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Final Rules for Group Health Plans and Health Insurance Issuers Under the Newborn and Mothers, Health Protection Act; Final Rule

DEPARTMENT OF THE TREASURY

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Final Rules for Group Health Plans and Health Insurance Issuers Under the Newborns' and Mothers' Health Protection Act

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: Final rules.

SUMMARY: This document contains final rules for group health plans and health insurance issuers concerning hospital lengths of stay for mothers and newborns following childbirth, pursuant to the Newborns' and Mothers' Health Protection Act of 1996 and the Taxpayer Relief Act of 1997.

DATES: *Effective Date:* These final regulations are effective December 19, 2008.

Applicability Dates: Group market rules. These final regulations for the group market apply to group health plans and group health insurance issuers for plan years beginning on or after January 1, 2009.

Individual market rules. These final regulations for the individual market apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; or Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267–2323 extension 61091.

Customer service information: Individuals interested in obtaining copies of Department of Labor publications concerning health care laws may request copies by calling the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or may request a copy of CMS's publication entitled ''Protecting Your Health Insurance Coverage'' by calling 1–800–633–4227. These regulations as well as other information on the Newborns' and Mothers' Health Protection Act and other health care laws are also available on the Department of Labor's Web site (*http://www.dol.gov/ebsa*), including the interactive web pages, Health *E*laws.

SUPPLEMENTARY INFORMATION:

I. Background

The Newborns' and Mothers' Health Protection Act of 1996 (Newborns' Act), Public Law 104–204, was enacted on September 26, 1996. The rules contained in this document implement changes made to the Employee Retirement Income Security Act of 1974 (ERISA) and the Public Health Service Act (PHS Act) made by the Newborns' Act, and parallel changes to the Internal Revenue Code of 1986 (Code) enacted as part of the Taxpayer Relief Act of 1997 (TRA '97). The Newborns' Act was enacted to provide protections for mothers and their newborn children with regard to hospital lengths of stay following childbirth. Interim final rules implementing the group and individual market provisions of the Newborns' Act were published in the **Federal Register** on October 27, 1998 (63 FR 57546) (the interim final rules).

These regulations being published today in the **Federal Register** finalize the interim final rules. The final regulations implementing the group market provisions of the Newborns' Act are issued jointly by the Secretaries of the Treasury, Labor, and HHS.[1] The individual market final regulations are issued solely by HHS.[2]

II. Overview of the Regulations

Section 9811 of the Code, section 711 of ERISA, and sections 2704 and 2751 of the PHS Act (the Newborns' Act provisions) provide a general rule under which a group health plan and a health insurance issuer may not restrict mothers' and newborns' benefits for a hospital length of stay in connection with childbirth to less than 48 hours following a vaginal delivery or 96 hours following a delivery by cesarean section. The interim final rule—

- Provided that the attending provider makes the determination that an admission is in connection with childbirth;
- Determined when the hospital stay begins for purposes of application of the general rule;
- Provided an exception to the 48-hour (or 96-hour) general rule if the attending provider decides, in consultation with the mother, to discharge the mother or her newborn earlier;
- Clarified the application of authorization and precertification requirements with respect to the 48-hour (or 96-hour) stay;
- Explained the application of benefit restrictions and cost-sharing rules with respect to the 48-hour (or 96-hour) stay;
- Clarified the prohibitions with respect to a plan or issuer offering mothers incentives or disincentives to encourage less than the 48-hour (or 96-hour) stay;
- Clarified the prohibitions against incentives and penalties with respect to attending providers; and
- Included the statutory notice provisions under ERISA and the PHS Act. In general, these final regulations do not change the interim final rules. However, the text of these final regulations incorporates a clarifying statement from the preamble of the interim final rules that the definition of attending provider does not include a plan, hospital, managed care organization, or other issuer. The text also makes a small clarification with respect to state law applicability.

In addition, these final regulations make minor clarifications to the notice requirements for nonfederal governmental plans. The interim final rules specified that the notice of post-childbirth hospitalization benefits must be included in the plan document that described plan benefits to participants and beneficiaries. These final regulations specify that any notice a nonfederal governmental plan must provide under these regulations can be included either in the plan document that describes benefits, or in the type of document the plan generally uses to inform participants and beneficiaries of plan benefit changes. These final regulations also specify that any time a plan distributes one or both of these documents after providing the initial notice, the applicable statement must

[1] 26 CFR 54.9811–1, 29 CFR 2590.711, 45 CFR 146.130.

[2] 45 CFR 148.170.

appear in one or both of these documents.

Hospital Length of Stay

The interim final rules and these final regulations provide that when a delivery occurs in the hospital, the stay begins at the time of delivery (or, in the case of multiple births, at the time of the last delivery) rather than at the time of admission or onset of labor. Also, the interim final rules and these final regulations provide that when a delivery occurs outside of the hospital, the stay begins at the time the mother or newborn is admitted (rather than at the time of delivery).

Some comments expressed concern that this rule somehow required birthing centers or other non-hospital facilities to extend the right to stay to more than 24 hours. These comments noted that such extended stays may violate local regulations or otherwise conflict with the operations of such facilities. The statute and these final regulations do not require hospitals or other facilities to provide particular lengths of stay, but instead require group health plans and health insurance issuers to provide benefits for particular hospital lengths of stay.

A comment recommended that if a delivery was planned for outside of a hospital, any following admission in response to complications resulting from that delivery should be excluded from the provisions providing for particular lengths of stay. These final regulations do not distinguish between a delivery that was planned for outside of the hospital and other deliveries occurring outside of a hospital.

Definition of Attending Provider

The mandatory coverage period provisions are not violated if the attending provider, in consultation with the mother, decides to discharge the mother or newborn earlier. Under the interim final rules and these final regulations, the attending provider is defined by a functional analysis of state licensure rules and the actual performance of care. Under this definition, the attending provider is restricted to an individual who is licensed under applicable state law to provide maternal or pediatric care and who is directly responsible for providing such care to a mother or newborn child. While the preamble to the interim final rules noted that this definition could include a nurse midwife or physician assistant, the regulation itself does not provide a list of titles or positions that qualify as attending providers.

Some comments requested that additional titles, such as pediatric nurse practitioners, or nurse practitioners, be specifically mentioned in the definition. While positions with these titles may meet the definition in many cases, as noted above, the language of the regulation takes a functional approach and does not provide a list of titles or positions that qualify as attending providers. This functional approach is more useful in addressing who the attending provider is on an ongoing basis, as specific position titles and responsibilities may vary from location to location as well as over time.

It was also suggested that the text of the final regulations incorporate a clarifying statement from the preamble of the interim final rules that the definition of attending provider does not include a plan, hospital, managed care organization, or other issuer. These final regulations adopt this suggestion.

Compensation of Attending Provider

Several comments addressed the provisions in the interim final rules that relate to the compensation of physicians and other attending providers. These provisions prohibit plans and issuers from penalizing attending providers who provide care in accordance with the regulations, and prohibit plans and issuers from inducing attending providers to provide care in a manner that is inconsistent with the regulations. At the same time, the statute specifies that plans and issuers are still free to negotiate with attending providers the level and type of compensation for care furnished in accordance with the regulations.

