

A-1: Does the regulation apply to benefit claims filed by enrollees in federal programs, such as Medicare and Medicaid, or to federal employees and their families covered under the Federal Employees Health Benefits Program (FEHBP)?

No. The regulation establishes requirements only for employee benefit plans that are covered under ERISA. See ERISA sections 3(1) and 3(2). Such plans are typically benefit programs provided by private-sector employers for their employees (or by unions, acting either independently or jointly with employers, for their members). Government programs, whether federal, state, or local, that are not related to employment, such as Medicaid and Medicare, are not covered by these claims procedure rules; neither are government-sponsored benefit programs for governmental employees, such as the FEHBP or benefit plans provided by state or local governments to their own employees. Such plans have their own specific rules for claims procedures, which may derive from other federal law (for federal programs) or from state or local law.

A-2: Does the regulation apply to benefit claims filed by persons who are both enrollees in Medicare + Choice programs and participants in an ERISA plan?

The regulation applies only to benefits provided under an ERISA plan that are outside the scope of what is regulated by the Medicare program. Benefits provided under ERISA plans vary from plan to plan based on plan design. When a benefit is provided under an ERISA plan pursuant to a separate group arrangement between the Medicare + Choice organization and the employer (or employee organization), even though the benefit is only available to enrollees in a Medicare + Choice program, we have been advised by HHS that the benefit would be outside the scope of what is regulated by the Medicare program. Claims for such benefits would be subject to the provisions of the regulation. The primary source of information about these ERISA benefits is the summary plan description for the plan, which is available on request from the plan administrator. On the other hand, benefits that are covered under a Medicare + Choice contract (whether they are Medicare benefits, additional benefits paid for by Medicare, or supplemental benefits paid for through a premium charged to all enrollees) are subject to the Medicare + Choice rules for organization determinations, appeals, and grievances under 42 CFR 422 and not the provisions of the regulation. See question A-1. A person who is covered by a Medicare + Choice program and wants more information on how these Medicare + Choice rules apply to his or her coverage should call 1.800.Medicare. He or she may also want to consult their Medicare Regional Office and 1.800.Medicare can assist them in contacting the appropriate office.

A-3: Does the regulation apply to a request for a determination whether an individual is eligible for coverage under a plan?

The regulation applies to coverage determinations only if they are part of a claim for benefits. The regulation, at § 2560.503-1(e), defines a claim for benefits, in part, as a request for a plan benefit or benefits made by a claimant in accordance with a plan's reasonable procedure for filing benefit claims. A claim for group health benefits includes pre-service claims (§ 2560.503-1(m)(2)) and post-service claims (§ 2560.503-1(m)(3)). If an individual asks a question concerning eligibility for coverage under a plan without making a claim for benefits, the eligibility determination is not governed by the claims procedure rules. If, on the other hand, the individual files a claim for benefits in accordance with the plan's reasonable procedures, and that claim is denied because the individual is not eligible for coverage under the plan, the coverage determination is part of a claim and must be handled in accordance with the claims procedures of the plan and the requirements of the regulation. See 65 FR at 70255.

A-4: Does the regulation apply to a request for prior approval of a benefit or

service when such prior approval is not required under the terms of the plan?

No. If the plan does not require prior approval for the benefit or service with respect to which the approval is being requested, the request is not a claim for benefits (§ 2560.503-1(e)) governed by the regulation. The regulation defines pre-service claim by reference to the plan's requirements, not the claimant's decision to seek the medical care, nor the doctor's decision to provide care. Thus, in the absence of any plan requirement for prior approval, mere requests for advance information on the plan's possible coverage of items or services or advance approval of covered items or services do not constitute pre-service claims under the regulation. See § 2560.503-1(m)(2).

A-5: Is a plan required to treat all questions regarding benefits as claims for benefits under the plan?

No. The regulation does not govern casual inquiries about benefits or the circumstances under which benefits might be paid under the terms of a plan. On the other hand, a group health plan that requires the submission of pre-service claims, such as requests for preauthorization, is not entirely free to ignore pre-service inquiries where there is a basis for concluding that the inquirer is attempting to file or further a claim for benefits, although not acting in compliance with the plan's claim filing procedures. In such a case, the regulation requires the plan to inform the individual of his or her failure to file a claim and the proper procedures to be followed. Specifically, this type of notification is required where there is a communication by a claimant or authorized representative (e.g., attending physician) that is received by a person or organizational unit customarily responsible for handling benefit matters (e.g., personnel office) and that communication names the specific claimant, specific medical condition or symptom and a specific treatment, service, or product for which approval is requested. Under the regulation, notice must be furnished as soon as possible, but not later than 24 hours in the case of urgent care claims or 5 days in the case of non-urgent claims. Notice may be oral, unless a written notification is requested. See § 2560.503-1(c)(1).

A-6: Do the requirements applicable to group health plans apply to dental benefits offered as a stand-alone plan or as part of a group health plan?

Yes, in both cases. The regulation defines group health plan as an employee welfare benefit plan within the meaning of ERISA section 3(1) to the extent that such plan provides medical care within the meaning of section 733(a) of ERISA. See § 2560.503-1(m)(6). Section 733(a)(2) defines medical care, in part, to mean the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body. Accordingly, for purposes of the claims procedure rules, the provision of dental benefits, either as part of a larger welfare plan, or as a stand-alone plan, would be subject to the requirements of the regulation applicable to group health plans.

A-7: Do the requirements applicable to group health plans apply to prescription drug benefit programs offered as a stand-alone plan or as part of a group health plan?

