

Notice of Proposed Rulemaking for Health Coverage Portability

Notice of Proposed Rulemaking for Health Coverage Portability: Tolling Certain Time Periods and Interaction With the Family and Medical Leave Act Under HIPAA Titles I & IV

REG-130370-04

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: These proposed rules would clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. These rules propose to implement changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

DATES: Written comments on this notice of proposed rulemaking are invited and must be received by the Departments on or before March 30, 2005.

ADDRESSES: Written comments should be submitted with a signed original and three copies (except for electronic submissions) to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments.

Comments to the IRS can be addressed to:

CC:PA:LPD:PR (REG-130370-04)
Room 5203
Internal Revenue Service
POB 7604, Ben Franklin Station
Washington, DC 20044

In the alternative, comments may be hand-delivered between the hours of 8 a.m. and 4 p.m. to:

CC:PA:LPD:PR (REG-130370-04)
Courier's Desk
Internal Revenue Service
1111 Constitution Avenue, NW,
Washington, DC 20224

Alternatively, comments may be transmitted electronically via the IRS Internet site at: www.irs.gov/regs or via the Federal eRulemaking Portal at www.regulations.gov (IRS — REG-130370-04).

Comments to the Department of Labor can be addressed to:

U.S. Department of Labor
Employee Benefits Security
Administration
200 Constitution Avenue, NW,
Room C-5331
Washington, DC 20210

Attention: Proposed Portability Requirements

Alternatively, comments may be hand-delivered between the hours of 9:00 a.m. and 5:00 p.m. to the same address. Comments may also be transmitted by e-mail to: e-ohpsca.ebsa@dol.gov.

Comments to HHS can be submitted as described below:

In commenting, please refer to file code CMS-2158-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid
Services
Department of Health and Human
Services
Attention: CMS-2158-P
P.O. Box 8017
Baltimore, MD 21244-8010

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey
Building
200 Independence Avenue, SW
Washington, DC 20201; or

7500 Security Boulevard
Baltimore, MD 21244-1850

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC, from 9 a.m. to 4 p.m.

All submissions to the Department of Labor will be open to public inspection and copying in the Public Disclosure Room, Employee Benefits Security Administration, U.S. Department of Labor, Room N-1513, 200 Constitution Avenue, NW, Washington, DC, from 8:30 a.m. to 4:30 p.m.

All submissions timely submitted to HHS will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters for the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 410-786-7195.

FOR FURTHER INFORMATION

CONTACT: Dave Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at 1-877-267-2323 ext. 61565; Amy Turner, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; or Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080.

SUPPLEMENTARY INFORMATION:

Customer Service Information

To assist consumers and the regulated community, the Departments have issued questions and answers concerning HIPAA. Individuals interested in obtaining copies of Department of Labor publications concerning changes in health care law may call a toll free number, 1-866-444-EBSA (3272), or access the publications on-line at www.dol.gov/ebsa, the Department of Labor's website. These regulations as well as other information on the new health care laws are also available on the Department of Labor's interactive web pages, *Health Elaws*. In addition, CMS's publication entitled "Protecting Your Health Insurance Coverage" is available by calling 1-800-633-4227 or on the Department of Health and Human Services' website (www.cms.hhs.gov/hipaa1), which includes the interactive webpages, HIPAA

Online. Copies of the HIPAA regulations, as well as notices and press releases related to HIPAA and other health care laws, are also available at the above-referenced websites.

A. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. HIPAA amended the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) to provide for, among other things, improved portability and continuity of health coverage. Interim final regulations implementing the HIPAA provisions were first made available to the public on April 1, 1997 (published in the **Federal Register** on April 8, 1997, 62 FR 16894) (April 1997 interim rules) (T.D. 8716, 1997-1 C.B. 225). On December 29, 1997, the Departments published a clarification of the April 1997 interim rules as they relate to excepted benefits. On October 25, 1999, the Departments published a notice in the **Federal Register** (64 FR 57520) soliciting additional comments on the portability requirements based on the experience of plans and issuers operating under the April 1997 interim rules.

After consideration of all the comments received on the portability provisions, the Departments are publishing final regulations (T.D. 9166) elsewhere in this issue of the Bulletin. These proposed rules address additional and discrete issues for which the Departments are soliciting further comment before promulgating final regulations.

B. Overview of the Proposed Regulations

1. *Rules Relating to Creditable Coverage* — 26 CFR 54.9801-4, 29 CFR 2590.701-4, 45 CFR 146.113

Tolling of the 63-day break-in-coverage rule

These proposed rules would modify the 63-day break-in-coverage rules with one significant substantive change. Under the proposed rules, the beginning of the period that is used for determining whether a

significant break in coverage has occurred (generally 63 days) is tolled in cases in which a certificate of creditable coverage is not provided on or before the day coverage ceases. In those cases, the significant-break-in-coverage period is tolled until a certificate is provided but not beyond 44 days after the coverage ceases.

The Departments have fashioned this tolling rule (and a similar tolling rule for the 30-day period for requesting special enrollment) in an effort to address the inequity of individuals' losing coverage without being aware that the coverage has ended while minimizing the burdens on subsequent plans and issuers that are not responsible for providing the missing or untimely certificates. Numerous situations have come to the attention of the Departments in which an individual's health coverage is terminated but in which the individual does not learn of the termination of coverage until well after it occurs. The statute generally requires that a certificate of creditable coverage be provided at the time an individual ceases to be covered under a plan. The statute, the April 1997 interim rules, and the final regulations (published elsewhere in this issue of the Bulletin) all permit a plan or issuer to provide the certificate at a later date if it is provided at a time consistent with notices required under a COBRA continuation provision. The statute also directs the Secretaries to establish rules to prevent a plan or issuer's failure to provide a certificate timely from adversely affecting the individual's subsequent coverage. If a plan or issuer chooses to provide a certificate later than the date an individual loses coverage, as the regulations permit in certain circumstances, these proposed rules provide that an individual should not suffer from this rule of convenience for the plan or issuer. However, to prevent the abuse that might result from an open-ended tolling rule, an outside limit of 44 days is placed on this relief. This reflects the fact that, in most cases, plans and issuers are required to provide certificates within 44 days (although some plans and issuers may be required to provide certificates sooner than 44 days after coverage ceases and some entities are not required to provide certificates at all). The Departments have adopted this uniform limit on the tolling rule for purposes of

consistency. New examples have been added to illustrate the tolling rule.

2. *Evidence of Creditable Coverage* — 26 CFR 54.9801–5, 29 CFR 2590.701–5, 45 CFR 146.115

Information in certificate and model certificate

These proposed rules would modify the required elements for the educational statement in certificates of creditable coverage to require a disclosure about the

Family and Medical Leave Act. Use of the first model certificate below by group health plans and group health insurance issuers, or use of the appropriate model certificate that appears in the preamble to the related final regulations published elsewhere in this issue of the Bulletin, will satisfy the requirements of paragraph (a)(3)(ii) in this section of the final regulations. Similarly, for purposes of complying with those final regulations, State Medicaid programs may use the second version below, or may use the appropriate model certificate that appears in the

preamble to those final regulations. Thus, until this proposed regulation is published as a final regulation, entities may use either the model certificates published below, or those published elsewhere in this issue of the Bulletin. For entities that choose not to use the model certificates below until this proposed regulation is published as a final regulation, we welcome comments as to the applicability date for using them.

CERTIFICATE OF GROUP HEALTH PLAN COVERAGE

1. Date of this certificate: _____

2. Name of group health plan: _____

3. Name of participant: _____

4. Identification number of participant: _____

5. Name of individuals to whom this certificate applies:

6. Name, address, and telephone number of plan administrator or issuer responsible for providing this certificate: _____

7. For further information, call: _____

8. If the individual(s) identified in line 5 has (have) at least 18 months of creditable coverage (disregarding periods of coverage before a 63-day break), check here and skip lines 9 and 10: _____

9. Date waiting period or affiliation period (if any) began: _____

10. Date coverage began: _____

11. Date coverage ended (or if coverage has not ended, enter “continuing”): _____

[Note: separate certificates will be furnished if information is not identical for the participant and each beneficiary.]

Statement of HIPAA Portability Rights

IMPORTANT — KEEP THIS CERTIFICATE. This certificate is evidence of your coverage under this plan. Under a federal law known as HIPAA, you may need evidence of your coverage to reduce a preexisting condition exclusion period under another plan, to help you get special enrollment in another plan, or to get certain types of individual health coverage even if you have health problems.

Preexisting condition exclusions. Some group health plans restrict coverage for medical conditions present before an individual’s enrollment. These restrictions are known as “preexisting condition exclusions.” A preexisting condition exclusion can apply only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the 6 months before your “enrollment date.” Your enrollment date is your first day of coverage under the plan, or, if there is a waiting period, the first day of your waiting period (typically, your first day of work). In addition, a preexisting condition exclusion cannot last for more than 12 months after your enrollment date (18 months if you are a late enrollee). Finally, a preexisting condition exclusion cannot apply to pregnancy and cannot apply to a child who is enrolled in health coverage within 30 days after birth, adoption, or placement for adoption.

If a plan imposes a preexisting condition exclusion, the length of the exclusion must be reduced by the amount of your prior creditable coverage. Most health coverage is creditable coverage, including group health plan coverage, COBRA continuation coverage, coverage under an individual health policy, Medicare, Medicaid, State Children’s Health Insurance Program (SCHIP), and coverage through high-risk pools and the Peace Corps. Not all forms of creditable coverage are required to provide certificates like this one. If you do not receive a certificate for past coverage, talk to your new plan administrator.

You can add up any creditable coverage you have, including the coverage shown on this certificate. However, if at any time you went for 63 days or more without any coverage (called a break in coverage) a plan may not have to count the coverage you had before the break.

- ▶ Therefore, once your coverage ends, you should try to obtain alternative coverage as soon as possible to avoid a 63-day break. You may use this certificate as evidence of your creditable coverage to reduce the length of any preexisting condition exclusion if you enroll in another plan.

