetic information." Treas. Reg. §54.9801-3(b)(6)(i).

b. "However, if an individual is diagnosed with a condition, even if the condition relates to genetic information, the plan may impose a pre-existing condition exclusion with respect to the condition, subject to the other limitations of this section." Treas. Reg. §54.9801-3(b)(6)(i).

c. An example is given in which an individual was told, during the 6-month look-back period, that she was genetically predisposed to breast cancer, but she was not diagnosed with breast cancer during that period. If she is diagnosed with breast cancer 9 months after

enrollment in the plan, her genetic predisposition may not be excluded as a pre-existing condition. Treas. Reg. §54.9801-3(b)(6)(ii).

5. Pregnancy. Pregnancy may never be treated as a pre-existing condition. Code §9801(d)(3); ERISA §701(d)(3); Public Health Service Act §2701(d)(3). Treas. Reg. §54.9801-3(b)(5).

6. Measurement of Pre-Existing Condition Exclusion Period.

   a. Regular Enrollees**.** For most people, the maximum pre-existing condition exclusion period be 12 months from the enrollment date. Treas. Reg. §54.9801-3(a)(ii).

   b. Late Enrollees**.** In the case of "late enrollees," the maximum pre-existing condition exclusion period will be 18 months from the enrollment date. Treas. Reg. §54.9801-3(a)(ii).

   c. Measurement. In either case, the maximum exclusion period begins on the enrollment date and ends 12 (or 18) calendar months thereafter. If the enrollment date is the first day of a calendar month, the end of that period will be the last day of the 12^{th} (or 18^{th}) calendar month of coverage. Treas. Reg. §54.9801-3(a)(ii).

   d. Enrollment Date Defined.

      (1) At the latest, the enrollment date is the first day of coverage. But in the case of a regular enrollee in a plan with an eligibility waiting period, the enrollment date is the first day of the waiting period. If the individual "changes benefit packages, or if the plan changes . . . issues, the individual's enrollment date does not change." Treas. Reg. §54.9801-3(a)(3)(i).

      (2) In the case of a late enrollee or a special enrollee, the enrollment date is the first day of coverage.

7. Special Rule for Late Enrollees.

   a. Exclusion Period Extended**.** Late enrollees may be subject to an 18-month pre-existing condition limitation or exclusion period. Code §9801(a)(2); ERISA §701(a)(2); Public Health Service Act §2701(a)(2); Treas. Reg. §54.9801-3(a)(2)(iii).

b. Late Enrollee Defined**.** A late enrollee is one who enrolls after the first date on which he is eligible to do so, except that those with special enrollment rights, as described in more detail below, are not treated as late enrollees. Code §9801(b)(3); ERISA §701(b)(3); Public Health Service Act §2701(b)(3).

(1) The 2004 Final HIPAA Regulations defined a late enrollee as one " whose enrollment in the plan is a late enrollment." Treas. Reg. §54.9801-3(a)(3)(iv).

(2) The 2004 Final HIPAA Regulations defined "late enrollment" as enrollment on other than:

(a) the earliest date on which coverage can become effective for the individual under the terms of the plan, or

(b) through special enrollment.

Treas. Reg. §54.9801-3(a)(3)(v).

(3) Under the 2004 Final HIPAA Regulations, a person with eligibility both before and after a termination of employment or a suspension of coverage will have only the most recent period of enrollment taken into account to determine whether he or she is a late enrollee.

(a) For example, a person who passes up coverage the first time, quits, returns to employment and enters at the earliest time permitted based on the rehire date, will NOT be a late enrollee, because there was no passing up of coverage with respect to the second period of employment.

(b) Also, if coverage is suspended generally under the plan and then reactivated, those who had previously declined coverage may enter when coverage is reactivated without being deemed late enrollees.

Treas. Reg. §54.9801-3(a)(3)(vi)(*1*)(B).

8. <u>Rule for Newborns and Children Adopted or Placed for Adoption</u>.

a. General Rule**.** Newborn and newly adopted children, and children newly placed for adoption, cannot be subjected to a pre-existing condition exclusion or limitation if they are enrolled within 30 days of the birth, adoption or placement for adoption. Code §9801(d)(1) and (2); ERISA §701(d)(1) and (2); Public Health Service Act §2701(d)(1) and (2). Treas. Reg. §54.9801-3(b).

b. Newborn Children**.** Under the 2004 Final HIPAA Regulations:

(1) A child enrolled within such time frame in one plan, who later switches to another plan without incurring a 63-day break in coverage, will not be subject to any pre-existing condition exclusion period in the second plan either. Treas. Reg. §54.9801-3(b)(1)(ii), Example 1.

(2) If policy is required by state law to cover the first 30 days after birth to any mother covered by the policy, even if the child is never enrolled and thus ceases to be covered by that policy at the end of the 30-day period, the child is deemed to be automatically enrolled in the plan even if the parents take no action to enroll the child. The child can then be enrolled in another plan, and if no 63-day break in coverage has occurred, no pre-existing condition exclusion can be imposed on the child. Treas. Reg. §54.9801-3(b)(1)(ii), Example 2. Note, however, that this conclusion is based on a particular state law requirement for insurers in that state – many plans do not enroll children and cover their first 30 days of medical expenses unless the parents specifically enroll the child.

c. Adopted Children**.** Under the 2004 Final HIPAA Regulations:

(1) This protection only applies to children adopted or placed for adoption before they are 18 years of age.

(2) Such a child who is covered by creditable coverage, within the 30-day period beginning on the date of the adoption or placement for adoption, will not be subject to any pre-existing condition exclusion period.

(3) The protections afforded a child enrolled within 30 days following adoption or placement do not apply to coverage before the adoption or placement. Therefore, a child against whom a pre-existing condition exclusion could have been

asserted will have his status converted upon being adopted or placed for adoption.

Treas. Reg. §54.9801-3(b)(2).

9. Notice Requirements.

a. General Notice**.** A group health plan imposing a pre-existing condition exclusion must provide a written general notice of pre-existing condition exclusion to participants under the plan and cannot impose a pre-existing condition exclusion with respect to a participant or a dependent of the participant until such a notice is provided. Treas. Reg. §54.9801-3(c). Corresponding requirements are imposed on issuers.

(1) Manner and Timing of Notice.

(a) If the plan distributes written application materials for enrollment, the general notice must be included in those materials.

(b) "If the plan does not distribute such materials, the notice must be provided by the earliest date following a request for enrollment that the plan, acting in a reasonable and prompt fashion, can provide the notice."

Treas. Reg. §54.9801-3(c)(1).

(2) Content. The general notice must:

(a) Notify participants of the "existence and terms of any pre-existing condition exclusion under the plan." This description includes:

i) The length of the plan's look-back period (not to exceed 6 months);

ii) The maximum pre-existing condition exclusion period under the plan, not to exceed 12 months (or 18 months for late enrollees); and

iii) "How the plan will reduce the maximum pre-existing condition exclusion period by creditable coverage."

Treas. Reg. §54.9801-3(c)(2)(i).

(b) Provide the participants with a "description of the rights of individuals to demonstrate creditable coverage, and any applicable waiting periods, through a certificate of creditable coverage" (or through other means permitted by the 2004 Final HIPAA Regulations). This description must include "the right of the individual to request a certificate from a prior plan or issuer, if necessary, and a statement that the current plan will assist in obtaining a certificate from any prior plan or issuer, if necessary." Treas. Reg. §54.9801-3(c)(2)(ii).

(c) Identify a "person to contact (including an address or telephone number) for obtaining additional information or assistance regarding the pre-existing condition exclusion." Treas. Reg. §54.9801-3(c)(2)(iii).

Treas. Reg. §54.9801-3(c)(4) includes sample language for the initial notice.

(3) No Duplication. If the issuer, TPA, or another party provides this notice, the plan is not required to also do so. Treas. Reg. §54.9801-3(c)(3). Similarly protections are offered to the issuer if the plan or another party provides the notice.

b. Determination of Creditable Coverage.

(1) Upon receipt of creditable coverage information, a plan must "make a determination regarding the amount of the individual's creditable coverage and the length of any exclusion that remains." Treas. Reg. §54.9801-3(d)(1).

(2) The determination must be made "within a reasonable time following receipt" of the information. Treas. Reg. §54.9801-3(d)(1).

(a) "Whether this determination is made within a reasonable time depends on the relevant facts and circumstances. Relevant facts and circumstances include whether a plan's application of a pre-existing condition exclusion would prevent an individual from having access to urgent medical care." Treas. Reg. §54.9801-3(d)(1).

(b) An example assumes that a newly covered individual develops an "urgent health condition before receiving a certificate of creditable coverage" from the individual's prior plan, but presents other evidence of having been covered. The regulation notes that "the plan must review the evidence presented . . . and make a determination of creditable coverage within a reasonable time that is consistent with the urgency of [the individual's] health condition." The example goes on to note that the determination may later be modified if it turns out that the individual did not in fact have the creditable coverage claimed. Treas. Reg. §54.9801-3(d)(3).

(3) A plan must take into account all evidence "that it obtains or that is presented on behalf of an individual" in making a determination of creditable coverage." Treas. Reg. §54.9801-5(b)(3)(i).

(a) An individual must be treated as having creditable coverage if:

i) "The individual attests to the period of creditable coverage,"

ii) "The individual also presents relevant corroborating evidence of some creditable coverage during the period," and

iii) "The individual cooperates with the plan's efforts to verify the individual's coverage."

Treas. Reg. §54.9801-5(c)(3)(i)(A).

(b) Failure to cooperate may be treated as evidence of a lack of creditable coverage, but failure to obtain a

certificate may not be so treated. Treas. Reg. §54.9801-5(c)(3)(i)(B).

(c) Corroborating documents include:

i) Explanations of Benefits "or other correspondence from a plan or issuer indicating coverage."

ii) Pay stubs showing a payroll deduction for health insurance coverage.

iii) Health insurance identification cards.

iv) A "certificate of coverage under a group health policy."

v) Medical records showing payments to providers from health insurance.

vi) Third-party "statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage."

Treas. Reg. §54.9801-5(c)(3)(ii). Corroboration must also be permitted by telephone or other reasonable means. Treas. Reg. §54.9801-5(c)(3)(iii).

(4) Corresponding requirements are imposed on issuers.

(5) A plan may not impose any time limit on providing evidence of creditable coverage. Treas. Reg. §54.9801-3(d)(2).

c. Individual Notice.

(1) In General. Once an individual has presented all available evidence of his or her creditable coverage, the individual must be notified specifically as to the extent of any pre-existing condition exclusion applicable to him or her.

(a) Such a notice need not identify any specific medical conditions that may be subject to the exclusion.

(b) The individual notice is not necessary "if the plan does not impose any pre-existing condition exclusion on the individual or if the plan's pre-existing condition exclusion is completely offset by the individual's prior creditable coverage."

Treas. Reg. §54.9801-3(e). Corresponding requirements are imposed on issuers.

(2) Manner and Timing. "The individual notice must be provided by the earliest date following a determination that the plan, acting in a reasonable and prompt fashion, can provide the notice." Treas. Reg. §54.9801-3(e)(1).

(3) Content. The notice must disclose:

(a) The plan's "determination of any pre-existing condition exclusion period that applies to the individual (including the last day on which the pre-existing condition exclusion applies)." Treas. Reg. §54.9801-3(e)(2)(i).

(b) The basis for the plan's determination, "including the source and substance of any information on which the plan relied." Treas. Reg. §54.9801-3(e)(2)(ii).

(c) "An explanation of the individual's right to submit additional evidence of creditable coverage." Treas. Reg. §54.9801-3(e)(2)(iii).

(d) "A description of any applicable appeal procedures established by the plan." Treas. Reg. §54.9801-3(e)(2)(iv).

(4) No Duplication. If the issuer, TPA, or another party provides this notice, the plan is not required to also do so. Treas. Reg. §54.9801-3(e)(3). Similarly protections are offered to the issuer if the plan or another party provides the notice.

(5) Reconsideration. Once a plan has given an individual such a notice, the plan may still re-evaluate its determination if it determines that its initial determination was erroneous – i.e., "if it determines that the individual did not have the claimed creditable coverage." If a plan does so:

(a) A new notice must be provided complying with all the requirements for an individual notice.

(b) Until the new notice is provided, the plan must act "in a manner consistent with the initial determination" when taking action to approve "access to medical services (such as a pre-surgery authorization)."

Treas. Reg. §54.9801-3(f).

10. Reductions in Maximum Pre-Existing Condition Exclusion Period.

a. Waiting Period**.** The otherwise applicable maximum must be reduced by any waiting period imposed by the plan. Code §9801(b)(2); ERISA §701(b)(2); Public Health Service Act §2701(b)(2). Under the 2004 Final HIPAA Regulations:

(1) A waiting period is defined as "the period that must pass before coverage for an employee or dependent who is otherwise eligible to enroll under the terms of a group health plan can become effective."