Yes, in both cases. Prescription drug benefits would, like dental benefits, constitute medical care within the meaning of Section 733(a)(2). See question A-6. Accordingly, the provision of prescription drug benefits, either as a stand-alone plan, or as part of a group health plan, would be subject to the requirements of the regulation applicable to group health plans. Whether, and under what circumstances, specific practices permitted under the plan, such as the submission of a prescription to a pharmacy or pharmacist, will constitute a claim for benefits governed by the claims procedure rules will depend on the terms of the plan.

A-8: Do the requirements applicable to group health plans apply to contractual disputes between health care providers (e.g., physicians,

hospitals) and insurers or managed care organizations (e.g., HMOs)?

No, provided that the contractual dispute will have no effect on a claimant's right to benefits under a plan. The regulation applies only to claims for benefits. See questions A-3, A-4, A-5. The regulation does not apply to requests by health care providers for payments due them -- rather than due the claimant -- in accordance with contractual arrangements between the provider and an insurer or managed care organization, where the provider has no recourse against the claimant for amounts, in whole or in part, not paid by the insurer or managed care organization.

The following example illustrates this principle. Under the terms of a group health plan, participants are required to pay only a \$10 co-payment for each office visit to a preferred provider doctor listed by a managed care organization that contracts with such doctors. Under the preferred provider agreement between the doctors and the managed care organization, the doctor has no recourse against a claimant for amounts in excess of the co-payment. Any request by the doctor to the managed care organization for payment or reimbursement for services rendered to a participant is a request made under the contract with the managed care organization, not the group health plan; accordingly, the doctor's request is not a claim for benefits governed by the regulation.

On the other hand, where a claimant may request payments for medical services from a plan, but the medical provider will continue to have recourse against the claimant for amounts unpaid by the plan, the request, whether made by the claimant or by the medical provider (e.g., in the case of an assignment of benefits by the claimant) would constitute a claim for benefits by the claimant. For information on authorized representatives of claimants. See questions B-1, B-2, B-3.

A-9: What benefits are disability benefits subject to the special rules applicable under the regulation for disability claims?

A benefit is a disability benefit under the regulation, subject to the special rules for disability claims, if the plan conditions its availability to the claimant upon a showing of disability. It does not matter how the benefit is characterized by the plan or whether the plan as a whole is a pension plan or a welfare plan. If the claims adjudicator must make a determination of disability in order to decide a claim, the claim must be treated as a disability claim for purposes of the regulation. As the department stated in the preamble to the regulation, 65 FR at 70247, n.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. Accordingly, plans, including pension plans, that provide benefits conditioned upon a determination of disability must maintain procedures for claims involving such benefits that comply with the requirements of the regulation applicable to disability claims, including the requirements for de novo review, the consultation requirement for medical judgments, the limit on appeal levels, the time limits for deciding disability claims, and the disclosure requirements in connection with extensions of time.

However, if a plan provides a benefit the availability of which is conditioned on a finding of disability, and that finding is made by a party other than the plan for purposes other than making a benefit determination under the plan, then the special rules for disability claims need not be applied to a claim for such benefits. For example, if a pension plan provides that pension benefits shall be paid to a person who has been determined to be disabled by the Social Security Administration or under the employer's long term disability plan, a claim for pension benefits based on the prior determination that the claimant is disabled would be subject to the regulation's procedural rules for pension claims, not disability claims.

A-10: Do the time frames in these rules govern the time within which claims must be paid?

No. While the regulation establishes time frames within which claims must be decided, the regulation does not address the periods within which payments that have been granted must be actually paid or services that have been approved must be actually rendered. Failure to provide services or benefit payments within reasonable periods of

A-11: When a group health plan participant presents a prescription to a pharmacy to be filled at a cost to the participant determined by reference to a formula or schedule established in accordance with the terms of such plan and with respect to which the pharmacy exercises no discretion on behalf of the plan, does the regulation require that the presentation of the prescription be treated as a claim for benefits?

No. As indicated in question A-7, whether, and under what circumstances, specific practices permitted under a plan, such as the presentation of a prescription to a pharmacy, will constitute a claim for benefits governed by the claims procedure rules will depend on the terms of the plan. In this regard, a claim for benefits is defined in § 2560.503-1(e) to mean a request for a plan benefit or benefits made by a claimant in accordance with a plan's reasonable procedure for filing benefit claims. Accordingly, whether, and to what extent, the presentation of a prescription to a pharmacy which exercises no discretion on behalf of the plan will constitute a request for a plan benefit will be determined by reference to the plan's procedures for filing benefit claims.

It is not uncommon for group health plans to have arrangements with preferred or network providers (e.g., doctors, physical therapists, pharmacies, optometrists) to provide medical care-related services or products at a predetermined cost to covered plan participants and with respect to which the providers exercise no discretion on behalf of the plan. It is the view of the department that neither the statute nor the claims procedure regulation requires that a plan treat interactions between participants and preferred or network providers under such circumstances as a claim for benefits governed by the regulation. Moreover, if the pharmacy refuses to fill the prescription absent payment of the entire cost by the participant, the regulation does not require that this refusal be treated as an adverse benefit determination under the regulation. It should be noted, however, that where a plan provides such benefits the plan must maintain a reasonable procedure, in accordance with the regulation, for processing claims of participants relating to such benefits.

A-12: Does the regulation apply to benefit claims filed by participants in top hat plans, e.g., plans that are unfunded and maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees?

Yes. The regulation establishes requirements for all employee benefit plans that are covered under Part 5 of ERISA, which would include top hat plans. Certain top hat plans are specifically excluded from parts of ERISA (see, e.g., sections 201(2); 301(a)(3); 401(a)(1)), but that exclusion does not apply to section 503, under which the regulation was promulgated. In this regard, paragraph (b)(2) of the regulation requires that a description of the plan's claims procedures must be included as part of the plan's summary plan description meeting the requirements of 29 CFR § 2520.102-3. Where a top hat plan is not required to furnish summary plan descriptions, pursuant to 29 CFR § 2520.104-23 or 2520.104-24, such plan may satisfy the requirements of paragraph (b)(2) of the regulation by taking steps reasonably designed to ensure that participants in such plans are made aware of the existence of the plan's claims procedures in conjunction with enrollment in the plan and how to obtain such procedures upon request.