Right to get special enrollment in another plan. Under HIPAA, if you lose your group health plan coverage, you may be able to get into another group health plan for which you are eligible (such as a spouse's plan), even if the plan generally does not accept late enrollees, if you request enrollment within 30 days. (Additional special enrollment rights are triggered by marriage, birth, adoption, and placement for adoption.)

- ▶ Therefore, once your coverage ends, if you are eligible for coverage in another plan (such as a spouse's plan), you should request special enrollment as soon as possible.

Prohibition against discrimination based on a health factor. Under HIPAA, a group health plan may not keep you (or your dependents) out of the plan based on anything related to your health. Also, a group health plan may not charge you (or your dependents) more for coverage, based on health, than the amount charged a similarly situated individual.

Right to individual health coverage. Under HIPAA, if you are an "eligible individual," you have a right to buy certain individual health policies (or in some states, to buy coverage through a high-risk pool) without a preexisting condition exclusion. To be an eligible individual, you must meet the following requirements:

- You have had coverage for at least 18 months without a break in coverage of 63 days or more;
- Your most recent coverage was under a group health plan (which can be shown by this certificate);
- Your group coverage was not terminated because of fraud or nonpayment of premiums;
- You are not eligible for COBRA continuation coverage or you have exhausted your COBRA benefits (or continuation coverage under a similar state provision); and
- You are not eligible for another group health plan, Medicare, or Medicaid, and do not have any other health insurance coverage.

The right to buy individual coverage is the same whether you are laid off, fired, or quit your job.

- ▶ Therefore, if you are interested in obtaining individual coverage and you meet the other criteria to be an eligible individual, you should apply for this coverage as soon as possible to avoid losing your eligible individual status due to a 63-day break.

Special information for people on FMLA leave. If you are taking leave under the Family and Medical Leave Act (FMLA) and you drop health coverage during your leave, any days without health coverage while on FMLA leave will not count towards a 63-day break in coverage. In addition, if you do not return from leave, the 30-day period to request special enrollment in another plan will not start before your FMLA leave ends.

- ▶ Therefore, when you apply for other health coverage, you should tell your plan administrator or health insurer about any prior FMLA leave.

State flexibility. This certificate describes minimum HIPAA protections under federal law. States may require insurers and HMOs to provide additional protections to individuals in that state.

For more information. If you have questions about your HIPAA rights, you may contact your state insurance department or the U.S. Department of Labor, Employee Benefits Security Administration (EBSA) toll-free at 1-866-444-3272 (for free HIPAA publications ask for publications concerning changes in health care laws). You may also contact the CMS publication hotline at 1-800-633-4227 (ask for "Protecting Your Health Insurance Coverage"). These publications and other useful information are also available on the Internet at: <http://www.dol.gov/ebsa>, the DOL's interactive web pages — *Health Elaws*, or <http://www.cms.hhs.gov/hipaa1>.

CERTIFICATE OF MEDICAID COVERAGE

1. Date of this certificate: _____
2. Name of state Medicaid program: _____

3. Name of recipient: _____
4. Identification number of recipient: _____
5. Name of individuals to whom this certificate applies:

6. Name, address, and telephone number of state Medicaid agency responsible for providing this certificate: _____

7. For further information, call: _____
8. If the individual(s) identified in line 5 has (have) at least 18 months of creditable coverage (disregarding periods of coverage before a 63-day break), check here and skip lines 9: _____
9. Date coverage began: _____
10. Date coverage ended (or if coverage has not ended, enter "continuing"): _____

[Note: separate certificates will be furnished if information is not identical for the recipient and each dependent.]

Statement of HIPAA Portability Rights

IMPORTANT — KEEP THIS CERTIFICATE. This certificate is evidence of your coverage under this state Medicaid program. Under a federal law known as HIPAA, you may need evidence of your coverage to reduce a preexisting condition exclusion period under a group health plan, to help you get special enrollment in a group health plan, or to get certain types of individual health coverage even if you have health problems.

Preexisting condition exclusions. Some group health plans restrict coverage for medical conditions present before an individual's enrollment. These restrictions are known as "preexisting condition exclusions." A preexisting condition exclusion can apply only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the 6 months before your "enrollment date." Your enrollment date is your first day of coverage under the plan, or, if there is a waiting period, the first day of your waiting period (typically, your first day of work). In addition, a preexisting condition exclusion cannot last for more than 12 months after your enrollment date (18 months if you are a late enrollee). Finally, a preexisting condition exclusion cannot apply to pregnancy and cannot apply to a child who is enrolled in health coverage within 30 days after birth, adoption, or placement for adoption.

If a plan imposes a preexisting condition exclusion, the length of the exclusion must be reduced by the amount of your prior creditable coverage. Most health coverage is creditable coverage, including group health plan coverage, COBRA continuation coverage, coverage under an individual health policy, Medicare, Medicaid, State Children's Health Insurance Program (SCHIP), and coverage through high-risk pools and the Peace Corps. Not all forms of creditable coverage are required to provide certificates like this one. If you do not receive a certificate for past coverage, talk to your new plan administrator.

You can add up any creditable coverage you have, including the coverage shown on this certificate. However, if at any time you went for 63 days or more without any coverage (called a break in coverage) a plan may not have to count the coverage you had before the break.

- ▶ Therefore, once your coverage ends, you should try to obtain alternative coverage as soon as possible to avoid a 63-day break. You may use this certificate as evidence of your creditable coverage to reduce the length of any preexisting condition exclusion if you enroll in a group health plan.

Right to get special enrollment in another plan. Under HIPAA, if you lose your group health plan coverage, you may be able to get into another group health plan for which you are eligible (such as a spouse's plan), even if the plan generally does not accept late enrollees, if you request enrollment within 30 days. (Additional special enrollment rights are triggered by marriage, birth, adoption, and placement for adoption.)

- ▶ Therefore, once your coverage in a group health plan ends, if you are eligible for coverage in another plan (such as a spouse's plan), you should request special enrollment as soon as possible.

Prohibition against discrimination based on a health factor. Under HIPAA, a group health plan may not keep you (or your dependents) out of the plan based on anything related to your health. Also, a group health plan may not charge you (or your dependents) more for coverage, based on health, than the amount charged a similarly situated individual.

Right to individual health coverage. Under HIPAA, if you are an “eligible individual,” you have a right to buy certain individual health policies (or in some states, to buy coverage through a high-risk pool) without a preexisting condition exclusion. To be an eligible individual, you must meet the following requirements:

- You have had coverage for at least 18 months without a break in coverage of 63 days or more;
- Your most recent coverage was under a group health plan;
- Your group coverage was not terminated because of fraud or nonpayment of premiums;
- You are not eligible for COBRA continuation coverage or you have exhausted your COBRA benefits (or continuation coverage under a similar state provision); and
- You are not eligible for another group health plan, Medicare, or Medicaid, and do not have any other health insurance coverage.

The right to buy individual coverage is the same whether you are laid off, fired, or quit your job.

- ▶ Therefore, if you are interested in obtaining individual coverage and you meet the other criteria to be an eligible individual, you should apply for this coverage as soon as possible to avoid losing your eligible individual status due to a 63-day break.

Special information for people on FMLA leave. If you are taking leave under the Family and Medical Leave Act (FMLA) and you drop health coverage during your leave, any days without health coverage while on FMLA leave will not count towards a 63-day break in coverage. In addition, if you do not return from leave, the 30-day period to request special enrollment in another plan will not start before your FMLA leave ends.

- ▶ Therefore, when you apply for other health coverage, you should tell your plan administrator or health insurer about any prior FMLA leave.

State flexibility. This certificate describes minimum HIPAA protections under federal law. States may require insurers and HMOs to provide additional protections to individuals in that state.

For more information. If you have questions about your HIPAA rights, you may contact your state insurance department or the U.S. Department of Labor, Employee Benefits Security Administration (EBSA) toll-free at 1-866-444-3272 (for free HIPAA publications ask for publications concerning changes in health care laws). You may also contact the CMS publication hotline at 1-800-633-4227 (ask for “Protecting Your Health Insurance Coverage”). These publications and other useful information are also available on the Internet at: <http://www.dol.gov/ebsa> or <http://www.cms.hhs.gov/hipaa1>.

3. *Special Enrollment Periods — 26 CFR 54.9801-6, 29 CFR 2590.701-6, 45 CFR 146.117*

Tolling of the special enrollment period

Under HIPAA, the April 1997 interim rules, and the final regulations, an individual wishing to special enroll following a loss of coverage is generally required to request enrollment not later than 30 days after the loss of eligibility, termination of employer contributions, or exhaustion of COBRA continuation coverage. For individuals whose coverage ceases and a certificate of creditable coverage is not provided on or before the date coverage ceases, this regulation provides for proposed tolling rules similar to those described above for determining a significant break. That is, the special enrollment period terminates at the end of the 30-day period that begins on the first day after

the earlier of the date that a certificate of creditable coverage is provided or the date 44 days after coverage ceases.

Modification of special enrollment procedures and when coverage begins under special enrollment

The April 1997 interim rules did not establish procedures for processing requests for special enrollment beyond affirming the statutory requirement that requests be made not later than 30 days after the event giving rise to the special enrollment right and providing that the same requirements could be imposed on special enrollees that were imposed on other enrollees (*e.g.*, that the request be made in writing). Some examples in the April 1997 interim rules could be read to suggest that plans and issuers could require individuals requesting special enrollment to file completed appli-

cations for health coverage by the end of the special enrollment period.

It has been brought to the Departments' attention that some plans and issuers were imposing application requirements that could not reasonably be completed within the special enrollment period (for example, requiring the social security number of a newborn within 30 days of the birth), effectively denying individuals their right to special enroll their dependents. In this regard, the statute merely requires an employee to request special enrollment, or an individual to seek to enroll, during the special enrollment period. These proposed regulations preserve individuals' access to special enrollment by clarifying that during the special enrollment period individuals are only required to make an oral or written request for special enrollment.

