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, Labor.

ACTION: Final regulation.

SUMMARY: This document contains a final 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). The regulation establishes new standards for the processing of claims under group health plans and plans providing disability benefits and further clarifies existing standards for all other employee benefit plans. The new standards are intended to ensure more timely benefit determinations, to improve access to information on which a benefit determination is made, and to assure that participants and beneficiaries will be afforded a full and fair review of denied claims. When effective, the regulation will affect participants and beneficiaries of employee benefit plans, employers who sponsor 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: *Effective Date:* January 20, 2001.

Applicability Date: This regulation applies to all claims filed on or after January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Susan M. Halliday or Susan G. Lahne, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 219–7461. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

On September 9, 1998, the Department of Labor (the Department) published a notice in the **Federal Register** (63 FR 48390) containing a proposed regulation, designated as proposed § 2560.503–1 of Title 29 (the proposal), intended to substantially revise the minimum requirements for benefit claims procedures of all employee benefit plans covered under Title I of ERISA. The reforms contained in the proposal, as explained in the preamble that accompanied it, were based in part on comments the Department had previously received in response to a Request for Information (the RFI) published in the **Federal Register** (62 FR 47262) on September 8, 1997. In addition, the proposal was developed to respond to a memorandum from the President, 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 non-urgent care'' and ''to ensure the information [group health plans] provide to plan participants is consistent with the Patients' Bill of Rights.'' [1]

In response to the RFI comments, the President's directives, and the recommendations of the Commission, the Department developed a proposal to substantially reform the standards for the resolution of benefit claims under all employee benefit plans covered by the Act. The revised standards derive from section 503 of ERISA, which requires every employee benefit plan, in accordance with regulations of the Department, to ''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 to ''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.'' While focusing primarily on group health plans and plans providing disability benefits, the proposal contained provisions altering the benefit claims procedures for all employee benefit plans. Among other reforms, the proposal imposed new notice requirements with respect to incomplete or incorrectly filed claims, altered the standards for appeals of denied claims, and increased or made more specific the disclosure obligations of plans generally with respect to procedural rights and denials of claims. With respect to group health plans and plans providing disability benefits specifically, the proposal shortened the time periods for making initial benefit claims decisions and decisions on appeal of denied claims and imposed additional obligations with respect to group health claims that involved urgent care.

The Department received more than 700 letters of comment in response to the proposal. A public hearing on the proposal was held in Washington, DC., on February 17, 18, and 19, 1999. More than 60 speakers, representing a fair cross-section of the interested public, including benefit plan sponsors, service providers, health care professionals, benefit claimants, health care organizations, and insurance companies, presented testimony and were questioned by a panel of Departmental officials.

After due consideration of the issues raised by the written comments and oral testimony, the Department has modified the scope of the proposal, refined its requirements as to minimum procedural standards for the resolution of benefit claims disputes, and is now publishing in this notice, in final form, regulation § 2560.503–1, establishing new minimum procedural requirements for benefit claims under employee benefit plans. In the course of developing this final regulation, the Department took serious notice of the issues raised by commenters on behalf of the employers that sponsor employee benefit plans and the institutions that aid in their administration or provide the promised benefits. In making changes in the regulation that respond to those issues, the Department has attempted to reconcile the need for procedural protections with the purely voluntary nature of the system through which these vital benefits are delivered. The Department believes, however, that the procedural reforms contained in this regulation are necessary to guarantee important procedural rights to benefit claimants.

While the Department has made a number of significant changes to the proposal, in particular by limiting the scope of its reforms principally to group health plans and plans providing disability benefits and by moderating the severity of the decisionmaking time frames applicable to such plans, the regulation preserves the core reforms of the proposal. In publishing this

[1] The President's memorandum specifically endorsed the reports of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (the Commission), which set out specific rights of health care consumers that should be protected, including the right ''to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that service them, including a rigorous system of internal review and an independent system of external review.''

regulation, the Department believes it has responded to the needs of employers and employees and has successfully implemented, to the extent of its regulatory authority under the Act, the protections recommended by the President's Commission. This action, the Department believes, will ensure that benefit claimants, at least in ERISA-covered plans, are provided faster, fuller, and fairer decisions on their benefit claims.

The following summarizes the most important modifications that the Department adopted in developing this regulation. It further describes generally the comments that gave rise to those changes and explains the Department's reasons for those modifications.

Scope

The proposal contained a number of provisions that would have established new, substantially uniform procedural requirements for all employee benefit plans, including improved notice and disclosure protections and strengthened standards of conduct on review. A substantial number of commenters expressed concern about the scope of the proposal, pointing out that the Department's expressed reasons for procedural reform, as set forth in the preamble to the proposal, focused almost exclusively on perceived problems arising specifically under group health plans and plans providing disability benefits. These commenters claimed that the Department's record does not demonstrate a clear need to change the procedural rules in effect for plans other than group health plans and plans providing disability benefits.

The Department believes, in light of the comments received on this issue, that it is premature to conclude that the proposed reforms are equally appropriate for all plans. In particular, the Department is concerned that it may not have an adequate record regarding the need for reform of procedural standards for pension plans. Accordingly, the Department has determined to limit more narrowly to group health plans and plans providing disability benefits the reforms presently adopted in the regulation and to reserve for further consideration the question of the appropriateness of extending these reforms to pension plans and welfare plans other than group health plans and plans providing disability benefits. The regulation, thus, contains standards respecting benefit claims procedures for pension and other welfare plans that are substantially similar to those currently in effect under the regulation promulgated by the Department in 1977 (the 1977 regulation).[2] As a result, under the regulation, pension plans and welfare plans other than group health plans and plans providing disability benefits will not generally be required to revise their procedures.

In revising the proposal in this manner, however, the Department notes its continuing interest in assessing the appropriateness of the 1977 regulation's standards for pension and other welfare plans. In this regard, the Department is soliciting public comment on this issue to facilitate development of an adequate record upon which to consider additional reforms.

One commenter requested clarification as to the application of the proposed regulation to ''long-term care benefits.'' This commenter described long-term care benefits as clearly distinguishable from group health or disability benefits. Long-term care benefits, it was suggested, have been designed uniquely to provide assistance in tasks of daily living to individuals with disabilities or chronic conditions. Eligibility for long-term care benefits is based, according to the commenter, solely on whether an individual is ''unable to perform a requisite number of the activities of daily living due to the loss of functional capacity or requires substantial supervision due to severe cognitive impairment.'' The commenter reported that ''long term-care benefits'' generally include a wide range of services, including respite care, coverage for home modifications for the disabled, nursing-home care, and payment for family care givers, all directed towards meeting the routine needs of daily life, but do not include ''medical care'' within the meaning of section 733(a)(2) of the Act or replacement income as is usual under disability plans. It is the view of the Department that the provision of the type of benefits described by the commenter would not, in and of itself, cause a plan to be treated as a group health plan or a plan providing disability benefits for purposes of this regulation.

Time Frames for Decisionmaking

The proposal contained new time frames for claims decisions by group health plans and plans providing disability benefits at both the initial claims decision stage and on review. In its treatment of group health claims, the proposal distinguished between claims involving urgent care and all other group health claims, setting different maximum time periods for the two categories of group health claims,[3] and, with respect to disability claims,[4] the proposal provided a separate set of maximum time periods somewhat longer than for group health plans. In proposing these relatively short time frames, the Department emphasized that they reflected specific ''best practices'' discussed in the RFI comments and the Department's belief that speedy decisionmaking is a crucial protection for claimants who need either medical care or the replacement income that disability benefits provide.[5] The Department specifically solicited further public comment on the adequacy of the proposal's definition of claims involving urgent care, explaining that speedy decisionmaking has increased significance when a claim must be approved prior to a claimant's receiving medical care.

There was relatively little objection among the commenters regarding the proposed decisionmaking time frames for urgent care group health claims. The majority of those commenting either actively supported or accepted the necessity for this reform, indicating that at the present time urgent care decisions are generally being made within the proposed time frames.[6] In discussing

[2] It should be noted that the regulation as it applies to such plans is not identical to the 1977 regulation. In some respects, the language of the regulation has been updated to reflect current practices and to incorporate the Department's longstanding interpretations of the 1977 regulation. In addition, as noted specifically below, some provisions of the 1977 regulation have been clarified in this regulation, and such clarifications apply uniformly to all employee benefit plans covered under the Act.

[3] The proposal required urgent care claims decisions to be made during a stringent maximum 72-hour period at both the initial and review stages. All other group health claims were required under the proposal to be resolved within not more than 15 days, with respect to both initial and review decisions. The proposal did not provide for any extensions of these periods by plans in any circumstances, although it did not prohibit consensual agreements between claimants and plans on the timing of decisions.

[4] Where a single plan provides more than one type of benefit, it is the Department's intention that the nature of the benefit should determine which procedural standards apply to a specific claim, rather than the manner in which the plan itself is characterized.

[5] The proposal also eliminated, for group health plans and plans providing disability benefits, the time extension on review available, under the 1977 regulation, to plans administered by boards of directors or committees that meet at least quarterly.

[6] The rules contained in subparagraph (f)(2)(i) regarding treatment of claims involving urgent care are, therefore, largely unchanged from those contained in the proposal. A few commenters suggested that the definition of ''claims involving urgent care'' be expanded to include the concept of ''maintaining'' maximum function, as well as regaining maximum function. The Department has not made this change, but it is the view of the Department that the definition as proposed, and as adopted in this regulation, addresses the concern for protecting ''maximum function'' by providing

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the time frames proposed for other group health and disability decisionmaking, however, a large number of commenters objected to the shortness of the time frames.

With respect to the proposed time frames for non-urgent group health claims, many commenters acknowledged the legitimacy of the Department's concern for affording claimants speedy access to medical care, but asserted that the Department's concerns regarding access to care did not justify treating all non-urgent claims the same. These commenters asserted that it would be extremely difficult and expensive, if not impossible, to satisfy the proposal's requirement that all non-urgent group health claims be decided within not more than 15 days. They urged the Department to consider distinguishing between ''pre-service'' claims, that is, those claims that must be decided before a claimant will be afforded access to health care, and claims that involve only the payment or reimbursement of the cost for medical care that has already been provided (''post-service'' claims).[7] The pre-service claims, the commenters argued, should be subject to a shorter decisionmaking time frame. Other non-urgent group health claims, these commenters argued, do not raise the same degree of concern since they do not represent cases in which claimants may actually be denied medical care. In many instances, the commenters asserted, a longer decisionmaking period for these post-service claims may be appropriate, even necessary, since a longer period of deliberation may in some proportion of cases result in the grant of benefits that might otherwise be denied.

The Department has seriously considered the arguments and testimony put forth on this issue, and it has concluded that there is substantial justification for treating non-urgent health care claims along the lines suggested in the comments. Accordingly, the regulation makes a distinction, in setting the maximum time periods for deciding non-urgent group health claims, between group health claims that involve access to medical care (pre-service claims) and group health claims that involve purely the payment or reimbursement of costs for medical care that has already been provided (post-service claims).

Subparagraph (m)(2) defines a ''pre-service claim'' as any request for approval of a benefit with respect to which the terms of the plan condition receipt of the benefit, in whole or in part, on approval of the benefit in advance of obtaining medical care. In this regard, it is the Department's view that any review or approval that a plan requires as part of the process of receiving a benefit, even if such review or approval does not guarantee that the plan will ultimately grant the benefit, involves a ''claim'' and must be treated as such for purposes of this regulation. For example, a request for pre-approval under a utilization review program or for a prior authorization of health care items or service would be a ''pre-service claim'' under this definition, as would any request for a preauthorization that a plan requires a claimant to obtain as a precondition to the claimant's receiving a larger benefit (e.g., payment of 80% of the cost of the preauthorized service, rather than 50%). ''Post-service claims'' are defined in subparagraph (m)(3) as all claims under a group health plan that are not pre-service claims.

Subparagraph (f)(2)(iii)(A) requires that pre-service claims be decided within a maximum[8] of 15 days at the initial level, and subparagraph (i)(2)(ii) permits a maximum of 30 days on review of an adverse benefit determination.[9] Post-service claims are subject to a maximum time period of 30 days for the initial decision under subparagraph (f)(2)(iii)(B) and a maximum of 60 days on review under subparagraph (i)(2)(iii)(A). With respect to both pre- and post-service claims, the regulation further provides for limited extensions of time.[10] In the Department's view, establishing separate time frames for these two groups of claims, and providing more generous time frames for each group, will balance the needs of claimants and the business considerations raised by the commenters representing plans, employers, and administrators. These time frames accommodate both the need for additional time in some cases and the need for speedy decisionmaking when access to medical care is at stake.

Concurrent Care Decisions

The proposal contained a provision that would accelerate decisionmaking in the case of an urgent care claim arising out of a termination or reduction of previously granted benefits being provided over a period of time. Under the proposal, any such termination or reduction would be treated as an adverse benefit determination, and plans would be required to provide notice in such circumstances of the termination or reduction of benefits at a time sufficiently in advance of the termination or reduction so as to allow the claimant to appeal the denial before the termination or reduction takes effect. This proposal was intended to address RFI comments that expressed concern over the harm that patients suffer from interruptions in treatment that should have been provided on a continuous basis. The Department believed that the dangers of this harm could be minimized if patients are provided an opportunity to argue in favor of uninterrupted continuing care before treatment is cut short or reduced. No serious objections to this provision were raised in the comment record.

In finalizing the regulation, the Department has concluded that there is no strong basis for providing this protection only for terminations or reductions involving urgent care.[11] Any

that if delaying deciding a claim could seriously jeopardize the claimant's ''life'' or ''health,'' the claim involves urgent care. Any effect on a claimant's ''maximum function'' that is less than serious jeopardy to life or health should not be considered a ''claim involving urgent care.''

[7] The record indicates also that representatives of claimants do not generally oppose making this distinction.

[8] As in the 1977 regulation and the proposal, the times established for decisionmaking are maximum times only. Decisions are required to be made, generally, within a reasonable period of time appropriate to the circumstances. Accordingly, in some cases, delaying a decision until the end of the applicable maximum period may be unreasonable under the circumstances and thus a violation of the procedural standards.

[9] Various commenters requested clarification as to whether the term ''days'' as used in the proposal was intended to refer to calendar days or to some other more limited construct, such as ''business'' days. It was the Department's intention in the proposal, and it continues to be the Department's position with respect to this regulation, that the term ''days'' means calendar days. In light of the need for speedy decisionmaking in many of the time frames involved, the Department has determined not to restrict the counting of days as used in the regulation to less than every calendar day, but rather to provide reasonable periods of time determined by reference to calendar days.

[10] The regulation's provisions for extension of time for group health plans and plans providing disability benefits are discussed generally below. In addition, the regulation leaves in place a restricted form of the ''quarterly meeting'' rule contained in the 1977 regulation, permitting extension of the decisionmaking time on review, under subparagraph (i)(2)(iii)(B) for post-service claims and under subparagraph (i)(3)(ii) for claims for disability benefits. The extension of time for plans administered by boards of trustees or committees that meet at least quarterly is available, under the regulation, only for multiemployer plans. It is the Department's view that such plans, in which employee representation is guaranteed, will delay decisionmaking by exercising this privilege only when it is necessary and not harmful to claimants.

