DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2560

RIN 1210—AA61

Employee Retirement Income Security Act of 1974; Rules and Regulations for Administration and Enforcement; Claims Procedure

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains a proposed regulation revising the minimum requirements for benefit claims procedures of employee benefit plans covered by Title I of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). This proposed regulation would establish new standards for the processing of group health disability, pension, and other employee benefit plan claims filed by participants and beneficiaries. In the case of group health plans, as well as certain plans providing disability benefits, the new standards are intended to ensure more timely benefit determinations, improved access to information on which a benefit determination is made, and greater assurance that participants and beneficiaries will be afforded a full and fair review of denied claims. If adopted as final, the proposed regulation would affect participants and beneficiaries of employee benefit plans, plan fiduciaries, and others who assist in the provision of plan benefits, such as third-party benefits administrators and health service providers or health maintenance organizations that provide benefits to participants and beneficiaries of employee benefit plans.

DATES: Written comments (preferably at least three copies) concerning the proposed regulation must be received by the Department of Labor on or before November 9, 1998.

ADDRESSES: Interested persons are invited to submit written comments (preferably at least three copies) concerning the proposed rule to: Pension and Welfare Benefits Administration, Office of Regulations and Interpretations, Room N–5669, 200 Constitution Ave., N.W., Washington, DC 20210. Attention: ''Benefit Claims Regulation.''

All submissions to the Department of Labor will be open to public inspection and copying in the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5638, 200 Constitution Avenue, NW, Washington, DC from 8:30 a.m. to 5:30 p.m.

FOR FURTHER INFORMATION CONTACT: Jeffrey J. Turner or Susan G. Lahne, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210, telephone (202) 219–7461. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

Section 503 of Employee Retirement Income Security Act of 1974 (ERISA or the Act), 29 U.S.C. 1133, provides that every employee benefit plan shall, in accordance with regulations of the Department of Labor (the Department) ''provide adequate notice in writing to every participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant'' and shall also ''afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.'' In 1977, the Department published a regulation pursuant to section 503, establishing minimum requirements for benefit claims procedures for employee benefit plans. That regulation, 29 CFR 2560.503–1 (the current regulation) sets procedural standards that apply without distinction to all employee benefit plans covered under Title I of ERISA, including employee pension benefit plans and employee welfare benefit plans. The current regulation was drafted in response to concerns that predated enactment of ERISA, in particular the lack of any uniform procedural standards for benefit claims resolution and participants' lack of information about claims procedures generally. In order to establish procedural safeguards for individuals promised benefits under ERISA, the current regulation set minimum requirements for the procedures that plans must provide regarding the treatment of benefit claims. The standards applicable under the current regulation are described below.

On September 8, 1997, the Department published in the **Federal Register** (62 FR 47262) a Request for Information (RFI), seeking the views of the public on the advisability of amending the current regulation. The reasons prompting issuance of the RFI were set forth in that document. The RFI articulated a series of questions focusing principally on standards and practices for benefit claim procedures utilized with respect to group health plans, although the RFI also requested information and views on claims procedures more generally. The Department received over 90 comment letters in response to the RFI. The comment letters came from several distinct groups of interested parties: (1) Plan sponsors (employers) and law firms or interest groups representing plan sponsors; (2) plan administrators and benefit provider networks (including insurance companies, ''managed care'' (health benefit provider) networks, third-party administrators, and claim processors) and interest groups representing those parties; (3) benefit claimants and law firms or interest groups representing benefit claimants; and (4) health services providers and interest groups representing them. The National Association of Insurance Commissioners (NAIC) also submitted a comment referring to the model acts that the NAIC has developed for use by states in setting procedural standards for claims and grievances under ''managed care'' arrangements. These comments presented a broad spectrum of opinion on the diverse questions posed in the RFI. The majority of commenters representing employers and benefit administrators argued that no change in the current regulation is needed, especially as the procedural practices currently in use provide substantial protections to claimants in excess of what the current regulation requires. The majority of commenters representing claimants, however, strongly supported procedural reforms that would bring the current regulation more in line with the standards set by the NAIC model acts and by the Health Care Financing Administration (HCFA) with respect to Medicare beneficiaries who receive managed care benefits. The Department believes that the responses represent a fair cross-section of public opinion on the issues of whether and in what fashion the current regulation should be amended. The Department has carefully considered these comments in formulating the proposal. The substance of the comments is summarized below as relevant to specific changes contained in the proposed regulation.

The Department's review of the comments received in response to the RFI has led the Department to conclude that the procedural standards set in the current regulation are no longer adequate to protect participants and

beneficiaries of employee benefit plans. As the Department noted in the RFI, dramatic changes in the more than 20 years since adoption of the current regulation have altered the systems by which employee benefits are delivered and the nature of the benefits themselves. Technological advances have revolutionized systems of communications. Business relationships, including those involving pension and welfare benefits, have become more complex and sophisticated.

The most dramatic changes have occurred in the health industry. The current regulation was adopted at a time when access to health services was controlled principally by the independent judgments of physicians and other health care professionals. Disputes over health benefits almost always took place after the health care services had been provided and concerned whether the group health plan or the individual patient would pay retrospectively for the care, not whether the plan would prospectively authorize coverage for the patient's care. Since that time, the growth of managed care delivery systems [1] has largely transformed the relationship between patient and health care provider. Employee benefit plans that provide health benefits are no longer predominantly indemnity-based, and even those that are indemnity-based generally require preapproval for expensive procedures or hospital admissions. While managed care delivery systems have been instrumental in controlling the rapid rise of health care costs and may, in many instances, provide valuable services in monitoring the quality of health care services provided within a managed care delivery system, they also heighten concern about the fair and expeditious resolution of benefit disputes. Within managed care delivery systems, the separation between medical decision making and decisions on coverage under health benefit plans has been substantially eroded, particularly since a decision to deny coverage for an expensive medical procedure in effect denies that procedure to a participant who cannot afford to pay for the procedure on their own. Access to health care services may be directly ''managed'' (and thereby controlled) by those in charge of coverage under a health benefit plan, rather than by the health care professional with whom an individual consults.

In addition to considering the comments received in response to the RFI, the Department also took into account, in developing this proposal, the recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (the Commission), as set forth in its November 20, 1997, report entitled ''Consumer Bill of Rights and Responsibilities'' (the Consumer Bill of Rights). Among other things, the Consumer Bill of Rights articulates the right of all ''health care consumers'' (including participants and beneficiaries in group health plans covered by ERISA) ''to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.'' In its Report to the President on February 19, 1998 (the February 19 Report), the Department set forth specific steps that it had determined it could take towards implementation of the Commission's recommendations. The following describes the specific commitments with regard to health benefits that the Department made in the February 19 Report, together with references to the specific provisions in the proposal that carry out those commitments:

- The Report indicated that the Department could make clear that a denial includes adverse determinations under a utilization review program; denials of access to (or reimbursement for) medical services; denials of access to (or reimbursement for) specialists; and any decision that a service, treatment, drug, or other benefit is not medically necessary. The proposal provides at paragraph (j)(2) for a definition of ''adverse benefit determination'' that specifically includes these denials.[2]
- The Report indicated that the Department could require that benefit claims and appeals involving urgent care be processed within a time frame appropriate to the medical emergency, but not to exceed 72 hours. The proposal creates expedited time frames for ''claims involving urgent care'' at paragraphs (d)(2)(i) and (g)(2)(ii).
- With respect to non-urgent benefit claims, the Report indicated that the Department could require that the plan either decide the claim or notify the claimant that the claim is incomplete within 15 days of receipt of the claim; claimants would then be afforded not less than 45 days to provide any information that the plan has indicated is necessary to complete the claim; once the claim was complete, it would have to be decided within 15 days. The proposal so provides at paragraph (d)(2)(iii).
- The Report indicated that the Department could make clear that benefit denials must be accompanied by a clear statement of the claimant's right to appeal and of the appeal process. The proposal mandates this specific disclosure at paragraph (e)(1)(iv).
- The Report indicated that the Department could require that, if a non-urgent claim is denied in whole or in part, the claimant must be afforded at least 180 days to appeal the claim and a decision on the appealed claim must be made within 30 days of receipt of the appeal by the plan. The proposal establishes these requirements at paragraphs (f)(2)(i)(A) and (g)(2)(i).
- The Report indicated that the Department could require consultation with qualified medical professionals in deciding appeals involving medical judgments. The proposal imposes this obligation at paragraph (f)(2)(ii)(A).
- The Report indicated that the Department could require that appealed claims be reviewed *de novo* (that is, review may not be limited to information and documents considered in the initial claims denial) and be decided by a party other than the party who made the original claims determination. The proposal incorporates these requirements in paragraphs (f)(2)(i)(D) and (E).

Following the Department's submission of its February 19 Report, the President issued a memorandum dated February 20, 1998, directing the Secretary of Labor to ''propose regulations to strengthen the internal appeals process for all Employee Retirement Income Security Act (ERISA) health plans to ensure that decisions regarding urgent care are resolved within not more than 72 hours and generally resolved within 15 days for

[1] The term ''managed care delivery systems,'' as used here, is intended to include any measures taken by medical practitioners, groups of which medical practitioners are part, insurers, or group health plans to control costs by limiting access to medical services.

[2] The proposal adopts the concept of ''adverse benefit determination'' as a substitute for the less precise concept of ''denial'' under the current regulation. This term is defined to include not only refusals to provide or make payment (in whole or in part) for a benefit, but also any terminations or reductions in providing or paying benefits. The term also expressly includes any such refusal that results from the application of a utilization review directed at cost containment, such as the common current requirement in ''managed care'' and many fee-for-service health arrangements for ''pre-certification'' or ''pre-authorization'' of coverage, and any failure to cover an item of service for which benefits are otherwise available on the basis that the item is ''experimental,'' ''investigational,'' or ''not medically necessary or appropriate.'' Prop. Reg. § 2560.503–1(j)(2). The Department solicits comments on this definition.

non-urgent care.''[3] The proposal incorporates the ameliorative steps outlined in the Department's February 19 Report to the President and takes into account the President's directive. Consistent with the Department's commitment, the adoption of the amendments contained in the proposal will strengthen the internal claims and appeals process for all ERISA plans.

The proposal also builds upon the commitments made to the President, addressing several additional issues not dealt with in the February 19 Report. In particular, the proposal clarifies who is a ''claimant'' and when the time limits begin to apply to a claim. With respect to the concept of a ''claimant,'' the proposal explicitly provides that a claimant is the participant or beneficiary to whom the benefit may be due. The proposal also clarifies the right of claimants to have individuals act on their behalf by eliminating the requirement in the current regulation that claimant representatives be ''duly authorized.'' Prop. Reg. §§ 2560.503–1(a), (b)(5). In this respect, it is the Department's view that an individual's attending physician would generally be treated as a representative of the claimant. The proposal further clarifies that, whether or not a representative is acting for a claimant, notices must, at a minimum, be provided to the claimant. This clarification is provided to reduce any confusion that may result from providing notice only to a representative.

Because the proposal would replace the current regulation in its entirety, much of the proposed regulation is not limited to group health plans. Much of it changes the claim and appeal procedures of employee benefit plans generally, including pension plans, disability plans, and other benefit plans. (Apprenticeship plans are excluded from the proposed regulation, however.) The Department believes that the proposed changes that apply to non-health plans will be beneficial and that it is desirable, as appropriate, to have uniform claim and appeal procedures for different types of employee benefits. The Department solicits comments on the application of the changed claim and appeal procedures to non-health benefit plans.

It is the Department's view that the administrator of a plan has the responsibility to ensure that procedures consistent with section 503 and the Department's regulation are established and maintained. The plan can only act through its trustees, administrators, or others to whom specific responsibilities have been assigned by those trustees and administrators. The proposal therefore clarifies the plan administrator's responsibility with respect to each of the procedural steps delineated in the proposal. The Department understands, however, that plan administrators may contract with third-party administrators or others to carry out aspects of the plan administrator's responsibilities, and this proposal is not intended to preclude such contracts. While the plan administrator may designate another individual or entity to carry out the responsibilities assigned to it under the proposal, the plan administrator would remain responsible for ensuring the required responsibility is discharged in a manner consistent with the Act and regulations.