The proposed regulations provide further that after a timely request, the plan or

issuer may require the individual to complete all enrollment materials within a reasonable time after the end of the special enrollment period. However, the enrollment procedure may only require information required from individuals who enroll when first eligible and information about the event giving rise to the special enrollment right. While a plan can impose a deadline for submitting the completed enrollment materials, the deadline must be extended for information that an individual making reasonable efforts cannot obtain within that deadline.

Thus, even where a plan requires social security numbers from individuals who enroll when first eligible, the plan must provide an extended deadline for receiving the social security number in the case of a newborn. In no event could a plan deny special enrollment for newborns because an employee could not provide a social security number for the newborn within the special enrollment period.

As regards the effective date of coverage for special enrollments, the proposed rules generally follow the statute, the April 1997 interim final rules, and the final regulations being published elsewhere in this issue of the Bulletin. However clarifications of the effective date of coverage are added to conform to the clarification of the special enrollment procedures. Where the special enrollment right results from a loss of eligibility for coverage or marriage, coverage generally must begin no later than the first day of the first calendar month after the date the plan or issuer receives the request for special enrollment. However, if the plan or issuer requires completion of additional enrollment materials, coverage must begin no later than the first day of the first calendar month after the plan or issuer receives enrollment materials that are substantially complete.

Where the special enrollment right results from a birth, coverage must begin on the date of birth. In the case of adoption or placement for adoption, coverage must begin no later than the date of such adoption or placement for adoption. If a plan or issuer requires completion of additional enrollment materials, the plan or issuer must provide benefits once the plan or issuer receives substantially complete enrollment

materials. However, the benefits provided at that time must be retroactive to the date of birth, adoption, or placement for adoption.

The Departments welcome comments on these aspects of the proposed rule.

4. Interaction with the Family and Medical Leave Act — 26 CFR 54.9801–7, 29 CFR 701–8, 45 CFR 146.120

The proposed rules address how the HIPAA portability requirements apply in situations where a person is on leave under the Family and Medical Leave Act of 1993 (FMLA). A general principle of FMLA is that an employee returning from leave under FMLA should generally be in the same position the employee was in before taking leave. At issue is how to reconcile that principle of FMLA with the HIPAA rights and requirements that are triggered by an individual ending coverage under a group health plan. These proposed regulations provide specific rules that clarify how HIPAA and FMLA interact when the coverage of an employee or an employee's dependent ends in connection with an employee taking leave under FMLA.

With respect to the rules concerning a significant break in coverage, if an employee takes FMLA leave and does not continue group health coverage for any part of the leave, the period of FMLA leave without coverage is not taken into account in determining whether a significant break in coverage has occurred for the employee or any dependents. To the extent an individual needs to demonstrate that coverage ceased in connection with FMLA leave (which would toll any significant break with respect to another plan or issuer), these regulations provide that a plan or issuer must take into account all information that it obtains about an employee's FMLA leave. Further, if an individual attests to the period of FMLA leave and the individual cooperates with a plan's or issuer's efforts to verify the individual's FMLA leave, the plan or issuer must treat the individual as having been on FMLA leave for the period attested to for purposes of determining if the individual had a significant break in coverage. Nonetheless, a plan or issuer is not prevented from modifying its initial determination of FMLA

leave if it determines that the individual did not have the claimed FMLA leave, provided that the plan or issuer follows procedures for reconsideration similar to those set forth in the final rules governing determinations of creditable coverage.

The question has arisen whether it would be appropriate to waive the general requirement to provide automatic certificates of creditable coverage in the case of an individual who declines coverage when electing FMLA leave if the individual will be reinstated at the end of FMLA leave. At the time an employee elects FMLA leave, the employer (as well as the employee) may not know if the employee will later return from FMLA leave and elect to be reinstated. Requiring plans and issuers to provide certificates when individuals cease health coverage in connection with FMLA leave may result in some certificates being issued when individuals ceasing coverage will not need the certificates as evidence of coverage (because of later reinstatement). However, automatic issuance likely imposes less burden because the plan or issuer does not need to determine whether a certificate is required. Moreover, automatic issuance eliminates the need for remedial measures if an individual expected to be reinstated in fact is not later reinstated. Thus, these proposed regulations clarify there is no exception to the general rule requiring automatic certificates when coverage ends and provide that if an individual covered under a group health plan takes FMLA leave and ceases coverage under the plan, an automatic certificate must be provided.

With respect to the special enrollment rules, an individual (or a dependent of the individual) who is covered under a group health plan and who takes FMLA leave has a loss of eligibility that results in a special enrollment period if 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. This special enrollment period begins when the period of FMLA leave ends. Moreover, the rules that delay the start of the special enrollment period until the receipt of a certificate of creditable coverage continue to operate.

Determination of number of plans

Various provisions in Chapter 100 of the Code, Part 7 of Subtitle B of Title I of ERISA, and Title XXVII of the PHS Act apply when an individual commences coverage or terminates coverage under a group health plan. For example, a certificate of creditable coverage must be provided when an individual ceases to be covered under a group health plan. Under the April 1997 interim rules, it was not always clear whether an individual changing benefit elections among those offered by an employer or employee organization was merely switching between benefit packages under a single plan or was switching from one plan to another. These proposed regulations add rules to remove this uncertainty.

Under these proposed regulations, all medical care benefits made available by an employer or employee organization (including a board of trustees of a multi-employer trust) are generally considered to constitute one group health plan (the default rule). However, the employer or employee organization can establish more than one group health plan if it is clear from the instruments governing the arrangements to provide medical care benefits that the benefits are being provided under separate plans and if the arrangements are operated pursuant to the instruments as separate plans. A multiemployer plan and a nonmultiemployer plan are always separate plans. Under an anti-abuse rule, separate plans are aggregated to the extent necessary to prevent the evasion of any legal requirement.

These rules provide plan sponsors great flexibility while minimizing the burden of making decisions about how many plans to maintain. For example, many employers may wish to minimize the number of certificates of creditable coverage required to be furnished to continuing employees. Under the default rule, because all health benefits provided by an employer are considered a single group health plan, there is no need to furnish a certificate of creditable coverage when an employee merely

switches coverage among the options made available by the employer. This need would arise only if the employer designated separate benefit packages as separate plans in the plan documents and only if the benefit packages were also operated pursuant to the plan documents as separate plans.

The anti-abuse rule limits the flexibility of these rules to prevent evasions. For example, a plan sponsor might design an arrangement under which the participation of each of many employees in the arrangement would be considered a separate plan. On the face of it, such an arrangement might appear to satisfy the requirement for a plan being exempt from the requirements of Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act because on the first day of the plan year each plan would have fewer than two participants who are current employees. This would give the impression that the plans would not have to comply with the prohibitions against discriminating based on one or more health factors, with the restrictions on preexisting condition exclusions, nor with any of the other requirements of Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act. The anti-abuse rule would require the aggregation of plans under such an arrangement to the extent necessary to make the plans subject to the requirements of Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act. The anti-abuse rule would apply in similar fashion to prevent the evasion of any other law that applies to group health plans or to the parties administering them or providing benefits under them.

Counting the average number of employees

These proposed regulations add rules for counting the average number of employees employed by an employer during a year.¹ Various rules in Chapter 100 of the Code, Part 7 of ERISA, and Title XXVII of the PHS Act require the determination of such an average number, including the Mental Health Parity Act provisions, the guaranteed access provisions under the PHS Act for small employers,

and the exemption from the excise tax under the Code for certain small employers.

Under these proposed regulations, the average number of employees employed by an employer is determined by using a full-time equivalents method. Each full-time employee employed for the entire previous calendar year counts as one employee. Full-time employees employed less than the entire previous calendar year and part-time employees are counted by totaling their employment hours in the previous calendar year (but not to exceed 40 hours for any week) and dividing that number by the annual full-time hours under the employer's general employment practices (but not exceeding 40 hours per week). Any resulting fraction is disregarded. For example, if these calculations produce a result of 50.9, the average number of employees is considered to be 50. If an employer existed for less than the entire previous calendar year (including not being in existence at all), then the determination of the average number of employees is made by estimating the average number of employees that it is reasonably expected that the employer will employ on business days in the current calendar year. For a multiemployer plan, the number of employees employed by the employer with the most employees is attributed to each employer with at least one employee participating in the plan.

C. Economic Impact and Paperwork Burden

Summary — Department of Labor and Department of Health and Human Services

HIPAA's group market portability provisions, which limit the scope and application of preexisting condition exclusions and establish special enrollment rights, provide a minimum standard of protection designed to increase access to health coverage. The Departments crafted these proposed regulations to secure these protections under certain special circumstances, consistent with the intent of Congress, and to do so in a manner that is economically efficient. The Departments are unable to quantify the regulations' economic

¹ The rules for determining the average number of employees employed by an employer during a year are not used for counting the number employed by the employer on a given day, such as the first day of a plan year.

benefits and costs, but believe that their benefits will justify their costs.

HIPAA's primary economic effects ensue directly from its statutory provisions. HIPAA's statutory group market portability provisions extend coverage to certain individuals and preexisting conditions not otherwise covered. This extension of coverage entails both benefits and costs. Individuals enjoying expanded coverage will realize benefits, sometimes including improvements in health and relief from so-called "job lock." The costs of HIPAA's portability provisions generally include the cost of extending coverage, as well as certain attendant administrative costs. The Departments believe that the benefits of HIPAA are concentrated in a relatively small population, while the costs are distributed broadly across group plan enrollees. The economic effects of HIPAA's statutory portability provisions are discussed in detail in the preamble to the final regulation under the "Effects of the Statute" of the "Basis for Assessment of Economic Impact" section, published elsewhere in this issue of the Bulletin.

By clarifying and securing HIPAA's statutory portability protections, these proposed regulations will help ensure that HIPAA rights are fully realized. The result is likely to be a small increase at the margin in the economic effects of HIPAA's statutory portability provisions.