A-13: Would a determination of disability for purposes of receiving a premium waiver under a contributory life insurance plan be governed by the special rules applicable to disability benefits under the claims procedure regulation?

Yes. A benefit is a disability benefit under the regulation, subject to the special rules for disability claims, if the plan conditions availability of the benefit on a showing of disability. As noted in question A-9, however, if a plan provides

a benefit the availability of which is conditioned on a finding of disability, and that finding is made by a party other than the plan for purposes other than making a benefit determination under the plan, then the special rules for disability claims need not be applied to a claim for such benefits. The department notes that the inclusion of a premium waiver in a plan that is not otherwise covered by ERISA would not, in and of itself, cause the plan to become subject to the regulation.

B-1: May a plan require that a claimant complete and file a form identifying any person authorized to act on his or her behalf with respect to a claim?

Yes, with one exception. The regulation provides that a reasonable claims procedure may not preclude an authorized representative of a claimant from acting on behalf of a claimant with respect to a benefit claim or appeal of an adverse benefit determination. The regulation also provides, however, that a plan may establish reasonable procedures for determining whether an individual has been authorized to act on behalf of the claimant. Completion of a form by the claimant identifying the authorized representative would be one method for making such a determination.

The one exception is where a claim involves urgent care. In such instances, a plan must, without regard to the plan's procedures for identifying authorized representatives, permit a health care professional with knowledge of the claimant's medical condition (e.g., a treating physician) to act as the authorized representative of the claimant. This exception is intended to enable a health care professional to pursue a claim on behalf of a claimant under circumstances where, for example, the claimant is unable to act on his or her own behalf. See § 2560.503-1(b)(4).

B-2: Does an assignment of benefits by a claimant to a health care provider constitute the designation of an authorized representative?

No. An assignment of benefits by a claimant is generally limited to assignment of the claimant's right to receive a benefit payment under the terms of the plan. Typically, assignments are not a grant of authority to act on a claimant's behalf in pursuing and appealing a benefit determination under a plan. In addition, the validity of a designation of an authorized representative will depend on whether the designation has been made in accordance with the procedures established by the plan, if any.

B-3: When a claimant has properly authorized a representative to act on his or her behalf, is the plan required to provide benefit determinations and other notifications to the authorized representative, the claimant, or both?

Nothing in the regulation precludes a plan from communicating with both the claimant and the claimant's authorized representative. However, it is the view of the department that, for purposes of the claims procedure rules, when a claimant clearly designates an authorized representative to act and receive notices on his or her behalf with respect to a claim, the plan should, in the absence of a contrary direction from the claimant, direct all information and notifications to which the claimant is otherwise entitled to the representative authorized to act on the claimant's behalf with respect to that aspect of the claim (e.g., initial determination, request for documents, appeal, etc.). In this regard, it is important that both claimants and plans understand and make clear the extent to which an authorized representative will be acting on behalf of the claimant.

B-4: What kind of administrative processes and safeguards must a plan have in place to ensure and verify appropriately consistent decision making?

The department did not intend to prescribe any particular process or safeguard to ensure and verify consistent decision making by plans. To the contrary, the department intended to preserve the greatest flexibility possible for designing and operating claims processing systems consistent with the prudent administration of a plan. The

department believes that prudent plan administration requires ensuring that similarly situated claims are, under similar circumstances, decided in a consistent manner. Consistency in the benefit claims determinations might be ensured by applying protocols, guidelines, criteria, rate tables, fee schedules, etc. Consistent decision making might be ensured and verified by periodic examinations, reviews, or audits of benefit claims to determine whether the appropriate protocols, guidelines, criteria, rate tables, fee schedules, etc. were applied in the claims determination process. See § 2560.503-1(b)(5).

B-5: For purposes of furnishing relevant documents to a claimant, what kind of disclosure is required to demonstrate compliance with the administrative processes and safeguards required to ensure and verify appropriately consistent decision making in making the benefit determination?

What documents will be required to be disclosed will depend on the particular processes and safeguards that a plan has established and maintains to ensure and verify appropriately consistent decision making. See 65 FR at 70252. The department does not anticipate new documents being developed solely to comply with this disclosure requirement. Rather, the department anticipates that claimants who request this disclosure will be provided with what the plan actually used, in the case of the specific claim denial, to satisfy this requirement. The plan could, for example, provide the specific plan rules or guidelines governing the application of specific protocols, criteria, rate tables, fee schedules, etc. to claims like the claim at issue, or the specific checklist or cross-checking document that served to affirm that the plan rules or guidelines were appropriately applied to the claimant's claim. Plans are not required to disclose other claimants' individual records or information specific to the resolution of other claims in order to comply with this requirement. See § 2560.503-1(m)(8)(iii). See question D-12.

B-6: Do the regulation's limits on the use of pre-dispute arbitration extend to other actions that a participant or beneficiary might pursue with regard to a health care provider or other person or entity?

No. The regulation is intended to regulate pre-dispute arbitration only with respect to group health and disability benefits provided under ERISA-covered plans. The regulation is not intended to affect the enforceability of a pre-dispute arbitration agreement with respect to any other claims or disputes. Accordingly, the regulation should not be read to affect the obligation of a participant or beneficiary to arbitrate such other claims and disputes within the scope of the arbitration agreement. See 29 CFR § 2560.503-1(c)(3)(iii).

C-1: When does the time period for making an initial decision on a claim begin to run?