(a) The period before a late enrollee or a special enrollee becomes covered is NOT a waiting period.

(b) The waiting period for an individual seeking coverage in the individual market "begins on the date the individual submits a substantially complete application for coverage." The waiting period for such an individual ends:

i) The date coverage begins if the application actually results in coverage. Treas. Reg. §54.9804-3(a)(3)(iii)(A).

ii) The "date on which the application is denied by the issuer or the date on which the offer of coverage lapses" in situations where the application does not result in coverage. Treas. Reg. §54.9804-3(a)(3)(iii)(B). This feature of the definition is different from the 1997 HIPAA Regulations, which only treated the period following the application as a waiting

period in cases where the application did eventually result in coverage. The problem was that some issuers would take a long time to reject an applicant, or charge exorbitant premiums that caused the individual to reject the coverage, and many applicants were suffering 63-day breaks in coverage before they could actually become covered by an alternative policy.

(2) Several examples are given, illustrating the following:

(a) If a plan limits coverage to full-time employees, and a part-time employee becomes a full-time employee and thus qualifies to enter the plan, the employee's waiting period begins on the day he first becomes a full-time employee, and only the time from that date to his actual coverage date will constitute a waiting period. Treas. Reg. §54.9801-4(a)(3)(iv), Example 4.

(b) Similarly, if a plan requires a minimum number of hours worked during a calendar quarter for an individual to become eligible, any calendar quarter in which the individual failed to work the necessary hours will NOT be part of the individual's waiting period. Rather, the waiting period will be considered as starting at the beginning of the calendar quarter in which he did in fact work the requisite number of hours. Treas. Reg. §54.9801-4(a)(3)(iv), Example 5.

b. Creditable Coverage**.** The pre-existing condition exclusion period under a plan must be reduced for an individual by the individual's number of days of creditable coverage. Code §9801(c)(1); ERISA §701(c)(1); Public Health Service Act §2701(c)(1).

(1) An example in the 2004 Final HIPAA Regulations makes clear that this is true even if the individual is continuing to be covered, following enrollment in the new plan, under the plan from which the creditable coverage is being reported. Treas. Reg. §54.9804-3(a)(2)(iii).

(2) Creditable coverage includes coverage under:

(a) Another group health plan.

(b) Health insurance (whether or not the insurance policy in question is subject to HIPAA).

(c) Medicare Part A or Part B.

(d) Medicaid.

(e) Coverage under the programs providing "medical and dental care for members and certain former members of the uniformed services and for their dependents," (including "the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service").

(f) A medical care program of the Indian Health Service or of a tribal organization.

(g) A State health benefits risk pool, including:

i) An organization qualifying under Section 501(c)(26) of the CodeA

ii) A qualified high risk pool under Section 2744(c)(2) of the PHSA.

iii) "Any other arrangement sponsored by a State, the membership composition of which is specified by the State and which is established and maintained primarily to provide health insurance coverage for individuals who are residents of such State and who, by reason of the existence or history of a medical condition" are uninsurable or insurable only at "a rate which is substantially in excess of the rate for such coverage through the membership organization."

(h) The health plan covering peace corps workers.

(i) A public health plan, which "means any plan established or maintained by a State, the U.S. government, a foreign country, or any political subdivision of a State, the U.S. government, or a foreign country that provides health insurance

coverage to individuals who are enrolled in the plan." The 1997 HIPAA Proposed Regulations specifically requested public comment on the extent, if any, to which the public health services of other countries should be treated as creditable coverage. In issuing the 2004 Final HIPAA Regulations, the Departments concluded that such coverage would constitute creditable coverage.

Treas. Reg. §54.9801-4(a)(1).

c. Excluded Coverage**.** "Creditable coverage does not include coverage of solely excepted benefits." Treas. Reg. §54.9801-4(a)(2). (See detailed definition elsewhere in this outline.)

d. Break in Coverage.

(1) Creditable coverage before a significant break in coverage may be disregarded.

(a) A significant break in coverage is a continuous period of at least 63 days in which the employee had no creditable coverage at any time.

(b) A waiting period to enter a plan is not treated as any part of a break in coverage. However, the waiting period is not counted as creditable coverage.

Code §9801(c)(2); ERISA §701(c)(2); Public Health Service Act §2701(c)(2).

(2) Under the 2004 Final HIPAA Regulations:

(a) Days prior to a 63-day break in coverage, or a "significant break in coverage," are not counted as creditable coverage. Treas. Reg. §54.9801-4(b)(2)(ii).

(b) "A significant break in coverage means a period of 63 consecutive days during each of which an individual does not have any creditable coverage." Treas. Reg. §54.9801-4(b)(2)(iii).

i) State insurance laws requiring a longer period without coverage to constitute a significant break in coverage are not preempted with

respect to insured plans. Treas. Reg. §54.9801-4(b)(2)(iii).

ii) However, an example makes clear that preemption does apply to such requirements for self-funded plans. Treas. Reg. §54.9801-4(b)(2)(v), Example 3.

iii) The 2004 Final HIPAA Regulations added a new tolling provision. "Days in a waiting period and days in an affiliation period are not taken into account in determining whether a significant break in coverage has occurred. In addition, for an individual who elects COBRA continuation coverage during the second election period provided under the Trade Act of 2002, the days between the date the individual lost group health plan coverage and the first day of the second COBRA election period are not taken into account in determining whether a significant break in coverage has occurred." Treas. Reg. §54.9801-4(b)(2)(iv).

iv) The 2004 Proposed HIPAA Regulations propose to also add a tolling period for up to 44 days after coverage ceases for the time during which the individual has not yet been provided with a certificate of creditable coverage. Prop. Treas. Reg. §54.9801-4(b)(2)(iv).

(3) Under the 2004 Proposed HIPAA Regulations, "if the individual takes FMLA leave and does not continue group health coverage for any period of FMLA leave, that period is not taken into account in determining whether a significant break in coverage has occurred." Prop. Treas. Reg. §54.9801-7(b). Otherwise, the 2004 Final HIPAA Regulations will fully apply to individuals on FMLA leave (and their dependents). Prop. Treas. Reg. §54.9801-7(a).

(a) If an individual's health coverage is terminated during an FMLA leave, an automatic certificate of creditable coverage must be provided in accordance with the normal timing rules for issuing such certificates for

reasons not constituting a COBRA qualifying event "(which generally require plans to provide certificates within a reasonable time after coverage ceases)." Prop. Treas. Reg. §54.9801-7(c)(1)(i).

(b) If an individual's coverage is terminated at the end of an FMLA leave, an automatic certificate of creditable coverage must be provided in accordance with the normal timing rules for issuing such certificates for reasons that do constitute a COBRA qualifying event "(which generally require plans to provide a certificate no later than the time a notice is required to be furnished for a qualifying event under a COBRA continuation provision)." Prop. Treas. Reg. §54.9801-7(c)(1)(ii).

(c) Demonstrating FMLA Leave.

i) A plan must "take into account all information about FMLA leave that it obtains or that is presented on behalf of an individual." A plan is required to "treat the individual as having been on FMLA leave for a period" if the individual "attests to the period of FMLA leave," and "cooperates with the plan's efforts to verify the individual's FMLA leave." Prop. Treas. Reg. §54.9801-7(c)(2)(i).

ii) However, a plan may modify its initial determination of FMLA leave if it determines that the individual did not have the claimed FMLA leave, provided that the plan follows procedures for reconsideration similar to" those set forth in the regulations for reconsidering determinations of creditable coverage. Prop. Treas. Reg. §54.9801-7(c)(2)(ii).

(d) Loss of Eligibility. In the case of "an individual (or a dependent of the individual) who is covered under a group health plan and who takes FMLA leave," and "the individual's group health coverage is terminated at any time during FMLA leave" and the "individual does not return to work for the employer at the end of FMLA leave," a loss of eligibility is deemed to occur

"when the period of FMLA leave ends." Prop. Treas. Reg. §54.9801-7(c)(2)(ii). This provision gives guidance to in individual, who becomes a special enrollee in another plan as a result of loss of coverage in connection with an FMLA leave from which an employee fails to return, as to when the 30-day period begins to run for notifying the new plan as to the loss of coverage under the old plan – specifically, the loss of coverage occurs at the end of the FMLA period, even if the coverage is lost earlier in the FMLA period.

e. Methods of Crediting Coverage**.**

(1) Standard Method.

(a) In general, any coverage counts, regardless of the benefits provided under the program or the level of coverage. Code §9801(c)(3)(A); ERISA §701(c)(3)(A); Public Health Service Act §2701(c)(3)(A).

(b) "Under the standard method, the amount of creditable coverage is determined without regard to the specific benefits included in the coverage." Treas. Reg. §54.9801-4(b)(1).

(c) *Counting of Creditable Coverage.*

i) The counting of creditable coverage is normally based on the number of days on which an individual had one or more types of creditable coverage. Treas. Reg. §54.9801-4(b)(2)(i).

a) If an individual has creditable coverage from more than one source on a given day, that day is still only counted once. Treas. Reg. §54.9801-4(b)(2)(i).

b) Days in a waiting period for coverage from a particular source are not creditable coverage unless the individual also has creditable coverage

from another source on those days (i.e., COBRA coverage from a prior plan). Treas. Reg. §54.9801-4(b)(2)(i).

ii) A plan may use an alternative method of crediting creditable, coverage provided it is at least as favorable to the individual. For example, the plan could stop the running of a pre-existing condition exclusion period on the first day of a calendar month in situations where the daily counting method would ordinarily permit it to run until later in the month. Treas. Reg. §54.9801-4(b)(2)(vi).

(2) Alternative Method. A plan or insurer may elect to apply the rules separately to each of several "classes or categories of benefits." Code §9801(c)(3)(B); ERISA §701(c)(3)(B); Public Health Service Act §2701(c)(3)(B).

(a) Such an election must be made in accordance with regulations, and on a uniform basis for all participants and beneficiaries. Code §9801(c)(3)(B); ERISA §701(c)(3)(B); Public Health Service Act §2701(c)(3)(B).

(b) "Under the alternative method, a group health plan determines the amount of creditable coverage based on coverage within any category of benefits . . . and not based on coverage for any other benefits."

i) "The plan may use the alternative method for any or all of the categories."

ii) "The plan may apply a different pre-existing condition exclusion period with respect to each category (and may apply a different pre-existing condition exclusion period for benefits that are not within any category)."

iii) "The creditable coverage determined for a category of benefits applies only for purposes of reducing the pre-existing condition exclusion period with respect to that category."

iv) "An individual's creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method."

Treas. Reg. §54.9801-4(c)(1).

(c) The alternative method must be set forth in the plan. Treas. Reg. §54.9801-4(c)(2).

(d) *Notice Requirement.*

i) A plan or insurer electing the alternative method must:

a) prominently disclose that the plan is using such method in any disclosure statements concerning the plan,

b) state to each enrollee at the time of enrollment under the plan that it is using such method, and

c) include in such statements a description of the effect of this election, including an identification of the categories used.

Code §9801(c)(3)(C); ERISA § 701(c)(3)(C); Public Health Service Act §2701(c)(3)(C); Treas. Reg. §54.9801-4(c)(4).

ii) Insurers must make similar disclosures to small employers when offering them coverage, and in their general descriptive materials for policies offered to small employers. Public Health Service Act §2701(c)(3)(D).

(e) Under the 2004 Final HIPAA Regulations, a plan may allow some insurers offering coverage to use the Alternative Method even if other insurers under the same plan use the standard method. However, in all

other respects, a plan must apply the alternative method uniformly. Treas. Reg. §54.9801-4(c)(2).

(f) *Categories.* Under the 2004 Final HIPAA Regulations, the term "class or category of benefits'" which may be treated separately from major medical benefits, is limited to:

i) dental care,

ii) vision care,

iii) prescription drugs,

iv) substance abuse treatment, and

v) mental health.

Treas. Reg. §54.9801-4(c)(3).

(g) *Counting of Creditable Coverage.*

i) Under the alternative method, creditable coverage for a class or category of benefits is counted "if any level of benefits is provided within the category." Treas. Reg. §54.9801-4(c)(6)(i).

a) The 1997 Proposed HIPAA Regulations note the government's concern about the adverse selection potential of a person going from a high deductible to a low deductible policy, and specifically ask for comment on whether deductible differences should ever be treated as a separate class or category of coverage. In preparing the 2004 Final HIPAA Regulations, however, the Departments decided that there was no way to compare levels of coverage of the various benefit structures in use.

b) "Coverage under a reimbursement account or arrangement, such as a

flexible spending arrangement . . . does not constitute coverage within any category." Treas. Reg. §54.9801-4(c)(6)(i).

ii) Within a category, the same method of counting days of creditable coverage is used as is discussed above for the standard method. Again, a more favorable method may be used. Treas. Reg. §54.9801-4(c)(6)(ii).