These proposed regulations are intended to secure and implement HIPAA's group market portability and special enrollment provisions under certain special circumstances. The regulations will secure HIPAA's portability rights for individuals who are not timely notified that their coverage has ended and for individuals whose coverage ends in connection with the taking of leave that is guaranteed under FMLA. The regulations also will clarify and thereby secure individuals' special enrollment rights under HIPAA, and clarify the methodologies to be used by employers to determine the number of plans offered and the average number of individuals employed during a given year.

Additional economic benefits derive from the regulations' clarifications of HIPAA requirements. The regulations will reduce uncertainty and costly disputes between employees, employers and issuers, and promote confidence among employees in health benefits' value, thereby

promoting labor market efficiency and fostering the establishment and continuation by employers of group health plans.

Benefits under these regulations will be concentrated among a small number of affected individuals while costs will be spread thinly across group plan enrollees.

Affected individuals will generally include those who would have lost access to coverage for needed medical care after being denied HIPAA portability and/or special enrollment rights due to time spent without coverage prior to receiving a certificate or while on FMLA-guaranteed leave. The benefits of these regulations for any particular affected individual may be significant. As noted above and under "Effects of the Statute" in the "Basis for Assessment of Economic Impact" section of the preamble to the final regulation, published elsewhere in this issue of the Bulletin, access to coverage for needed medical care is important to individuals' health and productivity. However, the number of affected individuals, and therefore the aggregate cost of extended access to coverage under these regulations, is expected to be small, for several reasons. First, these regulations extend HIPAA rights only in instances where individuals are not timely notified that their coverage has ended or their coverage ends in connection with the taking of FMLA-guaranteed leave. Second, the period over which this regulation extends rights will often be short, insofar as certificates are often provided promptly after coverage ends and many family leave periods are far shorter than the guaranteed 12 weeks. Third, it is generally in individuals' interest to minimize periods of uninsurance. Individuals are likely to exercise their portability and special enrollment rights as soon as possible after coverage ends, which will often be before any extension of such rights under these regulations becomes effective. Fourth, only a portion of individuals who enroll in health plans in circumstances where these regulations alone guarantee their special enrollment or portability rights would otherwise have been denied such rights. Fifth, only a small minority of individuals who avoid a significant break in coverage as a direct result of these regulations would otherwise have lost coverage for needed medical care. (The affected minority would be those who suffer from

preexisting conditions, join health plans that exclude coverage for such conditions, and require treatment of such conditions during the exclusion periods.)

Affected individuals may also include some who would have been denied special enrollment rights if plans or issuers failed to recognize their requests for special enrollment or imposed unreasonable deadlines or requirements for completion of enrollment materials.

As noted above, the Departments expect that these regulations will increase at the margin the economic effects of HIPAA's statutory portability provisions. For the reasons stated immediately above, the Departments believe that these increases will be small on aggregate, adding only a small increment to the costs attributable to HIPAA's statutory portability provisions, which themselves amount to a small fraction of one percent of health plan expenditures. Additionally, as with the cost of HIPAA's statutory portability provisions, the majority of these costs will be borne by group plan enrollees. The Departments expect these regulations to have little or no perceptible negative impact on employers' propensity to offer health benefit plans or on the generosity of those plans. In sum, the Departments expect that the benefits of these regulations, which can be very large for a particular affected individual, will justify their costs. The basis for the Departments' conclusions is detailed below.

The Departments solicit comments on their conclusions and their basis for them, and empirical data or other information that would support a fuller or more accurate analysis.

Executive Order 12866 — Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 551735, Oct. 4, 1993), the Departments must determine whether a regulatory action is "significant" and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more, or adversely and materially

affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of the Executive Order, the Departments have determined that this action raises novel policy issues arising out of legal mandates. Therefore, this notice is “significant” and subject to OMB review under Section 3(f)(4) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this regulatory action. The Departments’ assessment, and the analysis underlying that assessment, is detailed below. The Departments performed a comprehensive, unified analysis to estimate the costs and benefits attributable to the regulations for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act.

Statement of need for proposed action

These proposed regulations clarify and interpret the HIPAA portability provisions under Section 701 of the Employee Retirement Income Security Act of 1974 (ERISA), Section 2701 of the Public Health Service Act, and Section 9801 of the Internal Revenue Code of 1986. The regulations are needed to secure and implement HIPAA’s portability rights for individuals who are not timely notified that their coverage has ended and for individuals whose coverage ends in connection with the taking of leave that is guaranteed under FMLA, and to clarify and secure individuals’ special enrollment rights under HIPAA.

Economic effects

As noted above, HIPAA’s primary economic effects ensue directly from its statutory provisions. HIPAA’s statutory group market portability provisions extend cov-

erage to certain individuals and preexisting conditions not otherwise covered. This extension of coverage entails both benefits and costs. The economic effects of HIPAA’s statutory portability provisions is summarized above and discussed in detail under the “Basis for Assessment of Economic Impact” section of the preamble to the final regulation, published elsewhere in this issue of the Bulletin.

Also as noted above, by clarifying and securing HIPAA’s statutory portability protections, these regulations will help ensure that HIPAA rights are fully realized. The result is likely to be a small increase at the margin in the economic effects of HIPAA’s statutory portability provisions. The benefits of these regulations will be concentrated among a small number of affected individuals, while their costs will be spread thinly across plans and issuers. The regulations also will reduce uncertainty about health benefits’ scope and value, thereby promoting employee health benefit coverage and labor market efficiency. The Departments believe that the regulations’ benefits will justify their cost. The Departments assessment of the expected economic effects of the regulation are summarized above and discussed in detail below.

Regulatory Flexibility Act — The Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Section 603 of the RFA stipulates that an agency, unless it certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, must present an initial regulatory flexibility analysis at the time of publication of the notice of proposed rulemaking that describes the impact of the rule on small entities and seeks public comment on such impact. Small entities include small businesses, organizations, and governmental jurisdictions.

For purposes of analysis under the RFA, the Departments consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis for this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for simplified annual reporting and disclosure if the statutory requirements of part 1 of Title I of ERISA would otherwise be inappropriate for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department of Labor has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46 and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans covering fewer than 100 participants and which satisfy certain other requirements.

Further, while some small plans are maintained by large employers, most are maintained by small employers. Both small and large plans may enlist small third party service providers to perform administrative functions, but it is generally understood that third party service providers transfer their costs to their plan clients in the form of fees. Thus, the Departments believe that assessing the impact of this rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (5 U.S.C. 631 *et seq.*). The Department of Labor solicited comments on the use of this standard for evaluating the effects of the proposal on small entities. No comments were received with respect to the standard. Therefore, a summary of the initial regulatory flexibility analysis based on the 100 participant size standard is presented below.

The economic effects of HIPAA’s statutory provisions on small plans are discussed extensively under the “Regulatory Flexibility Act — Department of Labor and Department of Health and Hu-

man Services” section of the preamble to the final regulation, published elsewhere in this issue of the Bulletin.

By clarifying and securing HIPAA’s statutory portability protections, these regulations will help ensure that these benefits are fully realized. The result is likely to be a small increase in the economic effects of HIPAA’s statutory provisions. The Departments were unable to estimate the amount of this increase. However, the direct financial value of coverage extensions pursuant to HIPAA’s statutory portability provisions are estimated to be approximately \$180 million for small plans, or a small fraction of one percent of total small plan expenditures.²

The regulations also will reduce uncertainty about health benefits’ scope and value, thereby promoting employee health benefit coverage, including coverage under small plans, and labor market efficiency.

The benefits of these regulations will be concentrated among a small number of affected small group plan enrollees, while their costs will be spread thinly across small group plans enrollees. The benefits of these regulations for any particular affected individual, which may include improved health and productivity, may be significant. However, as previously noted, the number of affected individuals, and therefore the aggregate cost of these regulations, is expected to be small. The Departments believe that the benefits to affected individuals of the application of these regulations to small plans justify the cost to small plans of such application. The basis for the Departments’ conclusions is detailed below.

The Departments generally expect the impact of the regulations on any particular small plan to be small. A very large majority of small plans are fully insured, so the cost will fall nominally on issuers rather than from plans. Issuers are expected to pass this cost back to plans and enrollees, but will spread much of it across a large number of plans, thereby minimizing the impact on any particular plan. However, it is possible that small plans that self-insure, or fully insured small plans whose premiums are tied closely to their particular

claims experience, might bear all or most of the cost associated with extensions of coverage attributable directly to these regulations. The Departments have no way to quantify the incidence or magnitude of such costs, and solicit comments on such incidence and magnitude, and on whether these regulations would have a significant impact on a substantial number of small plans.

Special Analyses — Department of the Treasury

Notwithstanding the determinations of the Departments of Labor and of Health and Human Services, for purposes of the Department of the Treasury this notice of proposed rulemaking is not a significant regulatory action. Because this notice of proposed rulemaking does not impose a collection of information on small entities and is not subject to section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5), the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply pursuant to 5 U.S.C. 603(a), which exempts from the Regulatory Flexibility Act’s requirements certain rules involving the internal revenue laws. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Paperwork Reduction Act

Department of Labor

These final regulations include three separate collections of information as that term is defined in the Paperwork Reduction Act of 1995 (PRA 95), 44 U.S.C. 3502(3): the Notice of Enrollment Rights, Notice of Preexisting Condition Exclusion, and Certificate of Creditable Coverage. Each of these disclosures is currently approved by the Office of Management and Budget (OMB) through October 31, 2006, in accordance with PRA 95 under control numbers 1210–0101, 1210–0102, and 1210–0103.

Department of the Treasury

These final regulations include a collection of information as that term is defined in PRA 95: the Notice of Enrollment Rights, Notice of Preexisting Condition Exclusion, and Certificate of Creditable Coverage. Each of these disclosures is currently approved by OMB under control number 1545–1537.

Department of Health and Human Services

These final regulations include three separate collections of information as that term is defined in PRA 95: the Notice of Enrollment Rights, Notice of Preexisting Condition Exclusion, and Certificate of Creditable Coverage. Each of these disclosures is currently approved by OMB through June 30, 2006, in accordance with PRA 95 under control number 0938–0702.