The time for making an initial claims decision begins to run when the claim is filed in accordance with a plan's reasonable filing procedures, regardless of whether the plan has all of the information necessary to decide the claim at the time of the filing.

For purposes of calculating the time period within which a claim must be decided, a plan cannot extend the time period by treating as filed only those claims with respect to which all the information necessary to make a decision has been submitted (often referred to as clean claims). See § 2560.503-1(f)(4).

C-2: May a plan's claims procedures require claimants to submit relevant medical information or information relating to coordination of benefits prior to the plan's making a decision on a claim?

Plans have considerable flexibility in defining the procedures to be followed for the initiation, processing, and appeal

of benefit claims. However, while plans may require the submission of specific information necessary to a benefit determination under the terms of the plan, including medical and coordination of benefit information, the plan may nonetheless have to make a decision on the claim before receiving such information. As noted in question C-1, the time periods applicable to deciding claims begin to run on the date a claim is filed in accordance with reasonable procedures of the plan, without regard to whether all the information necessary to make a benefit determination accompanies the filing. See § 2560.503-1(f)(4).

C-3: If the period within which a group health claim must be decided is ending and the claimant has yet to furnish all the information necessary to decide the claim, may the plan extend the time period for deciding the claim and, if so, for how long?

In general, a group health plan may unilaterally extend the decision making on both pre-service and post-service claims for 15 days after the expiration of the initial period, if the administrator determines that such an extension is necessary for reasons beyond the control of the plan. There is no provision for extensions in the case of claims involving urgent care.

If the reason for taking the extension is the failure of the claimant to provide information necessary to decide the claim, and the claimant is so notified of this fact, the time period for making the decision is suspended (tolled) from the date of the notification to the claimant to the earlier of:

- The date on which a response from the claimant is received by the plan
- The date established by the plan for the furnishing of the requested information (at least 45 days)

The extension period (15 days) – within which a decision must be made by the plan – will begin to run from the date on which the claimant's response is received by the plan (without regard to whether all of the requested information is provided) or, if earlier, the due date established by the plan for furnishing the requested information (at least 45 days). See §§ 2560.503-1(f)(2)(iii) (A) and (B); 2560.503-1(f)(4); 2560.503-1(i)(4). Also see 65 FR at 70250, n.21.

C-4: Many plans, including group health and disability plans, require claimants to submit to examination by an expert or experts of the plan's choosing in connection with the plan's consideration of the claimant's claim. How do the regulation's time limits apply to the completion of such examinations?

The regulation's time limits begin to run when a claim is filed in accordance with the reasonable procedures of the plan for filing claims. See question C-1. A plan that requires a physical or other examination of the claimant to evaluate a claim must design a process that provides for decision making within the time frames of the regulation.

If necessary, however, in the circumstances of a specific claim, a plan may take an extension of time to enable the claimant to submit requested information (including the report of a required examination). The regulation's provisions on extensions of time and tolling, discussed in question C-3, would apply to these situations to determine when an extension is permitted and when an extension would begin and end. Under those rules, when a plan takes an extension of time because additional information must be obtained from a claimant, the claimant must be provided at least 45 days within which to provide the information or submit to the requested examination. Plans may, of course, provide claimants longer periods of time for this purpose.

C-5: May a claimant agree to an extension or further extension of the time period within which a plan must decide a claim?

Yes. The only limits on extensions of time established by the regulation are imposed on plans. Claimants may

voluntarily agree to provide a plan additional time within which to make a decision on a claim, even under circumstances where the plan could not unilaterally extend the decision making period, such as in the case of a claim involving urgent care or a claim on appeal.

See §§ 2560.503-1(f)(2)(i); 2560.503-1(i). Also see 65 FR at 70250, n.21.

C-6: What responsibility does the plan have for determining whether any specific claim involves urgent care and must therefore be decided on an expedited basis?

A plan has a duty to make this determination on the basis of the information provided by, or on behalf of, the claimant. 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 could seriously jeopardize the life or health of the claimant or the claimant's ability to regain maximum function, or -- 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.

In determining whether a claim involves urgent care, the plan must apply the judgment of a prudent layperson who possesses an average knowledge of health and medicine. However, if a physician with knowledge of the claimant's medical condition determines that a claim involves urgent care, the claim must be treated as an urgent care claim. See § 2560.503-1(m)(1).

C-7: Under the regulation, urgent care claims must be decided as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt, and pre-service claims must be decided within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt. Can a plan's claims procedures require claimants to explain or describe whether, and what, medical exigencies or medical circumstances exist?

Yes. While the department has indicated that the time periods for decision making are generally maximum periods and not automatic entitlements, the department recognizes that assessments of the appropriate timeframe for making benefit determinations will, in large part, be dependent on the information provided by the claimant. Requesting specific information from the claimant regarding whether and what medical circumstances exist that may give rise to a need for expedited processing of the claim would appear to facilitate claims processing and, therefore, would not, in the view of the department, be an unreasonable plan request. If, on the other hand, the plan believes based on its own review of the claim that expedited processing is required, it is the view of the department that the claim must be processed on an expedited basis without regard to the claimant's failure to provide information relating to whether expedited processing is necessary.

C-8: If a claimant requests a plan to extend a previously approved course of treatment, by either increasing the number of treatments or the period of time for treatments, and that request is determined by the claimant's treating physician to be a claim involving urgent care, within what period must the plan approve or deny the claimant's request?

Under the concurrent care provisions of the rule, any request that involves both urgent care and the extension of a course of treatment beyond the period of time or number of treatments previously approved by the plan must be decided as soon as possible, taking into account the medical exigencies, and notification must be provided to the

claimant within 24 hours after receipt of the claim, when the request is made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments. If such a request is not made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments, the request must be treated as a claim involving urgent care and decided in accordance with the urgent care claim timeframes, i.e., as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt. See § 2560.503-1(f)(2)(i) and (ii) (B).