[11] The regulation calls this type of decisionmaking ''concurrent care decisions'' because the decision to reduce the treatment is made concurrently with the treatment itself. The regulation clarifies that the provision applies to ongoing treatment covering either a period of time or a number of treatments. If a plan approves a course of treatment that has no finite termination date, such as treatments to be provided ''as long as medically necessary,'' a reduction or termination of that course of treatment is considered a concurrent care decision under the regulation.

decision to terminate or reduce benefits that have already been granted will cause disruption and potential harm to patients receiving the ongoing care. In our view, claimants faced with such a disruption should be afforded an adequate opportunity to contest the termination or reduction of already granted benefits before it takes effect. Accordingly, subparagraph (f)(2)(ii)(A) retains the basic protection provided in the proposal as to the termination or reduction of previously granted benefits, but expands its scope to encompass any termination or reduction of already granted benefits.

Some commenters urged the Department to consider extending the protection of this special timing rule to requests for additional care discovered to be necessary during the course of the initially prescribed treatment. In response to these suggestions and to minimize the possibility of harm from interruptions in treatment, the regulation further provides that any urgent care claim requesting to extend a course of treatment beyond the initially prescribed period of time or number of treatments must be decided within not more than 24 hours, provided that the claim is made at least 24 hours prior to the expiration of the initially prescribed period. If such a claim is denied, it would be appealable as an urgent care claim. [12]

Time Frames for Plans Providing Disability Benefits

The proposal established time frames for resolution of disability claims that were shorter than those in the 1977 regulation.[13] Commenters representing disability insurers voiced concern over this aspect of the proposal. These commenters argued that disability claims are often difficult to resolve inasmuch as they present complex issues requiring consideration of not only a claimant's medical condition, but also the claimant's continuing vocational capabilities. These commenters asserted that the proposed time frames were far too short to accommodate the individualized decisionmaking process involved in resolving most disability claims. Commenters representing claimants, especially long-term disability claimants, took an opposite position, arguing that disability providers frequently delay resolving these claims unnecessarily in order to avoid beginning to make payments. They emphasized the economic hardships disabled claimants experience as a result of any unnecessary delays in receiving the replacement income that disability benefits are intended to provide.

After consideration of the comments and testimony on this issue, the Department has resolved to provide a limited opportunity for extension of time to resolve disability claims. Subparagraph (f)(3), in consequence, provides that disability claims must be resolved, at the initial level, within 45 days of receipt; a plan may, however, extend that decisionmaking period for an additional 30 days for reasons beyond the control of the plan. If, after extending the time period for a first period of 30 days, the plan administrator determines that it will still be unable, for reasons beyond the control of the plan, to make the decision within the extension period, the plan may extend decisionmaking for a second 30-day period. The regulation requires that the plan provide a disability claimant with an extension notice that details the reasons for the delay. Thus, a plan may take, under limited and justifiable circumstances, up to 105 days to resolve a disability claim at the initial claims stage, provided that appropriate notice is provided to the claimant before the end of the first 45 days and again before the end of each succeeding 30-day period. In the Department's view, this framework will enable a plan to take sufficient time to make an informed decision on what may be a complex matter, but the plan will be required to keep the claimant well informed as to the issues that are retarding decisionmaking and any additional information the claimant should provide. By limiting the reasons for which decisions may be delayed, the regulation also requires prompt decisonmaking when appropriate.

With respect to the review of adverse benefit determinations involving disability claims, subparagraph (i)(3)(i) adopts the basic approach of the proposal, permitting a maximum of 45 days to complete a review,[14] but it further permits plans providing disability benefits to extend the decisionmaking time on review for an additional 45-day period under the rules applicable to pension and other welfare plans, and under subparagraph (i)(3)(ii) allows multiemployer plans providing disability benefits that are administered by boards of trustees or committees meeting at least quarterly to take advantage of the ''quarterly meeting'' extended time period on review.[15]

Incomplete Claims and Extensions of Time

The proposal specifically required all plans to make an early determination as to whether a filed claim is ''incomplete.'' Under the proposal, notification that a claim is incomplete, including a description of the information necessary to complete the claim, would be required to be provided to a claimant within 5 days of filing the claim. This provision, which responded directly to complaints expressed in the RFI comments, was intended to eliminate unnecessary causes of delay in the processing of claims and to speed communications between plan and claimant regarding essential information.

The Department received many comments on the proposal asserting that it is often not possible to determine whether a claim is incomplete without deciding the claim in its entirety.[16] The requirement to provide notice of incompleteness within 5 days, these commenters urged, would essentially force plans to make complete benefit determinations within that time. These commenters further suggested that providing an opportunity for extending the time for deciding ''incomplete'' group health and disability claims would better serve the purposes intended to be achieved by the notice of incompleteness.[17]

In light of these objections and arguments, the Department has reconsidered the structure of its proposed rule regarding incomplete claims and extensions of time. The regulation generally omits the provisions for incomplete claims except

[12] Of course, any request to extend a course of treatment that does not involve urgent care is a claim under the regulation and is governed by the standards generally applicable to such claims.

[13] Under the proposal, disability claims were subject to a 30-day maximum initial decisionmaking period, with the possibility of a 15-day unilateral extension; review of adverse benefit determinations of such claims were made subject to a 45-day maximum period, with a possible 45-day unilateral extension.

[14] Under the regulation, a plan cannot impose more than two levels of mandatory review with respect to denial of a disability claim.

[15] See below for explanation of the ''quarterly meeting'' rule.

[16] Representatives of claimants supported the proposed rule regarding incomplete claims, asserting that plans frequently and unnecessarily delay in informing claimants of obvious deficiencies in claims, thereby causing claims decisions to be made later than would otherwise be the case.

[17] The 1977 regulation permitted an extension of time of up to 90 days for processing claims under ''special circumstances.'' The proposal would have eliminated this provision and prohibited plans from taking extensions of time without the claimant's consent. Commenters representing plans, employers, and plan administrators objected to the prohibition on extensions of time as inappropriately inflexible.

with respect to urgent care claims.[18] Instead, the Department has modified the 1977 regulation's provisions for extensions of time to permit group health plans and plans providing disability benefits a limited opportunity to extend the period for decisionmaking at the initial level.[19] Under subparagraphs (f)(2)(iii)(A) and (B) group health plans may extend decisionmaking on both pre- and post-service claims for one additional period of 15 days after expiration of the relevant initial period, if the plan administrator determines that such an extension is necessary for reasons beyond the control of the plan. Under subparagraph (f)(3), plans providing disability benefits may avail themselves of a similar provision permitting a maximum of two extensions of time, each of 30 days, when necessary for reasons beyond the control of the plan.[20]

In each case, if the reason for taking the extension is the failure of a claimant to provide necessary information, the time period for making the determination is tolled from the date on which notice of the necessary information is sent to the claimant until the date on which the claimant responds to the notice.[21] In connection with providing an opportunity for extension, subparagraph (f)(4) further specifies that the time periods for making a decision are considered to commence to run when a claim is filed in accordance with the reasonable filing procedures of the plan, without regard to whether all of the information necessary to decide the claim accompanies the filing.

In providing a limited extension opportunity for deciding group health and disability claims, it is the Department's intention to provide plans with the flexibility necessary to handle all claims appropriately, whether such claims are easy or difficult, complete when filed or needing more information. The Department emphasizes that the time periods for decisionmaking are generally maximum periods, not automatic entitlements. If a specific claim presents no difficulty whatsoever, it may be unreasonable to delay in deciding that claim until the end of the maximum period; similarly, an extension may be imposed only for reasons beyond the control of the plan. For example, the Department would not view delays caused by cyclical or seasonal fluctuations in claims volume to be matters beyond the control of the plan that would justify an extension. The Department further notes that there is no provision for extensions of time in the case of claims involving urgent care.

Notice and Disclosure Requirements

The proposal contained several amplified notice and disclosure requirements, some of which were made applicable to all plans, and some of which applied specifically only to group health plans. Among such general new notice requirements was a provision requiring all plans to provide a specific notice, within 5 days (24 hours in the case of a claim involving urgent care), in any instance in which a participant or beneficiary made a request for a benefit, but failed to follow the plan's procedures for filing a claim.[22] The mandated notice for incorrectly filed claims would explain that the request for a benefit did not constitute a claim under the terms of the plan and would further describe the plan's procedures for filing a claim. The Department's intention in proposing this new notice requirement was to ensure that plans did not ignore, either deliberately or inadvertently, any reasonable, albeit unsuccessful, attempt by claimants or their representatives to make a claim.

Many commenters representing employers, plans, and plan administrators objected to this provision, asserting that plans would have difficulty determining whether a communication with the plan was a ''request for a benefit'' or a simple inquiry about the plan's provisions, unrelated to any specific benefit claim. These commenters argued that the notice requirement would be unduly expensive to implement because of the large number of plan-related individuals contact with whom could trigger the requirement. Commenters further argued that this notice requirement was superfluous since a plan's summary plan description (SPD) should clearly describe the requirements for filing a claim for benefits, and it can be assumed that claimants read and understand their plan's SPD.

After reconsidering this proposal in light of the comments, the Department has determined to clarify this notice requirement to eliminate uncertainty as to its meaning and to narrow its application to better target the perceived problem. Under subparagraph (c)(1)(i), the requirement to provide a notice informing claimants that they have failed to properly file a claim will arise only if a request is made that involves a pre-service claim. Further, under subparagraph (c)(1)(ii), the notice requirement will be triggered only by a communication from a claimant or a health care professional representing the claimant that specifies the identity of the claimant, a specific medical condition or symptom, and a specific treatment, service, or product for which approval is requested, and the communication is received by a person or organizational unit customarily responsible for handling benefit matters. In order to reduce the asserted costs of compliance, the regulation provides that the notice may be provided orally to the claimant or health care professional (as appropriate), unless the claimant or representative requests a written notice. Restricting the scope of this notice requirement in this manner will reduce the compliance difficulties posited by the commenters, while still requiring notice of a defective filing to be given in those instances most critical to claimants.

The proposal clarified the requirement under the 1977 regulation that a plan's claims procedures must be described in the SPD of the plan. The proposal specified that the description in the SPD must include all procedures for filing claim forms, providing notification of benefit determinations, and reviewing denied claims. With respect to group health plans, the proposal would require the SPD description to include any procedures for obtaining preauthorizations, approvals, or utilization review decisions.

As a concomitant to this basic disclosure, the proposal further clarified that a notice of adverse benefit determination (at both the initial level and on review)[23] must identify

[18] As was proposed, the regulation requires plans to provide notice of incompleteness, in the case of a claim involving urgent care, within 24 hours of receipt of the claim and does not permit a plan to unilaterally extend the time period for deciding an urgent care claim.

[19] With respect to pension and other welfare plans, this regulation fully continues the provisions of the 1977 regulation regarding extensions of time.

[20] The rules for disability claims are also described above.

[21] This tolling period ends on the date on which the plan receives the claimant's response to the notice, without regard to whether the claimant's response supplies all of the information necessary to decide the claim. Once the claimant responds, the plan will have the benefit of the extension of time (15 days for group health claims; 30 days for disability claims) within which to decide the claim. The plan may take only the extensions described in the regulation (*e.g.,* one extension for group health claims) and may not further extend the time for making its decision unless the claimant agrees to a further extension.

[22] The proposal listed a number of individuals and parties related to the plan and the employer, communication with whom would trigger the notice requirement.

[23] The proposal required written or electronic notice to be provided with respect to grants of benefits as well as denials. In view of the negative comments that the Department received regarding

specifically any internal rules, guidelines, protocols, etc. that served as a basis for the adverse benefit determination.[24] If such rules had served as a basis for the decision either at the initial level or on review, the proposal further required that a copy of the protocol be provided to the claimant upon request.

While there was little comment on the proposal's provision for disclosure in the SPD of the plan's claims procedures, some commenters representing plan administrators and health insurance or services provider organizations objected to the requirements regarding identification and furnishing of a utilized internal rule or protocol. In the view of these commenters, these requirements would impose excessive burdens on administration of group health plans and provide little in the way of useful information to claimants. While the testimony and comments on this issue were in some conflict,[25] a large number of commenters asserted that it would be expensive and difficult to specify in the notice of adverse benefit determination the individual protocol on which the decision was based because of the computerized nature of the determination processes. In addition, these commenters argued that specification of the protocol would not provide the claimant with useful information about why their benefit claim had been denied. These commenters also worried that the language of the proposal could be read to require plans routinely to furnish a copy of the specific protocol itself as part of the notice of adverse benefit determination. Because protocols can be of some length and complexity, providing these documents routinely with any adverse benefit determination could impose a large burden on the administration of group health plans.

The Department continues to believe that claimants have a need to know the specific basis for an adverse benefit determination. Where a plan utilizes a specific internal rule or protocol, understanding the terms of the specific protocol may be crucial to a claimant's ability to successfully contest the denial on review. Therefore, subparagraph (g)(1)(v) generally retains the requirements that a plan inform a claimant that a protocol has been relied upon and furnish the protocol upon request. To reduce the potential burden of complying with these requirements, the regulation makes clear that the notice of adverse benefit determination may either set forth the protocol on which it was based or a statement that a protocol was relied upon and that a copy of such protocol will be made available to the claimant free of charge upon request.

Several commenters requested that the Department amplify the disclosure requirements for adverse benefit determinations to require plans to provide an adequate explanation of the reason for an adverse benefit determination based on medical judgment especially when invoking plan exclusions based on ''medical necessity'' or similar broad terms. Commenters asserted that the reasons given in these circumstances were frequently ''cursory'' and ''vague and open ended.'' One commenter stated that when claimants receive such conclusory denials unsupported by scientific or clinical evidence, ''they are in the untenable position of having to refute arguments they are not allowed to understand.''

The Department agrees that claimants would benefit from receiving fuller explanations when a claim is denied because the care is not medically necessary, is experimental in nature, or some similar plan exclusion or limit is applied. Consequently, the Department is adding new subparagraphs (g)(1)(v)(B) and (j)(5)(ii) to require that the notification of an adverse benefit determination (at both the initial level and on review) based on medical necessity, experimental treatment, or other similar exclusion or limit either explain the scientific or clinical judgment of the plan in applying the terms of the plan to the claimant's medical circumstances, or include a statement that such an explanation will be provided free of charge to the claimant upon request. In response to comments, the Department is also adding subparagraph (j)(5)(iii) to require inclusion of a statement notifying claimants that they can seek additional information about potential alternative dispute resolution methods.

The preamble to the proposal discussed the Department's interest in providing claimants sufficient access to information that could aid them in determining whether a plan and its agents had acted fairly and consistently in denying their claims. In particular, the Department was concerned about claimants' difficulties in obtaining sufficient information to determine whether a particular claims decision comported with prior decisions on similar issues and whether a claimant would be justified in challenging a decision as defective under the Act on that basis. In this regard, the Department stated in the preamble that it was considering requiring plans to disclose, after an adverse benefit determination on review, documents and records relating to previous claims involving the same diagnosis and treatment decided by the plan within the five years prior to the adverse benefit determination (up to a maximum of 50 such claims). The disclosure obligation would have been limited to cases in which a claimant commences litigation over the benefit determination and would have been further limited, with respect to insured benefits, to claims involving the same plan or insurance contract language.