Small Business Regulatory Enforcement Fairness Act

The rule being issued here is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, will be transmitted to Congress and the Comptroller General for review. The rule is not a “major rule” as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. These

² Computer runs using Medical Expenditure Survey Household Component (MEPS-HC) and the Robert Wood Johnson Employer Health Benefits Survey determined that the share of covered private-sector job leavers at small firms average 35 percent of all covered private sector job leavers. From this, we inferred that the financial burden borne by small plans is approximately 35 percent of the total expenditures by private-sector group health plans which was estimated to be \$515 million.

proposed regulations have no such mandated consequential effect on state, local, or tribal governments, or on the private sector.

Federalism Statement Under Executive Order 13132 — Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by federal agencies in formulating and implementing policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments’ view, these proposed regulations have federalism implications because they may have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. However, in the Departments’ view, the federalism implications of these proposed regulations are substantially mitigated because, with respect to health insurance issuers, the vast majority of States have enacted laws which meet or exceed the federal HIPAA portability standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new section to ERISA (as well as to the PHS Act) narrowly preempting State requirements for issuers of group health insurance coverage. Specifically, with respect to seven provisions of the HIPAA portabil-

ity rules, states may impose stricter obligations on health insurance issuers.³ Moreover, with respect to other requirements for health insurance issuers, states may continue to apply state law requirements except to the extent that such requirements prevent the application of HIPAA’s portability, access, and renewability provisions.

In enacting these new preemption provisions, Congress intended to preempt State insurance requirements only to the extent that they prevent the application of the basic protections set forth in HIPAA. HIPAA’s conference report states that the conferees intended the narrowest preemption of State laws with regard to health insurance issuers. H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205 (1996). State insurance laws that are more stringent than the federal requirements are unlikely to “prevent the application of” the HIPAA portability provisions, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance insurers that are more restrictive than the federal law.

Guidance conveying this interpretation of HIPAA’s preemption provisions was published in the **Federal Register** on April 8, 1997, 62 F.R. 16904. These proposed regulations clarify and implement the statute’s minimum standards and do not significantly reduce the discretion given the States by the statute. Moreover, the Departments understand that the vast majority of States have requirements that meet or exceed the minimum requirements of the HIPAA portability provisions.

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. To date, CMS enforces the HIPAA portability provisions in only one State in accordance with that State’s specific request to do so. When exercising its responsibility to enforce the provisions of HIPAA, CMS works cooperatively with the State for the purpose of addressing the State’s concerns and avoiding conflicts with the exercise of State authority. CMS has developed procedures to implement its

enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA’s requirements in the first instance. CMS’s procedures address the handling of reports that States may not be enforcing HIPAA’s requirements, and the mechanism for allocating responsibility between the States and CMS. In compliance with Executive Order 13132’s requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the States, the Department of Labor and CMS have engaged in numerous efforts to consult and work cooperatively with affected State and local officials.

For example, the Departments sought and received input from State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and the four U.S. territories. In most States the Insurance Commissioner is appointed by the Governor, in approximately 14 States, the insurance commissioner is an elected official. Among other activities, it provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas and in-depth consideration of insurance issues by regulators, industry representatives and consumers. CMS and the Department of Labor staff have consistently attended these quarterly meetings to listen to the concerns of the State Insurance Departments regarding HIPAA portability issues. In addition to the general discussions, committee meetings, and task groups, the NAIC sponsors the standing CMS/DOL meeting on HIPAA issues for members during the quarterly conferences. This meeting provides CMS and the Department of Labor with the opportunity to provide updates on regulations, bulletins, enforcement actions, and outreach efforts regarding HIPAA.

The Departments received written comments on the interim regulation from the

³ States may shorten the six-month look-back period prior to the enrollment date; shorten the 12-month and 18-month maximum preexisting condition exclusion periods; increase the 63-day significant break in coverage period; increase the 30-day period for newborns, adopted children, and children placed for adoption to enroll in the plan with no preexisting condition exclusion; further limit the circumstances in which a preexisting condition exclusion may be applied (beyond the federal exceptions for certain newborns, adopted children, children placed for adoption, pregnancy, and genetic information in the absence of a diagnosis; require additional special enrollment periods; and reduce the HMO affiliation period to less than 2 months (3 months for late enrollees).

NAIC and from ten States. In general, these comments raised technical issues that the Departments considered in conjunction with similar issues raised by other commenters. In a letter sent before issuance of the interim regulation, the NAIC expressed concerns that the Departments interpret the new preemption provisions of HIPAA narrowly so as to give the States flexibility to impose more stringent requirements. As discussed above, the Departments address this concern in the preamble to the interim regulation.

In addition, the Departments specifically consulted with the NAIC in developing these proposed regulations. Through the NAIC, the Departments sought and received the input of State insurance departments regarding certain insurance industry definitions, enrollment procedures and standard coverage terms. This input is generally reflected in the discussion of comments received and changes made in Section B — Overview of the Regulations of the preamble to the final regulations published elsewhere in this issue of the Bulletin.

The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information on HIPAA is shared among federal regulators, State regulators and the regulated community. In particular, the Department of Labor has established a Health Benefits Education Campaign with more than 70 partners, including CMS, NAIC and many business and consumer groups. CMS has sponsored conferences with the States — the Consumer Outreach and Advocacy conferences in March 1999 and June 2000, and the Implementation and Enforcement of HIPAA National State-Federal Conferences in August 1999, 2000, 2001, 2002, and 2003. Furthermore, both the Department of Labor and CMS websites offer links to important State websites and other resources, facilitating coordination

between the State and federal regulators and the regulated community.

Throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and the Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in Section 8(a) of Executive Order 13132, and by the signatures affixed to proposed final regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached proposed regulation, Notice of Proposed Rulemaking for Health Coverage Portability: Tolling and Certain Time Periods and Interaction with the Family and Medical Leave Act under HIPAA Titles I & IV (RIN 1210-AA54 and RIN 0938-AL88), in a meaningful and timely manner.

Basis for Assessment of Economic Impact — Department of Labor and Department of Health and Human Services

As noted above, the primary economic effects of HIPAA's portability provisions ensue directly from the statute. The Department's assessment of the economic effects of HIPAA's statutory portability provisions and the basis for the assessment is presented in detail under the "Basis for Assessment of Economic Impact" section of the preamble to the final regulation, published elsewhere in this issue of the Bulletin. By clarifying and securing HIPAA's statutory portability protections, these regulations will help ensure that HIPAA rights are fully realized. The result is likely to be

a small increase in the economic effects of HIPAA's statutory portability provisions.

Additional economic benefits derive from the regulations' clarifications of HIPAA's portability requirements. The regulations provide clarity through both their provisions and their examples of how those provisions apply in various circumstances. By clarifying employees' rights and plan sponsors' obligations under HIPAA's portability provisions, the regulations will reduce uncertainty and costly disputes over these rights and obligations. They will promote employers' and employees' common understanding of the value of group health plan benefits and confidence in the security and predictability of those benefits, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans by employers.⁴

These proposed regulations are intended to secure and implement HIPAA's group market portability provisions under certain special circumstances. The regulations will secure HIPAA's portability rights for individuals who are not timely notified that their coverage has ended and for individuals whose coverage ends in connection with the taking of leave that is guaranteed under FMLA. The regulations also will clarify and thereby secure individuals' special enrollment rights under HIPAA, and clarify the methodologies to be used by employers to determine the number of plans offered and the average number of individuals employed during a given year.

The benefits of these regulations will be concentrated among a small number of affected individuals.

Affected individuals will generally include those who would have lost access to coverage for needed medical care after forfeiting HIPAA portability and/or special enrollment rights due to time spent without coverage prior to receiving a certificate or while on FMLA-guaranteed leave. Af-

⁴ The voluntary nature of the employment-based health benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. It is likely that 80% to 100% of the cost of employee benefits is borne by workers through reduced wages (see for example Jonathan Gruber and Alan B. Krueger, "The Incidence of Mandated Employer-Provided Insurance: Lessons from Workers Compensation Insurance," in David Bradford, ed., *Tax Policy and Economy*, pp:111-143 (Cambridge, MA: MIT Press, 1991); Jonathan Gruber, "The Incidence of Mandated Maternity Benefits," *American Economic Review*, Vol. 84 No. 3 (June 1994), pp. 622-641; Lawrence H. Summers, "Some Simple Economics of Mandated Benefits," *American Economic Review*, Vol. 79, No. 2 (May 1989), pp:177-183; Louise Sheiner, "Health Care Costs, Wages, and Aging," Federal Reserve Board of Governors working paper, April 1999; Mark Pauly and Brad Herring, *Pooling Health Insurance Risks* (Washington, DC: AEI Press, 1999); Gail A. Jensen and Michael A. Morrissey, "Endogenous Fringe Benefits, Compensating Wage Differentials and Older Workers," *International Journal of Health Care Finance and Economics* Vol 1, No. 3-4 (forthcoming), and Edward Montgomery, Kathryn Shaw, and Mary Ellen Benedict, "Pensions and Wages: An Hedonic Price Theory Approach," *International Economic Review*, Vol. 33 No. 1 (Feb. 1992.), pp:111-128.) The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits they will discount their value to adjust for this risk. This discount drives a wedge in the compensation negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. The extent to which workers perceive a federal regulation supported by enforcement authority to improve the security and quality of benefits, the differential between the employers costs and workers willingness to accept wage offsets is minimized.

affected individuals may also include some who would have been denied special enrollment rights if plans or issuers failed to recognize their requests for special enrollment or imposed unreasonable deadlines or requirements for completion of enrollment materials. The benefits of these regulations for any particular affected individual may be large. As noted above, access to coverage for needed medical care is important to individuals' health and productivity. However, the number of affected individuals, and therefore the aggregate cost of extended access to coverage under these regulations, is expected to be small, for several reasons.