The comments requested greater specificity in the final regulations for distinguishing between the types of compensation arrangements that are permissible under the negotiation provision and those that are impermissible under the prohibitions against penalties and inducements. One comment suggested that it is clear that a bonus arrangement for obstetricians and gynecologists contingent on the percentage of discharges within 24 hours would not be permitted. The comment requested confirmation that arrangements with a more general focus would be permitted, such as a global payment for prenatal care and childbirth, or a bonus for a multi-specialty group including obstetricians and gynecologists based on the utilization for all patients served by the group. Another comment expressed a concern about whether capitated arrangements are consistent with the hospital length-of-stay requirements.

The Departments devoted considerable resources over a sustained period of time to develop rules that provide greater specificity for distinguishing between negotiated compensation arrangements that would give attending providers an incentive to deliver health care services efficiently and arrangements that could give providers an incentive to discharge patients in contravention of the statute and regulations. The great variety, complexity, and mutability of such arrangements [3] would have required extensive rules that at best were likely to impose heavy administrative costs and yet were still of only marginal value in clarifying what arrangements would be permissible. For this reason, the rules on compensation arrangements for attending providers are adopted unchanged from the interim final rules.

The final regulations do not attempt to provide guidance on this issue through examples. Certainly the bonus arrangement described in one comment, based on the percentage of discharges within 24 hours, violates the prohibition against providing inducements for early discharge. Such an example is not included in the final regulations to avoid the inference that anything less blatant would be permissible. Examples of less blatant arrangements could be similarly misleading, whether the conclusion was that the arrangement was permissible or impermissible, since there are bound to be differences between arrangements that would have been described in the regulations and any actual arrangement for an attending provider, and in some cases even minor differences could change the result.

Authorization and Precertification

The interim final rules and these final regulations provide, under paragraph (a), that a group health plan or a health insurance issuer may not require a physician or other health care provider to obtain authorization from the plan or issuer to prescribe a hospital length of stay that is subject to the general rule.

[3] Broad classes of examples include fee-for-service, capitation, productivity-based salary, incentive contracting, blended systems, prospective versus post-service payment, etc. *See e.g., Theory and Practice in the Design of Physician Payment Incentives,* James C. Robinson (University of California, Berkley), The Milbank Quarterly, Vol. 79, No. 2, 2001; *Regulation of Managed Care Incentive Payments to Physicians,* Stephen Latham (Boston University School of Law), 22 Am. J.L. & Med. 399; *Blended Payment Methods in Physician Organizations Under Managed Care,* James C. Robinson, JAMA 1999;282:1258–1263; *The Alignment and Blending of Payment Incentives Within Physician Organizations,* JC Robinson, SM Shortell, R Li, LP Casalino, T Rundall, Health Services Research Vol 39, Issue 5, pages 1589–1606, Oct. 2004.

Under paragraph (b) of the interim final rules and these final regulations, a plan or issuer may not restrict benefits for part of a stay that is subject to the general rule in a way that is less favorable than a prior portion of the stay. An example in the interim final rules and these final regulations illustrates that a plan or issuer is precluded from requiring a covered individual to obtain precertification for any portion of a hospital stay that is subject to the general rule if precertification is not required for any preceding portion of the stay. However, the interim final rules do not prevent a plan or issuer from requiring precertification for any portion of a stay after 48 hours (or 96 hours), or from requiring precertification for an entire stay.

Under paragraph (c) of the interim final rules and these final regulations, a plan or issuer may not increase an individual's coinsurance for any later portion of a 48-hour (or 96-hour) hospital stay. An example in the interim final rules and these final regulations illustrates that plans and issuers may vary cost-sharing in certain circumstances, provided the cost-sharing rate is consistent throughout the 48-hour (or 96-hour) hospital length of stay.

One comment asked whether less favorable cost sharing for the 48-hour (or 96-hour) stay can be applied to covered individuals who fail to give advance notice or notice upon admission for the services or providers related to the stay, if such a penalty applies in other hospitalization situations. This issue was addressed in Example 2 of paragraph (c)(3) of the interim final rules. This example is repeated in the final regulations and illustrates that a plan may require advance notice for services or providers related to hospital length of stay in connection with childbirth, in order for a covered individual to obtain more favorable cost sharing under the plan or coverage. Such requirements may not be used to deny an individual benefits for any portion of the 48-hour (or 96-hour) stay based on a determination of medical necessity or appropriateness. Any variance in cost-sharing related to compliance with a plan's or an issuer's advance notice requirements must be applied consistently throughout the 48-hour (or 96-hour) stay. Under the principles set forth in the rule and illustrated in this example, a plan or issuer could generally apply less favorable cost sharing towards the hospital length of stay in connection with childbirth of an individual who failed to satisfy the plan's advance notice requirements, to the extent permissible under the preexisting condition rules in 26 CFR 54.9801–3, 29 CFR 2590.701–3, and 45 CFR 146.111 and 148.120.[4]

Notice Requirements under ERISA and the PHS Act

This section of the final regulations addresses the Newborns' Act notice requirements under ERISA and the PHS Act. The interim final rules, and these final regulations, contain different notice provisions for ERISA-covered group health plans, nonfederal governmental plans, and health insurance issuers in the individual market. ERISA-covered group health plans are required to comply with the ERISA notice regulations, whether insured or self-insured. Nonfederal governmental plans and health insurance issuers in the individual market are required to comply with the PHS Act notice regulations. Because there are fundamental differences between the types of entities regulated under ERISA as compared to the PHS Act, and in the structure of the two acts, the notice requirements in the ERISA regulations and PHS Act regulations differ.

Notice Requirements under ERISA. The interim final rules and these final regulations require group health plans that are subject to ERISA to comply with summary plan description (SPD) disclosure requirements at 29 CFR 2520.102–3(u). The SPD rules generally require that participants and beneficiaries in a group health plan be furnished an SPD to apprise them of their rights and obligations. The rules also prescribe the content of the SPD and the manner and timing in which participants and beneficiaries are to be notified of any material modification to the terms of the plan or any change in the information required to be included in the SPD.

In November 2000, the Department of Labor finalized the SPD content regulation (65 FR 70241) requiring that all group health plans (including insured plans not subject to the federal Newborns' Act) provide language in the SPD that describes the federal or state law requirements applicable to the plan or any health insurance coverage offered under the plan relating to hospital lengths of stay in connection with childbirth for the mother or newborn child. If federal law applies in some areas in which the plan operates and state law applies in other areas, the SPD should describe the different areas and the federal or state law requirements applicable in each. Model language for plans subject to the federal Newborns' Act's requirements is included in the SPD content regulation. This change became applicable as of the first day of the second plan year beginning on or after January 22, 2001.

Some comments asked for clarification about whether the notice can be provided through electronic media, as an alternative to traditional paper disclosure. Under ERISA, the notice can be provided through electronic media if the plan complies with ERISA's electronic disclosure rules in 29 CFR 2520.104b–1.