With respect to the application of time limits, the proposal clarifies that those limits begin to run at such time as a claim is first filed[4] with the plan or a party (including an insurance company or claims adjudicator) acting on behalf of the plan who has the authority to decide the claim. This clarification responds to comments suggesting that there is considerable uncertainty in the public view of the current regulation concerning the standards that should apply to third-party administrators and claims adjudicators hired by a plan to make benefit claims decisions. Many comments suggested that there is a prevalent view that the time limits do not apply to claims reviews conducted by a third party, such as an insurance company or claims adjudicator, that is hired by the plan to conduct an initial claims processing. The proposal articulates the Department's view of the current regulation on this issue and clarifies its application by eliminating the provisions in the current regulation that provide specific treatment for insured welfare or pension plans. *See* Reg. § 2560.503–1(c), (g)(2). It is the view of the Department that these provisions were included in the current regulation to make clear that plans could employ the services of insurance companies and other similar organizations as third-party administrators to make claims decisions, but not to imply that such plans are subject to different standards than other plans that do not employ the services of third-party administrators with respect to the obligations and duties of their administrators.[5] The Department considers that these provisions have become confusing in light of current practices and are no longer necessary to clarify what is permissible procedure.

The proposal also amplifies the provision in the current regulation prohibiting the use of procedures that unduly inhibit or hamper the initiation or processing of plan claims by adding specific examples of prohibited practices. *See* Reg. § 2560.503–1(b)(1)(iii); Prop. Reg. §§ 2560.503–1(b)(3), (b)(4). In this regard, the proposal retains the principle that any provision or practice that requires claimants to pay a fee or costs in order to make or appeal a claim would be considered unduly inhibiting. The proposal also makes clear that practices like the use of ''preauthorization'' requirements as a basis for denying a claim under circumstances in which obtaining the preauthorization is impossible, such as where the claimant is unconscious and in need of immediate medical care, but unable to secure the plan's authorization to obtain the necessary emergency services, are prohibited.

The proposal also clarifies the methods and means that are deemed appropriate for the plan administrator's delivery of the required notifications. The proposal provides that ''notice'' or ''notification'' under the proposal generally should be provided in a manner that satisfies the standards of 29 CFR 2520.104b–1(b) with reference to materials furnished or made available to individuals. Prop. Reg. § 2560.503–1(j)(3).[6] The proposal further specifies that the notices may be provided through electronic means that satisfy the standards of 29 CFR 2520.104b–1(c)(1)(i), (iii), and (iv). Those standards provide assurance that the claimant will know in advance that electronic means will be used for notification, that the

[3] The President further directed the Department to ''propose regulations that require ERISA health plans to ensure the information they provide to plan participants is consistent with the Patient Bill of Rights.'' The Department is publishing today in the **Federal Register** a proposal that would revise the Department's regulation at 29 CFR 2520.102–3 to accomplish, *inter alia,* this goal.

[4] Reference should be made to paragraph (d) of the current regulation for guidance on when a claim is deemed to have been filed.

[5] Whether a party with authority to make claims decisions is acting as a fiduciary depends on the extent to which the party ''exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of it assets, * * * or * * * has any discretionary authority or discretionary responsibility in the administration of such plan.'' ERISA § 3(21)(A).

[6] That regulation provides that plan administrators should use means ''reasonably calculated to ensure actual receipt,'' which include mailing to an address provided by the participant or beneficiary, personal delivery, and disclosure through electronic media provided certain specific standards for electronic distribution are met.

claimant will actually receive the notification, and that a paper copy of any electronically distributed notification will be provided upon request free of charge.

The changes to the minimum procedural standards applicable to claims decisions currently being proposed are intended to update the procedural standards generally applicable to all employee benefit plans and to provide specific, more tailored rules applicable to health care claims and disability claims.[7] It is the view of the Department that the proposed changes in minimum procedural standards for employee benefit plans would substantially improve the administration of employee benefit plans, provide benefit claimants with better understanding of their procedural rights, and ensure that benefit claims are expeditiously and fairly resolved.

This regulation is proposed to be effective 180 days after the date of adoption of a final rule. The Department proposes that the regulation would not be applicable to plans until the later of the effective date or the first day of the first plan year beginning after the effective date. A special applicability date for collectively bargained plans not subject to section 302(c)(5) of the Labor-Management Relations Act (29 U.S.C. 186(c)(5)) is also proposed.

The following discussion addresses other major procedural reforms adopted in the proposal.

1. New Time Frames for Decision-Making

The current regulation provides that all benefit claimants must be informed in writing ''within a reasonable period of time'' if a claim is partially or wholly denied. 29 CFR 2560.503–1(e)(1). The regulation defines any period in excess of 90 days as unreasonable for this purpose, unless ''special circumstances'' require an extension of time for processing, in which case an extension of an additional 90 days is available, provided the claimant is given notice describing the special circumstances prior to expiration of the original 90-day period.

The current regulation also provides that a plan may establish a limited period within which a claimant may seek review of a denial, but such period must be ''reasonable and related to the nature of the benefit which is the subject of the claim and to other attendant circumstances'' and may not be less than 60 days. 29 CFR 2560.503–1(g)(3). A decision on review must be made ''promptly,'' ''ordinarily'' not later than 60 days after request, unless ''special circumstances'' require an extension of time, in which case the decision must be made ''as soon as possible, but not later than 120 days after receipt.'' Special rules are provided for plans operated by committees or boards of trustees that regularly hold meetings at least quarterly. Such plans generally may decide reviews of denials by the date of the next scheduled meeting, unless the request is filed within 30 days preceding the next meeting, in which case the decision may be delayed until the next scheduled meeting. If ''special circumstances'' warrant further delay, the review decision may be delayed until the *third* scheduled meeting of the committee or board.

The proposed regulation retains the current time frames, with minor modifications, for claims under most pension plans and many welfare plans.[8] Prop. Reg. § 2560.503–1(d)(1), (g)(1). Claims involving group health benefits[9] would be governed by new, shorter time frames that are more appropriate to health care decisions. *Id.* at (d)(2), (g)(2). Disability benefit claims would also be subject to new, shorter time frames that, while not as short as the time limits imposed on health care decisions, would ensure more expeditious resolution of these types of claims. *Id.* at (d)(3), (g)(3). The Department solicits comments on the proposed shorter time frames pertinent to disability plans. For group health plans and for disability plans, the proposal also increases to 180 days the period of time during which plans must permit claimants under any plan to appeal an adverse benefit determination.[10] *Id.* at (f)(2)(i)(A). The Department solicits comments on the additional time for claimants to appeal disability determinations. For plans other than group health plans and disability plans, the proposal does not change the current 60 day period during which plans must permit claimants to appeal. The Department however is considering making the proposed 180-day period applicable to all plans. The Department solicits comments on whether the final regulation should provide that all plans must allow claimants at least 180 days to file an appeal from an adverse benefit determination.

With respect to group health claims, the proposal provides a time frame for deciding non-urgent health care benefit claims and a special expedited time frame for deciding health care claims involving urgent care. The proposal requires that notification of initial decisions on non-urgent health care benefit claims generally be provided by the plan administrator within a reasonable period, appropriate to the circumstances, taking into account any medical circumstances, but not later than 15 days after filing. If a claim that is filed is determined to be incomplete, however, for example because it does not contain sufficient factual information, the proposal requires the plan administrator to notify the claimant, within 5 days of receipt, of that fact and of the information necessary to complete the claim. The plan is then required to provide the claimant a period of not less than 45 days within which to provide the missing information. Notification of the decision on that claim would have to be provided within 15 days of the earlier of the date the claimant provides the additional information or the end of the additional period. With respect to decisions on review, the proposal requires plans to provide notifications of decisions on non-urgent health care claims not later than 30 days after receipt of the request for review. The

[7] The current regulation and this proposal pertain to procedures governing claims for benefits. The Department notes that section 206(d)(3) of the Act mandates certain plan procedures for determining the qualified status of domestic relations orders and administering qualified domestic relations orders. It is the view of the Department that issues pertaining to such domestic relations orders must be resolved pursuant to the procedures described in section 206(d)(3) of the Act and not the claims procedures governed by section 503 of the Act and the current regulation.

[8] Under the proposal, the current time frames would continue to apply to benefit determinations on pension benefit claims and welfare benefit claims other than those for group health and disability benefits. The proposal would modify those time frames, however, to require that plan administrators notify claimants, within 45 days of receipt, of any claim that is incomplete when filed and of the information necessary to complete the claim. A plan that provided notice that a claim was incomplete would be required to provide claimants a period of not less than 180 days within which to supplement the claim and would be required to resolve the claim within 45 days of the earlier of the date on which the claimant supplied the requested information or the end of the 180-day period. Prop. Reg. § 2560.503–1(d)(1).

[9] For purposes of the proposal, a ''group health plan'' is a plan within the meaning of section 733(a) of the Act. Prop. Reg. § 2560.503–1(j)(4).

[10] In this regard, the proposal responds to the numerous comments from claimants and their representatives that asserted that the current regulation's minimum standard of 60 days within which a claimant must be permitted to appeal a denial is inadequate. The Department believes, in light of these comments, that providing a longer minimum period of 180 days would ensure that claimants have an adequate period within which to consider whether appeal is warranted and to gather additional evidence to support their claims. The longer period would be unlikely, in the Department's view, to cause plans any additional costs or burdens. Comments are solicited on whether any additional costs or burdens would be imposed by this regulatory change.

Department solicits comment on this aspect of the proposed regulation.

The proposal does not provide for any extension of the time period for deciding non-urgent group health claims. The Department is concerned that providing for such an extension of time would create an opportunity for delay in resolving health care claims and could be subject to substantial abuse that could nullify the intended reform. The Department notes that nothing in the proposed regulation would preclude a claimant from agreeing to an extension of time sought by the plan, inasmuch as the claimant would be entitled, under the proposal, to decide whether to proceed to court in the event that the plan did not comply with the time limits mandated by the proposal.

In the case of group health plans and plans providing disability benefits, the Department is proposing to eliminate the special timing rules for appealed decisions by plans operated by committees or boards of trustees that regularly hold meetings on a quarterly basis. Under the current regulation, such plans are permitted to defer a decision on review until the meeting of the committee or board that immediately follows the plan's receipt of the request for review, unless the request for review is filed within 30 days preceding the date of such meeting, in which case the plan's review may be deferred until the second meeting following receipt of the claim. While elimination of the special rule may require changes in the operation of some group health and disability benefit plans, the Department believes that such changes are necessary and appropriate to ensure timely benefit determinations for participants and beneficiaries covered by such plans.

The proposal requires quicker resolution of health care claims involving urgent care. For purposes of the proposal, a ''claim involving urgent care'' is defined as any claim with respect to which the application of the non-urgent care time frames could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or, in the judgment of a physician with knowledge of the claimant's condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim. Prop. Reg. § 2560.503–1(j)(1). The decision whether a claim involves urgent care would generally be made by an individual acting on behalf of the plan and applying the standard of a reasonable individual who is not a trained health professional; however, any claim that a physician with knowledge of a claimant's medical condition determines to be a claim involving urgent care would be treated as such for purposes of the proposal. Under the proposal, thus, only those claims for which the delay resulting from application of the non-urgent 15-day schedule would carry a risk to the claimant are required to be resolved under the expedited time frame.[11] The Department solicits comment on the proposed definition of a ''claim involving urgent care.''

Under the proposal, claims involving urgent care must be decided as soon as possible after receipt of the claim, taking into account the medical exigencies of the case, but not later than 72 hours after receipt.[12] Prop. Reg. § 2560.503–1(d)(2)(i). Appeals of adverse determinations on urgent care claims also would be required to be decided, and communicated to the claimant, as soon as possible, taking into account the medical exigencies of the case, but not later than 72 hours after receipt of the request for review. *Id.* at (g)(2)(ii).