If a request to extend a course of treatment beyond the period of time or number of treatments previously approved by the plan does not involve urgent care, the request may be treated as a new benefit claim and decided within the timeframe appropriate to the type of claim, i.e., as a pre-service claim or a post-service claim. § 2560.503-1(f)(2)(iii).

C-9: In the case of a group health plan's decision to reduce or terminate a previously approved course of treatment, must claimants be afforded at least 180 days to appeal the plan's revised determination before the benefit can be reduced or terminated?

No. Under the concurrent care provisions of the rule, any reduction or termination of a course of treatment (other than by plan amendment) before the end of the previously approved period or number of treatments is treated as an adverse benefit determination. In such cases the rule requires that the plan administrator provide the claimant sufficient advance notice of the reduction or termination to allow the claimant to appeal and obtain a determination before the benefit is reduced or terminated. Generally, claimants must be afforded at least 180 days following an adverse benefit determination to appeal that determination. If the 180 day rule applied to appeals under concurrent care provisions of the regulations, notifications of reductions or terminations would, in every instance, have to be given at least six months in advance of the termination or reduction. This was not the intention of the department. Accordingly, while the department is of the view that plans must afford claimants a reasonable period of time within which to develop their appeal of a proposed reduction or termination, plans are not required to assume that claimants will need the full 180 days to file such an appeal before the benefit can be reduced or terminated under the special rules governing concurrent care claims. See § 2560.503-1(f)(2)(ii) (A).

C-10: In what circumstances, if any, would a post-service claim be a claim involving urgent care?

Post-service claims are those claims with respect to which plan approval is not a prerequisite to obtaining medical services and payment is being requested for medical care already rendered to the claimant. Accordingly, a post-service claim would never constitute a claim involving urgent care within the meaning of the regulation.

A post-service claim is defined in the regulation as any claim for a benefit under a group health plan that is not a pre-service claim. Pre-service claims are those claims 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. See question C-6, § 2560.503-1(m)(1), (2), and (3).

C-11: If a claim is determined to involve urgent care when it is initially filed, must it automatically continue to be treated as urgent if it is denied and the claimant files an appeal, regardless of whether, at that time, medical services have actually been provided and the only question to be resolved is who will pay for such services?

No. The nature of a claim or a request for review of an adverse benefit determination should be judged as of the time the claim or review is being processed. If requested services have already been provided between the time the claim was denied and a request for review is filed, the claim no longer involves urgent care because use of the post-service time frames for deciding the appeal could not jeopardize the claimant's life, health, or ability to regain

maximum function, or subject the claimant to severe pain. See § 2560.503-1(m)(1).

C-12: If a claimant submits medical bills to a plan for reimbursement or payment, and the plan, applying the plan's limits on co-payment, deductibles, etc., pays less than 100% of the medical bills, must the plan treat its decision as an adverse benefit determination?

Under the regulation, an adverse benefit determination generally includes any denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit. In any instance where the plan pays less than the total amount of expenses submitted with regard to a claim, while the plan is paying out the benefits to which the claimant is entitled under its terms, the claimant is nonetheless receiving less than full reimbursement of the submitted expenses. Therefore, in order to permit the claimant to challenge the plan's calculation of how much it is required to pay, the decision is treated as an adverse benefit determination under the regulation. Providing the claimant with the required notification of adverse benefit determination will give the claimant the information necessary to understand why the plan has not paid the unpaid portion of the expenses and to decide whether to challenge the denial, e.g., the failure to pay in full. This approach permits claimants to challenge whether, for example, the plan applied the wrong co-payment requirement or deductible amount. The fact that the plan believes that a claimant's appeal will prove to be without merit does not mean that the claimant is not entitled to the procedural protections of the rule. This approach to informing claimants of their benefit entitlements with respect to specific claims, further, is consistent with current practice, in which Explanation of Benefits forms routinely describe both payable and non-payable portions of claim-related expenses. See § 2560.503-1(m)(4).

C-13: Under what circumstances is a plan required to notify a claimant of a benefit determination that is not an adverse benefit determination, i.e., a complete grant of a claim?

In the case of urgent care claims and pre-service claims, the regulation requires that claimants be apprised of the plan's benefit determination, whether the determination is adverse or a complete grant. The rules require that this notification be furnished in accordance with the timeframes generally applicable to urgent care and pre-service claims. There is no specific notification requirement applicable to post-service claims that are fully granted. See § 2560.503-1(f)(2)(i) and (iii).

C-14: What information is a plan required to provide when giving notice of a claim determination that is not adverse (that has been completely granted), in the case of an urgent care or pre-service claim?

The regulation does not specify the information that must be provided in notices of benefit determinations that are not adverse. However, in accordance with the regulation's general requirement of reasonableness, the department anticipates that such notices will contain sufficient information to fully apprise the claimant of the plan's decision to approve the requested benefits. See § 2560.503-1(f)(2)(i) and (iii) (A).

C-15: When a plan has approved a benefit that will be provided over a period of time, such as a series of chemotherapy treatments, must the plan notify the claimant when the benefits end?

No. Provided that the plan complied with the regulation in adequately notifying the claimant regarding the scope of the benefit that was originally approved (e.g., for how long, how many treatments, etc.) and further provided that the plan has not decided to reduce or terminate early the course of treatment that was previously approved, the regulation does not require the plan to provide a formal notification that the course of treatment is coming to an end.

C-16: May a notice of an adverse benefit determination generally state that a rule, guideline or protocol may have been relied upon in making the benefit determination and satisfy the requirements of the regulation?