B. CERTIFICATIONS OF CREDITABLE COVERAGE.

1. Presentation by Employee. The employee can be required to present a certification of his creditable coverage upon enrollment in a plan. Code §9801(c)(4); ERISA §701(c)(4); Public Health Service Act §2701(c)(4).

2. Certification by Employer and/or Insurer.

a. Certification Requirement and Timing**.** The employer and insurer are required to provide a certification of creditable coverage to an individual. Code §9801(e)(1); ERISA §701(e)(1); Public Health Service Act §2701(e)(1). Such certificates must be provided:

(1) Automatically at the time the individual ceases coverage and becomes a COBRA qualified beneficiary or eligible for state continuation coverage. The 2004 Final HIPAA Regulations provide that the COBRA deadlines (or, in the case of an individual eligible for state continuation coverage, the deadlines provided by state law) will be applied to the certification requirements for such individuals. Treas. Reg. §§54.9801-5(a)(2)(ii)(A) and (B)(2);

(2) Automatically at the time the individual otherwise ceases coverage. The 2004 Final HIPAA Regulations provide that the plan must provide the certificate within a reasonable time after the end of coverage (or after the expiration of any applicable grace period). Treas. Reg. §54.9801-5(a)(2)(ii)(B).

(3) Automatically at the time the individual ceases to be covered under COBRA. The 2004 Final HIPAA Regulations provide that the plan must provide the certificate within a reasonable time after the end of coverage (or after the expiration of any applicable grace period). Treas. Reg. §54.9801-5(a)(2)(ii)(C).

(4) On request by or on behalf of the individual, provided the request is made within 24 months after coverage ceases. The

2004 Final HIPAA Regulations provide that the plan must provide the certificate no later than "the earliest date that the plan, acting in a reasonable and prompt fashion, can provide the certificate." Treas. Reg. §54.9801-5(a)(2)(iii).

(5) Automatically upon the first denial of a claim due to the individual's having reached the plan's lifetime cap. Treas. Reg. §54.9801-5(a)(2)(ii)(B)(3).

(6) Certificates must be provided upon each of the above occurrences, even if the individual has previously received a certificate due to another occurrence.

b. Form and Content of Certificate**.**

(1) In general, the certificate must be in writing ("including any form approved by the Secretary as a writing"). Treas. Reg. §§54.9801-5(a)(3)(i)(A).

(2) No written certificate is necessary if the plan receiving the information receives it in some other form with the receiving plan's and the individual's consent. Treas. Reg. §§54.9801-5(a)(3)(i)(B).

(3) The certificate must include:

(a) The date it is issued.

(b) The name of the group health plan.

(c) The name of the participant or dependent, "and any other information necessary for the plan providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the plan and the name of the participant if the certificate is for (or includes) a dependent."

(d) The name, address and phone number of the plan administrator providing the certificate.

(e) The phone number to call for further information.

(f) Either:

i) A statement that the individual has 18 months (546 days) of creditable coverage, or

ii) "The date any waiting period (and affiliation period, if applicable) began and the date creditable coverage began."

(g) "The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate."

(h) An educational statement, containing details as set forth in the 2004 Final HIPAA Regulations (with, if the 2004 Proposed HIPAA Regulations become effective, an additional statement regarding the impact of the Family and Medical Leave Act).

Treas. Reg. §54.9801-5(a)(3)(ii).

(4) When the certificate is being issued automatically, only the most recent period of creditable coverage ending on the date the certificate is issued must be provided. However, if the certificate is provided on request, all periods of creditable coverage during the preceding 24 months must be included. Treas. Reg. §54.9801-5(a)(3)(iii).

(5) A single certificate may combine the information for all family members. If the information for all family members is not identical, the certificate must separately identify the appropriate information for each family member. Treas. Reg. §54.9801-5(a)(3)(iv).

(6) The 2004 Final HIPAA Regulations provide a model certificate.

(7) No certificate is required for Excepted Benefits. However, if benefits that COULD BE excepted benefits are combined with benefits that constitute creditable coverage, then the benefits may not consist SOLELY of excepted benefits and a certificate of creditable coverage may be required. Treas. Reg. §54.9801-5(a)(3)(vi).

c. Procedures.

(1) Method of Delivery.

(a) First class mail is acceptable. If provided to the participant and the participant's spouse at their joint last known address, the certificate or certificates will be deemed to have been properly delivered to all individuals living at that address, and separate mailings are not required. If a dependent's last known address is different, a separate certificate must be sent to that address. Treas. Reg. §54.9801-5(a)(4)(i).

(b) The certificate must be given to the requesting individual, "or an entity requesting the certificate on behalf of the individual." Treas. Reg. §54.9801-5(a)(4)(i).

(c) An automatic certificate may be, and a certificate provided on request must be, provided to a recipient designated to receive it by the entitled individual. A plan providing the certificate to the designated individual will be deemed to have provided it in compliance with the regulations. Treas. Reg. §54.9801-5(a)(4)(iii).

(2) Requesting Certificate. A plan or issuer must have a written procedure for requesting a certificate of creditable coverage. The procedure "must include all contact information necessary to request a certificate (such as name and phone number or address)." Treas. Reg. §54.9801-5(a)(4)(ii).

d. Special Rules for Dependents**.**

(1) A plan must use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. No automatic certificate must be issued until the plan "knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan." Treas. Reg. §54.9801-5(a)(5)(i).

(2) If the certificate issued to a family does not specify the name of a dependent, the receiving plan must use the same procedures to permit the individual to demonstrate coverage as a dependent, or to permit a demonstration that "a child was covered under any creditable coverage within 30 days after

birth, adoption, or placement for adoption," as it would be required to use to allow a demonstration of creditable coverage in general. Treas. Reg. §§54.9801-5(a)(5)(ii) and (c)(5).

e. Insurer Certification Sufficient**.** The statute provides that to the extent that an insurer provides such certification, the employer is relieved from any responsibility to duplicate the insurer's efforts. Code §9801(e)(1)(C); ERISA §701(e)(1)(C); Public Health Service Act §2701(e)(1)(C).

(1) The 2004 Final HIPAA Regulations also provide that to the extent that any other party provides (or has contracted to provide) the certification, any the plan will be deemed to have fulfilled its obligations. Treas. Reg. §54.9801-5(a)(1)(ii). Corresponding rules exempt an issuer when another party provides the certificate.

(2) If the issuer's coverage ceases before the plan's coverage, the issuer must provide sufficient information to the plan so that it may provide a complete certificate of creditable coverage once the individual's coverage under the plan has ceased. Similarly, the issuer must cooperate with the plan in enabling it to issue a complete certificate on the request of the individual. Treas. Reg. §54.9801-5(a)(1)(iii)(B).

3. Alternative Method.

a. Upon request of a plan making an alternative method election, a plan previously covering its participant or beneficiary must disclose to the electing plan "information on coverage of classes or categories of benefits." But the plan providing the information may charge the requesting plan a reasonable charge. Code §9801(e)(2); ERISA §701(e)(2); Public Health Service Act §2701(e)(2). Treas. Reg. §§54.9801-5(b)(1) and (3).

b. A plan receiving such a request must respond promptly. Treas. Reg. §54.9801-5(b)(1).

c. The requesting plan may identify specific information that it needs, in which case the providing entity must provide the information. Treas. Reg. §54.9801-5(b)(2).

d. The rules outlined for demonstrating creditable coverage in general also apply for demonstrating creditable coverage in a particular category. Treas. Reg. §54.9801-5(c)(4).

4. Certification by Insurer. An insurer must certify health insurance coverage under an individual plan. The insurers issuing a policy are clearly subject to all the same requirements as the employers maintaining the plan, although not necessarily the same penalties or enforcement mechanisms. Code §9801(e)(2); ERISA §701(e)(2); Public Health Service Act §2701(e)(2).

C. SPECIAL ENROLLMENT RIGHTS.

1. Special Enrollment for those Losing Other Coverage.

a. An employee (or the employee's dependent) who was eligible for coverage under a plan, but who did not initially enroll, must be admitted immediately if the employee (or dependent) had other health coverage at the time of initial eligibility, and either:

(1) If the other coverage was under COBRA, the individual loses the other coverage due to the exhaustion of the COBRA coverage benefits, or

(2) Otherwise:

(a) If the coverage was lost due to loss of eligibility "(including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment)," or

(b) If employer contributions toward such coverage were terminated.

The employer may require that the employee (or dependent) state in writing, at the time enrollment is first declined, that the employee (or dependent) is covered by the other plan, provided the employer notifies the employee (or dependent) at the time enrollment is declined of the written notice requirement and of the consequences of declining coverage.

Code §9801(f)(1); ERISA §701(f)(1); Public Health Service Act §2701(f)(1).

b. If an employee fails to enroll in the employer's plan but does not have other coverage, but the employee's spouse has other coverage,

and if the spouse loses that other coverage, both the spouse and the employee will be entitled to special enrollment rights under the plan of the employee's employer. Treas. Reg. §54.9801-6(a)(2)(iii), Example 3.

c. Loss of eligibility for other coverage includes:

(1) Loss as a result of legal separation, divorce, cessation of dependent status, death of an employee, termination of employment, reduction in hours of employment, "and any loss of eligibility for coverage after a period that is measured by reference to any of the foregoing."

(2) Loss as a result of no longer living, residing or working in the service area of an HMO or similar arrangement "(whether or not within the choice of the individual)."

(3) Reaching a plan's lifetime cap.

(4) The plan's cessation of coverage to the class of similarly situated individuals.

Treas. Reg. §54.9801-6(a)(3)(i). Under the 2004 Final HIPAA Regulations, in the case of"an individual (or a dependent of the individual) who is covered under a group health plan and who takes FMLA leave," and "the individual's group health coverage is terminated at any time during FMLA leave" and the "individual does not return to work for the employer at the end of FMLA leave," a loss of eligibility is deemed to occur "when the period of FMLA leave ends." Prop. Treas. Reg. §54.9801-7(c)(2)(ii).

d. Termination of employer contributions includes termination of contributions toward either the employee's or dependent's coverage, and includes termination by either a current or a former employer. Treas. Reg. §54.9801-6(a)(3)(ii).

e. Exhaustion of COBRA coverage occurs:

(1) If the coverage ceases for any reason other than either:

(a) failure to pay COBRA premiums on a timely basis, or

(b) "for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan)."

(2) If the coverage ceases:

(a) "Due to failure of the employer or other responsible entity to remit premiums on a timely basis."

(b) Due to the individual's no longer living in the service area of an HMO or similar arrangement.

(c) Due to reaching the COBRA plan's lifetime cap.

Treas. Reg. §§54.9801-2 and 54.9801-6(a)(3).

f. Requesting Special Enrollment**.** The plan must offer at least 30 days after the date of the loss of coverage for an employee to request special enrollment for the employee or dependent. Treas. Reg. §54.9801-6(a)(4)(i).

(1) If the special enrollment rights arise out of reaching a lifetime cap, the 30 days cannot begin to run until the individual is notified that a claim is denied due to the cap. Treas. Reg. §54.9801-6(a)(4)(i).

(2) Coverage must begin no later than the first day of the calendar month following the plan's receipt of the application for special enrollment. Treas. Reg. §54.9801-6(a)(4)(ii).

(3) The 2004 Proposed HIPAA Regulations propose the following additional requirements:

(a) Method for Making of Request. A "request" (which is what must be made within the applicable period for requesting special enrollment) will be deemed made if it is made orally or in writing to any of the following:

i) The plan administrator.

ii) "An issuer offering health insurance coverage under the plan."

iii) "A person who customarily handles claims for the plan (such as a third party administrator)."

iv) "Any other designated representative."

Prop. Treas. Reg. §54.9801-6(a)(4)(i).

(b) Tolling of Period for Making Request. The 30-day period would not begin to run until the individual has received a certificate of creditable coverage from the plan whose coverage has been lost (but the extension would not exceed 44 days.) Prop. Treas. Reg. §54.9801-6(a)(4)(ii).

(c) Reasonable Procedures Required.

i) Once a person requests special enrollment within the required time period, a plan may place a reasonable time limit on the full completion of the enrollment materials.

a) The enrollment materials may require the special enrollee to provide only the same type and amount of information that a regular enrollee would be required to provide, plus reasonable information regarding the event creating the special enrollment rights.

b) Any deadline must be extended "for information that an individual making reasonable efforts does not obtain by that deadline."

Prop. Treas. Reg. §54.9801-6(a)(4)(iii).

ii) Date Coverage Must Begin.

a) If the plan does not require the completion of additional enrollment materials, coverage must begin "no later than the first day of the first calendar month beginning after the date the plan receives the request for special enrollment."

b) If the plan does require the completion of additional enrollment materials, coverage must begin "no later than the first day of the first calendar month beginning after the date the plan receives enrollment materials that are substantially complete."

Prop. Treas. Reg. §54.9801-6(a)(4)(iv).