The Department's view that these shorter time limits are necessary to ensure the timely resolution of group health claims is based in part on the comments received from interested parties in response to the RFI. The majority of commenters who spoke for health plan administrators and health plan sponsors asserted that their routine claims administration practices provide resolution of claims within periods far shorter than the 60 or 90 days referred to in the current regulation. The Department notes that several commenters representing plans indicated that health benefit claims are normally resolved within 5 to 7 days. The consensus of the comments appeared to be that health care claimants need prompt response to their benefit claims and that the health care delivery systems in place today are well-equipped to provide that response. The Department therefore believes that the proposed standards for determining when expedited handling of urgent care claims is necessary and for the timeliness of resolving such claims are both appropriate and feasible.

The proposal also adopts shorter, specific time limits for resolving disability claims. Prop. Reg. § 2560.503–1(d)(3), (g)(3). Under the proposal, those claims must be resolved initially within 30 days (with a further requirement that notification as to incomplete claims be made within 15 days), and appeals of adverse determinations on disability claims must be resolved within 45 days. This proposal is made in response to issues raised by commenters to questions in the RFI on timeliness of resolution of long-term disability claims. Most commenters representing claimants asserted that many disability plans take the maximum amount of time available under the current regulation to resolve disability claims, unnecessarily delaying decisions on benefit payments. Because many claimants are dependent upon these payments for general support, the Department believes that shorter periods for benefit determination are appropriate for these claims. The Department solicits comment on the shorter time limits to resolve disability claims.

2. New Disclosure Requirements

The proposal contains several new disclosure-type requirements that would be applicable to all plans. The Department solicits comment on the burden to plans of the new requirements for disclosure, including the effects on group health, pension, disability, and other benefit plans. First, the proposal reinforces the current requirement that a claims procedure will be considered ''reasonable'' only if it is described in the summary plan description (SPD) of the plan as required by 29 CFR 2520.102–3. Prop. Reg. § 2560.503–1(b)(2). The proposal clarifies that descriptions of all benefit claims procedures of the plan and the time limits applicable to the procedures must be disclosed as part of the SPD. The proposed regulation further clarifies that the plan's benefit claims procedures include all procedures for filing claim forms, providing notification of benefit determinations, reviewing denied claims, and, for group health plans, for obtaining preauthorizations, approvals, or utilization review decisions. It is the Department's intention in proposing this clarification to remove any uncertainty regarding whether

[11] It is anticipated that ''claims involving urgent care'' would largely involve claims for access to care, rather than claims respecting payment for care because, under the proposed definition, a claim would not involve urgent care unless failure to decide the claim on an expedited basis would create a risk to the claimant's health or cause unmanageable pain. This would not ordinarily be the case with claims where services have already been provided and only the question of payment remains unresolved.

[12] If the plan determines that an urgent care claim is incomplete, the plan administrator would be required under the proposal to notify the claimant of that fact, and of the missing information, within 24 hours of receipt of the claim, and the claimant would be permitted not less than 48 hours to provide the specified information. The decision on the claim would then be required to be provided to the claimant not later than 48 hours after the earlier of the plan's receipt of the specified information or the end of the additional period of time.

''managed care'' arrangements that involve pre-approval or pre-certification of eligibility for benefits are considered part of the plan's benefit claims procedures and therefore subject to disclosure. The Department considers this enhanced description of the mandated disclosure an important reform because of the apparent confusion about the treatment of such procedures demonstrated by the comments received in response to the RFI and because of the emphasis placed by the Commission on the need for increasing health consumers' awareness of the limits placed on benefit eligibility through such ''managed care'' measures.

The proposal also clarifies the current regulation's requirement that the written notification of an initial adverse benefit determination must include a reference to the plan provisions on which the determination is based. Prop. Reg. § 2560.503–1(e)(1)(ii). The proposal states that this reference must identify specifically any internal rules, guidelines, protocols, etc. that have been used by the initial decision-maker as a basis for denying the claim. The Department intends by this clarification to emphasize that such internal rules are ''instruments under which the plan is established or operated'' and, as such, cannot be concealed from claimants, who have a legitimate right to understand the rules that govern benefit claims decisions.[13]

Under the proposal, the notification is required to include a full description of the plan's review processes, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse determination on review. Prop. Reg. § 2560.503–1(e)(1)(iv). Many of the comments received from employers, plan representatives, and claimants alike requested that the disclosure be amplified to include fuller descriptions of the administrative review process and the possibility of court review. The comments indicate widespread misunderstanding among benefit claimants of their rights to appeal adverse benefit determinations, and this problem is confirmed by the Commission's findings. The Department agrees that claimants whose benefit claims are denied need to understand fully the basis for the denial and their avenues of appeal. While inclusion of a description of the benefit claims procedures in the SPD provides some basic level of information, claimants whose claims are denied have a more immediate need and will be provided more helpful guidance if this information is included directly in the notification of an adverse benefit determination. Better understanding by claimants of the plan's terms and the claimants' rights will, in the Department's view, serve to both expedite reviews and reduce unwarranted appeals.

Thirdly, the proposal clarifies the current regulation's requirement that claimants must be provided, upon receiving an adverse benefit determination, with access to ''pertinent documents.'' The comments received in response to the RFI support a need to clarify this requirement because they demonstrate substantial confusion about its scope. The proposal makes clear that claimants are entitled to review all documents, records, and information relevant to their claims for benefits, whether or not such documents, records, and information were in fact relied upon by the plan in making the adverse benefit determination. Prop. Reg. § 2560.503–1(f)(2)(i)(C). Such information would include internal rules, guidelines, protocols, and criteria under which the plan is operated and any documents or records that may be favorable to the claimant's position. In the Department's view, permitting the claimant access to relevant documents, records, and information would generally satisfy the claimant's need to understand the evidentiary basis for the decision and therefore to determine whether an appeal is justified and how such an appeal might best be pursued.

The proposal further provides claimants whose appeals on review are denied with access, upon request, to relevant documents, records, and information, to the extent not previously provided to the claimant. Prop. Reg. § 2560.503–1(h)(3). In particular, the proposal requires disclosure of any documents that were created or received during the review process, including, specifically, the reports and identities of any experts consulted by the plan during the review. In the view of the Department, allowing this further access would advance the same goals articulated above with respect to the request for review. In particular, claimants would be better equipped to determine whether to pursue their claims further by filing a civil action under section 502(a) of the Act.

The Department is concerned that claimants who have filed a civil action following an adverse benefit determination on review do not have sufficient access to information that will aid them in determining whether the plan and insurance issuer have acted fairly and consistently in denying their claims, in light of the plan's practices in deciding other claims that involve the same plan or contract language, the same diagnosis, and the same treatment. Such information may be important to claimants who file suit to recover benefits because courts have frequently held that, where plan fiduciaries have discretionary authority to determine eligibility for benefits, benefit claims decisions may be overturned only if the claimant demonstrates that the decision was unreasonable or arbitrary and capricious. *See, e.g., Firestone Tire & Rubber Co.* v. *Bruch*, 489 U.S. 101 (1989). Although evidence regarding plan decisions on other, similar claims may be necessary to support a case of unreasonable or arbitrary and capricious treatment, it is not clear that courts would allow a claimant access to such evidence as part of the discovery process. *See, e.g., Chambers* v. *Family Health Plan Corp.*, 100 F. 3d 818, 821 (10th Cir. 1996) (review of benefit denial limited to evidence before plan at time of denial, although court of appeals noted that ''magistrate judge stated that if she had been able to conduct a de novo review of all the evidence, she would have found that [plan's] denial of coverage was erroneous''). As a result, the Department is considering adding to the final regulation a requirement that the plan administrator provide each claimant who receives an adverse benefit determination on review with respect to a health benefit claim with a statement that, in the event of litigation challenging the benefit determination, he or she will be entitled to receive, upon request, reasonable access to and copies of all documents and records relating to previous claims involving the same diagnosis and treatment that were decided by the plan within the five years prior to the adverse benefit determination. If the claim involved benefits that were provided through insurance, the health insurance issuer would also be subject to this disclosure requirement with respect to previous claims involving the same diagnosis and proposed treatment and the same plan or insurance contract language. The plan and issuer would be required to provide information on claims decided in the previous five years, up to a

[13] In Advisory Opinion 96–14A (July 31, 1996), the Department stated its opinion that ''usual and customary'' fee schedules used as a basis for determining the dollar amount that would be paid for health claims are ''instruments under which the plan is established or operated'' within the meaning of section 104(b) of the Act and therefore must be furnished to participants and beneficiaries upon written request. The Department emphasized that under ERISA participants and beneficiaries should have access to documents that directly affect their benefit entitlements. This principle takes on an enhanced importance when such documents are directly relevant to the denial of a specific benefit claim.

maximum of 50 of the most recent such claims, and the claims records would have to be redacted or otherwise screened as necessary to protect the privacy of the claimants involved in the previous claims.

The Department solicits comments on the advisability of the proposed policy. Furthermore, the Department recognizes that there may be other ways to address the problem described above, and is open to consideration of whether such additional disclosure is necessary or sufficiently beneficial to justify any burdens or cost it may impose on plans. The Department solicits comment on the contemplated requirement and, in particular, about the burden on group health plans of this provision, including whether there should be a charge for redacting the records or providing such copies, as well as how the charge should be determined.

3. New Notice Requirements

The proposal contains new notice requirements that are intended to ensure that participants and beneficiaries are afforded fair and timely consideration of their claims and appeals of those claims as mandated by section 503 of the Act. In every instance, the plan administrator is responsible for providing claimants with the required notification at each level of the claims process. While the plan administrator may designate another individual or entity to generate and deliver the notices to claimants, in the Department's view, it is the plan administrator's responsibility to ensure that the required notification is provided.

First, the proposal requires notification to participants and beneficiaries where the participant or beneficiary makes a request for benefits, but fails to follow the plan's claim filing procedures. Prop. Reg. § 2560.503–1(b)(6). In such circumstances, the plan would have to provide the participant or beneficiary, within 5 days (24 hours in the case of an urgent care request), with a notice explaining that the participant's or beneficiary's request does not constitute a claim because it fails to satisfy the plan's filing procedures. The notice would also have to describe those filing procedures. This requirement would ensure that no reasonable attempt to file a claim could be ignored by a plan for failure to meet some aspect of the filing process set up by the plan, but would also preserve the integrity of those procedures.[14]

Second, as mentioned above in connection with the proposed new time frames, the proposal imposes an obligation on plan administrators to inform claimants promptly of any claims that, while properly filed, are found to be incomplete. Prop. Reg. § 2560.503–1(d)(1), (2). For each type of plan subject to a specific time frame, the proposal establishes an earlier time at which notification of an incomplete claim must be given. The notice would include a description of the information necessary to complete the claim. The comments submitted in response to the RFI suggested that in many instances plans delay in informing claimants of obvious deficiencies in their claim filings until the end of the maximum time period for making a decision, resulting in successive periods of delay. It is the view of the Department therefore that specification of this additional procedural step would significantly reduce unnecessary delay in resolving claims by focusing early attention on the completeness of any filing. Moreover, because, as discussed below, appealed claims must be reviewed by a party different from the initial claims reviewer, the Department believes that a mechanism is necessary to enable and encourage initial claims reviewers to compile complete files on a claim prior to a determination. This will reduce the number of claims denials that are likely to be reversed on appeal and increase the number of correct initial decisions.