This proposal was opposed by many commenters representing employers, plans, plan administrators, and insurers. They asserted that such a requirement would be prohibitively expensive to implement and would provide claimants with little information of any benefit. They also asserted that requiring this disclosure would be beyond the Department's regulatory authority under section 503 of the Act.

The Department has seriously considered the objections raised to this suggestion in the preamble of the proposal and has altered its approach to the problem in order to reduce the potential burden on plans and avoid any suggestion of possible interference with the civil discovery processes in litigation. Subparagraph (b)(5) provides, as a general requirement for reasonable claims procedures for all plans, that a plan's claims procedures must include administrative safeguards and processes designed to ensure and to verify that benefit claims determinations are made in accordance with governing plan documents and that, where appropriate, the plan provisions have been applied consistently with respect to similarly situated claimants. Courts have long recognized that such consistency is required even under the most deferential judicial standard of review.[26] It is the view of the

this requirement, the regulation requires written or electronic notice of benefit grants to be provided only in the case of claims involving urgent care and pre-service claims.

[24] It is the Department's view that such internal rules, guidelines, protocols, etc. are ''instruments under which the plan is established or operated'' within the meaning of section 104(b) of the Act and as such must be furnished to participants and beneficiaries upon written request. *See* Advisory Opinion 96–14A (July 31, 1996).

[25] Many commenters representing claimants affirmed the importance of having access to internal rules or protocols used in decisionmaking. Other testimony, in particular from insurers, indicated that specifically utilized protocols are currently available and furnished to claimants upon request. Other testimony indicated that such protocols can be obtained routinely only through discovery processes in litigation.

[26] *See, e.g., Lutheran Medical Center* v. *Contractors, Laborers, Teamsters and Engineers*

Continued

Department that this provision does no more than to require a plan to formalize, as a part of its claims procedures, the administrative processes that it must already have established and be using in operating the plan in order to satisfy basic fiduciary standards of conduct under the Act. The Department has not articulated specific requirements as to how such processes should be designed, believing that plans should have flexibility and are capable of monitoring their internal decisionmaking effectively and efficiently.

As a concomitant to this general requirement, subparagraph (m)(8)(iii) further provides that, among the information that a plan must provide a claimant upon request after receiving an adverse benefit determination, is any information that the plan has generated or obtained in the process of ensuring and verifying that, in making the particular determination, the plan complied with its own administrative processes and safeguards that ensure and verify appropriately consistent decisionmaking in accordance with the plan's terms. It is not the Department's intention in this regard to require plans to artificially create new systems for the sole purpose of generating documents that can be handed to a claimant whose claim is denied in order to satisfy this disclosure requirement. The Department anticipates that plans generally will have systems for ensuring and verifying consistent decisionmaking that may or may not result in there being disclosable documents or information pertaining to an individual claims decision.

The proposal attempted to clarify the 1977 regulation's requirement that claimants be afforded access, after a benefit denial, to ''pertinent documents.'' Based on its conclusion from RFI comments that there was substantial public confusion concerning the meaning of the term ''pertinent,'' the Department proposed to replace that term with the term ''relevant.'' The proposal further stated that a document would be considered ''relevant'' to a claim whether or not such document was in fact relied upon by the plan in making the adverse benefit determination. As stated in the preamble to the proposal, the Department believed that these changes would make clear that claimants must be provided access to all of the information present in the claims record, whether or not that information was relied upon by the plan in denying the claim and whether or not that information was favorable to the claimant. Such full disclosure, which is what the 1977 regulation contemplated, is necessary to enable claimants to understand the record on which the decision was made and to assess whether a further appeal would be justified.

Commenters representing plans, employers, insurers, and plan administrators expressed dissatisfaction with this attempted clarification.[27] The main source of their objection was that the proposal failed to define adequately the scope of the intended disclosure. In their view, the use of the term ''relevant,'' particularly when coupled with the modifier that information need not have been relied upon to be relevant, would impose an unlimited burden on plans to search their records for any information relevant in the broadest sense to the claim, whether it was in any way related to the actual claims process. These commenters feared that plans would face added costs of keeping track of, and disclosing, a large amount of information generally accessible to the decisionmaker, without regard to whether such information was in any way utilized in the decisionmaking process.

The regulation responds to this concern. While retaining the term ''relevant'' in subparagraph (j)(3) to describe the documents and other information that must be made available to a claimant free of charge upon request after receiving an adverse benefit determination, the regulation provides a specific definition of that term. Subparagraph (m)(8) states that a document, record, or other information is considered ''relevant'' if it was relied upon in making the determination, or was submitted to the plan, considered by the plan, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon in making the determination. Subparagraph (m)(8) further provides that the claimant should receive any information demonstrating that, in making the adverse benefit determination, the plan complied with its own processes for ensuring appropriate decisionmaking and consistency. Additionally with respect to group health and disability claims under subparagraph (m)(8), a document, record, or other information is considered ''relevant'' if it constitutes a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit for that claimant's diagnosis, without regard to whether such advice or statement was relied upon in making the determination. The Department believes that this specification of the scope of the required disclosure of ''relevant'' documents will serve the interests of both claimants and plans by providing clarity as to plans' disclosure obligations, while providing claimants with adequate access to the information necessary to determine whether to pursue further appeal.

Standards of Review

The proposal adopted new standards for a full and fair appeal of an adverse benefit determination. The proposal required that the review 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. In addition, with respect to group health claims, the proposal required fiduciaries reviewing any determination based on a medical judgment to consult with a health care professional with appropriate training and experience in the field of medicine involved in the medical judgment. Such health care professional was required to be ''independent'' of any health care professional consulted in making the initial adverse benefit determination.

Most commenters considering this aspect of the proposal strongly supported these reforms, agreeing that there is a need to ensure that claims decisions are reviewed by a party with sufficient independence to provide a full and fair review. A significant number of commenters urged the Department to extend the requirement of consultation with an appropriate health care professional to the review of decisions on disability claims. Some commenters, however, voiced concern regarding the additional cost that would be imposed by the requirement of a separate decisionmaker and consultation with health care professionals. In particular, it was argued that small employers, whose plans, it was asserted, generally are administered solely by a single individual who is either the owner of the business or the general manager of the business, would be caused

Health and Welfare Plan, 25 F.3d 616, 620–22 (8th Cir. 1994); *De Nobel* v. *Vitro Corp.,* 885 F.2d 1180, 1188 (4th Cir. 1989).

[27] Representatives of claimants, however, strongly supported this clarification, complaining that plan officials occasionally seek to withhold information that would tend to support granting the claim.

substantial additional expense to obtain the independent review. Some commenters further urged the Department to clarify the type of ''independence'' that would satisfy the Department's requirement for the health care professional who must be consulted on review.

Subparagraphs (h)(3) and (4) generally retain the proposed standards for the conduct of reviews of adverse benefit determinations with respect to group health plans and plans providing disability benefits. By limiting the scope of this reform to group health plans and plans providing disability benefits, the regulation greatly reduces, the Department believes, the cost implications for small employers. In addition, the regulation requires consultation with an appropriately qualified health care professional on review of denied disability claims involving medical judgments. Subparagraph (h)(3)(v) further clarifies that the standards for ''independence'' of a health care professional who is consulted in connection with a review are the same as those that apply to the appropriate named fiduciary under subparagraph (h)(3)(ii), that is, the individual who is consulted must be an individual different from, and not subordinate to, any individual who was consulted in connection with the initial decision. The Department believes that these changes will accommodate the interests of benefit claimants in having a full opportunity for an adequate review and the needs of employers and plans to limit the costs of providing such a review.

Permitted Levels of Review

The proposal provided that a plan may require only one appeal of a denied claim. This limitation was intended to assure that claimants whose claims are denied have the ability to take their claims to court without undue delay, as the Department believes was intended by section 503 of the Act. Nothing in the proposal, however, was intended to preclude a plan from offering, or a claimant from agreeing to utilize, additional voluntary administrative appeals processes. The proposal further banned plans from requiring that denied claims be submitted to arbitration or that any costs be imposed on a claimant as a condition for filing or appealing a claim.

These aspects of the proposal were opposed by many commenters representing employers, plans, plan administrators, benefit providers, and insurers. These commenters asserted that it is common practice among a large number of plans to provide more than one level of appeal for a denied claim and that such a practice generally benefits claimants by providing a less costly alternative to taking a denied claim to court. Such a practice is particularly common, it appears, with respect to insured benefits, where initial decisions and one or more appeals are handled within the insurer, and appeals at additional levels are to the plan or employer. Commenters representing claimants, on the other hand, supported the limitation on the number of mandatory appeals, arguing that multiple levels of administrative appeal often hamper and frustrate claimants, causing them to abandon claims. Such multiple levels often serve no actual purpose, these commenters assert, and provide no independent review.

The Department continues to believe that allowing plans to impose an unlimited number of levels of administrative appeals of denied claims does not serve the best interests of claimants. However, it has concluded that the strict limitation of appeals to a single level may be unnecessarily limiting. In the interests of providing plans some flexibility in creating claims processes, and to accommodate what appears to be a common practice, subparagraph (c)(2) permits two levels of mandatory appeal of an adverse benefit determination. [28] In order to promote speedy resolution of group health claims, however, subparagraph (i)(2) limits the overall time period within which plans must decide appeals of denied claims. [29]

With respect to the proposal's ban on arbitration, a significant number of commenters representing unions, [30] multiemployer plans, and employers objected that this reform was contrary to the general approach of the Federal government, as expressed in the Federal Arbitration Act, to encourage the appropriate use of alternative dispute resolution. In addition, these commenters suggested that arbitration generally provides a useful and less costly means of resolving benefit disputes than litigation. An equal number of commenters representing claimants, however, supported the proposed ban on mandatory arbitration, asserting that, as applied to claims disputes, arbitration is inherently unfair because of the difference in status between the typical benefit claimant and the typical plan or employer. Commenters also suggested that the practice of requiring plan participants to agree to arbitrate all benefits disputes as a condition of participation in the plan is inherently unfair due to the inequality in bargaining power between employers and employees. Further, they argued that the traditional methods of cost-sharing involved in commercial arbitration, in which each party pays half of the costs of the arbitration, may be prohibitively expensive for most claimants.

After careful deliberation on the issues raised by the commenters regarding the use of alternative dispute resolution for benefit claims disputes, the Department has revised its approach to permit plans, pursuant to subparagraph (c)(4), to require some limited forms of mandatory arbitration. In addition, in subparagraph (c)(3), the Department addresses more generally the subject of plans' offering additional, voluntary processes, including voluntary binding arbitration, after conclusion of the required claims review process. By retaining the complete prohibition on imposing costs on claimants in connection with filing or appealing a claim, however, subparagraph (b)(3) makes clear that any process used by a plan to resolve a claim dispute, including arbitration, must be conducted without imposing fees on the claimant. These restrictions apply, under the regulation, only to group health plans and plans providing disability benefits.

With respect to mandatory arbitration used as part of the claims process, subparagraph (c)(4) provides that a plan may require arbitration as one (or both) of the permitted levels of review of a denied claim, provided, first, that the arbitration is conducted in accordance with the requirements of the regulation applicable to such appeals and, second, that the claimant is not thereby precluded from challenging the arbitrator's decision, including pursuing the claim in court pursuant to section 502(a) of the Act. With respect to voluntary additional levels of appeal offered by a plan, including voluntary binding arbitration or other methods of dispute resolution, subparagraph (c)(3)(iii) provides that a plan may offer

[28] As with other aspects of the regulation's procedural reforms, this limit is imposed only with respect to group health plans and plans providing disability benefits. The Department solicits comments on whether this reform should be extended to other employee benefit plans.

[29] If a group health plan provides only one level of appeal, it may take up to 30 days to resolve an appeal of a pre-service claim denial; if it provides two levels of appeal, both levels must be concluded within that 30 days. For appeals of post-service claims denials, a plan with a single level of appeal may take up to 60 days to conclude that appeal; plans with two levels of appeal must complete both appeals within the same 60 days.

[30] The issue of the 1977 regulation's special treatment of grievance procedures, including arbitration, adopted by collectively bargained, single employer plans through the collective bargaining agreement, is discussed separately below.

such voluntary additional levels of appeal to a claimant as a method of resolving a benefit dispute only after the dispute has arisen. Subparagraph (c)(3)(iv) further requires the plan to provide the claimant with sufficient information about the voluntary process to permit the claimant to make an informed judgment about whether to submit the dispute to the voluntary process; this requirement includes information about the applicable rules, the process for selecting the decisionmaker, and the circumstances, if any, that may affect the impartiality of the decisionmaker, such as any financial or personal interests in the result or any past or present relationship with any party to the review process. The plan must also make clear to the claimant that the decision as to whether or not to submit a benefit dispute to the voluntary level of appeal will have no effect on the claimant's rights to any other benefits under the plan.[31] In addition, subparagraph (c)(3) includes two protections intended to make sure that additional appeal levels offered by a plan remain truly voluntary. First, subparagraph (c)(3)(i) requires any plan offering a voluntary appeal to agree not to later assert a defense of failure to exhaust available administrative remedies against a claimant who chooses not to make use of the voluntary appeal process. Second, subparagraph (c)(3)(ii) requires such plans to agree that any statute of limitations or other defense based on timeliness is tolled while the dispute is under submission to the voluntary process. The Department considers these protections to be essential to procedural fairness for a claimant who is offered or pursues voluntary administrative processes as an alternative to pursuing a claim in court.

Preemption of State Law

Section 514(a) of the Act provides that the provisions of the Act generally supersede State laws ''insofar as they may now or hereafter relate to any employee benefit plan [covered under the Act].'' Section 514(b)(2)(A), however, saves from the general preemption of section 514(a) State laws that regulate insurance, banking, or securities. The scope and meaning of the general preemption provision of section 514(a) and the savings clause contained in section 514(b)(2)(A) have been the subject of controversy since enactment of the Act.[32] The proposal did not address section 514 of the Act or in any way propose to regulate the relationship between the proposed minimum standards for benefit claims procedures of employee benefit plans and State law that might affect or relate to such standards.

Many commenters, including several State insurance commissioners, urged the Department to consider addressing the question of the preemptive effect of a final regulation on State law. Such commenters suggested that a failure to do so would exacerbate existing confusion about the possible preemption of State law efforts seeking to improve the quality of health care, especially those that seek to protect patients' rights by providing State-mandated systems for the review of disputes between patients and health care providers or insurers. Such State law, the commenters argued, may be considered to be preempted to the extent that the State-law requirements differ from or conflict with the requirements of this regulation. Some commenters urged the Department to provide in this regulation for the complete preemption of State law that provides procedures for the resolution of benefit claims disputes. Others urged the Department to model the extent of the regulation's preemptive effect on section 731(a) of the Act, which provides special, more limited preemption with respect to the provisions of the Part 7 of the Act, concerning portability, renewability, nondiscrimination, and other rights relating to group health plans. Overall, a large number of commenters agreed that there would be benefit to the public in general in the Department's clarifying its views as to the preemptive effect of the regulatory standards.