2. Special Enrollment Rights Based on Addition of Dependents.

a. In General. An employee who has met the requirements for covering dependents must be permitted, during the 30-day period after the dependent is acquired, to enroll any dependent acquired by:

(1) marriage, in which case coverage must be effective no later than "the first day of the first month beginning after the date the completed request for enrollment is received," or

(2) birth, adoption or placement for adoption, in which case coverage will be effective as of the date of the birth, adoption or placement for adoption.

Code §9801(f)(2); ERISA §701(f)(2); Public Health Service Act §2701(f)(2).

b. Eligible Individuals**.** The following individuals are eligible for this type of special enrollment under the following circumstances:

(1) Current Employee Only. A current employee is entitled to special enrollment rights if he or she acquires a dependent "through marriage, birth, adoption, or placement for adoption."

(2) Spouse of Participant Only. A participant's spouse is entitled to special enrollment rights if either:

(a) The participant and spouse become married, or

(b) The participant acquires "a dependent child through birth, adoption, or placement for adoption."

(3) Current Employee and Spouse. An employee and the employee's spouse are entitled to special enrollment rights if either:

(a) They become married, or

(b) The employee acquires "a dependent child through birth, adoption, or placement for adoption."

(4) Dependent of a Participant Only. A dependent of a participant is entitled to special enrollment rights if he or she becomes "a dependent child through birth, adoption, or placement for adoption."

(5) Current Employee and a New Dependent. The employee and a new dependent are entitled to special enrollment rights if the dependent becomes "a dependent child through birth, adoption, or placement for adoption."

(6) Current Employee, Spouse, and a New Dependent. The employee, the employee's spouse, and a new dependent are all entitled to special enrollment rights if the dependent becomes "a dependent child through birth, adoption, or placement for adoption."

Treas. Reg. §54.9801-6(b)(2). (Note that the category NOT included in the above list is existing dependent children when a new dependent child is acquired.

c. Timing.

(1) Request for Special Enrollment. The plan must offer at least 30 days after the date of the acquisition of a new dependent for an employee to request special enrollment for the employee or dependent. Treas. Reg. §54.9801-6(b)(3)(i).

(2) Coverage must begin no later than the first day of the calendar month following the plan's receipt of the application for special enrollment. Treas. Reg. §54.9801-6(a)(4)(ii).

(3) Date Coverage Must Begin.

(a) Marriage. In the case of marriage, coverage must begin no later than the first day of the first calendar month beginning after the date the application is

received by the plan or the insurer. Treas. Reg. §54.9801-6(b)(3)(ii)(A).

(b) Birth, Adoption, or Placement for Adoption.

i) In the case of birth, coverage must begin on the date of birth.

ii) In the case of adoption or placement for adoption, coverage must begin no later than the date of such adoption or placement for adoption.

iii) If the plan does not offer dependent coverage at the time of any such occurrence, special enrollment rights do not occur until such time as the plan makes such coverage available.

Treas. Reg. §54.9801-6(b)(3)(ii)(B).

(4) The 2004 Proposed HIPAA Regulations propose the following additional requirements:

(a) Method for Making of Request. A "request" (which is what must be made within the applicable period for requesting special enrollment) will be deemed made if it is made orally or in writing to any of the following:

i) The plan administrator.

ii) "An issuer offering health insurance coverage under the plan."

iii) "A person who customarily handles claims for the plan (such as a third party administrator)."

iv) "Any other designated representative."

Prop. Treas. Reg. §54.9801-6(b)(3)(i).

(b) Reasonable Procedures Required.

i) Once a person requests special enrollment within the required time period, a plan may place a reasonable time limit on the full completion of the enrollment materials.

a) The enrollment materials may require the special enrollee to provide only the same type and amount of information that a regular enrollee would be required to provide, plus reasonable information regarding the event creating the special enrollment rights.

b) Any deadline must be extended "for information that an individual making reasonable efforts does not obtain by that deadline."

Prop. Treas. Reg. §54.9801-6(b)(3)(ii).

ii) Date Coverage Must Begin.

a) *Marriage.* In the case of marriage:

II. If the plan does not require the completion of additional enrollment materials, coverage must begin "no later than the first day of the first calendar month beginning after the date the plan receives the request for special enrollment."

III. If the plan does require the completion of additional enrollment materials, coverage must begin "no later than the first day of the first calendar month beginning after the date the plan receives enrollment materials that are substantially complete."

Prop. Treas. Reg. §54.9801-6(b)(3)(iii)(A).

a) *Birth, Adoption or Placement for Adoption.* If the plan requires the completion of additional enrollment materials following the timely request for special enrollment rights, coverage provided once the additional materials have been completed must still be retroactive to the date of birth, adoption or placement for adoption. Prop. Treas. Reg. §54.9801-6(b)(3)(iii)(B).

i) An example is given of a participant requesting special enrollment rights for his wife and child based on the birth of the child. He makes the request within the 30-day period following the birth, and completes the additional materials within the plan's 14-day deadline for doing so, except that although he requests a copy of the child's birth certificate he is unable to obtain one until a later date (at which time he duly provides the birth certificate to the plan). In the example, the application is found to be "substantially complete" upon submission of all the materials except the birth certificate, such that "the plan must pay all of the claims submitted" even before the birth certificate is received. Prop. Treas. Reg. §54.9801-6(b)(4), Example 4. In this example, the regulation does not even appear to contemplate the possibility of the plan pending the claims until receipt of the birth certificate, and the regulation is silent on what happens if the birth certificate is in fact never presented.

3. Notice Requirements**.** "At or before the time an employee is initially offered the opportunity to enroll in a group health plan, the plan must furnish the employee with a notice of special enrollment that complies with" the following:

a. A description of the special enrollment rights must be included. The 2004 Final HIPAA regulations contain model language.

b. If applicable, the notice must inform individuals declining coverage that to protect their special enrollment rights they must designate in writing that they are doing so to take advantage of other coverage.l

Treas. Reg. §54.9801-6(c).

4. Rights of Special Enrollees**.**

a. An individual entitled to special enrollment rights must be treated as a special enrollee "even if the request for enrollment coincides with a late enrollment opportunity under the plan. Therefore, the individual cannot be treated as a late enrollee." Treas. Reg. §54.9801-6(d)(1).

b. "Special enrollees must be offered all the benefit packages available to similarly situated individuals who enroll when first eligible."

(1) Any difference in "benefits or cost-sharing requirements for different individuals constitutes a different benefit package."

(2) Special enrollees cannot be required to pay higher premiums than individuals who enroll when first eligible.

(3) The length of the special enrollee's pre-existing condition exclusion period cannot be greater than that applied to one who enrolls when first eligible (although the special enrollee's pre-existing condition exclusion period computation period will begin running at the time coverage begins rather than at the time a waiting period begins).

Treas. Reg. §54.9801-6(d)(2)

5. Case Law. In Livingston v. South Dakota State Medical Holding Company, Inc., 411 F.Supp.2d 1161 (D.S.D., 2006), the court held that an employee on maternity leave was still a full time employee entitled to special enrollment rights on the birth of her child for herself and the child. Further, on her later shift to part-time status, both she and the child are entitled to COBRA coverage.

a. Danielle Livingston had initially failed to elect coverage under the health plan of her employer, Wakonda Heritage Manor, because she and her children were eligible for Medicaid. DakotaCare provided the coverage under that plan. "On May 6, 2003, she gave birth to a

child 15 weeks prematurely. She did not return to work until June 19, 2003, when she returned to work on a part time basis. She resigned from her position and her employment with Manor was terminated on August 29, 2003. On June 4, 2003, within 30 days of the birth of her son, Livingston applied for DakotaCare benefits for herself and her child." At that time, Livingston was not working at all since she was still on maternity leave. At the commencement of the leave, however, she had been a full time employee. DakotaCare denied the application for coverage based upon information from the employer that Livingston was only working part time, but the court noted that the employer had done nothing to change her status to part time. "Nor could they have done so. For example, if a qualified employee has a baby, can the employer change the employee's status so as to prevent the employee and the child from being eligible to be enrolled and asking to be enrolled, e.g. by firing her or suspending her? The answer is clearly 'No.'"

b. DakotaCare contended that because Livingston was not actually working on June 4, 2003, at the time she made her special enrollment rights election, she was not eligible to be enrolled in the plan. The court held, however, that her election was retroactive, and that it was her status on that date that was relevant. The court noted that "Livingston was eligible . . . on May 6, 2004, to enroll in her employer's DakotaCare health care insurance plan. HIPAA's special enrollment provisions make her eligible for up to 30 days thereafter. The 30 day special enrollment period operates to backdate coverage to the date of birth. Under the statute, on the date of coverage, Livingston was a full time employee and otherwise eligible."

c. The court further noted that DakotaCare's position amounted to an "active at work" clause, and that such clauses were prohibited by HIPAA's non-discrimination requirements. "DakotaCare's denial of coverage amounts to a requirement that the employee be actively at work and not disabled during at least a part of the 30 day special enrollment period. However, HIPAA specifically prohibits discrimination with regard to eligibility for enrollment based upon, *inter alia*, health status, medical condition, or disability...The regulations prohibit a plan from establishing a rule for eligibility 'based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor . . . is treated . . . as being actively at work.' . . . It is clear from reading HIPAA and its regulations that Congress intended to expand eligibility for health care coverage for newborns and their parents. DakotaCare is not authorized to limit the

30 day special enrollment period by imposing restrictions that, in many cases, would eliminate the right to elect coverage."

d. The question of whether Livingston was on an approved leave was a question of fact. Apparently, DakotaCare's rules called for her employer to file its leave policy with DakotaCare, which had not been done. DakotaCare tried to take the position that its determination to deny special enrollment rights and COBRA coverage to Livingston and her child was entitled to an abuse of discretion standard. The court noted that the plan purported to give discretion to DakotaCare to determine eligibility for benefits. "However, even under the abuse of discretion standard this court is required to consider whether DakotaCare's decision denying benefits to Livingston conflicts with the requirements of ERISA." "The issue here is whether DakotaCare erred in denying benefits because the denial conflicts with the requirements of ERISA. If so, discretion or abuse of discretion is immaterial."

e. Livingston had assigned her rights to one of her providers, "Sioux Valley." DakotaCare contended that Sioux Valley lacked standing. Since Livingston herself was also a plaintiff in the case, the court decided that it need not consider whether her assignee had standing. However, the court went on to cite the Eighth Circuit's prior holding that "nothing in ERISA prohibits a plan participant from assigning a cause of action to a health care provider after the services have been rendered and the loss incurred, nor [is there] any language suggesting Congress intended to restrict such assignments. Denying standing to health care providers as assignees of beneficiaries may undermine the goal of ERISA, namely to improve benefit coverage for employees." The court determined that "standing exists."

f. DakotaCare also contended that Livingston was required to exhaust her administrative remedies before suing.

(1) The court felt that DakotaCare's position was so entrenched that exhaustion would be futile.

(2) In addition, however, the court declined to require exhaustion "because DakotaCare's plan does not clearly require exhaustion prior to bringing a claim under ERISA." The plan language said how a claim "may" be made, and how a member "'may' appeal that decision to the board of directors." "The plan's permissive language does not qualify as a clear exhaustion requirement."

(3) The court further notes that "DakotaCare maintains that Livingston is not and does not qualify as a member of the plan so she technically would have no appeal rights under the plan." Thus, DakotaCare's own position would give her nothing to exhaust.

(4) Finally, the court noted that "genuine issues of fact exist as to whether Livingston ever received formal notice of the denial of benefits so as to trigger the right to appeal and whether subsequent correspondence between the parties satisfies the plan's exhaustion procedures. These issues would preclude summary judgment in favor of DakotaCare."

g. No notice of COBRA rights had been given to Livingston. Having determined that Livingston and her child were entitled to be enrolled in the plan as of May 6, 2003, the court then found that they were entitled to COBRA rights. The court found that "Livingston was entitled to the initial COBRA notice at least by June 4, 2003." After a discussion as to whether her qualifying event occurred on June 19, 2003, when she returned to work part time, or on her later resignation, the court found that June 19, 2003 was the date of the qualifying event. The court noted that genuine issues of material fact existed as to the premiums that Livingston would owe, "and whether her benefit period was cut short by any event." Thus, the monetary consequences of the courts holdings were deferred to a later time.

h. In an interesting aside, the court refused to allow the filing of two affidavits that DakotaCare sought to file. One was rejected as being immaterial. The other, however, was of an employee of Livingston's employer that apparently would have contested Livingston's full time employment status on June 4, 2003, the date she made her special enrollment rights election. The court noted that the affidavit "not only contradicts the deposition testimony [of the affiant]; it also contradicts Swenson's employer's . . . answer filed in this court admitting that Livingston was granted leave without pay following the birth of her son. The affidavit should not and will not be considered."

D. HMO SPECIAL AFFILIATION PERIODS. A health maintenance organization that does not apply any pre-existing condition exclusion or limitation may apply an "affiliation period," during which no premium is collected and no care is provided, but:

1. The affiliation period must run concurrently with any waiting period under the plan.

2. The affiliation period cannot exceed 60 days (or 90 days in the case of a late enrollee).

A similar method of addressing adverse selection may be permitted if approved by the applicable State.