Third, the proposal requires notice to claimants in some instances in which health care benefits that are being provided over a period of time are subsequently terminated or reduced. The proposal provides that if a plan has granted a health care benefit that is to be provided over a period of time, whether for a specific time period or an unlimited period, and the plan later determines to reduce or terminate the benefit (before the end of a specified period for benefits of specific duration), the reduction or termination is deemed to be an adverse determination of a benefit claim.[15] Moreover, if the termination or reduction would create a situation meeting the proposal's definition of a ''claim involving urgent care,'' the plan administrator would be required to give notice of that decision at a time sufficiently in advance of the termination or reduction to provide the claimant with the opportunity to appeal before the termination or reduction takes effect.[16] Prop. Reg. § 2560.503–1(d)(2)(ii). The Department believes that, in circumstances where the denial of continuation of a benefit may create a health risk to the claimant, advance notice of the denial is necessary in order to ensure a timely full and fair review. Requiring advance resolution of any dispute over the denial of health benefits of a continuing nature, where serious harm to the claimant may be involved, will also reduce the possibility of unintended harm to the claimant.

4. New Standards of Review on Appeal

The proposal adopts new standards for what constitutes a full and fair appeal of an adverse benefit determination. In this respect, the proposal responds to comments that allege bias on the part of claims reviewers and a need for more independent decision-making. Under the current regulation, claimants whose claims have been denied must be provided an opportunity to request review and to submit issues and comments in writing. The proposal supplements these minimums by requiring that the review of an adverse benefit determination be conducted by an appropriate named fiduciary who is neither the party who made the initial adverse determination, nor the subordinate of such party; that the review not afford deference to the initial adverse benefit determination; and that the review take into account all comments, documents, records, and other information submitted by the claimant, without regard to whether such information was previously submitted or relied upon in the initial determination. Prop. Reg. § 2560.503–1(f)(2)(i)(D), (E). It is the Department's intention in making this proposal that a claimant be permitted upon appeal to raise, and have considered, additional issues and evidence beyond those presented at the initial determination.

With respect to adverse benefit determinations involving health care

[14] In this regard, the proposal eliminates the provision in the current regulation that deems a claim to be filed, with respect to a plan that does not have reasonable filing procedures, when it is brought to the attention of an appropriate person responsible for benefit claims decisions. This ''deeming'' provision is unnecessary and would be counterproductive in the context of the proposal because the proposal provides that, in any case in which a plan fails to provide reasonable procedures, a claimant is entitled to treat the procedures as having been exhausted and to immediately pursue the claim in court pursuant to section 502(a) of the Act. *See* Prop. Reg. § 2560.503–1(i).

[15] The proposal is not intended, however, to require settlor decisions to amend or terminate a plan to be treated as adverse benefit determinations, even if such decisions result in the termination or reduction of a benefit being provided over a period of time.

[16] The termination or reduction would have to cause a risk to the claimant's health of sufficient degree to make application of the standard time frames for deciding health care claims inappropriate. *See* Prop. Reg. § 2560.503–1(j)(1).

claims, the proposal requires that the review of any determination based on a medical judgment be conducted through consultation with a health care professional who is independent of any health care professional involved in the initial decision and who has appropriate training and experience in the field of medicine involved in the medical judgment.[17] Prop. Reg. § 2560.503–1(f)(2)(ii)(A). In addition, the proposal provides that any appeal of a claim involving urgent care must be conducted on an expedited basis in which the review may be requested orally or in writing and necessary information, including the decision on review, may be transmitted by telephone, facsimile, or other similarly expeditious means. Prop. Reg. § 2560.503–1(f)(ii)(C).

The Department believes that these minimum requirements are essential to affording participants and beneficiaries a full and fair review of their benefit claims. In the case of group health plans, the Department believes that the requirement to consult with an appropriately qualified health professional is consistent with the obligation of plan fiduciaries to discharge their duties ''with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.'' ERISA § 404(a)(1)(B). To the extent that the review of group health claims implicates medical judgments, a fiduciary would be constrained to consult an appropriate medical advisor to ensure that any such decisions comport with the standards of section 404(a)(1)(B) of the Act.

The comments indicate that, at least in some percentage of claims reviews, the same decision-maker (or a subordinate of such decision-maker) conducts both the initial processing of a claim and the review of a denial. The comments also assert instances in which decision-makers have refused to permit expansion of the evidentiary record on review or have ignored additional submissions in making decisions on review. The Department believes that the proposal would prevent these practices, consistent with the recommendations of the Commission, and would ensure full and fair review of adverse benefit determinations.

[17] Nothing in this proposal is intended to limit the extent to which a plan fiduciary may consult with others as appropriate under the circumstances in reaching a decision on appeal.

In proposing this regulation, one of the Department's primary concerns is to prevent unnecessary delays in resolving claims disputes, especially in situations where the dispute must be resolved before the plan will provide the requested benefit. The Department considers it essential that claimants be free to decide, after having completed the minimum number of administrative appeals necessary to allow for a full and fair review of the claim, whether to continue to pursue a claim through a plan's additional procedures, if any, or to file suit under section 502(a) of the Act. Thus, the proposed regulation provides that benefit claim procedures may not include more than one level of mandatory appeal and that plans are precluded from requiring claimants to submit to binding arbitration either subsequently or as part of that single level of appeal. In making this proposal, it is not the Department's intention to require plans to dismantle effective and fair claims procedures that they have already put in place. As a result, the Department is willing to consider whether procedures that require more than one appeal would be reasonable. The Department also notes that there is nothing in the proposal that would preclude a plan from establishing a second level review or appeal process following a determination on review in accordance with this regulation, or from offering to submit a determination to arbitration, provided that such review or arbitration is voluntary on the part of the claimant and does not otherwise serve to foreclose a claimant from pursuing his or her claim in court. The Department is particularly interested in receiving comments on whether limiting the number of appeals or precluding mandatory arbitration before filing suit is necessary or sufficiently beneficial to prevent delays or unfairness in making and reviewing benefit claims. The Department also solicits comments on the appropriate number of appeals at which such limit should be set.

5. Consequences of Failure to Establish and Follow Reasonable Claims Procedures

Many of the comments that the Department received in response to the RFI asserted that plans often fail to follow the minimum standards for procedural fairness set by the current regulation. The Department believes it is important to make clear that the claims procedure regulation prescribes the minimum standards for an administrative claims review process consistent with ERISA. Accordingly, a failure to provide the procedures mandated by the regulations effectively denies participants and beneficiaries access to the administrative review process mandated by the Act. It is the view of the Department that claimants should not be required to continue to pursue claims through an administrative process that fails to meet the minimum standards of the regulation. At a minimum, claimants denied access to the statutory administrative review process should be entitled to pursue claims under section 502(a) of the Act. In addition, such claimants should be entitled to a full and fair review of their claims in the forum in which they are first provided adequate procedural safeguards. The proposal therefore incorporates a new paragraph (i) that would specify more clearly the consequences that the Department believes flow from a failure to provide procedures that meet the minimum regulatory standards. Under the proposed paragraph (i), a claimant who attempts to pursue a claim is deemed to have exhausted the administrative remedies available to him or her if the plan fails to provide or to abide by procedures that meet the regulatory minimum standards required under the proposal. Such a claimant is entitled to pursue any remedies he or she may have under section 502(a) of the Act on the basis that the plan has failed to provide a reasonable claims procedure that would yield a full and fair decision on the merits of the claim. Prop. Reg. § 2560.503–1(i). It is the Department's view that, in such a case, any decision that may have been made by the plan with respect to the claim is not entitled to the deference that would be accorded to a decision based upon a full and fair review that comports with the requirements of section 503 of the Act.

In addition to the above, the failure to establish or maintain claims procedures in accordance with regulations issued by the Secretary pursuant to section 503 of ERISA, would be a violation of section 503 which could give rise to a cause of action under sections 502(a)(3) or (a)(5) of ERISA for appropriate equitable relief. It is also possible, depending on the circumstances, that an action or omission by a plan fiduciary which does not comply with the requirements of such regulations would also constitute a fiduciary breach in violation of ERISA sections 404(a)(1)(A), (B), or (D). Such potential consequences are beyond the scope of this rulemaking.

6. Other Changes

The Department is proposing to eliminate two provisions in the current regulation that provide special treatment for two classes of plans. First, the proposal eliminates the special

treatment afforded by paragraph (b)(2) of the current regulation for plans established and maintained pursuant to a collective bargaining agreement (other than plans subject to section 302(c)(5) of the Labor Management Relations Act of 1947, 29 U.S.C. 186 (c)(5)) (non-Taft-Hartley plans). The current regulation provides that such a collectively-bargained plan is deemed to satisfy the standards for claims filing procedures, procedures for initial decisions, and procedures for review if the collective bargaining agreement incorporates (by reference or directly) provisions for the filing and initial disposition of claims and for a grievance and arbitration procedure to which denied claims are subject.[18] Second, the Department is proposing to eliminate the special treatment afforded under paragraph (j) of the current regulation to certain plans that provide benefits through membership in a qualified health maintenance organization (HMO), as defined in section 1310(d) of the Public Health Service Act, 42 U.S.C. 300(e)-9(d) (the PHSA). The current regulation provides that such plans are deemed to satisfy the standards of the regulation with respect to such benefits if the claims procedures provided by the qualified health maintenance organization meet the requirements of section 1301 of the PHSA. Under the proposal, both of these types of plan would be fully subject to the new procedural standards applicable based on the type of benefit provided.

This approach is in accord with the majority of the comments received in response to the RFI. Several of the questions posed by the RFI focused on whether there is a perceived need for greater uniformity in the procedural standards applicable to employee benefit plans. A majority of the comments asserted that such a need exists and argued that the lack of uniformity, and specifically the special rules applicable to group health plans offering HMO-type benefits, has led to confusion among benefit claimants as their rights and their avenues of appeal. On this basis, the Department has determined to propose eliminating the special treatments provided under the current regulation. Elimination of these special provisions will help ensure that participants and beneficiaries will be provided timely benefit determinations and full and fair reviews of denied claims without regard to whether they participate in an HMO-type or collectively bargained plan. The Department solicits comment on these changes for greater uniformity in the standards for benefit plans.

[18] Alternatively, a non-Taft-Hartley collectively-bargained plan may comply with the initial filing and decision standards of the current regulation and be exempted from complying with its review standards if its collective bargaining agreement incorporates the grievance and arbitration procedure as the avenue for denied claims.

B. Economic Analysis Under Executive Order 12866

Under Executive Order 12866, the Department must determine whether the 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 consistent with the President's priorities as articulated in the President's February 20, 1998, directive to the Secretary of Labor to issue proposed rules implementing the recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. In addition, the Department estimates that this regulatory action will have an economic effect exceeding $100 million in the year 2000. Therefore, this notice is ''significant'' and subject to OMB review under sections 3(f)(1) and 3(f)(4) of the Executive Order.

Therefore, consistent with the Executive Order, the Department has undertaken to assess the costs and benefits of this regulatory action. The Department's assessment, and the analysis underlying that assessment, is detailed below.

The Department projects that the proposed regulation will prompt all ERISA-covered employee benefit plans to revise their claims and appeals procedures by the end of calendar year 2000. The new procedures will better ensure the timeliness, fairness, and accuracy of claims and appeals determinations, but will also be somewhat more costly to administer. Therefore, the proposed regulation is expected both to yield benefits and to impose costs. Expected improvements in the timeliness, accuracy, and fairness of determinations will be of benefit to plan participants and beneficiaries. Costs will be incurred in connection with the implementation and administration of improved claims and appeals procedures.

The Department estimates the proposed regulation will add $30 million to annual claims and appeals processing costs in 2000, reflecting the processing of 806 million claims. This amounts to $0.04 per claim or $0.09 per participant. This ongoing cost will change each year as claims volume increases or decreases or as the actual proportions of claims by type (*e.g.*, pension, health, long-term disability) differ from the proportions assumed for purposes of this analysis. The proposed regulation will also impose a one-time start-up cost of $125 million in 2000 to design and implement the new procedures. This amounts to $0.35 per participant.

The data, assumptions, and analysis underlying this assessment of costs are summarized following the discussions of the Regulatory Flexibility Act and the Paperwork Reduction Act.

These estimates are for administrative costs associated with processing claims and appeals. A separate question involves how many claims determinations might be changed as a result of this proposed regulation, and what the costs and benefits of those changed determinations might be.