Some comments requested that the rules require plans to provide information to patients and providers regarding who has legal oversight with respect to the Newborns' Act and who to contact in the event of a violation. However, this concern is already addressed by current regulation. Under 29 CFR 2520.102–3(t)(1) of the SPD content rules, ERISA plans are required to provide a statement of ERISA rights in the SPD. Among other things, this provision requires ERISA-covered plans to provide information on the enforcement of a participant or beneficiary's rights and who to contact if there are any questions about the plan.

Notice Requirements under the PHS Act. Nonfederal governmental plans. The Newborns' Act requires nonfederal governmental plans to comply with the Newborns' Act notice requirements under section 711(d) of ERISA as if section 711(d) applied to such plans.

The interim final rules and these final regulations require plans that are subject to the federal Newborns' Act requirements to provide a notice with specific language describing the federal requirements. Under the interim final rules and these final regulations, if federal law applies in some areas in which the plan operates and state law applies in others, the plan must provide the appropriate notice to each participant and beneficiary who is covered by federal law.

Several comments on the interim final rules objected that specific language was required for the disclosure statement, and suggested that the regulation instead should have provided guidelines for plans to base their own language on (such as language that

[4] In order to avoid imposing an impermissible preexisting condition exclusion, plans and group health insurance issuers that require individuals to notify the plan or issuer of pregnancy within a certain amount of time (for example, within the first trimester) must waive or modify the notice requirement for individuals who enroll in the plan after the time notice was required. This also applies to individual market issuers with respect to federally eligible individuals they are required to enroll.

comports with the Department of Labor's sample language). However, requiring specific language ensures the substantive adequacy of the notices. Additionally, because many plans presumably have already incorporated that mandatory language into their documents since the effective date of the interim final rules, continuing to require that language is the simplest approach.

As in the interim final rules, these final regulations require nonfederal governmental plans to provide notice not later than 60 days after the first day of the plan year following the effective date, regardless of whether the plan had already provided notice under the Department of Labor standards. This takes into account the fundamental differences between the nonfederal governmental plans regulated under the PHS Act and the types of entities regulated under ERISA. However, with respect to the requirement that notice be provided within that 60-day period, the final regulations include an exception for plans with regard to participants and beneficiaries for whom the plan has already provided notices in accordance with the interim final regulations that are consistent with these final regulations (such as self-insured nonfederal governmental plans that are subject to the federal Newborns' Act requirements and that have already provided such notices).

Health insurance issuers in the individual market. The Newborns' Act requires health insurance issuers in the individual market to comply with the Newborns' Act notice requirements under section 711(d) of ERISA as if section 711(d) applied to such issuers. Thus, the interim final rules and these final regulations require individual market health insurance issuers that provide benefits for hospital lengths of stay in connection with childbirth to include, in the insurance contract, a rider, or equivalent amendment to the contract, specific language that notifies policyholders of their rights under the Newborns' Act. The interim final rules and these final regulations also require such issuers to provide this notice not later than a specific time frame that is within a few months after the effective date of the regulations.

Several comments on the interim final rules objected that specific language was required for the disclosure statement and suggested instead there should be guidelines for issuers to base their own language on. However, requiring specific language ensures the substantive adequacy of the notices. Additionally, because issuers presumably have already incorporated that language into their documents since the effective date of the interim final rules, continuing to require that same language is the simplest approach.

These final regulations retain the notice exception in the interim final rules for issuers that are subject only to state insurance law requirements regarding hospital lengths of stay following childbirth.

Applicability in States

The statute and the interim final rules include an exception to the Newborns' Act requirements for health insurance coverage in certain states. Specifically, the Newborns' Act and the interim final rules do not apply with respect to health insurance coverage if there is a state law that meets any of the criteria [5] that follow:

- The state law requires health insurance coverage to provide at least a 48-hour (or 96-hour) hospital length of stay in connection with childbirth;
- The state law requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association; or
- The state law requires that decisions regarding the appropriate hospital length of stay in connection with childbirth be left to the attending provider in consultation with the mother. The interim final rules and these final regulations clarify that state laws that require the decision to be made by the attending provider with the consent of the mother satisfy this criterion.

Although this exception applies with respect to insured group health plans, it does not apply with respect to a group health plan to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage. Accordingly, self-insured plans in all states generally are required to comply with the federal requirements (except those nonfederal governmental plans that have opted out of the PHS Act requirements).

These final regulations repeat the statute and the interim final rules with one clarification. With respect to the second criterion above (professional guidelines), the statute only addresses the period following a vaginal delivery or a caesarean section. Accordingly, although guidelines issued by professional medical associations such as the American College of Obstetricians and Gynecologists (ACOG) cover a spectrum of care both before and after childbirth, the only relevant guidelines for this purpose are those pertaining to care following childbirth. Therefore, the final rules include an express clarification that State law need only require coverage in accordance with professional guidelines that deal with care following childbirth. Guidelines relating to other issues are not relevant for this purpose.

One comment to the interim final rules supported the criteria used in those rules for determining whether the federal Newborns' Act applies in a given state. However, another comment objected to the fact that issuers in states that have enacted one of the three types of state laws described in the federal Newborns' Act would arguably be exempt from several of the federal Act's requirements, such as the prohibitions on offering incentives to providers to induce them to provide care in a manner inconsistent with the Act. This comment asked us to reconsider whether the regulations should provide such a broad exception from the federal Act's requirements in such states. The statutory language does not require state law to include all the federal provisions, such as the anti-incentive provisions, in order for health insurance coverage in that state to be excepted from the federal requirements. In light of this flexibility, these final regulations retain the exception from the interim final rules.

Applicability Date

These final rules apply to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009. The final rules for the individual market apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of the regulations previously published in the **Federal Register** (63 FR 57546) and other applicable regulations.

[5] HHS has the responsibility to enforce the federal Newborns' Act with regard to issuers in states that do not have one of the three types of state laws described in the Newborns' Act. As of the publication of these final regulations, the only state in which HHS is enforcing the Newborns' Act with respect to issuers is Wisconsin.

III. Economic Impact and Paperwork Burden

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

The Newborns' Act provisions generally prohibit group health plans and group health insurance issuers from limiting hospital lengths of stay in connection with childbirth to less than 48 hours for vaginal deliveries and 96 hours for cesarean sections and from requiring a health care practitioner to obtain preauthorization for such stays. For insured coverage, the Newborns' Act allows any state law, meeting one of three criteria, to take its place. The Departments have crafted these regulations to secure the Act's protections in as economically efficient a manner as possible, and believe that the economic benefits of the regulations justify their costs.[6]

The primary economic benefits associated with securing these minimum lengths of stay derive from the reduction in complications linked to premature discharge of mothers and newborns. Complications that are easily treated and readily identifiable, like excessive bleeding and infection in new mothers and dehydration and hyperbilirubinemia in their newborns, are common causes for readmission following a premature discharge. These complications and the subsequent readmissions are expensive and cause avoidable suffering for mothers and their newborns.