ERISA §701(g); Public Health Service Act §2701(g).

IV. NON-DISCRIMINATION RULES FOR PLANS AND THEIR POLICIES.

A. DISCRIMINATION PROHIBITED. No group health plan or group health insurance issuer will be permitted to have eligibility (including continued eligibility) requirements that discriminate on the basis of a health factor. Code §9802(a)(1); ERISA §702(a)(1); Public Health Service Act §2702(a)(1). Treas. Reg. §54.9802-1(b); DOL Reg. §2590.702(b).

1. Health factors are the following health status factors:

   a. Health status;

   b. Medical Condition (including both physical and mental illnesses);

   c. Claims Experience;

   d. Receipt of health care;

   e. Medical history;

   f. Genetic information;

   g. Evidence of insurability; or

   h. Disability.

2. Evidence of insurability includes:

   a. Conditions arising out of acts of domestic violence (under final 2001 and 2006 HIPAA Regulations);

   b. Under 2006 HIPAA Regulations, it also includes "Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities."

1. Non-Health Factors. According to the 2006 HIPAA Regulations, the decision whether or not to elect health coverage "(including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor." Note, however, that special enrollees must be treated "the same as similarly situated individuals who are enrolled when first eligible."

2. Included in Eligibility. According to the 2006 HIPAA Regulations, eligibility includes:

    a. Enrollment;

    b. The effective date of coverage;

    c. Waiting (or affiliation) periods;

    d. Late and special enrollment;

    e. "Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages)";

    f. "Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles)";

    g. Continued eligibility; and

    h. "Terminating coverage (including disenrollment) of any individual under the plan."

3. Examples make clear that:

    a. Late enrollees cannot be forced to pass a physical examination in order to enroll.

    b. A plan with an HMO option and an indemnity option cannot force late enrollees to use the HMO option unless they provide evidence of good health. However it could limit ALL late enrollees to the HMO option so long as the requirement was imposed uniformly on all late enrollees, regardless of their health.

    c. A plan cannot exclude from enrollment "individuals who participate in recreational activities, such as motorcycling," as that would be a rule of eligibility. Note, however, that injuries incurred in such activities will not generally have to be covered by the plan.

d. Neither an insurer nor a plan, based on the insurer's gathering of individual medical information of potential plan participants, may exclude specific individuals from coverage under a plan's group policy. The insurer imposing such an exclusion would violate HIPAA's requirements both for employer-sponsored coverage and (assuming the plan is a small business plan) for guaranteed issue to small businesses. "If the plan provides coverage through this policy and does not provide equivalent coverage" for the excluded individuals through other means, the plan will also violate requirements imposed on the plan itself. (Presumably, this reference to "equivalent coverage . . . through other means" is an indication that an employer may utilize alternative coverages for individuals rejected by insurers – assuming, of course, that truly equivalent coverage can be found.)

4. Active at Work and Non-Confinement Clauses.

a. In general, no individual may be denied the right to enter the plan based on:

(1) confinement in a hospital on the day coverage is scheduled to begin;

(2) failure of the individual to be at work on the day coverage is scheduled to begin, unless such failure is limited to non-medical reasons for absence; or

(3) failure to complete a period of continuous employment due to the need to take one or more sick days.

b. However, so long as no exceptions are made for deferred starting dates due to non-health related causes, an employer who provides coverage beginning with the first day of employment may require that the employee actually work the first day of coverage. An example makes clear that a plan may also admit all entrants on the first day of the month following date of hire, and that (assuming equal treatment with other reasons for a delayed start date) an employee whose date of hire is delayed to the next calendar month due to the employee's illness may be made to wait until the beginning of the calendar month following the date the employee actually begins worik.

c. Also, multi-employer plans that require a stated number of hours of covered employment are permissible, even if illness is one reason an employee might have reduced hours.

d. Individuals away due to illness on the date their coverage would start, and beneficiaries confined on that date, must become covered on their scheduled coverage date even if they are still covered under an extension of benefit clause under a prior coverage. Normal coordination of benefit ("COB") rules would apply to determine the order of coverage, and such COB rules are expressly permitted (although not spelled out as to what the ordering would be) by the 2006 HIPAA Regulations.

5. Benign Discrimination. Nothing above will prevent an employer from admitting individuals with adverse health factors on a more favorable basis than other individuals. A common example is disabled adult dependent children, who are often allowed to remain covered past the maximum age for other dependent children.

Code §9802(a); ERISA §702(a); Public Health Service Act §2702(a); Treas. Reg. §54.9802-1 (a), (b)(1), (e) and (g); DOL Reg. §2590.702(a), (b)(1), (e) and (g).

B. APPLICATION TO SPECIFIC BENEFITS.

1. Statutory Provisions**.** The limitations on eligibility are not to be construed:

a. To require any plan to provide any specific benefits other than those provided under the terms of the plan, or

b. To prevent the plan from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated participants and beneficiaries.

Code §9802(a)(2); ERISA §702(a)(2); Public Health Service Act §2702(a)(2).

2. Under the 2006 HIPAA Regulations, "benefits provided under a plan must be uniformly available to all similarly situated individuals." Also, "any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances)."

a. "Thus, for example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain

types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries."

b. "A plan may impose annual, lifetime or other limits on benefits and my require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing arrangement applies uniformly to all similarly situated individuals and is not directed at individual participants and beneficiaries based on any health factor of the participants and beneficiaries."

c. A plan amendment "applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at an individual participants and beneficiaries."

d. However, an exclusion or limitation that does not apply equally to a broad-based group will be a violation if it is based on a health factor of one or more specific individuals. A broad-based exclusion may also be a violation if it is effective before the first day of the plan year following the date of its adoption.

e. Note that HIPAA is not the only statute controlling health plans, and a limitation or exclusion in full compliance with HIPAA may nevertheless violate some other state or federal law, such as the Americans with Disabilities Act.

Treas. Reg. §54.9802-1(b)(2); DOL Reg. §2590.702(b)(2).

3. Source of Injury Exclusions**.**

a. Although employees and dependents who engage in dangerous recreational activities cannot be excluded from the plan, the injuries incurred from engaging in such activities need not be covered. Treas. Reg. §54.9802-1 (a)(2)(ii) and (b)(2)(iii); DOL Reg. §2590.702(a)(2)(ii) and (b)(2)(iii).

b. However, activity-based benefit exclusion will be a violation if its cause is a physical or mental medical condition. For example, injuries caused by suicide attempts (or other self-inflicted injuries)

are specifically listed in an example as being required to be covered if the suicide attempt (or self-inflicted injury) was caused by depression. Also, one would presume that injuries or illness caused by smoking or other addictions would have to be covered. Treas. Reg. §54.9802-1 (b)(2)(iii); DOL Reg. §2590.702(b)(2)(iii).

c. No source-of-injury exclusion may be imposed on injuries resulting from domestic violence. Treas. Reg. §54.9802-1 (b)(2)(iii); DOL Reg. §2590.702(b)(2)(iii).

4. Pre-existing Condition Limitations or Exclusions.

a. Limitations otherwise permitted by HIPAA will not be deemed a violation of HIPAA's non-discrimination rules, so long as they are effective no sooner than the first plan year after they are adopted. Such a limitation may be a violation if it is made effective sooner than that, and if the facts indicate that it was directed at a specific individual.

b. In order to be valid, pre-existing condition exclusions or limitations must be applied uniformly to all similarly situated individuals. In an example, it is made clear that those who are able to be treatment-free for 6 months may not be exempted from the limitation without creating a violation with respect to those not exempted.

c. Similarly, imposing the pre-existing condition exclusion or limitation only on certain conditions would be a violation. Prior to the 2001 HIPAA Regulations, the DOL had made it clear through spokespersons, correspondence and enforcement activity that exclusions based on the time an injury or illness was contracted would be considered violations. For example, a plan that covered cosmetic reconstruction for burn victims limited that benefit to those who were covered when the injury was sustained, and such a clause was said to be a violation.

Treas. Reg. §54.9802-1 (b)(3); DOL Reg. §2590.702(b)(3).

5. Benign Discrimination. Nothing above will prevent an employer from admitting individuals with adverse health factors on a more favorable basis than other individuals. A common example is disabled adult dependent children, who are often allowed to remain covered past the maximum age for other dependent children. Treas. Reg. §54.9802-1 (g); DOL Reg. §2590.702(g).

C. PREMIUMS.

1. Individual premiums may not vary on the basis of any individual "health status-related factor."

2. However, this rule will not be construed to prevent:

   a. The insurer from basing the premium charged to the employer on the health status of the participants and beneficiaries in the aggregate. However "list billing," in which the insurer applies varying premiums to similarly situated individuals on the basis of claims experience, is specifically prohibited (except for favorable differentials to those with adverse health conditions).

   b. A plan or insurer from offering "discounts or rebates or modifying otherwise applicable copayments or deductibles, in return for adherence to programs of health promotion and disease prevention."

3. "Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium contribution rate."

4. Similarly situated individuals must be treated alike in the computation of premiums.

5. Benign Discrimination. Nothing above will prevent an employer from charging individuals with adverse health factors less than other individuals. Also, if a plan admits individuals on a more favorable basis because of an adverse health factor (for example, a plan allows disabled adult dependent children to remain covered past the maximum age for other dependent children), an individual who would no longer be covered but for the adverse factor may be charged a higher premium than others.

Code §9802(b); ERISA §702(b); Public Health Service Act §2702(b); Treas. Reg. §54.9802-1 (c) and (g); DOL Reg. §2590.702(c) and (g).

D. SIMILARLY SITUATED INDIVIDUALS.

1. Similarly situated individuals may be grouped by an employer on any reasonable basis that does not involve a health factor:

   a. Those selecting an option offered by the plan may be a separate group from those selecting other options.

   b. A *bona fide* employment-based classification used by the employer for other purposes may generally be used unless other facts and

circumstances surrounding its use make it suspect. Examples include:

(1) Full time vs. part time;

(2) Different geographic location;

(3) Membership in a collective bargaining unit;

(4) Date of hire;

(5) Length of service;

(6) Current employee vs. former employee; and

(7) Different occupations.

2. Dependents. Examples of permissible groupings for dependents include:

a. *Bona fide* employment-based classification of employee whose employment is basis for coverage (e.g., full time vs. part time, permanent vs. temporary or seasonal, current vs. former employees, or employees performing services vs. not performing services);

b. Relationship to participant (spouses may be treated differently than children);

c. Marital status;

d. Age or student status of children of participant;

e. Any other factor that is not a health factor.

3. Individuals with adverse medical factors may be given more favorable treatment.

4. Use of above classifications for differentiating individuals is only permitted if the classifications are not designed to discriminate against individuals based on health factors.

Treas. Reg. §54.9802-1 (d) and (g); DOL Reg. §2590.702(d) and (g).

E. WELLNESS PROGRAMS.

1. "A wellness program is any program designed to promote health or prevent disease." If a wellness program does not provide a reward, or if any reward provided is not conditioned "on an individual satisfying a standard that is related to a health factor," it will not violate the 2006 regulations so long as "participation in the program is made available to all similarly situated individuals." The following are examples of programs that will comply so long as they were offered on a non-discriminatory basis:

    a. Paying or reimbursing for fitness center memberships;

    b. A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes. Thus, a reward for getting cholesterol screening, getting prenatal care, taking smoking cessation classes, and many other healthy activities, is automatically non-discriminatory so long as the incentive is merely for participation in the program and does not vary according to the outcome of the test or other activity.

    c. Waiving normal group health plan copayments or deductibles "for the cots of, for example, prenatal care or well-baby visits."

    d. Reimbursing "employees for the costs of smoking cessation programs without regard to whether the employee quits smoking."

    e. Providing "a reward to employees for attending a monthly health education seminar."

    Treas. Reg. §54.9802-1(f)(1); DOL Reg. §2590.702-1(f)(1); HHS Reg. §146.121-1(f)(1).

2. A wellness program meeting the following requirements, as set forth in the 2006 HIPAA Regulations, will be permissible even if it discriminates based on health factors:

    a. The reward must not exceed 20% of the plan's costs (including both employer and employee contributions) for providing an individual with employee-only health coverage for a year under the benefit package the employee in question has elected. (If dependents are permitted to obtain the reward under the program, the maximum value would be 20% of the plan's total costs for family coverage.)

        (1) Rewards available through all of the wellness programs sponsored by an employer are aggregated for purposes of computing this limit for each of such wellness programs.

(2) If there are multiple benefit options (with varying total costs), the 20% cap applicable to an individual participant or family is based on the cost of the option in which the participant or family is enrolled.

(3) The reward can take "the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan."