The Department was unable to develop quantitative estimates of changes in determinations or of the associated costs and benefits, and solicits comments on the expected nature and magnitude of these changes, costs, and benefits. What follows is a qualitative discussion of these issues.

The Department expects that the proposed regulation will reduce the number of inaccurate claims determinations, especially following appeal. It will also accelerate any health and disability claims determinations that would otherwise have been delayed longer than permitted under the proposed regulation. The regulation is further likely to influence some claimants' decisions as to whether and how to appeal denied claims. Finally, if the proposed regulation increases the likelihood that some accurate and previously undisputed claim denials will now be appealed, and if the

expected cost of such appeals exceeds the cost of paying these claims, plans might elect to pay rather than deny them. The costs and benefits of each of these effects is considered below.

The proposed regulation's provisions requiring fuller review of denied claims aim to reduce the number of inaccurate claims determinations. In particular, the Department expects that some claims which otherwise would have been denied on appeal, but which in fact should have been paid under plans' terms, will now be paid. The Department has no data on how many denied appeals should have been approved. Economic theory suggests, however, that all else equal, improving adherence to private voluntary agreements such as plans' terms tends to increase economic efficiency by reducing losses of social welfare. Therefore, the Department believes that the benefits associated with this effect of the proposed regulation are likely to outweigh the costs. The Department also notes that plans' obligations to pay covered benefits arise from plans' terms and from ERISA's statutory provisions and are not modified by this proposed regulation.

Accelerating the processing of some claims and appeals may also change some claims determinations. For example, delays in processing health benefit claims can result in delays in medical treatment. Those delays in turn can result in the deterioration of claimants' medical condition to the point that the treatment is no longer medically safe or effective. Thus, accelerating the processing of medical claims may result in payment for some treatments that otherwise would not have been provided. On the other hand, deterioration in claimants' medical condition may result in additional claims for additional treatment. Thus, accelerating health benefit claims processing may eliminate some claims. The Department is uncertain of the magnitude of these two offsetting effects, but notes that both are associated with the potential for better medical outcomes and are therefore are likely to be of substantial economic benefit.

The Department also expects that the proposed regulation may influence denied claimants' decisions about whether to appeal. Providing claimants with fuller information on their appeal rights, with an opportunity for fuller and more timely review of their denied claims, and with a longer period of time in which to prepare and submit an appeal might prompt more claimants to appeal more denied claims. Providing claimants with fuller information on the reasons for claims denials might facilitate and prompt some appeals, but might discourage others. To the extent that additional appeals result in the reversal of inaccurate claims denials that would otherwise have been sustained, this would represent an improvement in the accuracy of claims determinations, as discussed above. Additional appeals that are denied would increase administrative cost, and reductions in appeals that would have been denied would reduce administrative cost. Discouraging appeals of inaccurate claims determinations, which would have been reversed on appeal, could reduce social welfare, but the Department believes providing fuller information to denied claimants will rarely discourage them from appealing inaccurate determinations. In summary, the main effects of any change in denied claimants' appeals decisions are likely to be some improvement in the accuracy of determinations and an increase or decrease in administrative costs.

Finally, the Department considered whether the proposed regulation might prompt plans to approve some claims that are not truly covered under plans' terms in order to avoid the higher expected cost of processing associated appeals. ERISA obligates plan fiduciaries to administer plans in accordance with the plans' terms. Nonetheless, it is possible that plans may engage in at least some such inaccurate claims approvals under the current regulation. Such inaccurate claims approvals might increase if the proposed regulation increases the likelihood that some accurate and previously undisputed claim denials will be appealed, and/or if it increases the expected cost of some appeals of accurate claims denials to an amount greater than the cost of paying these claims. Increasing inaccurate claims approvals could reduce overall social welfare. However, such losses might sometimes be accompanied by improved medical outcomes and associated economic benefits, and might be offset by potential welfare gains from discouraging appeals of accurate claims denials, which are noted above. The Department lacks data to estimate the potential increase in inaccurate claims approvals and associated costs and benefits, and solicits comments on this question.

The Department also considered potential indirect effects of the proposed regulation on plans sponsors' decisions regarding plan sponsorship, design, and benefit levels. Provisions that increase plans' administrative costs or that result in net increases in plans' claims payments might prompt plan sponsors to reduce benefits, to alter plan designs so as to offset or eliminate additional claims payments (for example by clarifying or expanding exclusions from coverage in a health benefit plan document), to fail to adopt or enrich benefit plans, or even to drop benefit plans entirely. Because the estimated cost of this proposed regulation is exceptionally small relative to the total cost of benefit plans, the Department expects that these effects will be equally small. However, the Department lacks the data to validate this expectation, and solicits comments on whether such effects might be more substantial.

1. Benefits of the Proposed Regulation

The Department believes that the benefits of this proposed regulation, although unquantified, will outweigh its potential costs. In particular, updating the regulation to address recent, dramatic changes in the delivery and financing of health care services can improve health care quality by preventing harmful, inappropriate delays and denials of health benefits, thereby yielding substantial social benefits. This conclusion is supported by the findings of the Commission, The Lewin Group,[19] and the U.S. General Accounting Office (GAO), and by responses to the Department's RFI.

The evidence of changes in the health care system is compelling. In a 1995 survey of 2,000 physicians, 59 percent said their decisions regarding hospital length of stay were subject to review. Forty-five percent were subject to review in connection with site-of-care decisions, as were 39 percent in connection with treatment appropriateness. On average for various types of treatment, plans initially denied between 1.8 percent (for cardiac catheterizations) and 5.8 percent (for mental health referrals) of physician-recommended actions. Average denial rates following appeal ranged from 0.7 percent (for cardiac catheterizations) to 3.0 percent (for mental health referrals). (Dahlia K. Remler *et al.*, ''What do Managed Care Plans Do to Affect Care?

[19] Two different reports prepared by The Lewin Group serve as sources of information for this analysis. In 1997, the Commission contracted with The Lewin Group to analyze the benefits and costs of the information disclosure and external appeals provisions of the Consumer Bill of Rights. The resulting report, dated November 15, 1997, is entitled ''Consumer Bill of Rights and Responsibilities: Information Disclosure and External Appeals.'' The Lewin Group also prepared a report dated May 21, 1998, for the Kaiser Family Foundation, Sierra Health Foundation, and California Wellness Foundation, entitled *Analysis of the Survey of Consumer Experiences in Managed Care, Summary of the Findings.*

Results from a Survey of Physicians,'' *Inquiry* 34: 196–204 (Fall 1997).)

The Department believes that excessive delays and inappropriate denials of health benefits are relatively rare. Most claims are approved in a timely fashion. Many claim denials and delays are appropriate given the plan's terms and the circumstances at hand. Nonetheless, a substantial number of excessive delays and inappropriate denials do occur. When they do, participants and beneficiaries can suffer grievous, avoidable harm.

The proposed regulation's new standards for processing health benefit claims will reduce the incidence of excessive delays and inappropriate denials, preventing serious, avoidable lapses in health care quality and resultant injuries and losses to participants and beneficiaries. It will raise participants' and beneficiaries' level of confidence in and satisfaction with their health care benefits, thereby enhancing the value of those benefits. It will improve plans' awareness of participant, beneficiary, and provider concerns, prompting plan responses that improve health care quality. Finally, by helping assure prompt and precise adherence to contract terms and by improving the flow of information between plans and enrollees, the proposed regulation will bolster the efficiency of health care insurance markets.

2. Preventing Harmful Errors

The 1997 survey of Sacramento-area managed care enrollees conducted by the The Lewin Group identified delay or denial of coverage as the single most prevalent difficulty, reported by 42 percent of enrollees with difficulty. Among those experiencing delays or denials, 41 percent suffered resultant financial losses, while 8 percent lost more than $1,000. Twenty-seven percent lost time from school or work, and 9 percent lost more than 10 days. Eleven percent reported worsened health; 3 percent were permanently disabled. It is likely that many of the reported coverage delays and denials were appropriate, but it is also likely that at least some were not. The proposed regulation will help reduce the number of managed care enrollees harmed by delay or denial of health coverage.

The report prepared for the Commission by the The Lewin Group documents the potential benefits of improved health benefits appeals processes. The report focuses on external appeals, but the Department believes that, by improving plans' internal appeals processes, the proposed regulation will yield at least some of these same benefits. According to Lewin, both consumers and plans can benefit from improved appeals processes. Effective appeals procedures can prevent claims disputes from escalating into costly litigation, thereby saving money for both plans and consumers. Such procedures can also improve consumer confidence and may elevate health care quality, Lewin says.

The Commission's Consumer Bill of Rights notes that improved claims and appeals procedures serve many purposes. It notes that ''first and foremost, enhanced internal and external review processes will assist consumers in obtaining access to appropriate services in a timely fashion, thus maximizing the likelihood of positive health outcomes.''

The Commission's final report to the President, entitled ''Quality First: Better Health Care for All Americans,'' also documents the expected benefits of improving claims and appeals procedures. Chapter 10, ''Reducing Errors and Increasing Safety in Health Care,'' points out that some patients suffer harm when ''inappropriate benefit coverage decisions * * * impinge on or limit the delivery of necessary care.'' A wrongful denial of coverage ''can lead to a delay in care or to a decision to forego care entirely.'' The report points out that ''even a small number of mistakes * * * can have serious, costly, or fatal consequences,'' such as ''additional health expenses, increased disability, lost wages, and lost productivity.''

3. Improving Consumer Confidence

With respect to consumer confidence, the Consumer Bill of Rights concludes that shorter time frames for claims and appeals handling will improve participants' and beneficiaries' confidence in their health plans. It states that ''the opportunity for consumers to be heard by people whose decisions significantly touch their lives evidences respect for the dignity of consumers as individuals and engenders their respect for the integrity of the institutions that serve them.''

The proposed regulation will do much to improve the public's general perception of managed care. In various surveys, consumers have expressed concern that plans sometimes withhold care or benefits. The ability to get a promised benefit, particularly when sick or disabled, is at the heart of these consumer concerns. A Kaiser Family Foundation/Harvard University survey [20] found that a majority of Americans say managed care plans have made it harder for people who are sick to see medical specialists and have decreased the quality of health care for the sick. A majority of those in managed care plans are very or somewhat worried that their health plan would be more concerned about saving money than about what is the best treatment for them if they are sick. Improved confidence may in itself represent derivation of greater value from health care coverage.

4. Signaling Consumer and Provider Concerns

Effective claims procedures can also improve health care and health plan quality by serving as a communication channel, providing feedback from participants, beneficiaries, and providers to plans about quality issues.

The Consumer Bill of Rights asserts that enhanced appeals procedures ''can be used to bridge communication gaps between consumers and their health plans and providers, and to provide useful information to all parties regarding effective treatment.''

GAO [21] points out that plan participants and beneficiaries who have a choice of coverage options and who experience difficulty with their health plan may respond by simply moving to a different coverage option. This response is especially likely if participants and beneficiaries believe that their plans' claims and appeals procedures will not effectively resolve their difficulty. Unlike initiating an appeal, however, this response may fail to alert plans to the difficulty that prompted it if plans do not inquire into their loss of members. More effective appeals procedures can give participants and beneficiaries an alternative way to respond to difficulties with their plans. Plans in turn can use the information gleaned from the appeals process to improve services.

By providing an alternative to disenrollment, improved claims and appeals procedures may also reduce disenrollment rates. Although such disenrollments may serve to lower expenses for managed care organizations (MCOs) in the short term, lowering disenrollment rates may offer MCOs additional incentives to keep enrollees healthy over the long term, prompting efforts to promote preventive

[20] ''Kaiser/Harvard National Survey of Americans' Views on Consumer Protection in Managed Care,'' Kaiser Family Foundation, January 1998.

[21] *HMO Complaints and Appeals: Most Key Procedures in Place, but Others Valued by Consumers Largely Absent* (GAO/HEHS–98–119, May 12, 1998)

care and healthy lifestyles. In contrast, the high disenrollment rates associated with ineffective claims and appeals procedures discourage MCOs from investing in such efforts. Such efforts by MCOs may yield long term improvements in population health and reductions in national health care costs.