By eliminating the need to obtain preauthorization for affected stays, the Act provides affected individuals with increased access to the health care system. Increased access fosters timelier and fuller medical care, better health outcomes, and improved quality of life. This is especially true for certain individuals affected by the Newborns' Act provisions. For example, lower-income individuals, when denied coverage for the full length of stay, are more likely to forego care for financial reasons. When adverse health outcomes result, costs for the individual and the plan are high. For these individuals especially, this requirement is more likely to mean receiving timely, quality postnatal care, and living healthier lives.

Any mandate to increase the richness of health benefits, however, adds to the cost of health coverage. Plans can mitigate costs by increasing cost-sharing or by reducing non-mandated benefits. This in turn shifts the economic burden of the regulation to plan participants, and may induce some employers and employees, as well as those in the individual insurance market, to drop coverage. The cost of enacting federal minimum stay regulation is estimated to fall between $139 and $279 million annually.[7] However, as this constitutes a small fraction of one percent of total health care expenditures, it would most likely be a small, possibly negligible, factor in most employers' decisions to offer health coverage and individuals' decisions to enroll.

While the interim final regulations clarified several provisions within the statute, this action serves primarily to provide the certainty associated with a final rule for the regulated community, as well as update the cost of the regulation, adjusting for changes in the landscape of the community. Because these regulations are being published several years after the Newborns' Act's passage and minimal interpretation of the statutory language was required, the regulatory implementation costs should be negligible. Costs of the final regulation are detailed below in the section entitled ''Unified Analysis of Costs and Benefits.'' Benefits of the regulation are also discussed in that section at length, although because the benefits primarily involve quality of life improvements, the Departments have not attempted to quantify them. They do, however, believe them to be sufficiently large so as to justify the cost of the regulation.

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

Under Executive Order 12866, 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, it has been determined that this action is ''economically significant'' and is subject to OMB review under Section 3(f) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this action. The Departments' assessment, and the analysis underlying the 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.

These final regulations are needed to provide certainty for the affected community, as well as clarify the economic burden that the Newborns' Act will place on health plans and their participants. The Departments believe that this regulation's benefits will justify its costs. This belief is grounded in the assessment of costs and benefits that is summarized earlier and detailed below.

Regulatory Flexibility Act—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 likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a final rule will not have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires that the agency present a final regulatory flexibility analysis (FRFA) at the time of the publication of the notice of final rulemaking describing

[6] The Newborns' Act still requires that insured plans disclose a notice outlining participants' rights regarding hospital lengths of stay related to childbirth. Nonetheless, final regulations related to that notice were published separately (see 65 FR 70266, Nov. 21, 2000) and so those costs are not included herein.

[7] The vast majority of this cost is attributable to the impact of the statute. ($14 million is the upper bound cost attributable to the exercise of regulatory discretion.) Moreover, there are no increased costs attributable to any new exercise of regulatory discretion in the final rule. Instead, the final rule repeats the interpretations of the interim final rule. Any increased costs over the 1998 estimate in the interim final rules are attributable to economic factors, such as increased cost of care (from 1996 to 2007 dollars), increased number of births, and increased number of participants and beneficiaries covered by self-insured plans to which the regulations apply.

the impact of the rule on small entities. Small entities include small businesses, organizations, and governmental jurisdictions.

Because the 1998 rules were issued as interim final rules and not as a notice of proposed rulemaking, the RFA did not apply and the Departments were not required to either certify that the rule would not have a significant impact on a substantial number of small entities or conduct a regulatory flexibility analysis. The Departments nonetheless crafted those regulations in careful consideration of effects on small entities, and conducted an analysis of the likely impact of the rules on small entities. This analysis was detailed in the preamble to the interim final rule.

For purposes of this discussion, the Departments consider a small entity to be an employee benefit plan with fewer than 100 participants. Pursuant to the authority of section 104(a)(3) of ERISA, 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 shift their costs to their plan clients in the form of fees. Thus, the Departments believe that assessing the impact of this final 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 impact of the proposed regulations on small entities. No comments were received with respect to this standard.

The Departments believe that the final regulation will not have a significant economic impact on a substantial number of small entities. The direct costs of restricting short stay policies is estimated to fall between $15 million and $31 million for small plans which amount to a per-participant cost of between nine and nineteen dollars for those plans affected, or a small fraction of one percent of total small plan expenditures.[8]

The Departments estimate that prior to the Act, 115,000 small plans with 1.6 million participants would have restricted lengths of stay in connection with childbirth or required preauthorization for such stays.[9] While this represents just 5 percent of all small plans, the Departments believe it may represent a substantial number of small entities.

Paperwork Reduction Act—Department of Labor and Department of Health and Human Services

1. Department of Labor

These rules contain no new information collection requirements that are subject to review and approval by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The Department of Labor reported the information collection burdens associated with the Newborns' Act in the interim rules (Interim Rules Amending ERISA Disclosure Requirements for Group Health Plans) implementing section 711(d) of ERISA that were published in the **Federal Register** on April 8, 1997 (62 FR 16979). OMB approved the information collection under OMB Control Number 1210–0039, expiring on March 31, 2010.

2. Department of Health and Human Services

These rules contain no new information collection requirements that are subject to review and approval by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). HHS reported the information collection burdens associated with the Newborns' Act in the interim rules (Information Collection Requirements Referenced in HIPAA for the Group Market, Supporting Regulations 45 CFR 146), published in the **Federal Register** on April 8, 1997. These collection requirements were approved under OMB Control Number 0938–0702, expiring on August 31, 2009.

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 it has been determined that this Treasury decision is not a significant regulatory action. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these Treasury regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Congressional Review Act

These regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review. These regulations, however, are considered a ''major rule,'' as that term is defined in 5 U.S.C. 804, because they are likely to result in an annual effect on the economy of $100 million or more.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments,[10] however, they include mandates which may impose an annual burden of $100 million or more on the private sector, updated annually for inflation. After applying the most

[8] Departments' estimates using the 2005 Medical Expenditures Panel Survey Household Component (MEPS–HC), the 2006 Medical Expenditures Panel Survey Insurance Component (MEPS–IC) and the National Centers for Disease Control and Prevention (CDC) National Hospital Discharge Survey: 2005 Annual Summary with Detailed Diagnosis and Procedure Data determined that of participants affected by the regulation, 11 percent were enrolled in small plans. Costs born by small plans were 11 percent of all costs.

[9] Estimates are based on the 2006 MEPS–IC. It should be noted, however, that the Pregnancy Discrimination Act of 1978 allows firms with less than 15 employees that offer health insurance to exclude maternity care. The 2000 Mercer/Foster Higgins National Survey of Employer Sponsored Health Plans found that 7 percent of firms with 10–24 employees did not offer such benefits, but the survey did not examine smaller firms. Rough estimates by the Departments suggest that the share of firms with 9 or fewer employees that offer health benefits but exclude maternity benefits is 21 percent. As the cost of these benefits rises, this share is likely to increase which, while having a small effect on the number of participants affected by the regulation, might significantly decrease the number of small plans affected by the regulation.

[10] Nonfederal governmental plans can opt-out of these requirements and it was assumed that those States that had rules in place that supplanted the Newborns' Act (that is, all States except one) would.

current gross domestic product implicit price deflator in 2008, that threshold is approximately $130 million.