First, these regulations extend HIPAA rights only in instances where individuals do not receive certificates immediately when coverage ends or their coverage ends in connection with the taking of FMLA-guaranteed leave. The Departments know of no source of data on the timeliness with which certificates are typically provided. The final regulations that accompany these proposed regulations permit plans to provide certificates with COBRA notices, up to 44 days after coverage ends. Plans, however, often do have the option of providing certificates immediately when coverage ends or even in advance, for example as part of exit packages given to terminating employees or in mailings to covered dependents in advance of birthdays that will end their eligibility for coverage. With respect to FMLA-protected leave, data provided in a 1996 report to Congress suggests that the number of employees who lose coverage in connection with FMLA-protected leave is likely to be small. The report notes that over an 18-month period just 1.2 percent of surveyed employees took what they reported to be FMLA leave. A similar survey of employers found that 3.6 percent of employees took such leave. Nearly all of those taking leave continued their health coverage. (This is not surprising, given that FMLA requires covered employers to extend eligibility for health insurance to employees on FMLA-protected leave on the same terms that applied when the em-

ployees were not on leave.) Just 9 percent of leave-takers reported that they lost some kind of employee benefit, with one-third of these reporting that they lost health insurance.⁵ Putting these numbers together and converting to an annual basis, in a given year between 0.02 percent and 0.07 percent of employees, or well under one in one thousand, might lose health coverage in connection with FMLA-protected leave. Many of these will ultimately exercise their right to be reinstated in the job from which they took leave and to exercise their FMLA-guaranteed right to resume their previous health coverage. Therefore, the number of employees who will lose coverage and then, later and at the conclusion of FMLA-protected leave, enjoy extended portability rights under HIPAA as a result of these regulations, is likely to be very small.

Second, the period over which this regulation extends rights will often be short, insofar as certificates are often provided promptly after coverage ends and many family leave periods are far shorter than the guaranteed 12 weeks. As noted above, plans generally are required to provide certificates no later than 44 days after coverage ends and may provide them sooner. According to the aforementioned report to Congress on FMLA-protected leave, 41 percent of employees taking FMLA-protected leave did so for less than 8 days. Fifty-eight percent were on leave for less than 15 days, and two-thirds were on leave for less than 29 days. (FMLA protects leaves of up to 12 weeks, or 84 days.)

Third, it is generally in individuals' interest to minimize periods of uninsurance. Individuals are likely to exercise their portability and special enrollment rights as soon as possible after coverage ends, which will often be before any extension of such rights under these regulations becomes effective. Over one 36-month period prior to HIPAA, 71 percent of Americans had continuous coverage — that is, incurred not even a single, one-month break in coverage. Just 4 percent were uninsured for the entire period. About one-half of observed spells without insur-

ance lasted less than 5 months. As noted above, few employees taking FMLA-protected leave had a lapse in health coverage.

Fourth, only a portion of individuals who enroll in health plans in circumstances where these regulations alone guarantee their special enrollment or portability rights would otherwise have been denied such rights. HIPAA special enrollment and portability requirements, both as specified under the final regulations and as modified under these proposed regulations, are minimum standards. Plans are free to provide additional enrollment opportunities.

Fifth, only a small minority of individuals who avoid a significant break in coverage solely as a direct result of these regulations would otherwise have lost coverage for needed medical care. The affected minority would be those who suffer from pre-existing conditions, join health plans that exclude coverage for such conditions, and require treatment of such conditions during the exclusion periods. GAO estimated that HIPAA could ensure continued coverage for up to 25 million Americans.⁶ More recent estimates suggest that the number of individual policy holders and their dependents which could be helped by HIPAA's portability provisions are more in the 14 million range.⁷ As noted above, however, the number of workers and dependents actually gaining coverage for a preexisting condition due to credit for prior coverage following a job change under HIPAA will be smaller than this. Both GAO's and our estimates of people who could benefit include all job changers with prior coverage and their dependents, irrespective of whether their new employer offers a plan, whether their new plan imposed a pre-existing condition exclusion period, and whether they actually suffer from a pre-existing condition. Accounting for these narrower criteria, CBO estimated that, at any point in time, about 100,000 individuals would have a preexisting condition exclusion reduced for prior creditable coverage. An additional 45,000 would gain added coverage in the individual market. The CBO estimate demonstrates that the num-

⁵ Commission on Family and Medical Leave and U.S. Department of Labor, *A Workable Balance: Report to Congress on Family and Medical Leave Policies*, transmitted April 30, 1996.

⁶ U.S. General Accounting Office, Report HEHS-95-257, "Health Insurance Portability: Reform Could Ensure Continued Coverage for up to 25 Million Americans," September 1995.

⁷ We calculated these estimates using internal runs off the MEPS-HC. These runs gave the number of total job changers, total job changers that had employer-sponsored insurance (ESI), and whether this coverage had been for less than 12 months or not. Estimates for dependents were based off the ratio of policy-holders to total dependents from the March 2003 Current Population Survey (March CPS). It should be noted, however, that the EBSA estimate of 14 million does not include estimate of individuals no longer eligible for COBRA continuation coverage or individuals facing job lock, while the GAO numbers do.

ber of individuals actually gaining coverage for needed medical services will be a small fraction of all those whose right to such coverage HIPAA's portability provisions guarantee. Accordingly, the Departments expect that the number gaining coverage for needed services as a direct result of these regulations will be a small fraction of the already small number whose right to such coverage these regulations would establish.

The Departments attempted to estimate the number of individuals who might avoid a break in coverage because of the provision of these proposed regulations that tolls the break until the individual receives a certification but not more than 44 days. The Departments examined coverage patterns evident in the Survey of Income and Program Participation (SIPP), a longitudinal household survey that tracks transitions in coverage. SIPP interviews households once every four months. The Departments estimate that, in a given year, about 7 million individuals have breaks in coverage lasting 4 months or less. The survey data suffer from so-called "seam bias" — respondents tend to report that status as unchanged over 4-month increments. Of the 7 million reporting breaks of 4 months or less, 6.5 million report breaks of exactly 4 months. This finding is consistent with the more general finding that breaks of 4 months or less are far more common than longer breaks. It seems likely that the 7 million breaks of 4 months or less actually included proportionate or disproportionately large share of breaks of 1 or 2 months. Assuming the breaks are actually distributed evenly by length between 1 day and 4 months, then about one-half of the breaks, or 3.5 million breaks, would have lasted less than 63 days and therefore would not have constituted breaks for purposes of HIPAA's portability protections even without reference to the provision of this proposed regulation that tolls the break until the individual receives a certification but not more than 44 days. Approximately three-fourths of the remaining breaks or about 2.6 million breaks, would have lasted between 1 and 44 additional days and thereby potentially have been tolled until the individuals received their certifications but not more than 44 days. Thus 2.6 million provides a reasonable upper bound on the number of individuals who might avoid a break in

coverage in a given year because of this tolling provision. It is not known what fraction of these would subsequently join group health plans that include preexisting condition exclusions while suffering from and requiring additional care for preexisting conditions. Comparing GAO's (20 million or more) and our (14 million) estimates of the number of individuals who could potentially benefit from HIPAA's portability protections (individuals with prior creditable coverage who join new health plans in a given year) with the CBO estimate of the number who might actually have added group coverage for needed care (100,000) produces a ratio of about 1 percent. If this proportion holds for group health plan enrollees who avoid breaks because of this tolling provision, then an upper bound of about 26,000 individuals annually might gain coverage for needed care under the proposed regulation's provision treating coverage under such programs as creditable coverage.

The Departments considered whether certain individuals whose HIPAA portability rights these proposed regulations would extend may be disproportionately likely to be in (or have dependents who are in) poor health. Specifically, individuals taking FMLA-protected leave, especially those who elect not to be reinstated in their prior jobs following FMLA-protected leave, may be so likely. On the other hand, individuals in such circumstances are also particularly unlikely to allow their health insurance from their prior job to lapse while they are on leave. Accordingly, most such individuals' special enrollment periods and countable breaks in coverage (if any) would probably have begun at the conclusion of the FMLA-protected leave even in absence of these proposed regulations. The Departments are therefore uncertain whether individuals who would exercise HIPAA portability rights extended solely by these regulations would be more costly to insure than others exercising HIPAA portability rights, and solicit comments on this question.

Affected individuals may also include some who would have been denied special enrollment rights if plans or issuers failed to recognize their requests for special enrollment or imposed unreasonable deadlines or requirements for completion of enrollment materials.

As noted above, the Departments expect that these regulations will result in a small increase in the economic effects of HIPAA's statutory provisions. For the reasons stated immediately above, the Departments believe that this increase will be small on aggregate, adding only a small increment to the cost attributable to HIPAA's statutory portability provisions, which themselves amount to a small fraction of one percent of health plan expenditures. Thus the increase will be negligible relative to typical year-to-year increases in premiums charged by issuers, which can amount to several percentage points or more. Therefore, the Departments expect these regulations to have little or no perceptible negative impact on employers' propensity to offer health benefit plans or on the generosity of those plans. In sum, the Departments expect that the benefits of these regulations, which can be very large for a particular affected individual, will justify their costs.

* * * * *

Proposed Amendments to the Regulations

Internal Revenue Service
26 CFR Chapter I

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54 — PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by:

- a. Revising the entries for §§54.9801–4 and 54.9801–6.
- b. Adding an entry in numerical order for §54.9801–7.

The addition and revisions read as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9801–4 also issued under 26 U.S.C. 9801(e)(3) and 9833. * * *

Section 54.9801–6 also issued under 26 U.S.C. 9801(e)(3) and 9833.

Section 54.9801–7 also issued under 26 U.S.C. 9833. * * *

§54.9801–1 [Amended]

Par. 2. Section 54.9801–1 is amended in paragraph (a)(1) by removing the language "54.9801–6" and adding "54.9801–7" in its place.

§54.9801-2 [Amended]

Par. 3. Section 54.9801-2 is amended in the first sentence by removing the language “54.9801-6” and adding “54.9801-7” in its place.

Par. 4. Section 54.9801-4 is amended by:

a. Revising paragraphs (b)(2)(iii) and (b)(2)(iv).

b. Adding *Examples 4* and *6* in paragraph (b)(2)(v).

The revisions and additions read as follows:

§54.9801-4 Rules relating to creditable coverage.