No. The regulation provides that if an internal rule, guideline, protocol, or similar criterion was relied upon in making an adverse benefit determination, the notification of the adverse benefit determination must either set forth the rule, guideline, protocol, or criterion or indicate that such was relied upon and will be provided free of charge to the claimant upon request. It would be sufficient, in the view of the department, in such a case, to indicate that an internal rule, etc., had been relied upon without specifying the identity of the specific rule and that the specific rule, etc. would be furnished to the claimant upon request. A notice that merely indicates, however, that a rule, guideline, protocol, or similar criterion may have been relied upon does not provide the claimant any specific information about the basis on which his or her claim was decided. Inasmuch as plans will know in every instance what rules, protocols, guidelines, etc. were relied upon in making a determination, providing an indication whether such was relied upon should not be difficult. Moreover, the department is concerned that the routine inclusion of such a statement in all adverse benefit determination notifications may undermine the significance of the required disclosure. See § 2560.503-1(g)(1)(v) (A). For similar reasons, a general statement in an adverse benefit determination notice would not be considered as satisfying the requirements of § 2560.503-1(g)(1)(v) (B). Also see § 2560.503-1(j)(5)(i) and (ii).

C-17: Is a plan required to provide a copy of an internal rule, guideline, protocol, or similar criterion when the applicable rule, guideline, protocol, or criterion was developed by a third party which, for proprietary reasons, limits the disclosure of that information?

Yes. It is the view of the department that where a rule, guideline, protocol, or similar criterion serves as a basis for making a benefit determination, either at the initial level or upon review, the rule, guideline, protocol, or criterion must be set forth in the notice of adverse benefit determination or, following disclosure of reliance and availability, provided to the claimant upon request. However, the underlying data or information used to develop any such rule, guideline, protocol, or similar criterion would not be required to be provided in order to satisfy this requirement. The department also has taken the position that internal rules, guidelines, protocols, or similar criteria would constitute instruments under which a plan is established or operated within the meaning of section 104(b)(4) of ERISA and, as such, must be disclosed to participants and beneficiaries. See §§ 2560.503-1(g)(v) (A) and (j)(5)(i); 65 FR at 70251. Also see §§ 2560.503-1(h)(2)(iii) and 2560.503-1(m)(8)(i); Advisory Opinion 96-14A (July 31, 1996).

C-18: If a plan conditions continuation of disability benefit payments on a periodic confirmation of the claimant's disability and, in conjunction with such a confirmation, determines that the claimant is no longer disabled and, accordingly, terminates payment of benefits, must the plan treat the termination as an adverse benefit determination under the regulation?

Yes. Under the regulation, an adverse benefit determination includes any denial, reduction, or termination of a benefit. Accordingly, where a plan terminates the payment of disability benefits under such circumstances, the plan is required to provide the claimant a notification of adverse benefit determination and the right to appeal that determination consistent with the regulation. See 29 CFR § 2560.503-1(m)(4), (g) and (h). If, on the other hand, a plan provides for the payment of disability benefits for a pre-determined, fixed period (e.g., a specified number of weeks or months or until a specified date), the termination of benefits at the end of the specified period would not constitute an adverse benefit determination under the regulation. Any request by a claimant for payment of disability

benefits beyond the specified period, therefore, would constitute a new claim. See 29 CFR § 2560.503-1(f)(3). Also see 29 CFR § 2560.503-1(f)(2)(ii).

C-19: Does the regulation limit a plan's ability to establish a maximum period for the filing of initial claims for benefits?

No. The regulation does not contain any specific rules governing the period of time that must be given to claimants to file their claims. However, a plan's claim procedure nonetheless must be reasonable and not contain any provision, or be administered in any way, that unduly inhibits or hampers the initiation or processing of claims for benefits. Adoption of a period of time for filing claims that serves to unduly limit claimants' reasonable, good faith efforts to make claims for and obtain benefits under the plan would violate this requirement. See 29 CFR § 2560.503-1(b)(3).

C-20: What timeframes apply when an extension of time is required by a plan in connection with an initial disability benefit determination?

The regulation addresses two situations in which a plan may have an extension of time for making a disability benefit determination. The first situation is when a decision cannot be rendered due to any matter beyond the control of the administrator other than the need for additional information from the claimant. In this situation, the extension period is added to the period within which the determination is required to be made. For example, if prior to the end of the initial 45-day period, the administrator determines that, for reasons beyond its control, a decision cannot be rendered, the plan may take up to an additional 30 days (i.e., 30 days in addition to the initial 45-day period). Similarly, if a decision cannot, for similar reasons, be rendered within the initial extension period, the plan may take up to an additional 30 days (i.e., 30 days in addition to the initial 30-day extension period) or up to a total of 105 days to decide the pending claim. See 29 CFR § 2560.503-1(f)(3). The second situation is when the plan requires additional information from the claimant to make a benefit determination. This situation is governed by the principles in question C-3.

C-21: If a plan determines that a claim does not provide sufficient information, must the plan take an extension of time and request additional information from the claimant?

No. The provisions governing extensions of time are permissive and not mandatory. As such, plans may provide for taking extensions of time or not, and plan administrators may be given the discretion to decide whether to take an extension of time in connection with any individual claim. Consequently, as a general matter, a plan may deny claims at any point in the administrative process on the basis that it does not have sufficient information; such a decision would allow the claimant to advance to the next stage of the claims process.

C-22: If a group health plan determines that an extension of time is necessary in order to obtain additional information from a claimant, may the administrator as part of the notice to the claimant of the need for the extension of time also include a notice of adverse benefit determination applicable if the claimant fails to provide any information within the period prescribed by the plan (i.e., at least 45 days)?