In response to these comments, the Department has added to the regulation a new paragraph (k) providing interpretive guidance on the question of the relationship of the substantive regulatory standards to State law. Subparagraph (k)(1) states that the regulatory standards should not be read to supersede State law regulating insurance (even when such State law prescribes standards for claims processes and internal review of claims) unless such State law prevents the application of a requirement of the regulation. For example, a State may have a law requiring insurers to allow oral appeals of all claims or to decide claims within shorter periods of time. These laws would not prevent the application of the regulation because plans could comply with both the regulation and the State laws.

Subparagraph (k)(2)(i) explains that a State law regulating insurance should not be considered to prevent the application of a requirement of the regulation merely because the State law establishes a review procedure to evaluate and resolve disputes involving adverse benefit determinations under group health plans, so long as the review procedure is conducted by parties other than the insurer, the plan, the plan's fiduciaries, the employer, or any employee or agent of any of the foregoing. Subparagraph (k)(2)(ii) further explains that, in the Department's view, the types of procedures described in subparagraph (k)(2)(i) are not part of the claims procedures contemplated by section 503 of the Act, but are ''external reviews'' that are beyond the scope of the regulation. As a result, while such procedures as established by State law are not preempted by the regulation, under subparagraph (k)(2)(ii), claimants cannot be required to submit their claims to such procedures in order to be entitled to file suit under section 502(a) of the Act.[33] There is nothing in the regulation, however, that would preclude a claimant from voluntarily submitting a claim for review pursuant to a State-provided external review process.

By providing that only State insurance law that does not prevent the application of the regulatory standards will be saved from preemption, subparagraph (k)(1) preserves the procedural protections required by the regulation, which the Department finds essential to the full and fair review mandated by section 503 of the Act,[34] but recognizes that States may impose non-conflicting standards for internal processes. Subparagraph (k)(2) of the

[31] In this regard, the regulation requires that any plan intending to offer an additional voluntary level of appeal must include, in the notice of adverse benefit determination on review, a statement describing the voluntary appeal procedure and the claimant's right to obtain the information about the process described in subparagraph (c)(3)(iv) free of charge before deciding to submit the claim to the voluntary level of appeal.

[32] *See, e.g., Pegram* v. *Herdrich,* 120 S. Ct. 2143 (2000); *Unum Life Ins. Co.* v. *Ward,* 526 U.S. 358, (1999); *Boggs* v. *Boggs,* 520 U.S. 833 (1997); *N.Y. State Conf. of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.,* 514 U.S. 645 (1995); *John Hancock Mut. Life Ins. Co.* v. *Harris Trust & Savings Bank,* 510 U.S. 86 (1993).

[33] It is the view of the Department that claimants would be entitled to have a claim dispute adjudicated in court pursuant to section 502(a) of the Act after exhausting the plan's claims procedures, but without regard to State law procedures described in subparagraph (k)(2), regardless of whether such State law procedures are mandatory pursuant to State law.

[34] Nothing in this regulation should be construed to limit a claimant's ability to pursue any state law remedy that may be available as a result of a medical decision, even where such decision implicates eligibility for benefits under a plan. *See Pegram v. Herdrich,* 120 S. Ct. 2143 (2000).

regulation clarifies the extent to which State law reform efforts regarding patients' rights may be affected by the preemption provided for in paragraph (k)(1). Subparagraph (k)(2) articulates the Department's view that procedural remedies established by State law that are ''external'' to the plan will not be preempted by the regulation. In this regard, subparagraph (k)(2)(i) defines the processes that will be considered ''external'' to the plan by reference to the party who is responsible for conducting the procedures. It is the Department's view that procedures that are conducted by parties other than the insurer providing benefits under the plan, the plan itself, the plan's fiduciaries, or the employer sponsoring the plan (or by any employee or agent of any of these parties) [35] are procedures sufficiently independent of the plan to be considered outside the scope of the process required by section 503 of the Act.

Other Issues

The regulation makes a number of additional changes to the proposal in response to comments. Other aspects of the proposal have been retained unchanged, despite comments, in light of the Department's conclusions as to their importance. The following briefly summarizes these other issues.

The proposal eliminated a provision in the 1977 regulation that seemed to imply that representatives of a claimant must be ''duly authorized'' to act on behalf of the claimant. This change reflected the perception of the Department that no single Federal standard governs the authorization of a representative and that claimants should be able to freely name representatives to act on their behalf. Many commenters representing employers and plans responded that elimination of the concept of an ''authorized'' representative could be read to require plans to accept anyone who claimed to be a representative of a claimant, without permitting plans to establish reasonable procedures to verify that status. This could prevent plans from protecting the privacy or other rights of claimants. The regulation responds to this concern by reinstituting a concept of authorization with respect to claimants' representatives.[36] Specifically, subparagraph (b)(4) provides that a plan's claims procedures may not preclude an authorized representative (including a health care provider) from acting on behalf of a claimant and further provides that a plan may establish reasonable procedures for verifying that an individual has been authorized to act on behalf of a claimant. However, subparagraph (b)(4) requires a group health plan to recognize a health care professional with knowledge of a claimant's medical condition as the claimant's representative in connection with an urgent care claim.

The proposal provided that a ''claim'' is any 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.[37] It further specified that, in the case of a group health plan, a request for a benefit 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. One commenter argued that the reference to ''coverage determination'' in this provision could be read to include determinations of eligibility under a group health plan, and that such determinations should not be treated as claims. The Department agrees that all requests for determinations of eligibility under a group health plan should not be required to be treated as claims for benefits for purposes of ERISA's claims procedure under section 503.[38] On the other hand, the Department also believes that where a claim for benefits is made in accordance with reasonable procedures and the claim is denied because the claimant is not eligible for benefits under the terms of the plan, the claimant should be afforded the right to appeal that determination in accordance with the claims procedures of the plan and this regulation.[39] In this regard, the reference to ''coverage determination'' has been eliminated from the description of a claim for benefits in paragraph (e). In an effort to clarify the application of the regulation to benefit claim denials based on eligibility, the Department has amended the definition of ''adverse benefit determination'' in subparagraph (m)(4) to include denials of benefits based on a determination of a claimant's eligibility to participate in the plan. The Department, nonetheless, is interested in receiving public comments concerning whether, and to what extent, questions to a plan regarding eligibility should be governed by a prescribed process, with timing and notice standards.

The proposal contained a provision setting forth the Department's view of the consequences that ensue when a plan fails to provide procedures that meet the requirements of section 503 as set forth in regulations. The proposal stated that if a plan fails to provide processes that meet the regulatory minimum standards, the claimant is deemed to have exhausted the available administrative remedies and is free to pursue the remedies available 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. The Department's intentions in including this provision in the proposal were to clarify that the procedural minimums of the regulation are essential to procedural fairness and that a decision made in the absence of the mandated procedural protections should not be entitled to any judicial deference.

Many commenters representing employers and plans argued that this provision would impose unnecessarily harsh consequences on plans that substantially fulfill the requirements of the regulation, but fall short in minor respects. These commenters suggested that the Department adopt instead a standard of good faith compliance as the

[35] Whether a party conducting a review procedure should be considered to act as the ''agent'' of a party related to the plan will depend on the independent authority with which the party is vested. That an insurer is required, under State law, to provide funds to pay for a review will not, in and of itself, cause the party who conducts the review to be considered an ''agent'' of the insurer.

[36] This provision, which is a clarification of current law, applies to all employee benefit plans covered under the Act.

[37] In this regard, the Department notes that all such claims for benefits are covered by this regulation, regardless of the reason or reasons a plan may have for denying the claim. For example, a claim for a health care service, even a health care service that is specifically excluded by the plan's governing documents, would be covered by the regulation.

[38] The Department notes that persons who need to establish their status as participants or beneficiaries under a plan have a number of ways to do so without implicating the claims procedures. Eligibility information is generally provided through the plan administrator, the summary plan description, and plan documents. If a person is unable to determine his or her status under the plan or if there is disagreement about a person's status under the plan, section 502(a)(1)(B) of the Act provides that participants and beneficiaries may bring a civil action to clarify their rights to future benefits under the terms of the plan.

[39] Sections 206(d)(3) and 609(a)(5) of the Act mandate certain specific plan procedures for determining the qualified status of domestic relations orders and medical child support orders, respectively, and for administering qualified domestic relations orders (QDROs) and qualified medical child support orders (QMCSOs). It is the view of the Department that issues pertaining to such orders must be resolved pursuant to the procedures described in section 206(d)(3) or 609(a)(5) of the Act, as appropriate, and not the claims procedures governed by section 503 of the Act and the current regulation.

measure for requiring administrative exhaustion. Alternatively, they suggested that the Department recognize the judicial doctrine under which exhaustion is required unless the administrative processes impose actual harm on the claimant.

Upon consideration, the Department has determined to retain this provision in paragraph (l). Inasmuch as the regulation makes substantial revisions in the severity of the standards imposed on plans, we believe that plans should be held to the articulated standards as representing the minimum procedural regularity that warrants imposing an exhaustion requirement on claimants. In the view of the Department, the standards in the regulation represent essential aspects of the process to which a claimant should be entitled under section 503 of the Act. A plan's failure to provide procedures consistent with these standards would effectively deny a claimant access to the administrative review process mandated by the Act. Claimants should not be required to continue to pursue claims through an administrative process that does not comply with the law. At a minimum, claimants denied access to the statutory administrative review process should be entitled to take that claim to a court under section 502(a) of the Act for a full and fair hearing on the merits of the claim. Further, the Department believes that it is unlikely that this provision, in and of itself, will result in an increase in benefit claims litigation. Given the limited remedies available in a suit under section 502(a) of the Act, claimants will have little incentive to invoke this provision unless they believe they will be unable to receive a fair consideration from the plan.

The proposal eliminated several special provisions contained in the 1977 regulations, including the special treatment provided for grievance procedures of collectively bargained, single-employer plans [40] and for benefits provided through Federally qualified health maintenance organizations (''HMOs'').[41] With respect to each of these special provisions, the Department requested comment on whether, in the interests of uniform treatment of benefit claims, these special treatments could be eliminated.

Comments on these subjects were relatively sparse. With respect to the special HMO exception, the Department has determined to retain the proposal's elimination of the special treatment. With respect to treatment of collectively bargained, single-employer plans, the Department received a few comments from interested parties, arguing that elimination of the special treatment would interfere unduly with the collective bargaining process and citing the Department's policy, articulated in the preamble to the 1977 regulation,[42] not to interfere with the operation of such agreements merely because they involve employee benefit plans. On review of the record, the Department has concluded that there is no reason to alter its policy position with regard to collective bargaining agreements that establish grievance procedures for single-employer collectively bargained plans and, accordingly, has determined to reinstate in subparagraph (b)(6) the special treatment provided in the 1977 regulation for such single-employer, collectively bargained plans.

The proposal stated that the regulation, when finalized, would be applicable to plans on the later of the effective date of the final regulation or the first day of the plan year beginning on or after the effective date, with a delayed compliance date for collectively bargained plans. Commenters argued that these applicability dates would be too soon, delineating the significant changes that would be required to achieve compliance with the proposal's requirements, such as review of third party administrator relationships, revisions to vendor contracts, systems redesign, amendment of documents, and preparation of appropriate disclosures for participants and beneficiaries. Several of these commenters requested a period of twelve months between publication of the final regulation and its applicability to plans. Recognizing these concerns, the Department has determined to provide a more substantial period of time for orderly and deliberate compliance efforts. Therefore, the regulation provides that its provisions will apply to claims filed under a plan on or after January 1, 2002.

B. Economic Analysis Under Executive Order 12866

Overview

In developing the regulation, the Department considered the potential economic effects of available alternative approaches. The regulation is crafted to maximize economic benefits net of costs. The Department believes that the regulation's benefits will substantially outweigh its costs.

The regulation will have two major, direct effects: it will change the timing and outcomes of some health and disability claims decisions, and it will require affected plans to modify claims decision-making processes.

The regulation will cause plans to promptly approve some valid claims that otherwise would have been denied. In economic terms, these changes in claims outcomes can be characterized as financial transfers that produce societal benefits. The cost to the plan of the services provided is offset by a benefit of equal financial value to the claimant, so the net cost to society is zero. The amount of the transfer cannot be estimated because there are no data on the number of valid claims that are denied today.

At least two societal benefits will derive from the prompt approval of valid benefit claims. The first benefit will be improved health outcomes and financial security. Claimants will be assured access to needed health care when ill or injured and financial support when disabled. The second will be more efficient labor and insurance markets, which should facilitate more and better health and disability benefit coverage. Employers will be more able and inclined to provide these benefits if employees are confident that valid claims will be approved. These benefits generally cannot be quantified, but they are expected to be large.

In estimating plans' cost to comply with the regulation, the Department considered the degree to which current claims handling practices conform to the regulation's requirements. Many claims are already handled in satisfaction of all or some applicable requirements, but assuring that all claims meet all the requirements will require at least some modifications to all plans' claims procedures. These modifications will entail one-time, ''start-up'' costs to establish the new processes, and ongoing costs to operate them.

The Department anticipates that all health and disability benefit plans will incur some start-up cost. Start-up costs are estimated at $119 million in 2001. Most of that cost, $103 million, is attributable to health plans, while the remaining $16 million is attributable to disability plans. Health plan start-up costs amount to an estimated $37 per plan and $0.75 per enrollee on average, while disability plan start-up costs are

[40] The 1977 regulation provides that such collectively bargained plans may substitute, for the provisions of the regulation, a collectively bargained procedure that either provides for filing, initial disposition of claims, and grievance and arbitration of benefit claims, or provides only for grievance and arbitration of such claims.

[41] The 1977 regulation provides that plans that provide benefits through membership in a qualified HMO, as defined in section 1310(d) of the Public Service Act, 42 U.S.C. 300e–9(d), are deemed to satisfy the regulation with respect to such benefits if the HMO satisfies the requirements of section 1310 of the Public Service Act.

[42] *See* 42 FR 27426 (May 27, 1977).

estimated to average $9 per plan and $0.24 per enrollee. Since most claims administrators serve many plans so costs generally will be spread widely across plans.

Ongoing costs will be incurred in connection with the subset of health and disability benefit claims that must be handled differently to satisfy the regulation's requirements. That subset will be small in connection with many of these requirements. Many claims are already handled in satisfaction of some requirements, such as the regulation's time frames for claims decisions, and many requirements apply only to a small subset of claims, such as urgent care claims or health benefit claims that are denied. Ongoing costs attributable to the regulation are estimated to be $399 million in 2002. Costs will fall over time with increased automation. Most of the ongoing cost, $379 million, is attributable to health benefit claims, while the remaining $21 million is attributable to disability benefit claims. Annual health plan costs amount to an average of $135 per plan. This is equivalent to $2.77 per enrollee on average, or approximately one-tenth of one percent of total plan premium. Disability plan ongoing costs average $12 per plan and $0.31 per enrollee. The cost to carry out any particular claims transaction in satisfaction of the regulation is likely to be low, but claims volume is high (1.4 billion health benefit claims per year), so aggregate costs are substantial.