Treas. Reg. §54.9802-1(f)(2)(i); DOL Reg. §2590.702-1(f)(2)(i); HHS Reg. §146.121-1(f)(2)(i).

b. "The program must be reasonably designed to promote good health or prevent disease." A program will meet this requirement if it "has a reasonable chance of improving the health of or preventing disease in participating individuals and is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease." Treas. Reg. §54.9802-1(f)(2)(ii); DOL Reg. §2590.702-1(f)(2)(ii); HHS Reg. §146.121-1(f)(2)(ii).

c. Eligible individuals must be given a new opportunity to earn the reward "at least once per year." Treas. Reg. §54.9802-1(f)(2)(iii); DOL Reg. §2590.702-1(f)(2)(iii); HHS Reg. §146.121-1(f)(2)(iii).

d. The reward "must be available to all similarly situated individuals." To meet this requirement, alternative standards must be available to those for whom "it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard," and to those for whom "it is medically inadvisable to attempt to satisfy the otherwise applicable standard."

(1) An example of an acceptable alternative standard is given where the wellness program rewards smoking cessation. A person unable to achieve that goal due to nicotine addiction could be allowed to meet an alternative standard of participating in a smoking cessation program, even if the person was unsuccessful at stopping smoking. Similar alternative standard examples are given for reducing a person's cholesterol level (participation in a dietary program) and for achieving a specific body mass index (walking 20 minutes three times a week).

(2) The 2006 HIPAA Regulations make clear that the plan may insist on a doctor's certification that it will truly be "unreasonably difficult" for a particular person to comply with the normal requirements for a particular reward.

Treas. Reg. §54.9802-1(f)(2)(iv) and (3); DOL Reg. §2590.702-1(f)(2)(iv) and (3); HHS Reg. §146.121-1(f)(2)(iv) and (3).

e. The plan must disclose the availability of the alternative standard in all materials in which the general standard is described.

(1) The alternative standard need only be described when the terms of the program are presented in materials, not when the existence of the program is merely mentioned.

(2) The regulations provide a safe harbor disclosure (although it is made clear that "substantially similar" language will be adequate): "If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward." Examples in the regulation contain alternative examples of acceptable disclosure language.

a. Treas. Reg. §54.9802-1(f)(2)(v); DOL Reg. §2590.702-1(f)(2)(v); HHS Reg. §146.121-1(f)(2)(v).

F. TRANSITION REGULATIONS. A "clarification" issued on December 29, 1997 to the temporary and proposed 1997 HIPAA Regulations applied to plans that previously had excluded people because of their poor health. The clarification applied to those who were directly excluded due to a health problem or health risk factor, or for those who did not apply because they assumed they would be denied coverage.

1. Individuals previously excluded from a plan due to "a health status-related factor" had to be offered enrollment at the time HIPAA became effective.

a. This requirement applied even for a plan that does not normally have open enrollment, and even for a plan that intended to prohibit all late enrollment after HIPAA. Except as required by the special enrollment rules for new dependents and loss of other coverage, HIPAA does not require the admittance of late enrollees at all — so long as the restriction applies to both the healthy and the unhealthy on an equal basis.

b. In addition to the requirement that an individual previously denied coverage be offered coverage on the plan's HIPAA effective date, the clarification also provided that the individual must not be treated as a late enrollee. Thus, the 12-month (not the 18-month) pre-existing condition exclusion or limitation period applied.

c. The clarification included an example of a person, called "A," who was hired May 3, 1992, and who was excluded at date of hire due to diabetes. Although the plan generally provided an open enrollment opportunity every January 1st, A assumed that the diabetes would continue to exclude A from the plan, and thus never applied again. The plan in the example is on a calendar plan year, so HIPAA was effective on January 1, 1998. According to that example, A had to be offered admission on January 1, 1998.

2. The 2001 HIPAA Regulations provided one more opportunity to cure any continuing exclusion due to a pre-HIPAA medical underwriting requirement.

a. Those excluded other than pursuant to a good faith interpretation of the statute and published guidance had to be offered admission either prospectively, or retroactively to the plan's HIPAA effective date (or such later date as the individual met the permissible eligibility requirements. Those admitted retroactively were to receive benefits from the effective date of their coverage, but could be asked to pay back premiums for such period. Affected individuals had to be given at least a 30-day period to enroll.

b. Those excluded pursuant to a good faith interpretation of the statute and published guidance had to be offered admission beginning either on the first day of the first plan year beginning on or after July 1, 2001, or no later than the first day of the month following receipt of application for such coverage.

V. MULTI-EMPLOYER AND MULTIPLE EMPLOYER PLANS. Multi-employer plans and MEWAs may not offer the employees of different employers different coverages **except** on the basis of:

A. Non-payment of contributions.

B. Fraud or other intentional misrepresentation of material fact by the employer.

C. Noncompliance with material plan provisions.

D. Cessation of coverage by multi-employer plan or MEWA in geographic area.

E. Failure to enroll any individuals through the employer who are living, residing or working in the service area of a network plan, provided the plan applies this factor "uniformly without regard to the claims experience of employers or any health status-related factor in relation to such individuals or their dependents."

1. Failure of the employer to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other gr requiring or authorizing contributions to the plan, or to employ employees covered by such an agreement.

Code §9803(a); ERISA §703.

VI. NEW REPORTING AND DISCLOSURE REQUIREMENTS.

A. NOTICE TO EMPLOYEES OF MATERIAL REDUCTION IN BENEFITS. Employees must be notified of any "material reduction in covered services or benefits provided under a group health plan." ERISA §734(c).

1. 60-Day Notice Period**.** In general, such notice must be "furnished to participants and beneficiaries not later than 60 days after the date of the adoption of the modification or change."

2. Alternative Method of Compliance. Alternatively, "plan sponsors may provide such description at regular intervals of not more than 90 days."

3. Regulations to be Issued. The Secretary of Labor must issue regulations as to how such notices are to be given, as alternatives to mailing, "within 180 days after the date of enactment."

ERISA §734(c)(1)(B).

B. INSURER IDENTIFIED IN SPD**.** The list of vital information in the summary plan description of a health plan must now include the name and address of the issuer of any insurance policy. ERISA §734(c)(2).

C. MEWA REPORTING**.** The Secretary of Labor may require MEWAs to submit annual reports even if the MEWA itself is not an ERISA plan. ERISA §734(g).

D. INSURER DISCLOSURE. HIPAA imposes various specific notice requirements on insurers offering health coverage.

VII. NON-DISCRIMINATION REQUIREMENTS FOR INSURERS.

A. RENEWABILITY GUARANTEED. An insurer may deny renewal in the large or small employer market only for the following reasons:

1. Non-payment of premiums by the plan sponsor.

2. Fraud by the plan sponsor.

3. Violation by the plan sponsor of participation or contribution rules.

4. The insurer is legally "ceasing to offer coverage in such market," except that:

   a. Insurers ceasing to offer one type of coverage must provide notice to the affected employers at least 90 days prior to the discontinuation and offers those employers other coverage that it continues to provide. An insurer must act "uniformly without regard to any health status-related factor."

   b. An insurer ceasing all coverage must give 180 days prior notice, and cannot reenter the market for 5 years.

5. Failure of any covered participants or beneficiaries to live, reside or work in the insurer's service area.

6. The employer ceases membership in a *bona fide* association, when coverage is legally limited to members of that association.

Public Health Service Act §2712.

B. AVAILABILITY OF INSURANCE TO SMALL EMPLOYERS.

1. Protections for Small Employers. An insurer offering health insurance in the small group market in a State must:

   a. Accept every small employer that applies.

      (1) A "small employer" is "an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year." Public Health Service Act §2791(e)(4).

      (2) An employer not in existence throughout the preceding calendar year will determine whether it is a small or large employer "based on the average number of employees that it

is reasonably expected such employer will employ on business days in the current calendar year." Public Health Service Act §2791(e)(6)(B).

(3) The aggregation rules of Sections 414(b), (c), (m) and (o) of the Code will be applied. Public Health Service Act §2791(e)(6)(A).

b. Accept for enrollment under such coverage, without restrictions based on medical factors, every individual "who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan."

Public Health Service Act §2711.

2. Computation of Average Number of Employees**.** The 2004 Proposed HIPAA Regulations propose guidance for computing the "average number of employees."

a. Full Time Equivalents**.** "The average number of employees is determined by calculating the average number of full-time equivalents on business days during the preceding calendar year." Prop. HHS Reg. §146.145(e)(2).[4]

b. Methodology. For the preceding calendar year, the average number of full-time equivalents is determined by:

(1) "Determining the number of employees who were employed full-time by the employer throughout the entire calendar year." Prop. HHS Reg. §146.145(e)(3)(i).

(2) Adding the full-time employees throughout the calendar year to a number determined to reflect the part-time employees and the full-time employees not employed throughout the calendar year, as follows:

(a) "Totaling all employment hours (not to exceed 40 hours per week) for each part-time employee, and for each full-time employee who was not employed full-time with the employer throughout the entire calendar year." Prop. HHS Reg. §146.145(e)(3)(ii).

[4] Parallel citations to Treasury and DOL regulations are generally not included.

(b) Dividing the total by "a figure that represents the annual full-time hours under the employer's general employment practices, such as 2,080 hours (although for this purpose not more than 40 hours per week may be used)." Prop. HHS Reg. §146.145(e)(3)(iii).

Prop. HHS Reg. §146.145(e)(3)(iv).

(3) Rounding. All fractions are disregarded. "For example, a figure of 50.9 is deemed to be 50." Prop. HHS Reg. §146.145(e)(4).

(4) New Employers. "In the case of an employer that was in existence for less than the entire preceding calendar year (including an employer that was not in existence at all), a determination of the average number of employees that the employer employs is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year." Prop. HHS Reg. §146.145(e)(5).

(5) Predecessor Employers. The term "employer" "includes any predecessor of the employer." Prop. HHS Reg. §146.145(e)(6).

(6) Multiemployer Plans. An "employer with at least one employee participating in the plan is considered to employ the same average number of employees," which is the highest average as computed above. Prop. HHS Reg. §146.145(e)(7).

C. EXCEPTIONS.

1. An insurer without adequate financial reserves to issue additional coverage will not be required to do so. If required to do so, it must demonstrate its financial capacity to the appropriate state authority, and it must apply the exception uniformly throughout the state, "consistent with applicable state law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents." Public Health Service Act §2711(d).

2. If permitted under state law, an insurer may establish

a. employer contribution rules ("relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries"), or

b. group participation rules ("relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer").

Public Health Service Act § 2711(e).

3. Coverage may be limited to *bona fide* members of an association. Public Health Service Act § 2711(f).

VIII. AVAILABILITY OF INSURANCE TO INDIVIDUALS.

A. NON-DISCRIMINATION REQUIREMENTS FOR INSURERS.

1. In General. An insurer offering health insurance in the individual market in a state must:

a. Accept for enrollment every individual who applies.

b. However, a state may establish an alternative mechanism, in which case the general HIPAA requirement that every individual applicant be accepted will not apply. Public Health Service Act §2741(a).

c. In a state with no alternative mechanism, an insurer may establish "at least two different policy forms of health insurance coverage" meeting the applicable requirements, and then it may offer other policies without regard to those requirements. The forms meeting the requirements may be:

(1) the insurer's two most popular policies offered in the individual market, or

(2) a combination of:

(a) a high-level policy, offering coverage with an actuarial value between 100% and 120% of the "weighted average" of either the insurer's own individual policies in the state or all individual policies in the state, and

(b) a low-level policy, offering coverage with an actuarial value between 85% and 100% of the "weighted average."

The actuarial value of the high level policy cannot be more than 15% greater than the actuarial value of the lower level policy.

Public Health Service Act §2741(c).

2. Renewability Guaranteed**.** An insurer may deny renewal in the individual market only for the following reasons:

a. Non-payment of premiums.

b. Fraud.

c. The insurer is legally "ceasing to offer coverage in such market," except that:

(1) Insurers ceasing to offer one type of coverage must provide notice to the affected individuals at least 90 days prior to the discontinuation and offers those individuals enrollment in other coverage that it continues to provide. An insurer must act "uniformly without regard to any health status-related factor."

(2) An insurer ceasing all coverage must give 180 days prior notice, and cannot reenter the market for 5 years.

d. Movement of the individual outside the insurer's service area, but only if coverage is terminated "uniformly without regard to any health status-related factor."

e. The individual ceases membership in a *bona fide* association, when coverage is legally limited to members of that association.

Public Health Service Act §2742.

3. Exceptions**.**

a. An insurer without adequate financial reserves to issue additional coverage will not be required to do so. If required to do so, it must demonstrate its financial capacity to the appropriate state authority, and it must apply the exception uniformly throughout the state, "consistent with applicable State law and without regard to the claims experience of those individuals (and their dependents) or any health status-related factor relating to such individuals and dependents." Public Health Service Act §2741(e).

b. Coverage may be limited to *bona fide* members of an association. Public Health Service Act §2742.