Yes. If the notice clearly states that the claim will be denied if the claimant fails to submit any information in response to the plan's request, it is the view of the department that the furnishing of a combined notice would not be contrary to the regulation, provided that the combined notice satisfied the content requirements applicable to both the extension notice and the notice of adverse benefit determination. In this regard, the notice of adverse benefit

determination should make clear that the period for appealing the denied claim begins to run at the end of the period prescribed in the notice for submitting the requested information (or such later date as may be provided under the terms of the plan). See 29 CFR § 2560.503-1(f)(2) and (3).

D-1: May a plan require that requests for review of adverse benefit determinations be made in writing?

Yes, with one exception. The regulation provides that a plan's claims procedure must provide a claimant with a reasonable opportunity for a full and fair review of a denied claim. A claims procedure that requires requests for reviews of adverse benefit determinations to be made in writing would not be unreasonable in that regard, except with respect to claims involving urgent care. In the case of urgent care claims, the regulation requires that a plan's procedures permit requests for expedited appeals to be submitted orally or in writing by the claimant. See § 2560.503-1(h)(2) and (3)(vi).

D-2: May the direct supervisor of the person(s) who makes initial claim determinations serve as the appropriate named fiduciary for purposes of reviewing those claims on appeal?

Yes. The only limitation that the rule imposes on who can serve as the named fiduciary for purposes of reviewing adverse benefit determinations is that the named fiduciary cannot be either the individual who made the initial benefit determination that is the subject of the appeal or a subordinate of that individual. The rule further requires that the reviewer, whoever that individual is, may not afford deference to the initial determination. That is, the reviewer must consider the full record of the claim and make an independent decision on whether it should be granted. See § 2560.503-1(h)(3)(ii).

D-3: If a group health plan provides for two levels of review, rather than one, following an adverse benefit determination, what standards, if any, govern the second level of review?

Where a plan provides for two levels of review on appeal, it is the view of the department that the second level of review is subject to the same standards that apply to the first level of review. For example, the second-level reviewer may not afford deference to the decision at the first level of review, and the reviewer must not be the same person who made the first level review decision on the claim or a subordinate of that person. See §§ 2560.503-1(c)(2) and 2560.503-1(h)(3)(ii).

D-4: If a group health plan provides for two levels of review following an adverse benefit determination, within what period must a determination be made at each level?

In the case of pre-service claims, a maximum of 15 days is provided for a benefit determination at each level. In the case of post-service claims, a maximum of 30 days is provided for a determination at each level. See § 2560.503-1(i)(2)(ii) and (iii).

For example, if a claimant appeals a pre-service adverse benefit determination, and the plan provides for two levels of review at the appeal level, the plan must make a determination within a reasonable period of time, taking into account the medical circumstances, but no later than 15 days after receipt of the appeal. If that claim is again denied at the first level of appeal and the claimant appeals that denial to the second level review stage, the plan must again make a determination within a reasonable period of time, taking into account the medical circumstances, but not later than 15 days after the plan's receipt of the claimant's second level appeal request.

In the case of urgent care claims, the regulation does not prescribe any specific period within which a determination must be made at each level of a two-level review process for such claims. Given the principles underlying the provisions governing pre- and post-service claims, however, it is the view of the department that each level of review of an urgent care claim would have to be completed in sufficient time to ensure that the total period for completing the reviews would not exceed the maximum period otherwise applicable to a process with only one level of review – as soon as possible, taking into account the medical exigencies, but not longer than 72 hours. See § 2560.503-1(i) (2)(i).

D-5: If a group health plan provides for two levels of review following an adverse benefit determination, how much time must a claimant be afforded to appeal the first level review determination to the second level review?

Under the regulation, claimants must be afforded at least 180 days following receipt of an adverse benefit determination to appeal that determination. In the case of a plan with a two-level review process, the 180-day rule applies to the period to be afforded claimants to appeal to the first review level. While the regulation does not specifically address the period of time to be afforded claimants to pursue the second level of review, the regulation requires that a plan's procedures must nonetheless be reasonable and, therefore, it is the view of the department that plans must afford claimants a reasonable opportunity to pursue a full and fair review at the second review level. See § 2560.503-1(h)(1) and (3)(i).

D-6: If a group health plan provides for two levels of review following an adverse benefit determination, may the plan use non-binding arbitration as a means for deciding the appealed claim?

Yes. A plan's procedures may provide for arbitration of benefit disputes at one of the two levels of appeal, provided two conditions are met. First, the arbitration must be conducted in a manner that will ensure that the timeframes and notice requirements otherwise applicable to appeals will be satisfied. Second, the arbitration must be non-binding – that is, the arbitration may not limit the claimant's ability to challenge the benefit determination in court. See § 2560.503-1(c)(4). The regulation also permits a plan to offer binding arbitration to a claimant after completion of the plan's appeal process. See questions E-1 and E-2

D-7: May the board of trustees or committee of a multi-employer group health plan or multi-employer disability benefit plan that generally reviews appealed benefit claims at their quarterly meetings provide for two levels of appeal consistent with the regulation?

Yes, under limited circumstances. In general, the regulation permits plans to maintain two levels of review for adverse benefit determinations and establishes special timing rules for making benefit decisions at each level of the review process. See §§ 2560.503-1(c)(2), 2560.503-1(i)(2)(ii) and (iii), 2560.503-1(i)(3). The regulation also provides special timing rules applicable to boards of trustees or committees of multi-employer group health plans and multi-employer disability benefit plans, pursuant to which such plans are excepted from the otherwise applicable timing requirements. Under these rules, such boards or committees generally are permitted to defer the decisions on adverse benefit determination appeals until the next regularly scheduled meeting of the plan's board or committee. See §§ 2560.503-1(i)(2)(iii) (B), 2560.503-1(i)(3)(ii). It is the view of the department that a multi-employer group health plan or a disability benefit plan could not, in a manner consistent with the regulation, rely on both the special rules governing the maintenance of two appeal levels and the special rules for regularly scheduled boards of trustees or committee meetings. On the other hand, the department does not believe a multi-employer plan is foreclosed by the regulation from electing to make appeal determinations in accordance with the special rules governing two levels of appeal, rather than in accordance with the quarterly meeting provisions of the regulation. In

addition, there is nothing in the regulation that would foreclose a multi-employer plan from making benefit review determinations in accordance with the quarterly meeting provisions and, following such determinations, providing claimants with an opportunity to voluntarily pursue an additional (second) review of their claim. See § 2560.503-1(c)(3).