The single largest ongoing cost is attributable to the regulation's time frames for health claims decisions. The Department believes that under plans' current practices up to 1 percent of claims decisions are not made within the regulation's maximum time periods. Accelerating these 14 million decisions to comply with the regulation is estimated to cost $222 million in 2002.

The economic costs of the regulation will be very small relative to the overall cost of providing and administering health and disability benefits. Health plans' ongoing cost of complying with the regulation will amount to just 0.1 percent of total plan expenditures. Costs of this relative magnitude are not expected to adversely affect employers' propensity to offer health and disability benefits.

The regulation does not substantially change the standards applicable to pension benefit claims or welfare benefit claims other than health and disability benefit claims. Its economic effects are therefore are limited to those associated with health and disability benefit claims.

The ongoing cost estimates for the regulation, presented here, are higher than the Department's ongoing cost estimates for the proposed regulation, previously presented in that proposed regulation's preamble. This should not be interpreted as an indication that the regulation will carry greater cost than would the proposed regulation. On the contrary, the regulation relaxes certain provisions of the proposed regulation, such as time frames for certain health benefit claims, in ways that will reduce economic costs without sacrificing economic benefits. The Department's estimation of the cost of the regulation incorporates new information, not available for estimating the cost of the proposed regulation, including the extensive public comments received in response to the proposed regulation. Based on this new information, the Department revised its estimations of the cost of certain provisions.

Required Analyses of Economic Impact

1. 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 propose regulations that, among other things, implement 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 impact exceeding $100 million in the year 2002, the year in which this regulation will be applicable to benefit claims. The total cost of this regulation is expected to be $399 million in 2002, and to decrease thereafter. This amount is approximately $2.77 per group health plan enrollee and $.31 per disability plan enrollee. Therefore, this notice is ''significant'' and subject to OMB review under Sections 3(f)(1) and 3(f)(4) of the Executive Order. Accordingly, the Department has undertaken to assess the costs and benefits of this regulatory action. The benefits of the regulation, although not quantifiable, are expected to exceed its cost. The Department's assessment of the regulation's costs and benefits is summarized above and detailed later in this preamble.

2. 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 that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a final rule will not have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires the agency to present a final regulatory flexibility analysis describing the impact of the rule on small entities at the time of publication of the notice of final rulemaking. Small entities include small businesses, organizations, and governmental jurisdictions.

For purposes of analysis under the RFA, PWBA continues 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 that 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.

PWBA believes that assessing the impact of this rule on small plans is an appropriate substitute for evaluating the effect on small entities. Because this definition differs from the definition of small business based on size standards, which is 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 solicited comments on its use of its standard for evaluating the effects of the proposal on small entities.

A few comments concerning the size standard were received from Congressional and administrative representatives. One commenter was concerned that prior to adopting the proposed size standard, the Department first consult with the Office of Advocacy of the Small Business Administration (SBA) and provide an opportunity for public comment. The Department consulted with the SBA regarding its proposed size standard prior to publication of the proposed regulation in the **Federal Register**. The SBA agreed with the proposed alternate size standard, indicating that Department provided a reasonable justification for its definition. No other comments were received with respect to this size standard.

A summary of the final regulatory flexibility analysis based on the 100 participant size standard is presented below.

This regulation applies to all small employee benefit plans covered by ERISA. Employee benefit plans with fewer than 100 participants include 631,000 pension plans, 2.8 million health plans, 1.7 million disability plans, and 1.7 million other welfare plans. The regulation makes substantial changes to the 1977 regulation, which it replaces, only in its provisions applicable to health and disability plans.

The final rule amends the Department's existing benefits claims regulation, which implements ERISA's claims and appeals requirements. Both ERISA and the existing regulation require plans to maintain procedures to determine claims and to review disputed claims determinations. The compliance requirements assumed for purposes of this regulation consist of new standards for claims and appeals procedures.

The objective of this revised regulation is to improve the accuracy and timeliness of health and disability benefit claims and appeals determinations. Certain provisions pertaining to group health plans are being implemented in response to the President's February 20, 1998, directive to the Secretary of Labor to propose regulations that among other things implements the recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. An extensive list of authorities may be found in the Statutory Authority section, below.

The Department believes that modifying and operating claims and appeals procedures in compliance with the regulation will require a combination of professional and clerical skills.

The Department estimates that the added cost to small plans of complying with the regulation will amount to $94 million over the years 2001 to 2002. This figure includes $24 million in one-time, start-up costs incurred in 2001 to revise health and disability benefit claims procedures and related systems, and $71 million in annual, ongoing added costs beginning in 2002 to handle health and disability benefit claims in compliance with the regulation's new standards. The annual ongoing cost in later years will change with claims volume and mix, and is expected to decrease with increasing automation in claims processing. The $71 million annual cost in 2002 averages $25 for each small health plan and $2.77 for each small health plan enrollee, and $1 for each small disability plan and $0.15 for each small disability plan enrollee. By contrast, the ongoing cost to large plans in 2002 is estimated at $329 million, or $6,183 for each large health plan and $2.77 for each large health plan enrollee, and $481 for each large disability plan and $0.35 for each large disability plan enrollee.

Start-up costs for small plans will be modest because a large majority of such plans purchase claims administration services from a relatively small number of insurers, HMOs, and other service providers. Service providers typically use a single claims processing system to service a large number of customers. Thus, the cost of revising and implementing a relatively small number of claims and appeals procedures is spread thinly over a far larger number of small plans. The regulation therefore is not expected to adversely affect small plans. Small and large plans and their respective enrollees will benefit equally from improved accuracy and timeliness in claims and appeals determinations.

The Department's assessment of the regulation's costs and benefits is detailed later in this preamble.

3. Paperwork Reduction Act

On September 9, 1998, the Pension and Welfare Benefits Administration published in the **Federal Register** (63 FR 48390), a Notice of Proposed Rulemaking concerning the Employee Retirement Income Security Act of 1974, Rules and Regulations for Administration and Enforcement; Claims Procedure, which included a request for comments on its information collection provisions. That proposal, if adopted as proposed, would have revised the information collection request (ICR) included in the existing regulation relating to the minimum requirements for benefits claims procedures for all employee benefit plans covered under Title I of ERISA. Also on September 9, 1998, the Department submitted the revised ICR to OMB for review and clearance under the Paperwork Reduction Act of 1995 (PRA 95), and solicited public comments concerning the revision of the information collection request (ICR) included in the proposal.

OMB has approved the ICR included in the Final Regulation concerning the Employee Retirement Income Security Act of 1974, Rules and Regulations for Administration and Enforcement; Claims Procedure. A copy of the ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor, Departmental Clearance Officer, Ira Mills, at (202) 693–4122. (Not a toll-free number.)

The burden estimates are summarized below. A more detailed description of the assumptions and methodology underlying these estimates will be found below in the analysis of costs.

Agency: Pension and Welfare Benefits Administration.

Title: Final Regulation, Employee Retirement Income Security Act of 1974; Rules and Regulations for Administration and Enforcement; Claims Procedure (Final Revisions to Benefit Claims Procedure Regulation Pursuant to 29 CFR 2560.503–1).

OMB Number: 1210–0053.

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

Frequency of Response: On occasion.

Total Respondents: 6.7 million (2001); 6.7 million (2002); 6.7 million (2003).

Total Responses: 118 million (2001); 118 million (2002); 118 million (2003).

Estimated Burden Hours: 316,000 (annual average 2001–2003).

Estimated Annual Costs (Operating and Maintenance): $96 million (annual average 2001–2003).

Persons are not required to respond to the revised information collection unless it displays a currently valid OMB control number.

4. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA), as well as Executive Order 12875, this rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, but does include mandates that may impose an annual

expenditure 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. Elsewhere in this preamble we have identified the authorizing legislation, presented cost-benefit analyses, described regulatory alternatives, and explained how we selected the least costly alternative as required by UMRA.

5. Small Business Regulatory Enforcement Fairness Act

This final rule 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. Accordingly, this final rule has been transmitted to Congress and the Comptroller General for review.

C. Detailed Assessment of Economic Benefits and Costs of the Regulation

Economic Benefits of the Regulation

The regulation will ensure the prompt approval of some health and disability claims that otherwise would have been wrongly denied. The approval of such claims can be characterized as financial transfers that will produce societal benefits. Quicker and more accurate health benefit claims determinations will serve to encourage the delivery of more beneficial health care. This in turn will improve health benefit claimants' health outcomes, productivity, and quality of life, and possibly avert the need for some later health care and associated expense. With respect to disability claims, timelier determinations will assure prompt replacement of lost income for successful claimants, thereby averting some financial hardships. Improved standards for handling health and disability claims will also increase enrollee confidence in their health and disability plans and thereby promote efficiency in group insurance and labor markets and employer sponsorship of health and disability plans.

These benefits of the regulation generally are impossible to quantify because of limitations in available data and the absence of reliable measures for their assessment. The Department's analysis is therefore restricted to identifying the categories of these benefits and describing their origins and anticipated magnitude.

1. Group Health Claims

The regulation updates ERISA's requirements for benefit claims processing in group health plans to address recent, dramatic changes in the delivery and financing of health care services. This will improve health care quality by averting harmful, inappropriate delays and denials of health benefits, thereby yielding substantial social benefits. It will also increase confidence in the employment-based health benefits system, increase transparency and enrollee access to information related to their benefit claims, and help streamline and make more uniform and predictable claims and appeals procedures. In so doing, it can help increase the efficiency of health benefit plans and of health insurance, health care markets, and labor markets at large.

The Department expects that the economic benefits of the regulation will be large. Benefits are expected to be large in part because serious weaknesses in current claims determination processes, which the regulation will help correct, are widespread. Elements of health claims and appeals processes that are widely considered to be essential are often lacking, the U.S. General Accounting Office has reported. Just 41 percent of HMOs and 50 percent of indemnity insurers studied by GAO provided for appeals decisions to be made by individuals not involved in the original denial. Written denial notices explaining appeal rights were provided by 97 percent of HMOs, but just 67 percent of indemnity insurers. Expedited reviews were provided by 94 percent of HMOs, but just 67 percent of indemnity insurers.[43]

Improving Health Outcomes

There is broad agreement that more accurate and timely claims determinations can yield large economic benefits in the form of improved health outcomes. In one survey, 59 percent of physicians 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 and 5.8 percent of physician-recommended actions.[44] In another survey, 87% of physicians reported that managed care health plans denied one or more patients' claims for medical services during a two-year period, often adversely affecting patients' health.[45] In yet another survey, 17 percent of insured adults under age 65 reported problems with delayed or denied coverage, and 12 percent reported billing or payment problems. Of adults reporting problems, 21 percent said the problem resulted in them losing time from school or work, 21 percent reported worsened health, and 6 percent reported suffering a permanent or long-lasting disability.[46] These figures demonstrate the potential importance of prompt and accurate claims determinations to health outcomes.

The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (the Commission) placed ''highest priority'' on ''creating systems that minimize errors and correct them in a timely fashion,'' adding that improvements to appeals processes could avert injuries.[47]

Lacking data on the number of claims and appeals that are wrongly denied and the incidence and severity of resultant injuries, the Department was unable to quantify the economic benefits of improved health outcomes under the regulation. There is evidence, however, that additional spending on appropriate health care increases social welfare.[48] The Department believes that the economic benefits of improved health outcomes under the regulation will be large.

Improving Market Efficiency

By improving claims and appeals processes, the regulation will increase efficiency in the operation of employee benefit systems and health care, health insurance, and labor markets.

The regulation will increase efficiency by reducing complexity. Idiosyncratic

[43] GAO, *HMO Complaints and Appeals: Most Key Procedures in Place, but Others Valued by Consumers Largely Absent*, GAO/HEHS, 98–119, May 1998; and GAO, *Indemnity Health Plans: Key Features of Consumer Complaint and Appeals Systems*, GAO/HEHS 98–189, June 1998.

[44] Dahlia K. Remler et. al., ''What Do Managed Care Plans Do To Affect Care? Results from a Survey of Physicians,'' *Inquiry* 34: 196–204 (Fall 1997).

[45] Kaiser Family Foundation Press Release, ''New Survey Shows that Providers and Health Plans Clash Often over Patient Care'' (July 28, 1999).

[46] Kaiser Family Foundation, ''National Survey on Consumer Experiences with Health Care Plans'' (June 2000).

[47] The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans*, Final Report to the President of the United States. The report 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 forgo care entirely.'' The report adds 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.''

[48] See, e.g., David M. Cutler and Elizabeth Richardson, ''Your Money and Your Life: The Value of Health and What Affects It,'' in *Frontiers in Health Policy Research* (Alan M. Garber, ed., Cambridge: MIT Press, 1999, at 99–132).

requirements, time-frames, and procedures for claims processing impose substantial burdens on participants, their representatives, and service providers. By establishing a more complete, uniform set of minimum requirements the regulation will reduce the complexity of claims processing requirements, thereby increasing efficiency.

The regulation will improve the efficiency of private employee benefits systems by enhancing its transparency and fostering participants' confidence in its fairness. In various surveys, consumers have expressed concern that plans sometimes withhold care or benefits.[49] The ability to get a promised benefit, particularly when sick or disabled, is at the heart of these consumer concerns. The regulation will also increase efficiency by better informing claimants. When information about the terms and conditions under which benefits will be provided is unavailable to enrollees, they will discount the value of benefits to compensate for the perceived risk.

The voluntary nature of the employment-based health benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. It is likely that 80% to 100% of the cost of employee benefits is borne by workers through reduced wages.[50] The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits, they will discount the value of such benefits to adjust for this risk. This discount drives a wedge in the compensation negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. To the extent that workers perceive that a federal regulation, supported by enforcement authority, reduces the risk of inappropriate denials of benefits, the differential between the employers' costs and workers' willingness to accept wage offsets is minimized.

Effective claims procedures can also improve health care, health plan quality, and market efficiency by serving as a communication channel, providing feedback from participants, beneficiaries, and providers to plans about quality issues. Aggrieved claimants are especially likely to disenroll if they do not understand their appeal rights, or if they believe that their plans' claims and appeals procedures will not effectively resolve their difficulties. Unlike appeals, however, disenrollments fail to alert plans to the difficulties that prompted them. 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 aggrieved claimants with an alternative to disenrollment, improved claims and appeals procedures will reduce disenrollment rates. Lower disenrollment rates in turn will increase plans' incentive to keep enrollees healthy over the long term, prompting managed care organizations (MCOs) to step up efforts to promote preventive 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.

The disenrollments that will be discouraged by the regulation would have been economically inefficient. Such disenrollments can be characterized as instances where aggrieved claimant, lacking access to or knowledge of a full and fair appeals process, drop their otherwise preferred health coverage option in favor of an inferior option. By discouraging such disenrollments, the regulation will increase social welfare.