(b) *Standard method.******

(2) *Counting creditable coverage.******

(iii) *Significant break in coverage defined.* A significant break in coverage means a period of 63 consecutive days during each of which an individual does not have any creditable coverage, except that periods described in paragraph (b)(2)(iv) of this section are not taken into account in determining a significant break in coverage. (See section 731(b)(2)(iii) of ERISA and section 2723(b)(2)(iii) of the PHS Act, which exclude from preemption state insurance laws that require a break of more than 63 days before an individual has a significant break in coverage for purposes of state law.)

(iv) *Periods that toll a significant break.* 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. Moreover, in the case of an individual whose coverage ceases, if a certificate of creditable coverage with respect to that cessation is not provided on or before the date coverage ceases, then the period that begins on the first date that an individual has no creditable coverage and that continues through the earlier of the following two dates is not

taken into account in determining whether a significant break in coverage has occurred:

(A) The date that a certificate of creditable coverage with respect to that cessation is provided; or

(B) The date 44 days after coverage ceases.

(v) *Examples.******

Example 4. (i) *Facts.* Individual *B* terminates coverage under a group health plan, and a certificate of creditable coverage is provided 10 days later. *B* begins employment with Employer *R* and begins enrollment in *R*'s plan 60 days after the certificate is provided.

(ii) *Conclusion.* In this *Example 4*, even though *B* had no coverage for 69 days, the 10 days before the certificate of creditable coverage is provided are not taken into account in determining a significant break in coverage. Therefore, *B*'s break in coverage is only 59 days and is not a significant break in coverage. Accordingly, *B*'s prior coverage must be counted by *R*'s plan.

Example 6. (i) *Facts.* Employer *V* sponsors a group health plan. Under the terms of the plan, the only benefits provided are those provided under an insurance policy. Individual *D* works for *V* and has creditable coverage under *V*'s plan. *V* fails to pay the issuer the premiums for the coverage period beginning March 1. Consistent with applicable state law, the issuer terminates the policy so that the last day of coverage is April 30. *V* goes out of business on July 31. On August 15 *D* begins employment with Employer *W* and enrolls in *W*'s group health plan. *W*'s plan imposes a 12-month preexisting condition exclusion on all enrollees. *D* never receives a certificate of creditable coverage for coverage under *V*'s plan.

(ii) *Conclusion.* In this *Example 6*, the period from May 1 (the first day without coverage) through June 13 (the date 44 days after coverage under *V*'s plan ceases) is not taken into account in determining a 63-day break in coverage. This is because, in cases in which a certificate of creditable coverage is not provided by the date coverage is lost, the break begins on the date the certificate is provided, or the date 44 days after coverage ceases, if earlier. Therefore, even though *D*'s actual period without coverage was 106 days (May 1 through August 14), because the period from May 1 through June 13 is not taken into account, *D*'s break in coverage is only 62 days (June 14 through August 14). Thus, *D* has not experienced a significant break in coverage, and *D*'s prior coverage must be counted by *W*'s plan.

Par. 5. Section 54.9801-5 is amended by:

a. Redesignating paragraphs (a)(3)(ii)(H)(5) and (6) as paragraphs (a)(3)(ii)(H)(6) and (7), respectively.

b. Adding a new paragraph (a)(3)(ii)(H)(5).

The addition reads as follows:

§54.9801-5 Evidence of creditable coverage.

(a) *Certificate of creditable coverage.******

(3) *Form and content of certificate.******

(ii) *Required information.******

(H)*****

(5) The interaction with the Family and Medical Leave Act;

Par. 6. Section 54.9801-6 is amended by:

a. Revising paragraph (a)(1).

b. Revising paragraph (a)(4).

c. Revising paragraph (b)(1).

d. Revising paragraph (b)(3).

e. Revising *Example 2* in paragraph (b)(4).

f. Adding *Examples 3, 4, and 5* in paragraph (b)(4).

The additions and revisions read as follows:

§54.9801-6 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage* — (1) *In general.* A group health plan is required to permit current employees and dependents (as defined in §54.9801-2) who are described in paragraph (a)(2) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(3) of this section are satisfied. Paragraph (a)(4) of this section describes procedures that a plan may require an employee to follow and describes the date by which coverage must begin. The special enrollment rights under this paragraph (a) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan. (See section 701(f)(1) of ERISA and section 2701(f)(1) of the PHS Act, under which this obligation is also imposed on a health insurance issuer offering group health insurance coverage.)

(4) *Applying for special enrollment and effective date of coverage* — (i) *Request.* A plan must allow an employee a period of at least 30 days after an event described in paragraph (a)(3) of this section (loss of eligibility for coverage, termination of employer contributions, or exhaustion of

COBRA continuation coverage) to request enrollment (for the employee or the employee's dependent). For this purpose, any written or oral request made to any of the following constitutes a request for enrollment —

(A) The plan administrator;

(B) An issuer offering health insurance coverage under the plan;

(C) A person who customarily handles claims for the plan (such as a third party administrator); or

(D) Any other designated representative.

(ii) *Tolling of period for requesting special enrollment.* (A) In the case of an individual whose coverage ceases, if a certificate of creditable coverage with respect to that cessation is not provided on or before the date coverage ceases, then the period for requesting special enrollment described in paragraph (a)(4)(i) of this section does not end until 30 days after the earlier of —

(1) The date that a certificate of creditable coverage with respect to that cessation is provided; or

(2) The date 44 days after coverage ceases.

(B) For purposes of this paragraph (a)(4), if an individual's coverage ceases due to the operation of a lifetime limit on all benefits, coverage is considered to cease on the earliest date that a claim is denied due to the operation of the lifetime limit. (Nonetheless, the date of a loss of eligibility for coverage is determined under the rules of paragraph (a)(3) of this section, which provides that a loss of eligibility occurs when a claim that would meet or exceed a lifetime limit on all benefits is incurred, not when it is denied.)

(C) The rules of this paragraph (a)(4)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *V* provides group health coverage through a policy provided by Issuer *M*. Individual *D* works for *V* and is covered under *V*'s plan. *V* fails to pay *M* the premiums for the coverage period beginning March 1. Consistent with applicable state law, *M* terminates the policy so that the last day of coverage is April 30. On May 15, *M* provides *D* with a certificate of creditable coverage with respect to *D*'s cessation of coverage under *V*'s plan.

(ii) *Conclusion.* In this *Example 1*, the period to request special enrollment ends no earlier than June 14 (which is 30 days after May 15, the day a certificate of creditable coverage is provided with respect to *D*).

Example 2. (i) *Facts.* Same facts as *Example 1*, except *D* is never provided with a certificate of creditable coverage.

(ii) *Conclusion.* In this *Example 2*, the period to request special enrollment ends no earlier than July 13. (July 13 is 74 days after April 30, the date coverage ceases. That is, July 13 is 30 days after the end of the 44-day maximum tolling period.)

Example 3. (i) *Facts.* Individual *E* works for Employer *W* and has coverage under *W*'s plan. *W*'s plan has a lifetime limit of \$1 million on all benefits under the plan. On September 13, *E* incurs a claim that would exceed the plan's lifetime limit. On September 28, *W* denies the claim due to the operation of the lifetime limit and a certificate of creditable coverage is provided on October 3. *E* is otherwise eligible to enroll in the group health plan of the employer of *E*'s spouse.

(ii) *Conclusion.* In this *Example 3*, the period to request special enrollment in the plan of the employer of *E*'s spouse ends no earlier than November 2 (30 days after the date the certificate is provided) and begins not later than September 13, the date *E* lost eligibility for coverage.

(iii) *Reasonable procedures for special enrollment.* After an individual has requested enrollment under paragraph (a)(4)(i) of this section, a plan may require the individual to complete enrollment materials within a reasonable time after the end of the 30-day period described in paragraph (a)(4)(i) of this section. In these enrollment materials, the plan may require the individual only to provide information required of individuals who enroll when first eligible and information about the event giving rise to the special enrollment right. A plan may establish a deadline for receiving completed enrollment materials, but such a deadline must be extended for information that an individual making reasonable efforts does not obtain by that deadline.

(iv) *Date coverage must begin.* If the plan requires completion of additional enrollment materials in accordance with paragraph (a)(4)(iii) of this section, 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. If the plan does not require 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 under paragraph (a)(4)(i) of this section.

(b) *Special enrollment with respect to certain dependent beneficiaries* — (1) *In general.* A group health plan that makes

coverage available with respect to dependents is required to permit individuals described in paragraph (b)(2) of this section to be enrolled for coverage in a benefit package under the terms of the plan. Paragraph (b)(3) of this section describes procedures that a plan may require an individual to follow and describes the date by which coverage must begin. The special enrollment rights under this paragraph (b) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan. (See 29 CFR 2590.701-6(b) and 45 CFR 146.117(b), under which this obligation is also imposed on a health insurance issuer offering group health insurance coverage.)

* * * * *

(3) *Applying for special enrollment and effective date of coverage* — (i) *Request.* A plan must allow an individual a period of at least 30 days after the date of the marriage, birth, adoption, or placement for adoption (or, if dependent coverage is not generally made available at the time of the marriage, birth, adoption, or placement for adoption, a period of at least 30 days after the date the plan makes dependent coverage generally available) to request enrollment (for the individual or the individual's dependent). For this purpose, any written or oral request made to any of the following constitutes a request for enrollment —

(A) The plan administrator;

(B) An issuer offering health insurance coverage under the plan;

(C) A person who customarily handles claims for the plan (such as a third party administrator); or

(D) Any other designated representative.

(ii) *Reasonable procedures for special enrollment.* After an individual has requested enrollment under paragraph (b)(3)(i) of this section, a plan may require the individual to complete enrollment materials within a reasonable time after the end of the 30-day period described in paragraph (b)(3)(i) of this section. In these enrollment materials, the plan may require the individual only to provide information required of individuals who enroll when first eligible and information about the event giving rise to the special enrollment right. A plan may establish a deadline for receiving completed enrollment materials, but such a deadline must be extended

for information that an individual making reasonable efforts does not obtain by that deadline.