5. Improving Health Market Efficiency

Finally, clarification of existing requirements for information disclosure with respect to claims and appeals procedures may have significant benefits for participants and beneficiaries, according to GAO and others. Several studies have found that participants and beneficiaries generally do not understand procedures or their rights with respect to claims and appeals. GAO contends that effective communication with plan participants is one of the most important elements of a claims and appeals procedure, and that improved understanding of these procedures is likely to result in expedited claims and a reduction of unwarranted appeals.

6. Beneficial Improvements

The proposed regulation includes elements of effective claims and appeals procedures that are highly likely to yield substantial benefits. These elements have been identified and endorsed by several respondents to the Department's RFI, GAO, and/or the Commission.

The Department's RFI elicited a number of responses highlighting serious weak points in current health benefits claims and appeals procedure standards. Several respondents cited instances of delays of 120 days or even 6 or 7 months in deciding claims and appeals, and a lack of objectivity in some decisions. They characterized as inadequate the information plans provide to participants and beneficiaries when denying claims and appeals. (Some similar responses were received in connection with non-health welfare and pension benefit claims.) Several respondents specifically recommended requiring fuller disclosure of information on claims and appeal procedures and decisions, and faster and fuller reviews of disputed claims, including review by medical professionals where appropriate.

GAO interviewed organizations representing a range of interests, including private accreditation agencies, consumer advocates, regulators, and the health industry. Through these interviews, GAO heard consistently that there are three essential elements to any complaint and appeal system. These elements are timeliness, integrity in the decision making process, and effective communications. The Department supports the view that improved requirements regarding these features of a claims and appeals process will be beneficial to participants and beneficiaries and has addressed each of these areas in the proposed regulation.

Based on its interviews, GAO further found that timeliness generally consists of two key elements—explicit time periods and expedited review. Although the organizations varied as to the exact length of time that they considered appropriate, all agreed that expedited procedures are critical. The Department supports the view that procedures that are responsive to the clinical urgency of a situation can prevent harm to a patient's health or life and thus have a positive impact on health outcomes.

All the organizations interviewed by GAO agreed that integrity of the decision making process is a critical component of an appeals procedure. GAO concluded that procedures consisting of certain key elements can empower participants and enhance the perception of fairness regarding a plan's procedures. The proposed regulation incorporates many of these factors, including requiring that certain decisions be made with the assistance of a medical professional with appropriate expertise, and that certain decisions be made by individuals not involved in previous denials.

The Commission's final report placed ''highest priority'' on ''creating systems that minimize errors and correct them in a timely fashion,'' concluding that ''one way to reduce the number of injuries related to inappropriate decisions to deny insurance coverage for services that ultimately are determined to be medically necessary and covered by the plan is to establish more timely systems to allow consumers to appeal plan decisions. Establishment of such systems can go a long way toward reducing the number of injuries caused by inappropriate decisions to deny coverage.'' The proposed regulation will help ensure the establishment of such systems.

C. Regulatory Flexibility Act

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. If an agency determines that a proposed rule is likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations, and governmental jurisdictions.

For purposes of analysis under the RFA, the Pension and Welfare Benefits Administration (PWBA) proposes to continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for simplified annual reporting and disclosure if the statutory requirements of part 1 of Title I of ERISA would otherwise be inappropriate for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department 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 large employers may have small plans, in general most small plans are maintained by small employers. Thus, PWBA believes that assessing the impact of this proposed 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.*). PWBA therefore requests comments on the appropriateness of the size standard used in evaluating the impact of this proposed rule on small entities.

On this basis, however, PWBA has preliminarily determined that this rule will not have a significant economic impact on a substantial number of small entities. In support of this determination, and in an effort to provide a sound basis for this conclusion, PWBA has considered the elements of an initial regulatory flexibility analysis in the discussion that follows.

This regulation applies to all small employee benefit plans covered by ERISA. Employee benefit plans with fewer than 100 participants include 629,000 pension plans, 2.6 million health plans, and 3.4 million non-health welfare plans (mainly life and disability insurance plans).

The proposed regulation amends the Department's current benefit claims regulation, which implements ERISA's statutory claims and appeals requirements. Both the Act and the current regulation require plans to maintain procedures to determine claims and to review disputed claims determinations. The compliance requirements of this proposed regulation consist of new standards for claims and appeals procedures.

The Department believes that revising claims and appeals procedures to meet the new standards and administering those revised procedures requires a combination of professional and clerical skills. Some claims determinations involve unique circumstances or issues and therefore demand professional attention, while others are straightforward or formulaic and can be carried out by clerical personnel. Professional skills pertaining to employee benefits law and plan design and administration are needed to design new procedures, to weigh facts and circumstances against plan provisions in order to reach decisions on unique claims, and to prepare forms to be used in providing notice of claims and appeals determinations. Clerical skills are needed to make formulaic determinations and to fill in and distribute notice forms.

The Department estimates that the ongoing, annual cost to small plans of complying with the proposed regulation will amount to $6 million on aggregate, which amounts to $0.04 per claim or $0.13 per participant, in 2000. This ongoing cost will change each year as claims volume increases or decreases or as the types, or ''mix,'' of claims that are filed change. The proposed regulation will also impose a one-time start-up cost of $102 million, or $2.16 per participant, in the year 2000 to design and implement the new procedures.

Most of the one-time start-up cost is attributable to small pension plans. The start-up costs for health plans and other welfare plans are modest primarily because the features of a majority of small welfare plans are chosen from a finite menu of products offered by insurers and HMOs. The insurers and HMOs process claims and appeals the same way or in only a few different ways for all of their small plan customers. Thus, the cost of revising and implementing a relatively small number of claims and appeal procedures is spread thinly over a far larger number of small plans.

The basis of these estimates is explained below, following the discussion of the Paperwork Reduction Act.

D. Paperwork Reduction Act

The Department, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, PWBA is soliciting comments concerning the proposed revision of the information collection request (ICR) included in this Notice of Proposed Rulemaking with respect to Rules and Regulations for Administration and Enforcement; Claims Procedure. A copy of the ICR may be obtained by contacting the office listed in the addressee section of this notice.

The Department has submitted a copy of the proposed information collection to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Pension and Welfare Benefits Administration. Although comments may be submitted through November 9, 1998, OMB requests that comments be received within 30 days of publication of the Notice of Proposed Rulemaking to ensure their consideration.

ADDRESSES (PRA 95): Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, NW, Room N–5647, Washington, D.C. 20210. Telephone: (202) 219–4782; Fax: (202) 219–4745. These are not toll-free numbers.

Appendix

I. Background

Section 503 of ERISA provides that, pursuant to regulations promulgated by the Secretary of Labor, each employee benefit plan must provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied. This notice must set forth the specific reasons for the denial and must be written in a manner calculated to be understood by the claimant. Each plan must also afford a reasonable opportunity for any participant or beneficiary whose claim has been denied to obtain a full and fair review of the denial by the appropriate named fiduciary of the plan.

The Department previously issued a regulation pursuant to section 503 that establishes certain minimum requirements for employee benefit plan procedures pertaining to claims. The ICR included in the benefit claims regulation generally requires timely written disclosures to participants and beneficiaries of employee benefit plans of information concerning the plan's claims procedures, the basis for the denial of a claim, and time limits for addressing or appealing the denial of a claim. These requirements are intended to ensure that plan administrators provide a full and fair review of claims and that plan participants and beneficiaries have information that is sufficient to allow them to exercise their rights under the plan.

II. Current Actions

As described in detail in this preamble, the Department proposes a number of modifications to the current regulation pursuant to ERISA section

503, which establishes minimum requirements for benefit claims procedures for employee benefit plans. Generally, modifications are proposed for provisions affecting time frames for decision making, disclosure and notice requirements, standards of review on appeal, and consequences of failure to establish and follow reasonable claims procedures. The methodology and assumptions used in estimating the burden hours and costs associated with employee benefit plan claims procedure rules as proposed are described in the analysis of cost, which follows.

Agency: Department of Labor, Pension and Welfare Benefits Administration.

Title: Benefit Claims Procedure Regulation pursuant to 29 CFR 2560.503–1.

Type of Review: Revision of a currently approved collection.

OMB Numbers: 1210–0053.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Total Respondents: 6,690,345.

Total Responses: 63,317,000.

Frequency of Response: On occasion.

Total Annual Burden: 496,000 (1998); 504,000 (1999); 730,000 (2000).

Estimated Annual Cost (Operating and Maintenance): $53,710,000 (1998); $54,520,000 (1999); $89,520,000 (2000).

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record.

Analysis of Cost

The Department performed a comprehensive, unified analysis to estimate the costs of the proposed regulation for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The methods and results of that analysis are summarized below.

To estimate the cost of the proposed regulation, it was necessary to estimate the number of claims procedures and the volume of claims by type in the ERISA-covered employee benefit plan universe and to make certain assumptions about the cost of bringing those procedures and claims and appeals transactions into compliance with the proposed regulation's provisions.

The Department estimated the number of claims procedures based on Form 5500 Series data and other sources. With respect to pension plans, the Department assumes that each plan designs and implements its own procedure. With respect to welfare plans, the number of claims procedures is estimated to be smaller than the number of plans. While large welfare plans are assumed to design and implement their own procedures, small plans are assumed typically to buy a limited number of standard products from vendors.

NUMBER OF CLAIMS AND APPEALS PROCEDURES

	Pension	Health	Non-health welfare
Small Plans	629,000	11,000	14,000
Large Plans	62,000	40,000	41,000
Total	690,000	51,000	55,000

The Department estimated claims and appeals volume based on plan participation and various sources of data indicative of the number of claims and appeals per participant. The number of claims per participant is estimated to be far higher for plans with ongoing claim activity, such as health and dental plans, than for plans with one-time or highly contingent claim activity, such as pension and disability plans. Volume was adjusted to account for expected growth in participation.

Where appropriate, the estimated number of claiming events affected by the proposed regulation was reduced to reflect the generally high levels of compliance with the proposed regulation's provisions represented by plans' current, normal business practices. (Responses to the Department's RFI and numerous other sources indicate that many plans are already largely in compliance with many of the proposed regulation's provisions, either as a result of state law or other requirements, or in response to plan sponsor and participant demands.)

For purposes of the Paperwork Reduction Act, the Department assumes that 100 percent of small, fully insured welfare plans and 75 percent of all other plans use service providers to carry out information collection and disclosure tasks. Based on these assumptions, plan participation and numbers of procedures are distributed as shown in the chart below.

PARTICIPATION AND PROCEDURES BY PLAN TYPE AND USE OF SERVICE PROVIDERS

	Service providers	In-house
Pension Plans:		
Participation	65 MM	22 MM
Procedures	518,000	173,000
Health Plans:		
Participation	56 MM	14 MM
Procedures	39,000	12,000
Other Welfare Plans:		
Participation	131 MM	37 MM
Procedures	44,000	11,000

The Department classified as preparation burden the resources expended on a one-time, start-up basis to revise the forms used for notices required by the proposed regulation and attributed this burden to the year 2000. These costs were estimated as a function of the number of claims and appeals procedures affected. The Department

classified as distribution burden the resources expended to process claims and appeals, including the resources used to fill in and distribute notice forms and provide for any associated disclosures. These costs were estimated as a function of the number of claims and appeals affected.

The Department developed assumptions regarding the burden of complying with the proposed regulation's provisions, attributing for the purpose of this analysis a $11 hourly cost to purely clerical tasks and a $50 hourly rate to combined professional and clerical tasks, along with a $0.50 to $1.00 unit cost for materials and distribution of each claim or appeal decision notice. These assumptions yield the following estimates of the burden of the proposed regulation's notice and disclosure requirements for the year 2000. Recall that the preparation burden is a one-time cost and will be zero in other years, while the distribution burden will vary with claims volume and mix.