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 final 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 final regulations are substantially mitigated because, with respect to health insurance issuers, all but one of the States have requirements that prescribe benefits for hospital lengths of stay in connection with childbirth that satisfy the Newborns' Act hospital length of stay requirements.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, but preserves State laws that regulate insurance. At the same time, however, ERISA prohibits States from regulating a plan as an insurance company. HIPAA added a new section to ERISA (as well as to the PHS Act and the Code) narrowly preempting State requirements for issuers of group health insurance coverage.[11] HIPAA's conference report states that the conferees intended only the narrowest preemption of State laws with regard to health insurance issuers. H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205 (1996).

The Newborns' Act also added a new section to ERISA (and to the PHS Act and the Code) which provides that the federal requirements applicable to group health plans and health insurance issuers concerning hospital lengths of stay for mothers and newborns following childbirth do not apply if State law meets one or more of three specific criteria in the statute.[12] The accompanying conference report states that it is the intent of the conferees that States may impose more favorable requirements for the treatment of maternity coverage under health insurance coverage than required by the Newborns' Act. H.R. Conf. Rep. No. 104–812, 104th Cong. 2d Session 88 (1996).

Guidance conveying the Newborns' Act hospital length of stay requirements was published in the **Federal Register** on October 27, 1998 (63 FR 57546). These final 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 all but one State have requirements that prescribe benefits for hospital lengths of stay in connection with childbirth that satisfy the Newborns' Act requirements.

The Newborns' Act modified HIPAA's framework to provide that the States have primary responsibility for enforcement of the provisions of the Newborns' Act as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provision that a State fails to substantially enforce. To date, CMS enforces the Newborns' Act hospital length of stay requirements in only one State. When exercising its responsibility to enforce the Newborns' Act provisions, 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 the Newborns' Act requirements in the first instance. CMS procedures address the handling of reports that States may not be enforcing the Newborns' Act 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 consulted and worked 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 Department of Labor staff have consistently attended these quarterly meetings to listen to the views of the State insurance departments.

In addition, the Departments informally consulted with the NAIC in developing the interim final regulations. Through the NAIC, the Departments sought and received the input of State insurance departments regarding preemption of State laws, applicability of the Newborns' Act provisions, and certain insurance industry definitions (*e.g.*, attending provider). In general, these final regulations do not change the interim final rules. Significantly, the Departments received only eleven formal comment letters on the interim final regulation, none of which were from or on behalf of the NAIC or any of the States.

The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information 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

[11] The Newborns' Act was incorporated into the administrative framework established by HIPAA.

[12] The federal requirements concerning hospital lengths of stay in connection with childbirth do not apply with respect to health insurance coverage if state law requires (1) such coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour length of stay following a delivery by cesarean section, (2) such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations, or (3) in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother.

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 Web sites offer links to important State Web sites 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 and the Newborns' Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and 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 these 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 Final Regulations for Group Health Plans and Health Insurance Issuers Under the Newborns' and Mothers' Health Protection Act (RIN 1210–AA63 and RIN 0938–AI17), in a meaningful and timely manner.

Unified Analysis of Costs and Benefits

1. Introduction

The Newborns' Act's provisions generally prohibit group health plans and health insurance issuers from: (1) Limiting hospital lengths of stay in connection with childbirth to less than 48 hours for vaginal deliveries and 96 hours for cesarean sections, and (2) requiring preauthorization for the 48/96 hour stays. The primary effect and intent of the provision is to reduce postpartum complications associated with premature discharge.

These regulations draw on the Departments' authority to clarify and interpret the Newborns' Act's statutory provisions in order to secure the protections intended by Congress for newborns and mothers. The Departments crafted them to satisfy this mandate in as economically efficient a manner as possible, and believe that the economic benefits of the regulations justify their costs. This conclusion takes into account both the effect of the statute and the impact of the discretion exercised in the regulations.

This regulation is needed to clarify and interpret the Newborns' Act provisions under section 711 of ERISA, sections 2704 and 2751 of the PHS Act, and section 9811 of the Internal Revenue Code and to ensure that group health plans and health insurance issuers subject to these rules do not impermissibly restrict benefits or require preauthorization for 48-hour or 96-hour hospital lengths of stay in connection with childbirth.

2. Costs and Benefits of the Statute

The Departments provide qualitative assessments of the nature of the costs and benefits that are expected to derive from the statutory provisions of the Newborns' Act. In addition, the Departments provide summaries of any credible, empirical estimates of these effects that are available.

In order to determine how many plan participants could benefit from the Newborns' Act provision, the Departments considered the estimated 2.8 million births in 2005 by women with private health insurance.[13] Of these, approximately 55.0 percent are assumed to be normal, healthy deliveries, and therefore eligible for early discharge.[14] Because legislation has been passed in every state but Wisconsin, the Departments limited their analysis to participants in self-insured group health plans throughout the country and all health plans within Wisconsin. Finally, because Health Maintenance Organizations (HMOs) have traditionally had more aggressive short-stay policies, the share of workers enrolled in HMOs versus commercial plans was taken into account as were the share of those plans with short-stay policies.[15]

Based on these assumptions, approximately 328,000 births or roughly 22 percent of healthy births by privately insured women would be affected by the provision.[16] If each woman then stayed the maximum period outlined in the statute, approximately 348,000 additional days of hospital care would be required.[17] Assuming hospitals charge $800 per day for postpartum care, the annual cost of the provision would be $279 million: $1.7 million of which would be attributable to the individual market in Wisconsin; the remaining $276.9 million would be attributable to the group market in Wisconsin and self-funded plans throughout the country. However, because the statute does not require a 48- or 96-hour stay, but instead gives the decision-making authority to the attending physician in consultation with the mother, it is expected that not all of these births will result in additional hospital time. If only one-half of affected mothers had their stays extended by the full amount, the annual cost of the provision would be $139 million, less than $1 million of which would be attributable to the individual market of Wisconsin.[18]

[13] Departments' estimate based on the 2005 MEPS–HC and the 2005 CDC Survey.

[14] The CDC reported that of the 4.0 million births in 2005, 2.2 million, or 55.0 percent of those newborns were categorized as without any illness or risk-related diagnosis (*e.g.* jaundice, respiratory distress, disorders relating to short gestation and low birth weight). No data are available on whether health of newborns varies by mothers' insurance status, although insured mothers are more likely to receive prenatal care and this would be expected to positively affect the share of ''healthy'' births (see Susan Egerter *et al.*, ''Timing of Insurance Coverage and Use of Prenatal Care Among Low-Income Women,'' *American Journal of Public Health,* v. 92(3): 423–427).

[15] Julie A. Gazmararian & Jeffrey Koplan found in, ''Length-of-Stay After Delivery: Managed Care versus Fee for Service,'' *Health Affairs,* v. 15(4): 74–80, that 35.9 percent of enrollees in commercial plans were discharged within one day after delivery compared to 57.7 percent from commercial HMOs. The shares of individuals enrolled in HMOs at self-insured and fully-insured plans were taken from the 2007 Kaiser Family Foundation's Survey of Employer Sponsored Insurance.