(iii) *Date coverage must begin — (A) Marriage.* In the case of marriage, if the plan requires completion of additional enrollment materials in accordance with paragraph (b)(3)(ii) of this section, 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. If the plan does not require such 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 under paragraph (b)(3)(i) of this section.

(B) *Birth, adoption, or placement for adoption.* Coverage must begin in the case of a dependent's birth on the date of birth and in the case of a dependent's adoption or placement for adoption no later than the date of such adoption or placement for adoption (or, if dependent coverage is not made generally available at the time of the birth, adoption, or placement for adoption, the date the plan makes dependent coverage available). If the plan requires completion of additional enrollment materials in accordance with paragraph (b)(3)(ii) of this section, the plan must provide benefits (including benefits retroactively to the date of birth, adoption, or placement for adoption) once the plan receives enrollment materials that are substantially complete.

(4) *Examples.* * * *

Example 2. (i) *Facts.* Individual *D* works for Employer *X*. *X* maintains a group health plan with two benefit packages — an HMO option and an indemnity option. Self-only and family coverage are available under both options. *D* enrolls for self-only coverage in the HMO option. Then, a child, *E*, is placed for adoption with *D*. Within 30 days of the placement of *E* for adoption, *D* requests enrollment for *D* and *E* under the plan's indemnity option and submits completed enrollment materials timely.

(ii) *Conclusion.* In this *Example 2*, *D* and *E* satisfy the conditions for special enrollment under paragraphs (b)(2)(v) and (b)(3) of this section. Therefore, the plan must allow *D* and *E* to enroll in the indemnity coverage, effective as of the date of the placement for adoption.

Example 3. (i) *Facts.* Same facts as *Example 1*. On March 17 (two days after the birth of *C*), *A* telephones the plan administrator and requests special enrollment of *A*, *B*, and *C*. The plan administrator sends *A* an enrollment form. Under the terms of the plan, enrollment is denied unless a completed form is submitted within 30 days of the event giving rise to the special enrollment right (in this case, *C*'s birth).

(ii) *Conclusion.* In this *Example 3*, the plan does not satisfy paragraph (b)(3) of this section. The plan may require only that *A* request enrollment during the 30-day period after *C*'s birth. *A* did so by telephoning the plan administrator. The plan may not condition special enrollment on filing additional enrollment materials during the 30-day period. To comply with paragraph (b)(3) of this section, the plan must allow *A* a reasonable time after the end of the 30-day period to submit any additional enrollment materials. Once these enrollment materials are received, the plan must allow whatever coverage is chosen to begin on March 15, the date of *C*'s birth.

Example 4. (i) *Facts.* Same facts as *Example 3*, except that *A* telephones the plan administrator to request enrollment on April 13 (29 days after *C*'s birth). Also, under the terms of the plan, the deadline for submitting the enrollment form is 14 days after the end of the 30-day period for requesting special enrollment (thus, in this case, April 28, which is 44 days after *C*'s birth). The form requests the same information for *A*, *B*, and *C* (name, date of birth, and place of birth) as well as a copy of *C*'s birth certificate. *A* fills out the enrollment form and delivers it to the plan administrator on April 28. At that time *A* does not have a birth certificate for *C* but applies on that day for one from the appropriate government office. *A* receives the birth certificate on June 1 and furnishes a copy of the birth certificate to the plan administrator shortly thereafter.

(ii) *Conclusion.* In this *Example 4*, *A*, *B*, and *C* are entitled to special enrollment under the plan even though *A* did not satisfy the plan's requirement of providing a copy of *C*'s birth certificate by the plan's 14-day deadline. While a plan may establish such a deadline, the plan must extend the deadline for information that an individual making reasonable efforts does not obtain by that deadline. *A* delivered the enrollment form to the plan administrator by the deadline and made reasonable efforts to furnish the birth certificate that the plan requires.

Example 5. (i) *Facts.* Same facts as *Example 4*. On May 3 (after *A* has delivered the enrollment form to the plan administrator but before *A* provides the birth certificate) *A* submits claims for all medical expenses incurred for *B* and *C* from the date of *C*'s birth.

(ii) *Conclusion.* In this *Example 5*, the plan must pay all of the claims submitted by *A*. Because the plan requires that individuals seeking special enrollment complete additional enrollment materials, it is required to provide benefits once it receives enrollment materials that are substantially complete. The form that *A* submitted on April 28 was substantially complete. Because *C*'s birth is the event giving rise to the special enrollment right, on April 28 *A*, *B*, and *C* become entitled to benefits under the plan retroactive to the date of *C*'s birth.

* * * * *

Par. 7. A new §54.9801-7 is added to read as follows:

§54.9801-7 *Interaction with the Family and Medical Leave Act.*

(a) *In general.* The rules of §§54.9801-1 through 54.9801-6 apply

with respect to an individual on leave under the Family and Medical Leave Act of 1993 (29 U.S.C. 2601) (FMLA), and apply with respect to a dependent of such an individual, except to the extent otherwise provided in this section.

(b) *Tolling of significant break in coverage during FMLA leave.* In the case of an individual (or a dependent of the individual) who is covered under a group health plan, 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 under §54.9801-4(b)(2)(iii).

(c) *Application of certification provisions — (1) Timing of issuance of certificate — (i)* In the case of an individual (or a dependent of the individual) who is covered under a group health plan, if the individual takes FMLA leave and the individual's group health coverage is terminated during FMLA leave, an automatic certificate must be provided in accordance with the timing rules set forth in §54.9801-5(a)(2)(ii)(B) (which generally require plans to provide certificates within a reasonable time after coverage ceases).

(ii) In the case of an individual (or a dependent of the individual) who is covered under a group health plan, if the individual takes FMLA leave and continues group health coverage for the period of FMLA leave, but then ceases coverage under the plan at the end of FMLA leave, an automatic certificate must be provided in accordance with the timing rules set forth in §54.9801-5(a)(2)(ii)(A) (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).

(2) *Demonstrating FMLA leave.* (i) A plan is required to take into account all information about FMLA leave that it obtains or that is presented on behalf of an individual. A plan must treat the individual as having been on FMLA leave for a period if —

(A) The individual attests to the period of FMLA leave; and

(B) The individual cooperates with the plan's efforts to verify the individual's FMLA leave.

(ii) Nothing in this section prevents a plan from modifying its initial determina-

tion 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 §54.9801-3(f).

(d) *Relationship to loss of eligibility special enrollment rules.* 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, a loss of eligibility for coverage under §54.9801-6(a) occurs when the period of FMLA leave ends if —

(1) The individual's group health coverage is terminated at any time during FMLA leave; and

(2) The individual does not return to work for the employer at the end of FMLA leave.

Par. 8. Section 54.9831-1 is amended by:

- a. Adding paragraph (a)(2).
- b. Revising paragraph (b).
- c. Revising paragraph (c)(1).
- d. Adding paragraph (e).

The additions and revisions read as follows:

§54.9831-1 Special rules relating to group health plans.

(a) *Group health plan.* * * *

(2) *Determination of number of plans.* The number of group health plans that an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans) maintains is determined under the rules of this paragraph (a)(2).

(i) Except as provided in paragraph (a)(2)(ii) or (iii) of this section, health care benefits provided by a corporation, partnership, or other entity or trade or business, or by an employee organization, constitute one group health plan, unless —

(A) 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

(B) The arrangement or arrangements are operated pursuant to such instruments as separate plans.

(ii) A multiemployer plan and a non-multiemployer plan are always separate plans.

(iii) 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.

(b) *General exception for certain small group health plans.* The requirements of §§54.9801-1 through 54.9801-7, 54.9802-1, 54.9802-2, 54.9811-1T, 54.9812-1T, and 54.9833-1 do not apply to any group health plan for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(c) *Excepted benefits* — (1) *In general.* The requirements of §§54.9801-1 through 54.9801-7, 54.9802-1, 54.9802-2, 54.9811-1T, 54.9812-1T, and 54.9833-1 do not apply to any group health plan in relation to its provision of the benefits described in paragraph (c)(2), (3), (4), or (5) of this section (or any combination of these benefits).

* * * * *

(e) *Determining the average number of employees* — (1) *Scope.* Whenever the application of a rule in this part depends upon the average number of employees employed by an employer, the determination of that number is made in accordance with the rules of this paragraph (e).

(2) *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.

(3) *Methodology.* For the preceding calendar year, the average number of full-time equivalents is determined by —

(i) Determining the number of employees who were employed full-time by the employer throughout the entire calendar year;

(ii) 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;

(iii) Dividing the total determined under paragraph (e)(3)(ii) of this section 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); and

(iv) Adding the quotient determined under paragraph (e)(3)(iii) of this section to the number determined under paragraph (e)(3)(i).

(4) *Rounding.* For purposes of paragraph (e)(3)(iv) of this section, all fractions are disregarded. For instance, a figure of 50.9 is deemed to be 50.

(5) *Employers not in existence in the preceding year.* 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.

(6) *Scope of the term "employer".* For purposes of this paragraph (e), employer includes any predecessor of the employer. In addition, all persons treated as a single employer under section 414(b), (c), (m), or (o) are treated as one employer.

(7) *Special rule for multiemployer plans.* (i) With respect to the application of a rule in this part to a multiemployer plan (as defined in section 3(37) of ERISA), each employer with at least one employee participating in the plan is considered to employ the same average number of employees. That number is the highest number that results by applying the rules of paragraphs (e)(1) through (6) of this section separately to each of the employers.

(ii) The rules of this paragraph (e)(7) are illustrated by the following example:

Example. (i) *Facts.* Twenty five employers have at least one employee who participates in Multiemployer Plan *M*. Among these 25 employers, Employer *K* has 51 employees, determined under the rules of paragraphs (e)(1) through (6) of this section. Each of the other 24 employers has fewer than 50 employees.

(ii) *Conclusion.* With respect to the application of a rule in this part to *M*, each of the 25 employers is considered to employ 51 employees.

Mark E. Matthews,
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