IX. IMPACT OF HIPAA ON ERISA PREEMPTION.

A. STATE INSURANCE LAWS AND PREEMPTION. In general, states will continue to be permitted to regulate the business of insurance, except to the extent that their rules conflict with HIPAA, and other state laws affecting ERISA plans will continue to be preempted. Public Health Service Act §2723(a).

B. SPECIAL PORTABILITY RULES. However, states may provide more strict requirements regarding:

1. Shortening the 6-month period during which diagnosis or treatment of a pre-existing condition may cause the condition to be limited or excluded.

2. Shortening the 12-month or 18-month maximum limitation or exclusion period.

3. Lengthens the 63-day break in coverage period that may be used to disregard pre-break coverage.

4. Limits the situations in which pre-existing condition exclusions or limitations may be applied.

5. Requires special enrollment periods in addition to those for individuals losing other coverage and newly acquired dependents.

6. Reduces the maximum affiliation period for HMOs that do not limit or exclude pre-existing conditions.

Public Health Service Act §2723(b). See also HHS Reg. §146.143, as included in 2004 Final HIPAA Regulations.

X. EFFECTIVE DATES OF HIPAA.

A. GENERAL EFFECTIVE DATE**.** In general, HIPAA is effective for plan years beginning after June 30, 1997. However, collectively bargained plans were not subject to these provisions until the expiration of the agreements as they were in force on the date of enactment of HIPAA. Code §9806(c); ERISA §734; Public Health Service Act §2792(c).

B. EFFECTIVE DATE OF 2001 HIPAA REGULATIONS.

1. The final Treasury and IRS regulations issued in 2001, and the corresponding DOL and HHS Interim Final Regulations, were effective March 9, 2001. These apply to:

   a. The definition of the term "health factors," in Treas. Reg. §54.9802-1(a)(1); DOL Reg. §2590.702(a)(1); HHS Reg. §146.121(a)(1)

   b. The inclusion of acts of domestic violence as a health factor by virtue of its inclusion in the term "evidence of insurability, in Treas. Reg. §54.9802-1(a)(2); DOL Reg. §2590.702(a)(2); HHS Reg. §146.121(a)(2).

   c. The general prohibition on discrimination based on health factors, in Treas. Reg. §54.9802-1(b)(1)(i) and (iii); DOL Reg. §2590.702(b)(1)(i) and (iii); HHS Reg. §146.121(b)(1)(i) and (iii).

   d. General rules as to the application of the non-discrimination rules to benefits, in Treas. Reg. §54.9802-1(b)(2)(i)(A); DOL Reg. §2590.702(b)(2)(i)(A); HHS Reg. §146.121(b)(2)(i)(A).

   e. General rules relating to discrimination relating to premiums and rates, in Treas. Reg. §54.9802-1(c)(1)(i) and (c)(2)(i); DOL Reg. §2590.702(c)(1)(i) and (c)(2)(i); HHS Reg. §146.121(c)(1)(i) and (c)(2)(i).

   f. General rules exempting *bona fide* wellness programs from HIPAA's non-discrimination rules, in Treas. Reg. §54.9802-1(c)(3); DOL Reg. §2590.702(c)(3); HHS Reg. §146.121(c)(3).

2. The temporary Treasury and IRS Regulations, the remaining Interim Final DOL Regulations, and the remaining Interim Final HHS Regulations, all issued in 2001, are effective for plan years beginning on or after July 1, 2001.

3. The proposed Treasury and IRS Regulations, the proposed DOL Regulations and the proposed HHS Regulations have no stated effective date.

C. EFFECTIVE DATES OF FINAL HIPAA REGULATIONS.

1. The 2004 Final HIPAA Regulations are generally effective February 28, 2005, and are applicable for plan years beginning on or after July 1, 2005.

2. The 2006 HIPAA Regulations are generally effective February 12, 2007, and are applicable for plan years beginning on or after July 1, 2007.

D. CREDITABLE COVERAGE BEFORE JULY 1, 1996.

1. In general, creditable coverage before July 1, 1996 is not counted.

2. However, individuals who need to demonstrate creditable coverage before July 1, 1996 will be allowed to do so, and the Secretary of Labor may issue regulations providing for the computation of pre-July 1996 creditable coverage when an employee needs to demonstrate such coverage.

a. Any such demonstration will be by documents or other "credible evidence of such coverage," and not through employer certification.

b. No plan or insurer will be "subject to any penalty or enforcement action with respect to the crediting (or not crediting)" pre-July 1, 1996 coverage if the plan or insurer "has sought to comply in good faith with the applicable requirements."

Code §9806(c); ERISA §734; Public Health Service Act §2792(c)

E. CERTIFICATIONS**.**

1. General Rule. In general, the certification requirements only apply to coverage termination "events" occurring after June 30, 1996.

2. Special Rules. However:

g. No certification of any such event is required to be provided before June 1, 1997, and

h. Certification for "events" occurring from July 1, 1996 through September 30, 1996 will only be required on the written request of the individual whose coverage is being certified.

Code §9806(c); ERISA §734; Public Health Service Act §2792(c).

3. Effect on Participants and Beneficiaries of Violation. The Secretaries of Labor and Health and Human Services are to issue regulations to protect the participants and beneficiaries from being adversely affected in their later coverages by violations of an employer or plan that fails to provide the required certifications. Code §9806(c); ERISA §734; Public Health Service Act §2792(c).

F. SPECIAL EFFECTIVE DATE FOR ENFORCEMENT ACTIONS. No enforcement action may be brought against a plan or insurer who is acting in good faith before the later of:

1. January 1, 1998, or

2. The issuance of regulations by the Secretaries of Labor, the Treasury, and Health and Human Services.

Code §9806(c)(5); ERISA §734; Public Health Service Act §2792(c)(5).

G. REGULATIONS REQUIRED. The Secretaries of Labor, the Treasury, and Health and Human Services, were required to issue regulations on or before April 1, 1997. Note that the effective date for enforcement actions specifically contemplated that such regulations might be late. Code §9806(c)(4); ERISA §734; Public Health Service Act §2792(c)(4). The 1997 HIPAA Regulations were late only by a few days (they were made available to the public on April 1, 1997, but not published in the Federal Register until April 8, 1997), but covered only the certification and pre-existing condition provisions in significant detail. And those regulations arguably expired three years from their date of issuance. Even with the issuance of the 2001 HIPAA Regulations, the Departments noted that many issues were still without any regulations. The issuance of the 2004 Final HIPAA Regulations fills some but not all of the regulatory gaps, and the issuance of the 2004 Proposed HIPAA Regulations is a step toward filling the remaining gaps.

H. PLAN YEAR DEFINED. A "plan year," as defined in the 2004 Final HIPAA Regulations, is the year designated as such in the plan document. If the plan document fails to designate a plan year, then the plan year is:

1. The year used for computing the plan's deductibles or out-of-pocket caps or other limitations.

2. If "the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year."

3. If neither 1 nor 2 is applicable, "then the plan year is the employer's taxable year."

4. If none of the above is applicable, "the plan year is the calendar year."

XI. ENFORCEMENT.

A. STATUTES AMENDED.

1. ERISA.

a. Description of Violations. HIPAA adds a new Part 7 to the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). Title I, Section 101 of HIPAA.

b. Enforcement Actions.

(1) Violations by employers, plan sponsors and plans will be subject to lawsuits by participants and beneficiaries or the Department of Labor, with the possibility of recovering required benefits plus attorneys' fees.

(2) Although the Secretary of Labor is specifically authorized to issue regulations with respect to these requirements, it is not permitted to "enforce under this part any requirement of part 7 against a health insurance issuer offering health insurance coverage in connection with a group health plan." ERISA §502(b).

c. Penalty Assessments. ERISA's $100 per day penalty for failure to provide documents to participants and beneficiaries, and its $1,000 per day penalties for failure to file required information returns, will apply to violations of applicable provisions. ERISA §734(g).

2. Internal Revenue Code.

a. Description of Violations. Sections 9801 through 9806 are added at the end of the Internal Revenue Code (the "Code"), prohibiting violations. Title IV, HIPAA § 401.

b. Penalty Tax. HIPAA adds a new Section 4980D to the Code, providing for penalties of $100 per day per violation. HIPAA §402. The structure and maximums of the penalty tax is similar to that provided under Section 4980B of the Code for COBRA violations.

(1) In the case of a multiemployer plan, the plan is liable for the penalty tax.

(2) In the case of a plan that is a MEWA violating the guaranteed renewability requirements, the plan will be liable for the penalty tax.

(3) In all other cases, the employer is liable for the penalty tax.

Code §4980D(e).

c. Delegation to States of MEWA Enforcement Authority**.** The Secretary of Labor may enter into agreements with States delegating some or all of its enforcement authority with respect to MEWAs to those States.

(1) Exemptions.

(a) Church plans are exempt from the penalty tax.

(b) In the case of a "small employer" (no more than 50 employees on business days during the preceding calendar year), the penalty tax will not apply to the employer if the violation is the fault of the insurer.

(2) The term "employer" is specifically defined to include "any predecessor of such employer." Unfortunately, the term "predecessor" is not defined.

Query: ***Does this mean that an employer will be liable for the violations and penalty taxes of its predecessors?***

3. Public Health Service Act.

a. Description of Violations. HIPAA adds a new Title XXVII at the end of the Public Health Service Act, prohibiting violations by insurers. Title I, HIPAA §102.

b. Suspension of Insurer from Small Business Market**.** An insurer declining to provide coverage in the small business market of a service area "may not offer coverage in the small group market within such service area for a period of 180 days after the date such coverage is denied." Public Health Service Act §2741(d)(2).

c. State Enforcement**.** States will generally enforce the requirements of HIPAA against insurers. However, the Secretary of Health and

Human Services has the authority to bring an enforcement action in a State that has not done so. Public Health Service Act §2745.

B. PENALTY ASSESSMENTS FOR NON-FEDERAL GOVERNMENTAL PLANS. Governmental plans (other than Federal governmental plans) and their insurers will be subject to penalty assessments, by the Secretary of Health and Human Services, of $100 per day per violation, under rules similar to the penalty taxes to which private plans and plan sponsors are subject.

XIII. NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT OF 1996.

A. GENERAL PROVISIONS.

1. No group health plan or insurer may "restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child":

   a. To less than 48 hours following a "normal vaginal delivery," or

   b. To less than 96 hours following a cesarean section.

2. The NMHPA Regulations provide that each such measuring period begins, in the case of a hospital birth, at the moment of delivery, regardless of how long the mother has already been in the hospital. Treas. Reg. §54.9801-1(a)(1) and (2)(i); DOL Reg. §2590.701(a)(1) and (2)(i).

   a. In the case of multiple births, the time period runs from the delivery of the last child. Treas. Reg. §54.9801-1(a)(2)(i); DOL Reg. §2590.701(a)(2)(i).

   b. In the case of a birth outside the hospital, the measuring period begins upon inpatient admission to the hospital. Treas. Reg. §54.9801-1(a)(2)(ii); DOL Reg. §2590.701(a)(2)(ii).

3. However, the above prohibitions do not apply if "the decision to discharge the mother or her newborn child… is made by an attending provider in consultation with the mother." Treas. Reg. §54.9801-1(a)(5); DOL Reg. §2590.701(a)(5).

   a. The NMHPA Regulations provide, in the case of the newborn, that the consultation shall be "with the mother (or the newborn's authorized representative)."

   b. The NMHPA Regulations define an attending provider as "an individual who is licensed under applicable State law to provide

maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. (Note that the attending provider is not limited to physicians, but includes any provider licensed to provide such care under State law.) Treas. Reg. §54.9801-1(a)(5)(iii); DOL Reg. §2590.701(a)(5)(iii).

<u>Query</u>: Does an attending physician "consulting with" the mother have to consider the mother's wishes?

B. SPECIFIC PROHIBITIONS. The following are specifically prohibited:

1. Denying the mother or the child "eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section." Treas. Reg. §54.9801-1(b)(1)(i)(A); DOL Reg. §2590.701(b)(1)(i)(A).
2. Providing "monetary payments or rebates to mothers to encourage such mothers to accept less than the minimum protections available under this section." Treas. Reg. §54.9801-1(b)(1)(i)(B); DOL Reg. §2590.701(b)(1)(i)(B).

3. Penalizing or otherwise reducing or limiting "the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section." Treas. Reg. §54.9801-1(b)(3)(i); DOL Reg. §2590.701(b)(3)(i).

4. Providing "incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section." Treas. Reg. §54.9801-1(b)(3)(ii); DOL Reg. §2590.701(b)(3)(ii).

5. Reducing benefits in any way for the protected period. Treas. Reg. §54.9801-1(b)(2); DOL Reg. §2590.701(b)(2). However, this provision is not to be construed to limit or restrict "deductibles, coinsurance, or other cost-sharing" so long as those requirements are not increased for the protected period. Treas. Reg. §54.9801-1(b)(3); DOL Reg. §2590.701(b)(3).