[16] The number of women age 10–54 with private insurance was estimated using the 2005 MEPS–HC. Fertility rates for different age brackets were taken from the 2005 CDC National Hospital Discharge Survey and were interacted with the number of privately insured women to ascertain the number of births by insured women. This was then interacted with the share of infants that were born healthy, as reported in the 2005 CDC report, to determine the number of healthy births to privately-insured women.

To restrict the number of privately insured women having healthy births to those with ESI, the share of all privately insured women, age 10–54, that had ESI was taken from the 2007 March CPS and interacted with the above number. To then discern the number of births that would be covered by the regulation, the 2006 MEPS–IC was used to ascertain the share of employees in ESI that were in self-insured plans that had maternal coverage. This number was further interacted by the share of employees in the share of those employees in HMO versus non-HMO health plans as provided by the 2007 Kaiser Family Foundation's Employer Health Benefits Survey.

Interacting all of these numbers results in the 328,000 number cited in the text.

[17] Based on 1995 discharge rates, approximately 94 percent of the 328,000 births required one additional day to meet the maximum period outlined by the statute; 6 percent required two additional days.

[18] The Congressional Budget Office (CBO) analyzed Senate proposal S. 969, which was an earlier version of the Newborns' Act. CBO estimated 900,000 insured births had stays shorter than the minimum specified in the bill, which would result in 400,000 additional inpatient days and an additional 200,000 additional out-patient visits at an annual cost of $360 million in 2007 dollars (or $800 for each additional day of inpatient care; $200 for outpatient care). The Departments' estimate is significantly less, primarily due to: (1) A large number of states either clarifying existing policies for short-stay deliveries or enacting new ones which supersede the federal statute for all but self-insured plans; and (2) the CBO estimates included costs for

Continued

While the Departments estimate that the cost of the NMHPA is as much as $279 million annually, health plans are estimated to have spent more than $775 billion in 2007 to cover approximately 201.7 million privately insured individuals.[19] Therefore, the upper estimate of the costs under the Newborns' Act's provisions represent a very small fraction of one percent of total health plan expenditures.

Moreover, the cost of this provision is likely to decline in the future, despite increases in overall health care spending. Since the statute was passed, there has been a significant increase in the number of cesarean births, compared to vaginal births. While traditionally cesarean births are associated with higher risk, an increasing number of women are now electing to have the procedure.[20] Women who elect to have a cesarean would presumably have a lower risk than those for whom the procedure is required and therefore may not require the prescribed 96-hour recovery period detailed in the statute.[21] If this trend continues, the burden of this statute should lessen.

The primary statutory economic benefits associated with the Newborns' Act's provisions derive from an increase in access to health plan coverage for postpartum care and monitoring of mothers and their newborns. Individuals without coverage for this care and monitoring are less likely to remain in the hospital for fear of incurring expenses that must be paid for 'out-of-pocket.' Lower-income individuals are more likely to forego care not covered by their insurance. Foregoing this care and monitoring increases the risk of adverse health outcomes, which in turn generates higher medical costs. Much of these costs may be shifted to public funding sources (and therefore to taxpayers) or to other payers.[22]

Foregoing appropriate care can also negatively affect the quality of life. Improved access to health coverage for mothers and newborns will lead to more appropriate medical care and monitoring, better health outcomes, and improved quality of life.[23] Denied coverage, individuals must choose whether to pay for the extra day(s) in the hospital and potentially suffer economic hardship or forego the care and monitoring, creating a risk of an adverse health outcome. Gaining coverage will sometimes mean receiving high quality care and living healthier lives.[24]

The provisions of the Newborns' Act and its regulation generally apply to both group health plans and health insurance issuers. While the costs of the Newborns' Act are substantial, economic theory predicts that issuers will pass their costs of compliance back to plans, and that plans may shift some or all of issuers' and their own costs of compliance to participants either through increases in premiums, increased cost-sharing, or reducing the richness of non-mandated health benefits.[25]

While 74 million individuals are enrolled in group or private health plans, only 15 million individuals are enrolled in plans that had policies affected by the Newborns' Act. Of these, only 328,000 individuals are expected to be annually directly impacted and receive additional coverage they were previously denied or restricted for 48 or

follow-up visits, a requirement that was dropped from the federal statute.

[19] The Departments' estimate is based on the Office of the Actuary at the Centers for Medicare & Medicaid Services (CMS) projected measure of total personal health expenditures by private health insurance in 2007.

[20] The share of all births that are cesarean rose from 20.7 percent in 1996 to an estimated 31.3 percent in 2005 (CDC (2005). ''National Hospital Discharge Survey'' *Vital and Health Statistics,* Series 13 (162)). A study by Health Grades Inc. found a 36.6 percent increase in the number of ''patient choice'' cesarean sections between 2001 and 2003.

[21] Most research comparing complication rates of cesarean to vaginal births focus on those women who previously had a cesarean section, as insufficient data are available to compare initial vaginal versus initial elected cesarean deliveries. As such, it is difficult to discern how the medically advisable stay of an elected cesarean section compares to that of an uncomplicated vaginal birth. However, there is much agreement that emergency cesarean sections, which typically follow a lengthy labor, are far more dangerous to mother and child than the elected variety. Given the Newborns' Act's prescribed 96-hour stays for cesarean births when elected cesareans comprised a smaller share of all cesareans, it would be reasonable to expect that the stays for elected cesareans may fall over time.

[22] For more information on health choices of lower-income individuals, see: Trude, Sally (2003). ''Patient Cost Sharing: How Much is Too Much,'' *Health System Change Issue Brief,* no. 72 (December).

[23] For more detailed information, see: O'Brien, Ellen (2003). ''Employer Benefits from Workers' Health Insurance,'' *Milbank Quarterly,* Vol. 1 No. 1. O'Brien provides an extensive analysis of the literature on benefits accruing to employers from offering health benefits and the costs to employers of unhealthy employees, as well as information on studies demonstrating that poor health may be related to lower productivity. In particular, she discusses studies that have examined the effects on workplace productivity of specific health conditions and shows that poor health reduces workers' productivity at work, and that effective health care treatments can reduce productivity losses and may even pay for themselves in terms of increased productivity.

[24] Research on the benefits of longer stays has been somewhat mixed. Some studies show short-stays to be correlated with decreased follow-up care and increased re-hospitalization, particularly for low-income families, which will ultimately increase societal costs (for further discussion, see: Galbraith, Alison A. *et al.* (2003) ''Newborn Early Discharge Revisited: Are California Newborns Receiving Recommended Postnatal Services?'' *Pediatrics,* vol. 111 (2): p. 364–371; Lock, Michael & Joel G. Ray. (1999) ''Higher Neonatal Morbidity after Routine Hospital Discharge: Are We Sending Newborns Home Too Early?'' *Canadian Medical Association Journal,* vol. 161 (3): p. 249–253; Malkin, Jesse D. *et al.* (2003) ''Postpartum Length of Stay and Newborn Health: A Cost-Effectiveness Analysis,'' Pediatrics, vol. 111 (4): p. 316–322).