Reducing economically inefficient turnover across health coverage options will also trim administrative costs. Plans incur costs directly to process enrollments and disenrollments. Turnover also imposes indirect transactions costs on enrollees and providers, including (sometimes) costs that arise when enrollees must change doctors or hospitals and when enrollees and doctors must become familiar with new plan provisions, including new claims procedures.

The Department also expects that the regulation's higher standard for claims adjudication will enhance some insurers' and group health plans' abilities to effectively control costs by limiting access to inappropriate care. Providing a more formally sanctioned framework for internal review and consultation on difficult claims facilitates the adoption of cost containment programs by employers who, in the absence of a regulation providing some guidance, may have opted to pay questionable claims rather than risk alienating participants or being deemed to have violated ERISA's fiduciary provisions.

Finally, it is worth noting that economic theory allows for regulation of managed care practices to be welfare-enhancing. For example, Korobkin contends that ''managed care organizations (MCOs) have an incentive to provide an inefficiently low quality of certain types of benefits because it is difficult for consumers to evaluate their quality prior to contracting, and because consumers who are able to evaluate quality after contracting are the customers that MCOs do not wish to retain.'' [51]

In summary, the regulation's new, higher standards for handling health benefit claims will reduce the incidence of excessive delays and inappropriate denials, averting serious, avoidable lapses in health care quality and resultant injuries and losses to enrollees. It will raise enrollees' level of confidence in and satisfaction with their health care 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 labor, health care, and insurance markets. The Department therefore concludes that the economic benefits of the regulation will outweigh its costs.

[49] For example, a 1997 Kaiser Family Foundation / Harvard University survey 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 were sick (Kaiser Family Foundation, ''Is There a Managed Care 'Backlash'?'' Press Release, National Toplines, and Chart Pack, November 7, 1997).

[50] See, e.g., Jonathan Gruber and Alan B. Krueger, ''The Incidence of Mandated Employer-Provided Insurance: Lessons from Workers Compensation Insurance,'' *Tax Policy and Economy* (1991); Jonathan Gruber, ''The Incidence of Mandated Maternity Benefits,'' *American Economic Review*, Vol. 84 (June 1994), at 622–641; Lawrence H. Summers, ''Some Simple Economics of Mandated Benefits,'' *American Economic Review*, Vol. 79, No. 2 (May 1989); Louise Sheiner, ''Health Care Costs, Wages, and Aging,'' Federal Reserve Board of Governors working paper, April 1999; and Edward Montgomery, Kathryn Shaw, and Mary Ellen Benedict, ''Pensions and Wages: An Hedonic Price Theory Approach,'' *International Economic Review*, Vol. 33 No. 1 (Feb. 1992).

[51] Russell Korobkin, ''The Efficiency of Managed Care 'Patient Protection' Laws: Incomplete Contracts, Bounded Rationality, and Market Failure,'' 85 *Cornell Law Review* 1 (1999).

2. Disability Benefit Claims

With respect to disability claims, timelier determinations will assure prompt replacement of lost income for successful claimants, thereby averting some financial hardships. Improving standards for handling disability claims will also increase enrollee confidence in disability plans and promote efficiency in disability insurance and labor markets.

Averting Financial Hardship

As with health benefit claims, the regulation is intended and expected to improve the timeliness and accuracy of disability benefit claims determinations. This will avert financial hardship for claimants whose claims or appeals would otherwise have been inappropriately delayed or denied.

No data are available on how much financial hardship might be attributable to such delays or denials, or how much hardship the regulation might avert, but the potential magnitudes are large.

Severe disabilities are not uncommon among the working age population. In 1994, 6 million Americans age 22 to 44 (or 6 percent of all those in the age group) were severely disabled, as were 3 million of those age 45 to 54 (12 percent) and 5 million of those 55 to 64 (22 percent). Altogether more than one-half of severely disabled Americans were age 22 to 64, and nearly one-half of these were age 44 or younger.

Severe disability often greatly impedes work and erodes income. The employment rate for people 21 to 64 years of age was 82 percent among those with no disability, but 26 percent among those with severe disabilities. The proportion of this age group with low income (less than one-half of the median) was 13 percent among those with no disability, but 42 percent among those with severe disabilities. [52]

More than 4 million disabled individuals under age 65 currently rely on Supplemental Security Income (SSI), a federal means-tested cash assistance program for disabled individuals with very low incomes and assets. More than one-half million disabled Americans join the SSI rolls each year.[53]

Private, employment-based disability insurance can help replace income people lose when disability forces them to terminate or curtail work. The Department estimates that in 2002 36 million U.S. private-sector employees (or 32 percent of all such employees) will be insured against short-term disability, and 26 million (or 23 percent) will be insured against long term disability. Insured workers may nonetheless suffer financial hardship, however, if their claims for disability benefits are wrongly denied or unduly delayed. Public comments on the proposed regulation provide examples of such hardships.

Improving Market Efficiency

The regulation's disability claims provisions will promote market efficiency in many of the same ways as its health claims provisions. Fuller information and fuller and fairer claims appeals processes will promote enrollee confidence and discourage workers from inappropriately discounting the value of their disability benefits, thereby fostering efficiency in disability insurance and labor markets. Fairer and faster determinations will also spare claimants and their representatives, including their health care providers, the incidental (but potentially large) costs associated with excessively cumbersome and lengthy claims and appeals processes. Finally, by averting some financial hardships, faster and more accurate claims determinations will relieve claimants and their creditors of some of the costs associated with borrower delinquency and bankruptcy.

Economic Costs of the Regulation

1. Cost Estimates

The Department performed a comprehensive, unified analysis to estimate the economic cost attributable to the final regulation for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The analysis takes into account a wide range of information, including public comments on the Department's proposed regulation.

Table 1 summarizes the Department's cost estimates, disaggregated by type of claim and plan size.[54] ''Small'' plans have fewer than 100 participants. Health claims, which at 1.4 billion annually are far more numerous than disability claims, account for the majority of costs. Ongoing costs will change over time with claims volume and mix, and will fall over time as health claims processing becomes more automated.

The Department does not anticipate any increase in the cost of processing pension claims or welfare plan claims other than health and disability claims. As noted earlier in this preamble, the regulation's standards applicable to pension claims and welfare claims other than health and disability claims are substantially similar to those currently in effect under the 1977 regulation.

TABLE 1.—SUMMARY OF ADMINISTRATIVE COSTS

Plan size	Start-up costs 2001			Annual costs 2002			Total costs 2001–2002		
	Small	Large	Total	Small	Large	Total	Small	Large	Total
Dollars in millions:									
Health	$20	$82	$103	$68	$310	$379	$88	$393	$481
Disability	4	13	16	2	18	21	6	31	37
Total	24	95	119	71	329	399	94	424	518
Dollars per enrollee:									
Health	0.81	0.73	0.75	2.77	2.77	2.77	3.58	3.50	3.51
Disability	0.24	0.24	0.24	0.15	0.35	0.31	0.40	0.59	0.55
Dollars per plan:									
Health	7	1,642	37	25	6,183	135	32	7,825	172
Disability	2	332	9	1	481	12	3	814	22

[52] John M. McNeil, ''Americans with Disabilities: 1994–95,'' U.S. Bureau of the Census, *Current Population Reports*, P 70–61 (August 1997).

[53] U.S. Social Security Administration, *Social Security Bulletin, Annual Statistical Supplement*, 1998.

[54] In the tables that follow, due to rounding, individual reported estimates may not always add to reported totals.

The regulation applies different standards to disability claims and to different kinds of health benefit claims. The start-up cost of meeting these standards reflects the number of claims processes that must be modified and the degree of changes to those processes that are necessary. The ongoing cost of adhering to the standards reflects the volume of claims transactions to which they apply and the necessary degree of change to bring all transactions into compliance. Based on public comments and other information, it is clear that many health and disability plans already comply or nearly comply with many of the regulations' standards in connection with a large number of claims, but that all or most will need to make at least some changes in their handling of at least some claims.

Table 2 connects the Department's cost estimates with the regulation's major provisions and the Department's estimates of affected claims processes and claims transactions. The single largest ongoing cost is attributable to the regulation's time frames for health claims decisions. The Department believes that under plans' current practices up to 1 percent of claims decisions would violate this provision. Accelerating these 14 million decisions is estimated to cost $222 million in 2002.

In estimating the start-up cost, the Department considered the major actions that plans (or their service providers) would undertake, including revising processes, modifying forms, modifying systems, and hiring or contracting where necessary. The Department estimated these combined costs at $119 million in 2001, or a little more than $12,000 on average for each entity that processes health or disability claims.

TABLE 2.—START-UP COSTS, AND ONGOING COSTS BY MAJOR PROVISION

Type of claim	Health benefit claims		Disability benefit claims	
	Affected procedures	Estimated cost ($MM)	Affected procedures	Estimated cost ($MM)
Start up, 2001	308,000	$103	24,000	$16
	Affected transactions (MM)	Estimated cost ($MM)	Affected transactions	Estimated cost ($MM)
Ongoing, 2002	.....	$379	.....	$21
Notices	114.6	27	179,000	6
Time frames	1,397.6	222	1,421,000	6
Fuller reviews	0.4	32	32,000	3
Disclosure on request	2.9	68	57,000	3
Expert consultations	0.2	30	32,000	3

2. Basis for Estimates

The Department's analysis relies on various government and private surveys and studies and the testimony, written comments, and other materials received by the Department in response to its proposed regulation and earlier request for information. The Department developed additional assumptions as necessary where no data were available.

Comments on the Department's proposed regulation were helpful to the Department's effort to estimate the cost impact of its regulation. Many commenters described how the proposed regulation's major requirements compared with, and would affect, their current business practices, and how the requirements would interact with state laws, accreditation standards, and other strictures on those practices. In estimating the cost of the regulation, the Department relied on these comments to gauge the differences between plans' current business practices and the regulation's requirements and to develop reasonable assumptions regarding the cost of compliance.

The Department separately estimated the one-time, start-up cost of coming into compliance with the regulation and the ongoing, annual cost of complying.

3. Start-Up Costs

In estimating start-up costs, the Department considered the number of claims processes that will be affected by the regulation. The overwhelming majority of health and disability benefit plans rely on service providers to administer their claims processes. Only a small fraction perform these administrative functions in-house. Those that do tend to be very large, self-insured plans. Service providers, which are less numerous than plans, tend to use a single claims process to service a large number of plans. They may also provide customized claims processes for some plans, especially for self-insured plans, which generally are not subject to state laws regarding benefit coverage. The Department expects that the start-up cost of revising claims processes, which for a given claims process may be large, in most cases will be spread thinly across plans and participants. Table 3 presents the Department's estimates of the number of affected health and disability claims processes.

TABLE 3.—AFFECTED PLANS AND CLAIMS PROCESSES

	Health benefit plans	Disability benefit plans
Number of plans	2,802,000	1,716,000
Number of claims processes	308,000	35,000
Maintained by plans that self-administer	4,000	3,000
Maintained by service providers	305,000	32,000

The Department considered the following major actions that plans (or their service providers) would undertake to come into compliance with the regulation: revising processes, revising forms, modifying systems, and hiring or contracting where necessary. The Department assumed that all health and disability plans would have to revise processes and forms and modify systems to at least some degree and that some would hire personnel or contract for additional or different services in order to achieve compliance.[55]

4. Ongoing Costs

In estimating the ongoing cost of various provisions, the Department considered the number of claims transactions to which they apply, the degree to which plans already comply in the course of normal business or in response to a state law or other mandate other than ERISA, and, to the degree that they do not, the likely cost of coming into compliance.

Claims volume was estimated by applying estimated claiming rates for various types of claims to projected estimates of plan enrollment in 2002. To estimate the application of the regulation's various requirements to different types of benefit claims, it was necessary to separately estimate health, disability, pension, and other benefit claims volumes. With respect to health benefit claims, it was necessary to separately estimate urgent, pre-service, and post-service claims volume, and the number of denials that are based on clinical or medical judgments. With respect to disability claims, it was necessary to estimate short-term and long-term disability claims separately. The Department also accounted separately for costs associated with approved and denied claims and appeals. Table 4 summarizes estimated 2002 claims volume.

TABLE 4.—SUMMARY OF CLAIMS VOLUME, 2002

	Health (MMs)	Disability (000s)	Pension (000s)	Other (000s)
Claims	1,369.7	1,389.7	2,122.1	244.5
Approved	1,328.6	1,304.9	2,104.0	236.4
Denied	41.0	84.8	18.0	8.1
Appeals	0.4	31.6	1.8	0.8
Approved	0.3	6.5	0.9	0.4
Denied	0.1	25.1	0.9	0.4
Health claims (MMs)	1,369.7			
Urgent pre-service	1.2			
Routine pre-service	40.0			
Post-service	1,328.5			
Denied health claims (MMs)	41.0			
Clinical/scientific basis	14.5			
Other basis	26.5			
Disability claims (000s)	1,389.7			
Short-term	1,162.7			
Long-term	227.1			

The Department applied estimates of health and disability benefit claiming rates and claims mix to its estimates of enrollment in health and disability plans to produce its estimates of total claims volume. The Department estimated claims volume and mix in light of comments received in response to its proposed regulation and other data that provide reasonable proxies for private-sector employment-based health and disability benefit plans' claim patterns. For example, comments on the proposed regulation indicated health benefit claiming rates ranging from about 5 to 18 claims per individual per year. The average rate across all comments reporting rates was 9 claims per year, and surveys available to the Department reported rates of 6[56] and 11[57] claims per year. Many of these reported figures may omit some health benefit claims, such as dental claims, made by the same individuals under separate plans. The Department assumed that the health benefit claiming rates average 10 per covered individual, believing that this is consistent with comments received and other available information.

The Department similarly relied on comments received and other available data to assess health benefit claims denial and appeal rates and the mix of urgent, pre- and post-service claims. The Department assessed disability claiming rates and claims mix based on comments received (including information from the life insurance industry) and available data on the incidence of temporary and permanent disability in the working age population.[58]

The Department separately considered the effect of each of the regulation's major provisions on each type of claim to which it applies. Based on its analysis, the Department attributed cost to the application of the regulation's notice, timeliness, disclosure, standard of review, and expert consultation requirements to health and disability claims and appeals.[59] Many plans' current, normal

[55] This estimate is not intended to include the cost of developing new explanations of claims processes for inclusion in plan descriptions. The Department separately accounts for that cost as part of the estimated cost of its regulation governing the content of summary plan descriptions.

[56] A published 1995 survey of 53 health insurers' claims systems by the Health Insurance Association of America.

[57] A survey of 7 managed care organizations conducted and provided to the Department in response to its proposed regulation.

[58] Primarily, data from the National Center for Health Statistics and the Social Security Administration.