SUMMARY OF NOTICE AND DISCLOSURE BURDENS, 2000

	Hours	Dollars
All Plans	3.5 MM	90 MM
Distribution	2.6 MM	55 MM
Preparation	0.9 MM	34 MM
Using Service Providers	2.7 MM	83 MM
Distribution	2.1 MM	49 MM
Preparation	0.7 MM	34 MM
Not Using Service Providers	0.7 MM	6 MM
Distribution	0.5 MM	6 MM
Preparation	0.2 MM	

For purposes of Executive Order 12866 and the Regulatory Flexibility Act, the Department estimated the incremental economic impact of the proposed regulation '' that is, the added cost of the proposed regulation relative to a baseline reflecting no proposed regulation.

Many of the provisions of the proposed regulation represent clarifications rather than changes of the existing regulation. Such provisions will have no economic impact. The Department estimated the impact of changes and additions embodied in the proposed regulation. The Department separately assessed ongoing costs, which will vary over time with claims volume and mix, and one-time, start-up costs, which are assumed to be incurred in 2000.

The Department's estimates of the proposed regulation's ongoing costs reflect provisions requiring notification following the submission of benefit requests that do not follow plan filing rules, limiting to one the appeals required before seeking legal redress, requiring fuller and fairer review of denied claims on appeal, requiring disclosure on request following denied appeals, and establishing longer minimum time allowances for denied health plan claimants to appeal. They also reflect certain provisions directed solely at health plans, including those requiring plans to notify participants in advance of certain terminations of services, consultation with medical professionals in deciding appeals that involve medical issues, and shorter deadlines for making standard and urgent claims and appeals determinations.

The Department developed assumptions regarding the cost of complying with the proposed regulation's provisions, attributing (as was done with respect to the burden analysis) an $11 hourly cost to purely clerical tasks and a $50 hourly rate to combined professional and clerical tasks. The Department further attributed a cost of $350 to professional medical reviews. Using these assumptions, the Department estimates the ongoing cost of the proposed regulation at $30 million in 2000, including $6 million for small plans and $24 million for large plans. This amounts to $0.04 per claim and $0.09 per participant. The aggregate amount will vary over time with claims volume and mix.

The proposed regulation will also prompt all plans to design and implement changes to their claims and appeals procedures, imposing a one-time, start-up cost. Whether changes will be required, and the extent of any required changes, depend not on the difference between the current and proposed regulations' standards, but on the difference between baseline plan practices and the proposed regulation's standards. As noted above, there is reason to believe that many plans are already in compliance or nearly in compliance with the proposed regulation. Health plan practices in particular often exceed the proposed regulation's new, higher standards. Nonetheless, it seems likely that many plans will need to revise at least some aspect of their formal procedures, even if this means little or no change to their actual practices.

The Department assumes an average cost to revise procedures of $100. This yields an estimated $80 million in start-up costs for all plans in 2000, including $65 million for small plans. Most of the small plan costs are attributable to small pension rather than health or other welfare plans, reflecting the Department's understanding that small welfare plans using service providers share a limited menu of common claims procedures and therefore share the cost of revising those relatively few procedures.

The Department also estimated the one-time cost of preparing claims and appeals determination forms as part of its estimates of the proposed regulation's notice and disclosure burdens in connection with the Paperwork Reduction Act, as discussed above. The total cost (including both the dollar burden and the dollar value of the hour burden) amounts to $45 million, including $37 million for small plans and $8 million for large plans. As with the cost to revise procedures, the small plan cost is attributable mostly to small pension plans.

Summing these, the Department estimates the total start-up cost associated with the proposed regulation at $125 million, including $102 million for small plans (most of this being for pension plans) and $22 million for large plans. Given the large volume of claims and number of participants involved, the costs per claim or per participant are small. These costs respectively amount to $0.15 and $0.35 for all plans, $0.65 and $2.16 for small plans, and $0.03 and

$0.07 for large plans. The Department solicits comments on these estimates.

Combining ongoing and start-up costs, the Department's estimates of the total cost of the proposed regulation in 2000 are reported in the table below. The Department solicits comments on these estimates. Recall that the one-time, start-up costs occur only in 2000 and not in other years, and that the ongoing costs will vary over time with claims volume and mix.

ESTIMATED TOTAL COST OF PROPOSED REGULATION, 2000

	All plans	Small plans	Large plans
Total Cost	$155 MM	$108 MM	$46 MM
Per claim	0.19	0.69	0.07
Per participant	0.44	2.29	0.15
Ongoing Cost	30 MM	6 MM	24 MM
Per claim	0.04	0.04	0.04
Per participant	0.09	0.13	0.08
Start-Up Cost	125 MM	102 MM	22 MM
Per claim	0.15	0.65	0.03
Per participant	0.35	2.16	0.07

E. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, this proposed rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, but does include mandates which may impose an annual burden of $100 million or more on the private sector. The basis for this statement is described in the analysis of costs for purposes of Executive Order 12866 and the Regulatory Flexibility Act.

F. Small Business Regulatory Enforcement Fairness Act

The rule proposed in this action is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) (SBREFA) and is a major rule under SBREFA. The rule, if finalized, will be transmitted to Congress and the Comptroller General for review.

Statutory Authority

This proposed regulation would be adopted pursuant to the authority contained in sections 503 and 505 of ERISA (Pub. L. 93–406, 88 Stat. 893, 894; 29 U.S.C. 1133, 1135) and under the Secretary of Labor's Order No. 1–87, 52 FR 13139 (April 21, 1987).

List of Subjects in 29 CFR Part 2560

Employee benefit plans, Employee Retirement Income Security Act, Benefit Claims Procedures.

For the reasons set out in the preamble, 29 CFR part 2560 is proposed to be amended as follows:

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

1. The authority citation for part 2560 continues to read as follows:

Authority: Secs. 502, 505 of ERISA, 29 U.S.C. 1132, 1135, and Secretary's Order 1–87, 52 FR 13139 (April 21, 1987).

Section 2560–502–1 also issued under sec. 502(b)(1), 29 U.S.C. 1132(b)(1).

Section 2560–502i-1 also issued under sec. 502(i), 29 U.S.C. 1132(i).

Section 2560–503–1 also issued under sec. 503, 29 U.S.C. 1133.

2. Section 2560.503–1, is proposed to be revised to read as follows:

§ 2560.503–1 Claims procedure.

(a) Scope and purpose. In accordance with the authority of sections 503 and 505 of the Employee Retirement Income Security Act of 1974 (ERISA or the Act), 29 U.S.C. 1133, 1135, this section sets forth minimum requirements for employee benefit plan procedures pertaining to claims for benefits by participants and beneficiaries (hereinafter referred to as claimants) or their representatives. Except as otherwise specifically provided herein, these requirements apply to every employee benefit plan described in section 4(a) and not exempted under section 4(b) of the Act.

(b) Obligation to establish and maintain reasonable claims procedures. Every employee benefit plan shall establish and maintain reasonable procedures governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefit determinations (hereinafter collectively referred to as claims procedures). The claims procedures for a plan will be deemed to be reasonable only if:

(1) The claims procedures comply with the requirements of paragraphs (c), (d), (e), (f), (g), and (h) of this section, as appropriate;

(2) A description of all claims procedures (including, in the case of group health plan services or benefits, procedures for obtaining preauthorizations, approvals, or utilization review decisions) and the applicable time frames is included as part of a summary plan description meeting the requirements of 29 CFR 2520.102–3;

(3) The claims procedures do not contain any provision, and are not administered in a way, that requires a claimant to submit an adverse benefit determination to arbitration or to file more than one appeal of an adverse benefit determination prior to bringing a civil action under section 502(a) of the Act;

(4) The claims procedures do not contain any provision, and are not administered in a way, that unduly inhibits or hampers the initiation or processing of claims for benefits. For example, a provision or practice that requires payment of a fee or costs as a condition to making a claim or to appealing an adverse benefit determination would unduly inhibit the initiation and processing of claims for benefits. Also, the denial of a claim for failure to obtain a preauthorization under circumstances that would make obtaining such preauthorization impossible or where application of the preauthorization process could seriously jeopardize the life or health of the claimant (*e.g.*, the claimant is unconscious and has no representative or is in extremely serious need of immediate care at the time medical treatment is required) would constitute a practice that unduly inhibits the initiation and processing of a claim;

(5) The claims procedures do not foreclose or limit the ability of a representative to act on behalf of the claimant; and

(6) The claims procedures provide that, in the event that a claimant or a representative of a claimant makes a benefit request that fails to comply with the requirements of the plan's procedures for making a claim, the plan administrator shall notify the claimant

of such failure and of the plan's procedures governing the making of a claim. The plan administrator shall provide this notification within a reasonable period of time appropriate to the circumstances, taking into account any pertinent medical exigencies, not to exceed 5 days (24 hours in the case of a benefit request involving urgent care) following receipt of the benefit request by the plan. The benefit request shall be deemed to have been received by the plan when the claimant or representative makes a communication reasonably calculated to bring the request to the attention of persons responsible for benefit claim decisions. Communication with any of the following shall be deemed a communication reasonably calculated to bring the claim to the attention of persons responsible for benefit claim decisions:

(i) In the case of a single employer plan, either the organizational unit customarily in charge of employee benefits matters for the employer or any officer of the employer;

(ii) In the case of a plan to which more than one employer contributes or which is established or maintained by an employee organization, the joint board, association, committee, or similar group (or any member of any such board, association, committee or group) responsible for establishing or maintaining the plan or the person or the organizational unit customarily in charge of employee benefit matters;

(iii) In the case of a plan the benefits of which are provided or administered by an insurance company, insurance service, third-party contract administrator, health maintenance organization, or similar entity, the person or organizational unit with the authority to pre-approve, approve, or deny benefits under the plan or any officer of the insurance company, insurance service, third-party contract administrator, health maintenance organization, or similar entity.

(iv) For purposes of paragraph (b)(6) of this section, a communication shall be deemed to have been brought to the attention of an organizational unit if it is received by any person employed in such unit.

(7) The claims procedures provide that, in the case of a claim involving urgent care within the meaning of paragraph (j)(1), for an expedited process pursuant to which—

(i) A request for an expedited determination may be submitted orally or in writing by the claimant or the claimant's representative; and

(ii) All necessary information, including the plan's benefit determination, shall be transmitted between the plan and the claimant by telephone, facsimile or other similarly expeditious method.

(c) Claim for benefits. For purposes of this section, a claim for benefits is a request for a plan benefit or benefits, made by a claimant or by a representative of a claimant, that complies with a plan's reasonable procedure for making benefit claims. In the case of a group health plan, a claim for benefits includes a request for a coverage determination, for preauthorization or approval of a plan benefit or for a utilization review determination in accordance with the terms of the plan.

(d) Notification of benefit determination. (1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, the plan administrator shall notify a claimant, in accordance with paragraph (e) of this section, of the plan's benefit determination within a reasonable period of time after receipt of the claim, but not later than 90 days after receipt of the claim by the plan, unless the claimant (or the claimant's representative) has failed to submit sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan. In the case of such a failure, the plan administrator shall notify the claimant as soon as possible, but not later than 45 days after receipt of the claim by the plan, of the specific information necessary to complete the claim. The claimant shall then be afforded not less than 180 days after receipt of such notice to furnish the specified information to the plan. The plan administrator shall notify the claimant of the plan's benefit determination within a reasonable period of time, but not later than 45 days after the earlier of: The plan's receipt of the specified additional information, or the end of the period afforded the claimant to submit the specified additional information. If special circumstances require an additional extension of time for processing the claim, the plan administrator shall provide the claimant with notice of the extension prior to the termination of the initial 90-day period. In no event shall such extension exceed a period of 90 days from the end of such initial period. The extension notice shall indicate the special circumstances requiring an extension of time and the date by which the plan expects to make the benefit determination.

(2) In the case of a group health plan, the plan administrator shall notify a claimant of the plan's benefit determination in accordance with paragraph (d)(2)(i), (d)(2)(ii), or (d)(2)(iii) of this section, as appropriate.