Since the statutes have been in place, other studies have argued that higher re-hospitalization rates found in short-stay newborns are due to more frequent post-stay evaluations in the four days following birth, considered the critical window for ascertaining newborn health, as mandated in health plans. Once new regulations were passed extending stays, health plans reduced their follow-up care policies and newborns were less likely to be examined in the days following discharge. This could result in an increase in costs. (For further discussion, see: Hyman, David A. (2001) ''What Lessons Should We Learn from Drive-Through Deliveries?'' *Pediatrics,* vol. 107 (2): 406–408; Madden, Jeanne M. *et al.* (2002) ''Effects of a Law Against Early Postpartum Discharges on Newborn Follow-up, Adverse Events, and HMO Expenditures,'' *New England Journal of Medicine,* vol. 347 (25): p. 2031–2038; Madden, Jeanne M. *et al.* (2004) ''Length-of-Stay Policies and Ascertainment of Postdischarge Problems in Newborns,'' *Pediatrics,* vol. 113 (1): p. 42–49.)

The Departments believe, however, that because most of the complications of newborns manifest themselves within the immediate 48 hours following birth, special protection much be given to that period. Moreover, since the decision to discharge the patients will be made by the doctor, in consultation with the mother, many of the concerns posed by those who oppose extended stays will be factored into that decision. As such, the Departments believe that the Newborns' Act will improve the health and welfare of mothers and newborns.

[25] 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,'' *Tax Policy and Economy* (1991); Jonathan Gruber, ''The Incidence of Mandated Maternity Benefits,'' *American Economic Review,* Vol. 84 (June 1994), pp. 622–641; Lawrence H. Summers, ''Some Simple Economics of Mandated Benefits,'' *American Economic Review,* Vol. 79, No. 2 (May 1989); Louise Sheiner, ''Health Care Costs, Wages, and Aging,'' Federal Reserve Board of Governors working paper, April 1999; 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). 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.

96-hour hospital stays following childbirth. Though these benefits are received by a small number of plan enrollees, the costs are distributed broadly among all plan participants. As a result, the cost of the Newborns' Act per individual enrollee is expected to be minimal—between 9 and 19 dollars per person for those enrolled in affected plans.[26] While it is possible that some enrollees on the margin will decline coverage in response to cost increases, the number of those acting in such a manner is expected to be negligible. As such, the benefits of this statute are believed to justify its costs.

3. Costs and Benefits of the Rules Applicable to the Newborns' Act

The interim final rule clarified when a stay begins under the Newborns' Act. Prior to this, private health plans could use the expectant mother's admittance time to determine the required stay, an assumption that consistently reduced the number of women experiencing stays less than those prescribed by the statute by 5 percent.[27] By clarifying this assumption in the interim final rule, the number of stays that would have been shorter than 48/96 hours increased by approximately 16,000 for all plans, and by approximately 2,000 for small plans. This in turn raised the direct costs to health plans by 5 percent (from $265 to $279 million for the upper bound for all plans and from $29 to $31 million for small plans). However, because it can take several hours for certain conditions to present themselves, such as jaundice and dehydration, the additional hours of hospital supervision—gained by generally not using an expectant mother's admittance time as the start of a stay—can be critical. Therefore, the benefits of this clarification should justify this additional cost.

The regulation also defines that for births occurring outside of a hospital, stays begin once the mother or newborn is admitted as a hospital inpatient in connection with childbirth, as defined by the attending provider. The Departments lack any firm basis for quantifying the number of individuals likely to be affected by this provision, and therefore are unable to quantify the increase in costs and benefits. However, given the special and narrow circumstances to which this provision applies, costs and benefits are expected to be small.

Statutory Authority

The Department of the Treasury final rule is adopted pursuant to the authority contained in sections 7805 and 9833 of the Code (26 U.S.C. 7805, 9833).

The Department of Labor final rule is adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c, sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003).

The Department of Heath and Human Services final rule is adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended by Public Law 104–191, 110 Stat. 1936, Public Law 104–204, 110 Stat. 2935 and Public Law 105–277, 112 Stat. 2681–436.

Accounting Statement

In accordance with OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf),* in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate for the annual costs associated with enacting the federal minimum stay final regulation.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, CY2008

[In millions]

Category	Cost estimates	
	Low	High
Annualized Monetized Costs	$139.30	$278.50

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter I

■ Accordingly, 26 CFR Part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9811–1 in numerical order and by removing the entry for § 54.9811–1T to read in part as follows:

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

Section 54.9811–1 also issued under 26 U.S.C. 9833. * * *

§ 54.9801–1 [Amended]

■ **Par. 2.** Section 54.9801–1(a) is amended by removing the language ''54.9811–1T'' and adding ''54.9811–1'' in its place.

[26] The total cost of the regulation was calculated by estimating the number of additional days in the hospital that short-stay deliveries would require under the statute. This number was then multiplied by $800, to reflect the per day hospitalization cost of a mother (this was a CBO number indexed to 2007 dollars). Having calculated the total cost of the regulation at $279 million (and a lower bound of $139 million), these numbers were then divided by the number of participants in affected health plans (a total of 15 million) to get an upper ($19) and lower bound ($9) of the per-participant cost of the regulation.

[27] Departments' estimate based on the CDC's 2005 Survey, Tables 37 and 42. The Departments looked at the share of stays that would be labeled ''short'' for both mothers and newborns in 1995 (before any part of the statute was enforced) and found that the share of newborns with a ''short stay'' was 5 percent higher. It was therefore assumed that starting the clock at the birth of a child would increase the number of ''short stays'' by 5 percent.

§ 54.9801–2 [Amended]

■ **Par. 3.** In § 54.9801–2, the introductory paragraph before the definitions is amended by removing the language ''54.9811–1T'' and adding ''54.9811–1'' in its place.

■ **Par. 4.** Section 54.9811–1 is added to read as follows:

§ 54.9811–1 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule.* Except as provided in paragraph (a)(5) of this section, a group health plan that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital.* If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital.* If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3,* the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan may not require that a physician or other health care provider obtain authorization from the plan, or from a health insurance issuer offering health insurance coverage under the plan, for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example,* the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2,* because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example,* the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1,* the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2,* the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* See 29 CFR 2520.102–3(u) for rules relating to a disclosure requirement imposed under section 711(d) of ERISA (29 U.S.C. 1181) on certain group health plans that provide benefits for hospital lengths of stay in connection with childbirth.

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 9811 and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 9811 and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 9811 and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 9811 and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection

with childbirth other than through health insurance coverage.

(3) *Preemption provisions under section 731(a) of ERISA.* See 29 CFR 2590.711(e)(3) for a rule providing that the preemption provisions contained in section 731(a)(1) of ERISA and 29 CFR 2590.731(a) do not supersede a state law if the state law is described in paragraph (e)(1) of 29 CFR 2590.711 (which is substantially similar to paragraph (e)(1) of this section).

(4) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this *Example 1*, the coverage is subject to state law, and the requirements of section 9811 and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this *Example 2*, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 9811 and this section.

(f) *Effective/applicability date.* This section applies to group health plans for plan years beginning on or after January 1, 2009.

§ 54.9811–1T [Removed]

■ **Par. 5.** Section 54.9811–1T is removed.