1. Under the NMHPA Regulations, a plan "may not require that a physician or other health care provider obtain authorization from the plan, or from a health insurance issue offering health insurance coverage under the plan, for prescribing the hospital length of stay." Treas. Reg. §54.9801-1(a)(4); DOL Reg. §2590.701(a)(4).

C. SPECIFIC PROVISIONS. The following are specifically permitted:

1. A plan may permit a mother to give birth outside of a hospital, or to leave the hospital early. Treas. Reg. §54.9801-1(c)(2); DOL Reg. §2590.701(c)(2).

2. A plan is not required by these rules to cover "hospital lengths of stay in connection with childbirth." Note, however, that the Pregnancy Discrimination Act of 1978 will require most affected plans to provide such coverage. The EEOC, in a letter dated July 28, 1997, expressed its concern that the fact that the NMHPA specifically does not require a plan to cover pregnancy might cause employers to think that the NMHPA allowed them to omit pregnancy coverage from their plans, overriding any other requirements. To the contrary, Title VII of the Civil Rights Act mandates that pregnancy be treated the same as other medical conditions, and an employer subject to that act must provide hospitalization benefits for pregnancy if it provides hospitalization benefits for other conditions. The EEOC requested to the DOL that the NMHPA regulations caution employers to comply with the Title VII requirements as well as the NMHPA requirements, the NMHPA regulations contain such a notation in Footnote 5.

3. Negotiating "the level and type of reimbursement" with providers "for care provided in accordance with this section" is specifically allowed. Treas. Reg. §54.9801-1(c)(4); DOL Reg. §2590.701(c)(4).

D. EFFECTIVE DATE AND NOTICE REQUIREMENT.

1. The statutory rules are effective with respect to group health plans and their insurers "for plan years beginning on or after January 1, 1998." They are effective with respect to the individual market for "health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998."

2. All participants and beneficiaries of plans and policies covered by HIPAA (whether or not they are generally covered by ERISA, and including policies issued in the individual market) are entitled to be given a notice of these requirements, as a summary of material modifications, "not later than 60 days after the first day of the first plan year in which such requirements apply." Treas. Reg. §54.9801-1(d); DOL Reg. §2590.701(d).

3. The NMHPA Regulations are effective for plan years beginning on or after January 1, 1999.

E. STATE EXCEPTIONS. Insurance policies in states with any of the following requirements will be subject to those requirements and not to Federal law:

1. The state requires coverage "for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital stay following a cesarean section."

2. The state requires "such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations."

3. The state requires "that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother."

However, self-funded plans are not entitled to these exemptions. Treas. Reg. §54.9801-1(e); DOL Reg. §2590.701(e).

XIV. MENTAL HEALTH PARITY ACT OF 1996.

A. GENERAL PROVISIONS.

1. No group health plan or insurance policy "that provides both medical and surgical benefits and mental health benefits" may impose an aggregate lifetime limit or an annual limit on mental health benefits that is less than the comparable limit on medical and surgical benefits.

2. Temporary and proposed regulations have been issued, providing guidance as to how plans may determine the permissible limit for mental health benefits. These regulations provide the following principles:

   a. A plan may apply the same limit to mental health benefits as it applies to medical and surgical benefits.

      (1) It may do so either by including mental health benefits within its overall limits, and applying a single limit to all medical, surgical and mental health benefits.

      (2) Alternatively, it may apply its limit separately to mental health benefits so long as the limit on mental health benefits is no less than the limit imposed on medical and surgical benefits.

   b. In the case of a plan with varying limits for different types of medical and surgical benefits:

(1) A plan that imposes no limit on one or more of its medical and surgical benefits cannot impose any limit on its mental health benefits. This is true even though a few specific medical or surgical plan benefits have limits.

(2) A plan that limits one or more of its benefits with a single limit will be limited to imposing no higher limit on mental health benefits.

(3) A plan in between (1) and (2) may apply a "weighted average" of the various limits, under a formula set forth in the regulations.

(4) All computations regarding the above principles that are not specifically set forth in the regulations must be calculated on a good faith basis.

B. EXEMPTIONS**.** The following are specifically exempted:

1. Small Employers**.** An employer is exempted for a plan year/calendar year if the employer "employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and. . .employs at least 2 employees on the first day of the plan year."

   a. The aggregation rules of Code §§414(b), (c), (m) and (o) are applied to determine the size of the employer.

   b. An employer not in existence the preceding year may use "the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year."

   c. A reference to an employer "shall include a reference to any predecessor of such employer."

2. Individual Market. No counterpart to these rules is imposed on the individual insurance market.

3. Increased Cost**.** If providing mental health parity under the provisions of MHPA would result "in an increase in the cost under the plan (or for such coverage) of at least 1 percent." This exemption will be applied separately to each separate benefit package under the plan.

   a. Based on the statutory provisions, much speculation existed as to whether this 1% exemption could be projected actuarially, or whether it had to be demonstrated based on an actual attempt to comply with

the statute. Temporary and proposed regulations have been issued making clear that the computation must be based on actual data for at least a 6-month period of compliance.

b. If a plan determines that it is exempt for one period, speculation also existed as to how the statute is applied to succeeding periods. The temporary regulations provide that if the requirements for the 1% exemption are met based on at least 6 months of actual compliance, the plan will be exempt for the remainder of the statute's existence based on its current sunset date.

C. SPECIFIC PROVISIONS**.** The following are specifically permitted:

1. A plan that provides medical or surgical benefits is not required by MHPA to provide mental health benefits.

2. Special limitations on "the terms and conditions (including cost sharing, limits on numbers of visits or days of coverage, and requirements relating to medical necessity) relating to the amount, duration, or scope of mental health benefits" are specifically permitted so long as they do not violate the general provisions.

3. Benefits for the "treatment of substance abuse or chemical dependency" are not covered by these new rules, and thus discrimination against such benefits is still permitted.

D. EFFECTIVE DATE AND SUNSET. MHPA is effective with respect to group health plans and their insurers "for plan years beginning on or after January 1, 1998." Originally, the MHPA was scheduled to sunset, and thus not apply, "to benefits for services furnished on or after September 30, 2001." The MHPA Amendments extended this sunset date to December 31, 2003, and the MHPRA extended the sunset date further to December 31, 2004. Subsequent legislation has extended the sunset date further to December 31, 2007. As of February, 2008, legislation was proposed to further extent the sunset date to December 31, 2008. (H.R. 4848, introduced Dec. 19, 2007).

XV. WOMEN'S HEALTH AND CANCER RIGHTS ACT OF 1998.

A. GENERAL PROVISIONS.

1. If a group health plan provides medical and surgical benefits with respect to a mastectomy, it must also provide, for a person receiving benefits for a mastectomy and who elects reconstruction, coverage for:

a. reconstruction of the breast on which the mastectomy was performed;

b. "surgery and reconstruction of the other breast to produce a symmetrical appearance;" and

c. Prostheses for the reconstructions.

2. In addition, a plan covering mastectomies must provide coverage for "physical complications" of "all stages of mastectomy, including lymphedemas."

3. The above must be provided "in a manner determined in consultation with the attending physician and the patient."

4. The coverage may be subject to the plan's normal deductibles and coinsurance provisions, but additional deductibles or coinsurance provisions may not be applied to reconstructive surgery in connection with a mastectomy.

B. APPLICABILITY AND PREEMPTION.

1. The WHCRA generally applies to group health plans and their insurers. Its provisions are set forth in Section 713 of ERISA and Section 2706 of the Public Health Service Act.

2. An additional provision of the WHCRA, however, which adds Section 2752 of the Public Health Service Act, extends the requirements of the WHCRA to "the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market."

3. State laws "in effect on the date of enactment of the WHCRA (October 21, 1998), which provide equal or greater coverage for reconstructive breast surgery, are not preempted."

4. The WHCRA does not require any plan to cover mastectomies.

C. SPECIFIC PROHIBITIONS**.** A group health plan is specifically prohibited from:

1. Denying a patient "eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;"

2. Penalizing or otherwise reducing or limiting provider reimbursement, or providing "incentives (monetary or otherwise) to an attending provider, to

induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section."

However, the WHCRA specifically states that nothing in it "shall be construed to prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating the level and type of reimbursement with a provider for care provided in accordance with this section."

D. NOTICE REQUIREMENTS.

1. The statute requires that written notice describing this coverage be delivered **to the participant** upon enrollment and annually thereafter. According to the DOL's published summary of the laws governing health plans, the notices "must be delivered in accordance with the Department of Labor's disclosure regulations applicable to furnishing summary plan descriptions."

   a. First class mail or any other means of delivery prescribed in the SPD regulation is acceptable.

   b. "It is the view of the Department that a separate notice would be required to be furnished to a group health plan beneficiary where the last known address of the beneficiary is different than the last known address of the covered participant."

2. Notice of the coverage must be provided **"to each participant and beneficiary"** "in accordance with regulations promulgated by the Secretary."

   a. This notice must be "in writing and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer."
   b. The notice must be transmitted no later than the earliest of:

      (1) "in the next mailing made by the plan or issuer to the participant or beneficiary;"

      (2) "as part of any yearly informational packet sent to the participant or beneficiary;" or

      (3) "not later than January 1, 1999."

   c. Note that the WHCRA was not enacted until October 21, 1998, thus making the above notice requirements very difficult to comply with. Unfortunately, the DOL's description in its health booklet adds nothing to the statute with respect to the timing of this initial notice, except to state that plan already in compliance do not need to provide

it "if the information required to be provided in the initial notice was previously furnished to participants and beneficiaries in accordance with the Department's regulations on disclosure of information to participants and beneficiaries."

3. As to content, the DOL booklet states that the notices must describe the benefits that the WHCRA requires the plan to cover. "The notice must indicate that, in the case of a participant or beneficiary who is receiving benefits under the plan in connection with a mastectomy and who elects breast reconstruction, the coverage will be provided in a manner determined in consultation with the attending physician and the patient," for:

   a. reconstruction of the breast on which the mastectomy was performed;

   b. surgery and reconstruction of the other breast to produce a symmetrical appearance; and

   c. prostheses and treatment of physical complications at all stages of the mastectomy, including lymphedemas.

   "The notice must also describe any deductibles and coinsurance limitations applicable to such coverage."

4. With respect to an insured plan, either the insurer (or HMO) or the plan may provide the notice, but both need not do so.

E. EFFECTIVE DATE.

1. The WHCRA is generally effective with respect to plan years beginning on or after October 21, 1998.

2. There is no special effective date for collectively bargained plans, but there is a special provision that any amendment adopted "solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement."

XVI. <u>GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008</u>. GINA amended the HIPAA provisions of ERISA, PHSA, and the Code to prohibit certain uses of genetic information in group health plans and group health plans offered by insurance companies as follows.

A. PROVISIONS RELATING TO GENETIC DISCRIMINATION IN HEALTH INSURANCE.

1. Group health plans and insurers are prohibited from changing or setting group premiums (or contribution levels) based on genetic information. An insurer may, however, raise premiums charged to the employer based on the "manifestation of a disease or disorder" of an individual who is enrolled in the plan.

2. Neither a group health plan nor an insurer may require an individual to undergo a genetic test. The plan or insurer may obtain and use the results of a genetic test in making payment determinations under the plan, but must limit such requests to the minimum information necessary.

3. Group health plans and insurers are prohibited from requesting, requiring, or purchasing genetic information for underwriting purposes, and are further prohibited from requesting, requiring, or purchasing genetic information with respect to any individual prior to the individual's enrollment in the plan. If the group health plan or insurer makes a legal request for information, and receives genetic information incidental to such request, that request is not considered a violation.

B. APPLICABILITY. The prohibitions on the use of genetic information apply to all group health plans and health insurance issuers, including those with less than 2 participants who are current employees.

C. DEFINITIONS. For purposes of the above rules, the statute provides the following definitions:

1. "Family members" includes an individual's dependents and any other first-, second-, third-, or fourth-degree relative of the individual.

2. "Genetic information" means information about an individual's genetic tests, the genetic tests of that individual's family members, and the manifestation of a disease or disorder in the individual's family members.

3. "Genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes, but excludes:

   a. An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

   b. An analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

4. "Underwriting purposes" is broadly defined to include:

   a. Rules for, or the actual determination of eligibility for benefits, including initial enrollment and continuing eligibility;

   b. Calculation of premiums or contribution amounts;

   c. Application of pre-existing condition exclusions; and

   d. "Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits."

D. ENFORCEMENT. The genetic nondiscrimination provisions will be enforced through changes to ERISA and PHSA that provide for penalties of $100 per day per person. The statute provides for minimum total penalties of $2,500 for de minimis violations and $15,000 for violations deemed to be severe. The maximum penalty for an unintentional violation is set at the lesser of $500,000 or 10 percent of the aggregate amount paid by the plan sponsor in the previous tax year. The Secretary has discretionary authority to waive penalties in cases of reasonable cause not due to willful neglect.