(i) In the case of a claim involving urgent care, within the meaning of paragraph (j)(1) of this section, the plan administrator shall notify the claimant, in accordance with paragraph (e) of this section, of the plan's benefit determination as soon as possible, taking into account the medical exigencies of the case, after receipt of the claim by the plan, but not later than 72 hours after receipt of the claim by the plan, unless the claimant (or the representative of the claimant) fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan. In the case of such a failure, the plan administrator shall notify the claimant as soon as possible, but not later than 24 hours after receipt of the claim by the plan of the specific information necessary to complete the claim. The claimant shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours, to provide the specified information. The plan administrator shall notify the claimant of the plan's benefit determination as soon as possible , but in no case later than 48 hours after the earlier of: The plan's receipt of the specified information, or the end of the period afforded the claimant to provide the specified additional information.

(ii) If a group health plan has approved a benefit or service to be provided for a specified or indefinite period of time, any reduction or termination of such benefit or service (other than by plan amendment or termination) before the end of such period shall constitute an adverse benefit determination within the meaning of paragraph (j)(2) of this section. To the extent that such an adverse benefit determination denies a claim involving urgent care, as defined in paragraph (j)(1) of this section, the plan administrator shall provide notice of the adverse benefit determination, in accordance with paragraph (e) of this section, at a time sufficiently in advance of the reduction or termination to allow the claimant (or a representative of the claimant) to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.

(iii) In the case of a claim that does not involve urgent care, the plan administrator shall notify the claimant, in accordance with paragraph (e) of this section, of the plan's benefit determination within a reasonable period of time appropriate to the circumstances, taking into account any

pertinent medical circumstances, but not later than 15 days after receipt of the claim by the plan, unless the claimant (or the claimant's representative) has failed to submit sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan. In the case of such a failure, the plan administrator shall notify the claimant of the specific information necessary to complete the claim within a reasonable period of time appropriate to the circumstances, taking into account any pertinent medical circumstances, but not later than 5 days after receipt of the claim by the plan. The claimant shall then be afforded not less than 45 days after receipt of such notice to furnish the specified information to the plan. The plan administrator shall notify the claimant of the plan's benefit determination within a reasonable period of time after the earlier of: The plan's receipt of the specified additional information, or the end of the period afforded the claimant to submit the specified additional information, but in no event later than 15 days after the earlier of those two dates.

(3) In the case of a plan that provides disability benefits, paragraph (d)(1) of this section shall apply to claims involving disability benefits, except that ''30 days'' shall be substituted therein for ''90 days'' and ''15 days'' shall be substituted therein for ''45 days,'' wherever such terms appear in that paragraph.

(e) Manner and content of notification of benefit determination. (1) Except as provided in paragraph (e)(2) of this section, the plan administrator shall provide a claimant with written or electronic notification of the plan's benefit determination. Any electronic notification shall comply with the standards imposed by 29 CFR 2520.104b–1(c)(1)(i), (iii), and (iv). In the case of an adverse benefit determination, within the meaning of paragraph (j)(2) of this section, the notification shall set forth, in a manner calculated to be understood by the claimant:

(i) The specific reasons for the adverse determination;

(ii) Reference to the specific plan provisions (including any internal rules, guidelines, protocols, criteria, etc.) on which the determination is based;

(iii) A description of any additional material or information necessary for the claimant to complete the claim and an explanation of why such material or information is necessary;

(iv) A description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review; and

(v) In the case of an adverse benefit determination by a group health plan involving a claim for urgent care, a description of the expedited review process applicable to such claims.

(2) In the case of an adverse benefit determination by a group health plan involving a claim for urgent care, the information described in paragraph (e)(1) of this section, may be provided to the claimant orally within the time frame prescribed in paragraph (d)(2)(i) of this section, provided that a written or electronic notification in accordance with paragraph (e)(1) of this section, is furnished to the claimant not later than 3 days after the oral notification.

(f) *Appeal of adverse benefit determinations.* (1) In general. Every employee benefit plan shall establish and maintain a procedure by which a claimant shall have a reasonable opportunity to appeal an adverse benefit determination, within the meaning of paragraph (j)(2) of this section, to an appropriate named fiduciary of the plan, and under which there will be a full and fair review of the claim and the adverse benefit determination.

(2) *Full and fair review.* A claims procedure will not be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless:

(i) In the case of all plans, the claims procedure—

(A) Provides claimants a reasonable period of time, related to the nature of the benefit which is the subject of the claim and the attendant circumstances within which to appeal the determination. In the case of a group health plan or a disability plan, such period shall not be less than 180 days following receipt by the claimant of a written notification of the adverse benefit determination. In the case of a plan, other than a group health plan or a disability plan, such period of time shall not be less than 60 days following receipt by the claimant of a written notification of the adverse benefit determination;

(B) Provides claimants the opportunity to submit written comments, documents, records, and other information relating to the claim for benefits;

(C) Provides that a claimant shall be provided, upon request, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits, without regard to whether such documents, records, and information were considered or relied upon in making the adverse benefit determination that is the subject of the appeal.

(D) Provides for a review that:

(*1*) Does not afford deference to the initial adverse benefit determination, and

(*2*) Takes into account all comments, documents, records, and other information submitted by the claimant (or the claimant's representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination; and

(E) Provides for review by an appropriate named fiduciary of the plan who is neither:

(*1*) The party who made the adverse benefit determination that is the subject of the appeal, nor

(*2*) The subordinate of such party.

(ii) In the case of a group health plan, the claims procedure—

(A) Provides that, in deciding appeals of any adverse benefit determination involving a medical judgment, including determinations with regard to whether a particular treatment, drug, or other item is experimental, investigational, or not medically necessary or appropriate, the appropriate named fiduciary shall consult with a health care professional, as defined in paragraph (j)(5) of this section, who has appropriate training and experience in the field of medicine involved in the medical judgment;

(B) Provides that the health care professional engaged for purposes of a consultation under paragraph (f)(2)(ii)(A) of this section shall be independent of any health care professional who participated in the initial adverse benefit determination; and

(C) Provides in the case of a claim involving urgent care, within the meaning of paragraph (j)(1) of this section, for an expedited review process pursuant to which—

(*1*) A request for an expedited appeal of an adverse benefit determination may be submitted orally or in writing by the claimant or the claimant's representative; and

(*2*) All necessary information, including the plan's benefit determination on review, shall be transmitted between the plan and the claimant by telephone, facsimile, or other available similarly expeditious method.

(g) Notification of benefit determination on review. (1) Except as

provided in paragraphs (g)(2) and (g)(3) of this section—

(i) The plan administrator shall notify a claimant, in accordance with paragraph (h) of this section, of the plan's benefit determination on review within a reasonable period of time, but not later than 60 days after the plan's receipt of the claimant's request for review of an adverse benefit determination, unless special circumstances (such as the need to hold a hearing, if the plan procedure provides for a hearing) require an extension of time for processing, in which case the claimant shall be notified of the plan's benefit determination on review as soon as possible, but not later than 120 days after receipt of a request for review.

(ii) In the case of a plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, the appropriate named fiduciary shall make a benefit determination no later than the date of the meeting of the committee or board that immediately follows the plan's receipt of a request for review, unless the request for review is filed within 30 days preceding the date of such meeting. In such case, a benefit determination may be made by no later than the date of the second meeting following the plan's receipt of the request for review. If special circumstances (such as the need to hold a hearing, if the plan procedure provides for a hearing) require a further extension of time for processing, a benefit determination shall be rendered not later than the third meeting of the committee or board following the plan's receipt of the request for review. If such an extension of time for review is required because of special circumstances, the plan administrator shall provide the claimant with written notice of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The plan administrator shall provide the claimant with notification of the benefit determination in accordance with paragraph (h) of this section as soon as possible, but not later than 5 days after the benefit determination is made.

(2) In the case of a group health plan—

(i) The plan administrator shall notify the claimant, in accordance with paragraph (h) of this section, of the plan's benefit determination on review within a reasonable period of time appropriate to the circumstances, taking into account any pertinent medical circumstances, but not later than 30 days after receipt by the plan of the claimant's request for review of an adverse benefit determination, unless the claim involves urgent care.

(ii) If a claim involves urgent care, the plan administrator shall notify the claimant of the plan's benefit determination on review as soon as possible, taking into account the medical exigencies of the case, after receipt by the plan of the request for review, but not later than 72 hours after receipt of the claimant's request for review of an adverse benefit determination.

(3) Claims involving disability benefits shall be governed by paragraph (g)(1)(i) of this section, except that ''45 days'' shall be substituted therein for ''60 days,'' and ''90 days'' shall be substituted therein for ''120 days,'' wherever such terms appear in that paragraph.

(4) The plan administrator shall, in accordance with the statements required by paragraphs (h)(3) and (h)(4) of this section, provide claimants with copies of, or reasonable access to, the documents and records described in paragraph (h)(3) or paragraph (h)(4) of this section, or both, as appropriate.

(h) Manner and content of notification of benefit determination on review. The plan administrator shall provide a claimant with written or electronic notification of a plan's benefit determination on review. Any electronic notification shall comply with the standards imposed by 29 CFR 2520.104b–1(c)(1)(i), (iii), and (iv). In the case of an adverse benefit determination, within the meaning of paragraph (j)(2) of this section, the notification must set forth, in a manner calculated to be understood by the claimant:

(1) The specific reasons for the adverse determination;

(2) Reference to the specific plan provisions (including any internal rules, guidelines, protocols, criteria, etc.) on which the benefit determination is based;

(3) A statement that the claimant is entitled to receive, upon request, reasonable access to, and copies of, all documents and records relevant to the claimant's claim for benefits, without regard to whether such records were considered or relied upon in making the adverse benefit determination on review, including any reports, and the identities, of any experts whose advice was obtained; and

(4) A statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review.

(i) Failure to establish and follow reasonable claims procedures. In the case of the failure of a plan to establish or follow claims procedures consistent with the requirements of this section, a claimant shall be deemed to have exhausted the administrative remedies available under the plan and shall be entitled to pursue any available remedies under section 502(a) of the Act on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim.

(j) Definitions. For purposes of this section—

(1) (i) A *claim involving urgent care* is any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations—

(A) Could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or,

(B) In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is subject of the claim.

(ii) Except as provided in paragraph (j)(1)(iii) of this section, whether a claim is a ''claim involving urgent care'' within the meaning of paragraph (j)(1)(i)(A) of this section is to be determined by an individual acting on behalf of the plan applying the judgment of a reasonable individual who is not a trained health professional.

(iii) Any claim that a physician with knowledge of the claimant's medical condition determines is a ''claim involving urgent care'' within the meaning of paragraph (j)(1)(i) of this section shall be treated as a ''claim involving urgent care'' for purposes of this section.

(2) The term *adverse benefit determination* means any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review directed at cost containment, as well as a failure to cover an item of service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(3) The term *notice* or *notification* means the delivery or furnishing of information to an individual in a manner that satisfies the standards of 29

CFR 2520.104b–1(b) as appropriate with respect to material required to be furnished or made available to an individual.

(4) The term *group health plan* has the meaning given that term by section 733(a) of the Act.

(5) The term *health care professional* means a physician or other health care professional licensed, accredited, or certified to perform specified health services consistent with State law.

(k) Apprenticeship plans. This section does not apply to employee benefit plans that provide solely apprenticeship training benefits.

(l) Effective date. This section is effective [180 days after publication of the final regulation].

(m) Applicability Dates. (1) Except as provided in paragraph (m)(2) of this section, this section shall be applicable to plans on the later of the effective date or the first day of the first plan year beginning on or after the effective date.

(2) In the case of a collectively bargained plan that is not subject to section 302(c)(5) of the Labor Management Relations Act, 1947, 29 U.S.C. 186(c)(5), this section is effective as of the first day of the plan year beginning on or after the later of: July 1, 1999, or the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after July 1, 1999).

Signed at Washington, D.C., this 28th day of August, 1998.

Meredith Miller,

Deputy Assistant Secretary for Policy, Pension and Welfare Benefits Administration, U.S. Department of Labor.

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