[59] The Department did not attribute cost to certain other major provisions of the regulation, including the regulation's prohibition against unduly inhibiting or hampering the initiation or processing of claims for benefits, the requirement that plans have procedures to ensure and verify appropriately consistent decisions, and the provisions applicable to pension plans and welfare plans other than health and disability benefit plans. These provisions merely clarify current law and do not impose new standards. Other provisions, including the requirement that certain health care professionals be treated as claimants' representatives in connection with urgent health benefit claims, the prohibition against requiring more than two mandatory levels of administrative appeal, the restrictions on arbitration, and the

Continued

business practices meet or nearly meet one or more of these requirements. Nonetheless, the Department believes that many health and disability benefit plans will have to modify their claims processes to some degree in order to meet all of these requirements in connection with all claims.[60]

As reported in table 2 (above), the Department attributed the single largest ongoing cost, $222 million, to the application of the regulation's timeliness requirements to health benefit claims. The magnitude of this estimated cost is a function of the large volume of total health benefit claims (estimated at 1.4 billion in 2002) and the proportion of these that will be affected by the time frames of the regulation. In light of comments received in response to its proposed regulation and other available information,[61] the Department assumed that 1 percent of claims and appeals determinations will have to be accelerated in order to comply with the regulation. On the same basis, it assumed that the unit cost of accelerating determinations will range from $10 for initial determinations that do not involve medical judgments to $50 for determinations on appeal that do involve such judgments. The low end of this range represents the use of administrative staff to accelerate precessing times, the higher end a substantially greater cost due to the need for consultation by a medical professional in some circumstances. On average the affected claims are expected to be close to the low end of the range because the majority of claims transactions are initial determinations that will not hinge on medical judgments.

The costs attributed to disclosure following adverse determinations, fuller reviews on appeal, and expert consultations in appeals involving medical judgments reflect the progressively smaller incidence (relative to total claims volume) of adverse determinations, appeals, and appeals involving medical judgments. Estimated unit costs associated with these provisions reflect comments received and other available information on the cost of these elements of health benefit claims processes and the degree to which plans' normal business practices currently conform to the provisions. For example, in light of such information, the Department believes that expert medical consultations for a typical appeal cost between $350 and $500. However, most plans' normal business practices already provide for some type of expert consultation in appeals involving medical judgments. The Department therefore assumed that the cost of such consultations will rise by $100 on average, reflecting the understanding that plans' normal business practices may not always provide consultations as required by the regulation's provisions.

5. Required Estimates

The Department developed estimates as appropriate for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. Because the regulation establishes new standards for, and will have a substantial economic impact on, health and disability claims, the Department estimated the cost of the regulation in connection with these claims for purposes of Executive Order 12866 and the Regulatory Flexibility Act, as well as for purposes of the Paperwork Reduction Act. Because it established no substantial new standards for pension claims and other welfare benefit claims, the Department estimated its cost in connection with these claims only for purposes of the Paperwork Reduction Act.

6. Changes in Claims and Appeals Volume and Disposition

The cost estimates reported above reflect administrative costs associated with processing claims and appeals, based on the assumption that the volume, mix, and disposition of claims and appeals remain constant. The regulation, however, is expected to change the overall volume and nature of appeals and to improve the accuracy of claims and appeals decisions. The Department was unable to quantify these changes, but undertook a qualitative assessment of their likely nature, magnitude, and social welfare effects. The Department believes that changes in the nature of appeals and in claims and appeals decisions may be large in number, but will be small as a fraction of total claims and appeals volume and will result in a substantial overall increase in social welfare.

The regulation may increase or decrease the actual number of appeals. It is expected to decrease the number of non-meritorious appeals and to encourage and help ensure the approval of meritorious claims. Improved accuracy of initial claims decisions under the regulation will serve to reduce the volume of appeals. The volume may increase, however, if the existence of fuller review processes and information disclosure under the regulation increases claimants' propensity to appeal denied claims. Fuller disclosure of information to claimants will also tend to encourage appeals that are meritorious and discourage those that are not. Improved accuracy of initial decisions provides social benefits without the administrative expense of appeals. Any new appeals arising as a result of the regulation are likely to be both meritorious and successful; such appeals are likely to deliver social benefits that are larger than the associated administrative cost. The regulation is also expected to reduce non-meritorious, unsuccessful appeals, which generally deliver no social benefits to justify their administrative cost.

Changes in claims and appeals decisions under the regulation are also expected to increase social welfare. The Department expects that the regulation will improve the timeliness and accuracy of decisions. In particular, the Department expects that some claims and appeals that otherwise would have been denied, but in fact should have been approved under plans' terms, will now be paid. Therefore, it is highly likely that the number and dollar amount of claims approved will increase. For example, encouraging meritorious over non-meritorious appeals should increase the number of favorable determinations on appeal. As noted earlier in this preamble, the approval of meritorious claims that otherwise would have been denied can be characterized as a financial transfer from plans to claimants that will have societal benefits. Economic theory suggests that, all else being equal, improving adherence to private voluntary agreements, such as plans' terms, tends to increase economic efficiency. In addition, as noted earlier in this preamble, there is evidence that additional spending on appropriate health care increases social welfare.

requirement of at least 180 days for filing appeals, are expected to have minimal impact on plan costs.

[60] For example, not all health plans currently include in denied claim notices statements of claimants' rights to request copies of any guidelines or protocols or explanations of any clinical or scientific judgments that were applied. Not all health and disability claims are decided within the time frames specified in the final regulation. Not all health and disability plans routinely disclose relevant information, such as statements of policy or guidance regarding denied treatments for claimants' conditions. Not all provide for decisionmakers on review who are different from and not subordinate to initial decisionmakers, or disclose the identity of medical experts consulted in connection with reviews.

[61] Including the 1995 survey of insurers cited above and a Mercer/Foster Higgins Survey of employment-based health plans.

D. Federalism Summary Impact Statement

Although the Department has identified this regulation as possibly having federalism implications, those implications are limited. Therefore, in compliance with Executive Order 13132, 64 FR 43255 (August 10, 1999), the Department has taken a number of steps to consult with affected entities.

First, the Department has, throughout the process of developing the proposed regulation and the final regulation, provided State and local officials with significant opportunities for meaningful and timely input. After issuance of the proposed regulation, the Department invited public comment from all affected parties, including States and local governments, and held the public comment period open for an extended period. The Department further held a three-day public hearing and consulted separately with the major organizations that represent state and local government prior to finalizing the regulation.

The insurance commissioners of various states, acting collectively through the National Association of Insurance Commissioners (NAIC), provided substantial public comment on the proposed regulation and participated in the public hearing by submitting written testimony, testifying personally, and engaging in public discussion with the Department's panel of officials. The Department also invited all of the ''Big 7'' organizations [62] that represent state and local government to meet separately with the Department to discuss this regulation.

The NAIC and the Big 7 attendees have generally praised the Department for taking this regulatory action regarding ERISA covered plans because the Department's approach has generally paralleled the approach taken by many States in regulating the conduct of insurance companies doing business in their States. However, both the NAIC and the Big 7 attendees asked the Department to limit the application of the regulation to ''self-funded'' plans, which do not provide benefits through insurance directly regulated by the States. The NAIC and Big 7 attendees argued that many States have already provided protections to participants in insured plans that are greater than that contained in the proposed regulation. The Department has not followed this suggestion, although the Department has sought to address the concerns raised by the NAIC and Big 7 attendees in other ways. (*See,* for example, the discussion below and elsewhere in this preamble regarding preemption.) It is the view of the Department that the importance of establishing uniform minimum procedural rights for all participants and beneficiaries in ERISA-covered group health plans outweighs the concerns of the State and local governments.

With respect specifically to preemption, Executive Order 13132 requires agencies taking such action to act in strict accordance with governing law and to restrict preemption to the minimum level necessary to achieve the objectives of the statute pursuant to which any regulations are promulgated. The Department has satisfied these requirements in this regulation.

The proposed regulation was silent on preemption. The Department intended that the scope of preemption that would result under the proposed regulation would be limited to the minimum level required by section 514 of the Act and the Supremacy Clause of the Constitution. The Department's intent remains the same with respect to this final regulation. The NAIC and other commenters argued that the proposal's silence on the subject of preemption was potentially confusing and asked the Department to make clear its views as to the preemptive effect of the final regulation. The Department has responded to these comments by adding paragraph (k) to the final regulation. Paragraph (k) provides interpretive guidance on preemption.

The Department's view of the preemptive effect of the regulation is consistent with the Department's intent that the regulation's preemptive effect be limited to the minimum required by section 514 and the Supremacy Clause. As explained elsewhere in this preamble, paragraph (k) specifically sets forth the Department view that State insurance laws are not preempted unless they ''prevent the application'' of a requirement of the regulation. In other words, State insurance laws are preempted by the final regulation only to the extent that those laws are in conflict with the regulation such that the State laws could not be read in harmony with the regulation.

In response to the specific concern most commonly expressed by state insurance commissioners, the Department stated further in paragraph (k)(2) its view that State-mandated external review procedures, which operate outside the scope of plans' internal review procedures, are not preempted by promulgation of the regulation.

Thus, the Department has made every effort to limit the effect that the regulation will have on State law to the minimum imposed by operation of the statute and the Constitution.

Finally, Executive Order 13132 limits the extent to which agencies may impose mandates on State and local governments. This regulation does not create a mandate on State or local governments. The regulation does not impose any enforceable duties on these entities. This regulation will be implemented at the Federal level and imposes compliance obligations only on private industry. The regulation therefore does not require imposition on States of substantial direct compliance costs, mandates, duties, or similar obligations.

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 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 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). Except as otherwise specifically provided in this section, 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.*

[62] The organizations invited were the National Governors Association, the National League of Cities, the National Conference of State Legislatures, the National Association of Counties, the U.S. Conference of Mayors, and the Council of State Governments. The meeting was attended by representatives of the National Governors Association, the National Conference of State Legislatures, and the National Association of Counties.

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), (h), (i), and (j) of this section, as appropriate, except to the extent that the claims procedures are deemed to comply with some or all of such provisions pursuant to paragraph (b)(6) of this section;

(2) A description of all claims procedures (including, in the case of a group health plan within the meaning of paragraph (m)(6) of this section, any procedures for obtaining prior approval as a prerequisite for obtaining a benefit, such as preauthorization procedures or utilization review procedures) 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 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 be considered to unduly inhibit the initiation and processing of claims for benefits. Also, the denial of a claim for failure to obtain a prior approval under circumstances that would make obtaining such prior approval impossible or where application of the prior approval process could seriously jeopardize the life or health of the claimant (e.g., in the case of a group health plan, the claimant is unconscious and in 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;

(4) The claims procedures do not preclude an authorized representative of a claimant from acting on behalf of such claimant in pursuing a benefit claim or appeal of an adverse benefit determination. Nevertheless, a plan may establish reasonable procedures for determining whether an individual has been authorized to act on behalf of a claimant, provided that, in the case of a claim involving urgent care, within the meaning of paragraph (m)(1) of this section, a health care professional, within the meaning of paragraph (m)(7) of this section, with knowledge of a claimant's medical condition shall be permitted to act as the authorized representative of the claimant; and

(5) The claims procedures contain administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents and that, where appropriate, the plan provisions have been applied consistently with respect to similarly situated claimants.

(6) In the case of a plan established and maintained pursuant to a collective bargaining agreement (other than a plan subject to the provisions of section 302(c)(5) of the Labor Management Relations Act, 1947 concerning joint representation on the board of trustees)—

(i) Such plan will be deemed to comply with the provisions of paragraphs (c) through (j) of this section if the collective bargaining agreement pursuant to which the plan is established or maintained sets forth or incorporates by specific reference—

(A) Provisions concerning the filing of benefit claims and the initial disposition of benefit claims, and

(B) A grievance and arbitration procedure to which adverse benefit determinations are subject.

(ii) Such plan will be deemed to comply with the provisions of paragraphs (h), (i), and (j) of this section (but will not be deemed to comply with paragraphs (c) through (g) of this section) if the collective bargaining agreement pursuant to which the plan is established or maintained sets forth or incorporates by specific reference a grievance and arbitration procedure to which adverse benefit determinations are subject (but not provisions concerning the filing and initial disposition of benefit claims).

(c) *Group health plans.* The claims procedures of a group health plan will be deemed to be reasonable only if, in addition to complying with the requirements of paragraph (b) of this section—

(1)(i) The claims procedures provide that, in the case of a failure by a claimant or an authorized representative of a claimant to follow the plan's procedures for filing a pre-service claim, within the meaning of paragraph (m)(2) of this section, the claimant or representative shall be notified of the failure and the proper procedures to be followed in filing a claim for benefits. This notification shall be provided to the claimant or authorized representative, as appropriate, as soon as possible, but not later than 5 days (24 hours in the case of a failure to file a claim involving urgent care) following the failure. Notification may be oral, unless written notification is requested by the claimant or authorized representative.

(ii) Paragraph (c)(1)(i) of this section shall apply only in the case of a failure that—

(A) Is a communication by a claimant or an authorized representative of a claimant that is received by a person or organizational unit customarily responsible for handling benefit matters; and

(B) Is a communication that names a specific claimant; a specific medical condition or symptom; and a specific treatment, service, or product for which approval is requested.

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

(3) To the extent that a plan offers voluntary levels of appeal (except to the extent that the plan is required to do so by State law), including voluntary arbitration or any other form of dispute resolution, in addition to those permitted by paragraph (c)(2) of this section, the claims procedures provide that:

(i) The plan waives any right to assert that a claimant has failed to exhaust administrative remedies because the claimant did not elect to submit a benefit dispute to any such voluntary level of appeal provided by the plan;

(ii) The plan agrees that any statute of limitations or other defense based on timeliness is tolled during the time that any such voluntary appeal is pending;

(iii) The claims procedures provide that a claimant may elect to submit a benefit dispute to such voluntary level of appeal only after exhaustion of the appeals permitted by paragraph (c)(2) of this section;

(iv) The plan provides to any claimant, upon request, sufficient information relating to the voluntary level of appeal to enable the claimant to make an informed judgment about whether to submit a benefit dispute to the voluntary level of appeal, including a statement that the decision of a claimant as to whether or not to submit a benefit dispute to the voluntary level of appeal will have no effect on the claimant's rights to any other benefits under the plan and information about the applicable rules, the claimant's right to representation, the process for selecting the decisionmaker, and the circumstances, if any, that may affect the impartiality of the decisionmaker,

such as any financial or personal interests in the result or any past or present relationship with any party to the review process; and

(v) No fees or costs are imposed on the claimant as part of the voluntary level of appeal.

(4) The claims procedures do not contain any provision for the mandatory arbitration of adverse benefit determinations, except to the extent that the plan or procedures provide that:

(i) The arbitration is conducted as one of the two appeals described in paragraph (c)(2) of this section and in accordance with the requirements applicable to such appeals; and

(ii) The claimant is not precluded from challenging the decision under section 502(a) of the Act or other applicable law.

(d) *Plans providing disability benefits.* The claims procedures of a plan that provides disability benefits will be deemed to be reasonable only if the claims procedures comply, with respect to claims for disability benefits, with the requirements of paragraphs (b), (c)(2), (c)(3), and (c)(4) of this section.

(e) *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 in accordance with a plan's reasonable procedure for filing benefit claims. In the case of a group health plan, a claim for benefits includes any pre-service claims within the meaning of paragraph (m)(2) of this section and any post-service claims within the meaning of paragraph (m)(3) of this section.