§ 54.9831–1 [Amended]

■ **Par. 6.** Section 54.9831–1(b) is amended by removing the language ''54.9811–1T'' and adding ''54.9811–1'' in its place.

Approved: September 23, 2008.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

Employee Benefits Security Administration

29 CFR Chapter XXV

■ For the reasons set forth above, 29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for Part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c, sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003).

■ 2. Section 2590.711 is revised to read as follows:

§ 2590.711 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule.* Except as provided in paragraph (a)(5) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital.* If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital.* If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3*, the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan or issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example*, the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this

section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example*, the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1*, because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the

coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* See 29 CFR 2520.102–3(u) (relating to the disclosure requirement under section 711(d) of the Act).

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 711 of the Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 711 of the Act and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 711 of the Act and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 711 of the Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 731(a) of the Act.* The preemption provisions contained in section 731(a)(1) of the Act and Sec. 2590.731(a) do not supersede a state law described in paragraph (e)(1) of this section.

(4) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this *Example 1,* the coverage is subject to state law, and the requirements of section 711 of the Act and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this *Example 2,* even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 711 of the Act and this section.

(f) *Applicability date.* This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

Signed at Washington, DC this 2nd day of October, 2008.

Bradford P. Campbell,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Adoption of Amendments to the Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR SUBTITLE A, SUBCHAPTER B

■ 45 CFR subtitle A, subchapter B, is amended as set forth below:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92).

■ 2. Section 146.130 is revised to read as follows:

§ 146.130 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule.* Except as provided in paragraph (a)(5) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital.* If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital.* If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In

each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3,* the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan or issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example,* the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2,* because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example,* the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after

the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, a group health plan that provides benefits for hospital lengths of stay in connection with childbirth must meet the following requirements:

(1) *Required statement.* The plan document that provides a description of plan benefits to participants and beneficiaries, or that notifies participants and beneficiaries of plan benefit changes, must disclose information that notifies participants and beneficiaries of their rights under this section.

(2) *Disclosure notice.* To meet the disclosure requirement set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

Statement of Rights Under the Newborns' and Mothers' Health Protection Act

Under federal law, group health plans and health insurance issuers offering group health insurance coverage generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the plan or issuer may pay for a shorter stay if the attending provider (*e.g.*, your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, plans and issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, a plan or issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your plan administrator.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to each participant covered under a group health plan, and each beneficiary receiving benefits under a group health plan, not later than 60 days after the first day of the first plan year beginning on or after January 1, 2009. Each time a plan distributes one or both of the documents described in paragraph (d)(1) to participants and beneficiaries after providing this initial notice, the disclosure notice in paragraph (d)(2) must appear in at least one of those documents.

(4) *Exceptions.* The requirements of this paragraph (d) do not apply in the following situations.

(i) *Self-insured plans that have already provided notice.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has already provided an initial notice that complies with paragraphs (d)(1) and (d)(2) of this section, the group health plan is not automatically required to provide another such notice to participants and beneficiaries who have been provided with the initial notice. However, following the effective date of these regulations, whenever such a plan provides one or both of the documents described in paragraph (d)(1) of this section to participants and beneficiaries, the disclosure notice in paragraph (d)(2) of this section must appear in at least one of those documents.

(ii) *Self-insured plans that have elected exemption from this section.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has made the election described in § 146.180 to be exempted from the requirements of this section, the group health plan is not subject to this paragraph (d).

(iii) *Insured plans.* If benefits for hospital lengths of stay in connection with childbirth are provided through health insurance coverage, and the coverage is regulated under a State law described in paragraph (e) of this section, the group health plan is not subject to this paragraph (d).

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2704 of the PHS Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2704 of the PHS Act and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 2704 of the PHS Act and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2704 of the PHS Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 2723(a) of the PHS Act.* The preemption provisions contained in section 2723(a)(1) of the PHS Act and § 146.143(a) do not supersede a state law described in paragraph (e)(1) of this section.

(4) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this *Example 1*, the coverage is subject to state law, and the requirements of section 2704 of the PHS Act and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this *Example 2*, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 2704 of the PHS Act and this section.

(f) *Applicability date.* Section 2704 of the PHS Act applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 1998. This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 3. The authority citation for part 148 continues to read as follows:

Authority: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–41 through 300gg–63, 300gg–91, and 300gg–92).

■ 4. Section 148.170 is revised to read as follows:

§ 148.170 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule.* Except as provided in paragraph (a)(5) of this section, an issuer offering health insurance coverage in the individual market that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital.* If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital.* If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the issuer provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a policy issued in the individual market goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a policy issued in the individual market gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a policy issued in the individual market gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3*, the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* An issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the issuer for

prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, an issuer subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the issuer requires an attending provider to complete a certificate of medical necessity. The issuer then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example*, the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, an issuer, plan, hospital, or managed care organization is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a policy offered by an issuer subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The issuer pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example*, the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* An issuer subject to the requirements of this section may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll in or renew coverage solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under a policy issued in the individual market are discharged within 24 hours after the delivery, the issuer will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the issuer violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the issuer provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2,* because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, an issuer may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* An issuer subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the issuer automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the covered individual must call the issuer to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the issuer will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example,* the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit an issuer from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the issuer based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* An issuer may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a covered individual in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a covered individual in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any issuer that does not provide benefits for hospital lengths of stay in

connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent an issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The issuer covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the issuer also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* An issuer generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the issuer will cover 80 percent of the cost of the stay if the covered individual notifies the issuer of the pregnancy in advance of admission and uses whatever hospital the issuer may designate.

(ii) *Conclusion.* In this *Example 2,* the issuer does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the issuer does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent an issuer from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(5) *Applicability.* This section applies to all health insurance coverage issued in the individual market, and is not limited in its application to coverage that is provided to eligible individuals as defined in section 2741(b) of the PHS Act.

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, an issuer offering health insurance in the individual market must meet the following requirements with respect to benefits for hospital lengths of stay in connection with childbirth:

(1) Required statement. The insurance contract must disclose information that notifies covered individuals of their rights under this section.

(2) Disclosure notice. To meet the disclosure requirements set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

Statement of Rights Under the Newborns' and Mothers' Health Protection Act

Under federal law, health insurance issuers generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the issuer may pay for a shorter stay if the attending provider (*e.g.* , your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, an issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your issuer.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to the covered individuals in the form of a copy of the contract, or a rider (or equivalent amendment to the contract) no later than December 19, 2008.

To the extent an issuer has already provided the disclosure notice in paragraph (d)(2) of this section to covered individuals, it need not provide another such notice by December 19, 2008.

(4) *Exception.* The requirements of this paragraph (d) do not apply with respect to coverage regulated under a state law described in paragraph (e) of this section.

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2751 of the PHS Act and this section do not apply with respect to health insurance coverage in the individual market if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Relation to section 2762(a) of the PHS Act.* The preemption provisions contained in section 2762(a) of the PHS Act and § 148.210(b) do not supersede a state law described in paragraph (e)(1) of this section.

(f) *Applicability date.* Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

Dated: May 11, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2007.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

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