(f) *Timing of notification of benefit determination.* (1) *In general.* Except as provided in paragraphs (f)(2) and (f)(3) of this section, if a claim is wholly or partially denied, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 90 days after receipt of the claim by the plan, unless the plan administrator determines that special circumstances require an extension of time for processing the claim. If the plan administrator determines that an extension of time for processing is required, written notice of the extension shall be furnished to the claimant 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 render the benefit determination.

(2) *Group health plans.* 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 (f)(2)(i), (f)(2)(ii), or (f)(2)(iii) of this section, as appropriate.

(i) *Urgent care claims.* In the case of a claim involving urgent care, the plan administrator shall notify the claimant of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim by the plan, unless 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. Notification of any adverse benefit determination pursuant to this paragraph (f)(2)(i) shall be made in accordance with paragraph (g) of this section. 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—

(A) The plan's receipt of the specified information, or

(B) The end of the period afforded the claimant to provide the specified additional information.

(ii) *Concurrent care decisions.* If a group health plan has approved an ongoing course of treatment to be provided over a period of time or number of treatments—

(A) Any reduction or termination by the plan of such course of treatment (other than by plan amendment or termination) before the end of such period of time or number of treatments shall constitute an adverse benefit determination. The plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the adverse benefit determination at a time sufficiently in advance of the reduction or termination to allow the claimant to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.

(B) Any request by a claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim involving urgent care shall be decided as soon as possible, taking into account the medical exigencies, and the plan administrator shall notify the claimant of the benefit determination, whether adverse or not, within 24 hours after receipt of the claim by the plan, provided that any such claim is made to the plan at least 24 hours prior to the expiration of the prescribed period of time or number of treatments. Notification of any adverse benefit determination concerning a request to extend the course of treatment, whether involving urgent care or not, shall be made in accordance with paragraph (g) of this section, and appeal shall be governed by paragraph (i)(2)(i), (i)(2)(ii), or (i)(2)(iii), as appropriate.

(iii) *Other claims.* In the case of a claim not described in paragraphs (f)(2)(i) or (f)(2)(ii) of this section, the plan administrator shall notify the claimant of the plan's benefit determination in accordance with either paragraph (f)(2)(iii)(A) or (f)(2)(iii)(B) of this section, as appropriate.

(A) *Pre-service claims.* In the case of a pre-service claim, the plan administrator shall notify the claimant of the plan's benefit determination (whether adverse or not) within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the plan. This period may be extended one time by the plan for up to 15 days, provided that the plan administrator both determines that such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 15-day period, of the circumstances requiring the extension of time and the date by which the plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information. Notification of any adverse benefit determination pursuant to this paragraph (f)(2)(iii)(A) shall be made in accordance with paragraph (g) of this section.

(B) *Post-service claims.* In the case of a post-service claim, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 30 days after receipt of the claim. This period may be extended one time by the plan for up to 15 days, provided that the plan administrator both determines that

such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 30-day period, of the circumstances requiring the extension of time and the date by which the plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

(3) *Disability claims.* In the case of a claim for disability benefits, the plan administrator shall notify the claimant, in accordance with paragraph (g) of this section, of the plan's adverse benefit determination within a reasonable period of time, but not later than 45 days after receipt of the claim by the plan. This period may be extended by the plan for up to 30 days, provided that the plan administrator both determines that such an extension is necessary due to matters beyond the control of the plan and notifies the claimant, prior to the expiration of the initial 45-day period, of the circumstances requiring the extension of time and the date by which the plan expects to render a decision. If, prior to the end of the first 30-day extension period, the administrator determines that, due to matters beyond the control of the plan, a decision cannot be rendered within that extension period, the period for making the determination may be extended for up to an additional 30 days, provided that the plan administrator notifies the claimant, prior to the expiration of the first 30-day extension period, of the circumstances requiring the extension and the date as of which the plan expects to render a decision. In the case of any extension under this paragraph (f)(3), the notice of extension shall specifically explain the standards on which entitlement to a benefit is based, the unresolved issues that prevent a decision on the claim, and the additional information needed to resolve those issues, and the claimant shall be afforded at least 45 days within which to provide the specified information.

(4) *Calculating time periods.* For purposes of paragraph (f) of this section, the period of time within which a benefit determination is required to be made shall begin at the time a claim is filed in accordance with the reasonable procedures of a plan, without regard to whether all the information necessary to make a benefit determination accompanies the filing. In the event that a period of time is extended as permitted pursuant to paragraph (f)(2)(iii) or (f)(3) of this section due to a claimant's failure to submit information necessary to decide a claim, the period for making the benefit determination shall be tolled from the date on which the notification of the extension is sent to the claimant until the date on which the claimant responds to the request for additional information.

(g) *Manner and content of notification of benefit determination.* (1) Except as provided in paragraph (g)(2) of this section, the plan administrator shall provide a claimant with written or electronic notification of any adverse benefit determination. Any electronic notification shall comply with the standards imposed by 29 CFR 2520.104b–1(c)(1)(i), (iii), and (iv). The notification shall set forth, in a manner calculated to be understood by the claimant —

(i) The specific reason or reasons for the adverse determination;

(ii) Reference to the specific plan provisions on which the determination is based;

(iii) A description of any additional material or information necessary for the claimant to perfect 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;

(v) In the case of an adverse benefit determination by a group health plan or a plan providing disability benefits,

(A) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or

(B) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

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

(h) *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 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.* Except as provided in paragraphs (h)(3) and (h)(4) of this section, the claims procedures of a plan 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 the claims procedures—

(i) Provide claimants at least 60 days following receipt of a notification of an adverse benefit determination within which to appeal the determination;

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

(iii) Provide that a claimant shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. Whether a document, record, or other information is relevant to a claim for benefits shall be determined by reference to paragraph (m)(8) of this section;

(iv) Provide for a review that takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(3) *Group health plans.* The claims procedures of a group health plan 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, in addition to complying with the requirements of paragraphs (h)(2)(ii) through (iv) of this section, the claims procedures—

(i) Provide claimants at least 180 days following receipt of a notification of an adverse benefit determination within which to appeal the determination;

(ii) Provide for a review that does not afford deference to the initial adverse benefit determination and that is conducted by an appropriate named fiduciary of the plan who is neither the individual who made the adverse benefit determination that is the subject of the appeal, nor the subordinate of such individual;

(iii) Provide that, in deciding an appeal of any adverse benefit determination that is based in whole or in part on 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 who has appropriate training and experience in the field of medicine involved in the medical judgment;

(iv) Provide for the identification of medical or vocational experts whose advice was obtained on behalf of the plan in connection with a claimant's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination;

(v) Provide that the health care professional engaged for purposes of a consultation under paragraph (h)(3)(iii) of this section shall be an individual who is neither an individual who was consulted in connection with the adverse benefit determination that is the subject of the appeal, nor the subordinate of any such individual; and

(vi) Provide, in the case of a claim involving urgent care, for an expedited review process pursuant to which—

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

(B) 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.

(4) *Plans providing disability benefits.* The claims procedures of a plan providing disability benefits will not, with respect to claims for such benefits, be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless the claims procedures comply with the requirements of paragraphs (h)(2)(ii) through (iv) and (h)(3)(i) through (v) of this section.

(i) *Timing of notification of benefit determination on review.* (1) *In general.* (i) Except as provided in paragraphs (i)(1)(ii), (i)(2), and (i)(3) of this section, the plan administrator shall notify a claimant in accordance with paragraph (j) of this section of the plan's benefit determination on review within a reasonable period of time, but not later than 60 days after receipt of the claimant's request for review by the plan, unless the plan administrator determines that special circumstances (such as the need to hold a hearing, if the plan's procedures provide for a hearing) require an extension of time for processing the claim. If the plan administrator determines that an extension of time for processing is required, written notice of the extension shall be furnished to the claimant prior to the termination of the initial 60-day period. In no event shall such extension exceed a period of 60 days from the end of the initial period. The extension notice shall indicate the special circumstances requiring an extension of time and the date by which the plan expects to render the determination on 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, paragraph (i)(1)(i) of this section shall not apply, and, except as provided in paragraphs (i)(2) and (i)(3) of this section, the appropriate named fiduciary shall instead 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's procedures provide 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 notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(2) *Group health plans.* In the case of a group health plan, the plan administrator shall notify a claimant of the plan's benefit determination on review in accordance with paragraphs (i)(2)(i) through (iii), as appropriate.

(i) *Urgent care claims.* In the case of a claim involving urgent care, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claimant's request for review of an adverse benefit determination by the plan.

(ii) *Pre-service claims.* In the case of a pre-service claim, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review within a reasonable period of time appropriate to the medical circumstances. In the case of a group health plan that provides for one appeal of an adverse benefit determination, such notification shall be provided not later than 30 days after receipt by the plan of the claimant's request for review of an adverse benefit determination. In the case of a group health plan that provides for two appeals of an adverse determination, such notification shall be provided, with respect to any one of such two appeals, not later than 15 days after receipt by the plan of the claimant's request for review of the adverse determination.

(iii) *Post-service claims.* (A) In the case of a post-service claim, except as provided in paragraph (i)(2)(iii)(B) of this section, the plan administrator shall notify the claimant, in accordance with paragraph (j) of this section, of the plan's benefit determination on review within a reasonable period of time. In the case of a group health plan that provides for one appeal of an adverse benefit determination, such notification shall be provided not later than 60 days after receipt by the plan of the claimant's request for review of an adverse benefit determination. In the case of a group health plan that provides for two appeals of an adverse determination, such notification shall be provided, with respect to any one of

such two appeals, not later than 30 days after receipt by the plan of the claimant's request for review of the adverse determination.

(B) In the case of a multiemployer plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, paragraph (i)(2)(iii)(A) of this section shall not apply, and the appropriate named fiduciary shall instead 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's procedures provide 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 notify the claimant in writing 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 notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(3) *Disability claims.* (i) Except as provided in paragraph (i)(3)(ii) of this section, claims involving disability benefits (whether the plan provides for one or two appeals) shall be governed by paragraph (i)(1) of this section, except that a period of 45 days shall apply instead of 60 days for purposes of that paragraph.

(ii) In the case of a multiemployer plan with a committee or board of trustees designated as the appropriate named fiduciary that holds regularly scheduled meetings at least quarterly, paragraph (i)(3)(i) of this section shall not apply, and the appropriate named fiduciary shall instead 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's procedures provide 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 notify the claimant in writing 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 notify the claimant, in accordance with paragraph (j) of this section, of the benefit determination as soon as possible, but not later than 5 days after the benefit determination is made.

(4) *Calculating time periods.* For purposes of paragraph (i) of this section, the period of time within which a benefit determination on review is required to be made shall begin at the time an appeal is filed in accordance with the reasonable procedures of a plan, without regard to whether all the information necessary to make a benefit determination on review accompanies the filing. In the event that a period of time is extended as permitted pursuant to paragraph (i)(1), (i)(2)(iii)(B), or (i)(3) of this section due to a claimant's failure to submit information necessary to decide a claim, the period for making the benefit determination on review shall be tolled from the date on which the notification of the extension is sent to the claimant until the date on which the claimant responds to the request for additional information.

(5) *Furnishing documents.* In the case of an adverse benefit determination on review, the plan administrator shall provide such access to, and copies of, documents, records, and other information described in paragraphs (j)(3), (j)(4), and (j)(5) of this section as is appropriate.

(j) *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, the notification shall set forth, in a manner calculated to be understood by the claimant—

(1) The specific reason or reasons for the adverse determination;

(2) Reference to the specific plan provisions on which the benefit determination is based;

(3) A statement that the claimant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. Whether a document, record, or other information is relevant to a claim for benefits shall be determined by reference to paragraph (m)(8) of this section;

(4) A statement describing any voluntary appeal procedures offered by the plan and the claimant's right to obtain the information about such procedures described in paragraph (c)(3)(iv) of this section, and a statement of the claimant's right to bring an action under section 502(a) of the Act; and

(5) In the case of a group health plan or a plan providing disability benefits—

(i) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of the rule, guideline, protocol, or other similar criterion will be provided free of charge to the claimant upon request;

(ii) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request; and

(iii) The following statement: ''You and your plan may have other voluntary alternative dispute resolution options, such as mediation. One way to find out what may be available is to contact your local U.S. Department of Labor Office and your State insurance regulatory agency.''

(k) *Preemption of State law.* (1) Nothing in this section shall be construed to supersede any provision of State law that regulates insurance, except to the extent that such law prevents the application of a requirement of this section.

(2) (i) For purposes of paragraph (k)(1) of this section, a State law regulating insurance shall not be considered to prevent the application of a requirement of this section merely because such State law establishes a review procedure

to evaluate and resolve disputes involving adverse benefit determinations under group health plans so long as the review procedure is conducted by a person or entity other than the insurer, the plan, plan fiduciaries, the employer, or any employee or agent of any of the foregoing.

(ii) The State law procedures described in paragraph (k)(2)(i) of this section are not part of the full and fair review required by section 503 of the Act. Claimants therefore need not exhaust such State law procedures prior to bringing suit under section 502(a) of the Act.

(l) *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.

(m) *Definitions.* The following terms shall have the meaning ascribed to such terms in this paragraph (m) whenever such term is used in 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 the subject of the claim.

(ii) Except as provided in paragraph (m)(1)(iii) of this section, whether a claim is a ''claim involving urgent care'' within the meaning of paragraph (m)(1)(i)(A) of this section is to be determined by an individual acting on behalf of the plan applying the judgment of a prudent layperson who possesses an average knowledge of health and medicine.

(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 (m)(1)(i) of this section shall be treated as a ''claim involving urgent care'' for purposes of this section.

(2) The term ''pre-service claim'' means any claim for a benefit under a group health plan with respect to which the terms of the plan condition receipt of the benefit, in whole or in part, on approval of the benefit in advance of obtaining medical care.

(3) The term ''post-service claim'' means any claim for a benefit under a group health plan that is not a pre-service claim within the meaning of paragraph (m)(2) of this section.

(4) 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 any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, 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, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(5) 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.

(6) The term ''group health plan'' means an employee welfare benefit plan within the meaning of section 3(1) of the Act to the extent that such plan provides ''medical care'' within the meaning of section 733(a) of the Act.

(7) 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.

(8) A document, record, or other information shall be considered ''relevant'' to a claimant's claim if such document, record, or other information

(i) Was relied upon in making the benefit determination;

(ii) Was submitted, considered, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon in making the benefit determination;

(iii) Demonstrates compliance with the administrative processes and safeguards required pursuant to paragraph (b)(5) of this section in making the benefit determination; or

(iv) In the case of a group health plan or a plan providing disability benefits, constitutes a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit for the claimant's diagnosis, without regard to whether such advice or statement was relied upon in making the benefit determination.

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

(o) *Applicability dates.* This section shall apply to claims filed under a plan on or after January 1, 2002.

Signed at Washington, DC, this 15th day of November, 2000.

Leslie Kramerich,

Acting Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

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