D-8: Does the regulation's requirement of consultation with appropriate health care professionals limit the discretion of a plan fiduciary reviewing an adverse benefit determination with respect to the advice the fiduciary may seek in resolving the issues raised by the review?

The regulation requires, for group health and disability claims, that the fiduciary deciding an appeal of an adverse benefit determination based in whole or in part on a medical judgment consult with an appropriate health care professional. This requirement of consultation is intended to ensure that the fiduciary deciding a claim involving medical issues is adequately informed as to those issues. The consultation requirement, however, is not intended to constrain the fiduciary from consulting any other experts the fiduciary considers appropriate under the circumstances. For example, in connection with the appeal of a denied disability claim, a fiduciary may consider it appropriate to consult with vocational or occupational experts. In all cases, a fiduciary must take appropriate steps to resolve the appeal in a prudent manner, including acquiring necessary information and advice, weighing the advice and information so obtained, and making an independent decision on the appeal. The regulation's provision for consultation with a health care professional is not intended to alter the fiduciary standards that apply to claims adjudication.

D-9: Under what circumstances must a group health plan (or disability benefit plan) disclose the identity of experts consulted in the course of deciding a benefit claim?

The regulation provides that, in order to allow claimants a reasonable opportunity for a full and fair review of their claim, a plan's claims procedures must provide for the identification of medical (or vocational) experts whose advice was obtained on behalf of the plan in connection with an adverse benefit determination, without regard to whether the advice was relied upon in making the determination. Under the rules, plans are not required to automatically provide, as part of a notice of an adverse benefit determination or otherwise, the identity of experts consulted during the claim determination process. Nor are plans required to disclose the name of experts in the absence of an adverse benefit determination. On the other hand, consistent with the procedural requirements of the regulation, the plan must provide the identity of any such experts when requested by a claimant in connection with an adverse benefit determination. See § 2560.503-1(h)(3)(iv) and (4).

D-10: Upon receipt of a request from a claimant for the identity of experts consulted by the plan in connection with an adverse benefit determination, may a plan satisfy the requirements of the regulation by providing only the name of the company employing the expert or the qualifications of the expert, rather than the name of the expert?

No. The regulation expressly requires that plans provide for the identification of the medical or vocational expert or experts whose advice was obtained on behalf of the plan in connection with the claimant's claim. Consequently, merely providing the name of the company employing the expert or the qualifications of the expert would not, in the department's view, satisfy this requirement of the regulation. See § 2560.503-1(h)(3)(iv) and (4). See question D-7.

D-11: Does the regulation require that a group health plan provide a claimant

with copies of the claimant's medical records relating to his or her benefit claim?

Yes. The regulation requires a plan to provide claimants, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to a claimant's claim for benefits. Under the regulation, relevant documents include, among other things, documents or records relied upon in making a benefit determination and documents and records submitted in the course of making the benefit determination. Inasmuch as a claimant's medical records relating to the benefit claim would be relevant documents, access to, and copies of, the claimant's medical records would have to be provided upon the claimant's request. The department notes, however, that if a plan has reason to believe that a claimant's medical records contain information that should be explained or disclosed by the physician (or other health professional) who developed the information, it would not be inconsistent with the regulation to refer the claimant to the physician (or other health professional) for such information prior to providing the requested documents directly to the claimant. However, if the physician to whom the claimant was referred failed to provide the requested information to the claimant in a reasonable period of time and without charge, the plan itself would be required to honor the claimant's request.

D-12: Does the regulation require that a plan provide claimants with access to or copies of files of other claimants?

No. The regulation requires that a claimant, have access to, and copies of, documents, records and other information relevant to the claimant's claim. For this purpose, the regulation defines as relevant any document, record, or other information that:

- Was relied upon in making the benefit determination
- Was submitted, considered, or generated in the course of making the benefit determination, without regard to whether it was relied upon
- Demonstrates compliance with the plan's administrative processes and safeguards for ensuring consistent decision making
- Constitutes a statement of policy or guidance with respect to the group health plan concerning the denied treatment option or benefit for the claimant's diagnosis, without regard to whether it was relied upon in making the benefit determination. See §§ 2560.503-1(h)(2)(iii) and 2560.503-1(m)(8)

While information and data from various claimants' files may have been compiled for purposes of developing a plan's criteria, standards, guidelines, or policies to be used in ensuring and demonstrating compliance with administrative processes and safeguards relating to consistent decision making, (see question B-5); or evaluating or assessing treatment options for benefit determinations, only the criteria, standards, guidelines, or policies themselves would have to be disclosed as information relevant to an individual claimant's claim, not the various claimants' files on which such criteria, standards, guidelines, or policies were based.

D-13: Must a plan include, in every notice of adverse benefit determination on review, a statement apprising claimants that -- You or your plan may have other voluntary 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?

The regulation, at § 2560.503-1(j)(5)(iii), provides for the inclusion of the statement described above in all notices of adverse benefit determination on review involving group health and disability claims. However, the department recognizes that information on the specific voluntary appeal procedures offered by the plan will be provided, consistent with § 2560.503-1(j)(4), in the notice of adverse benefit determination, along with a statement of the claimant's right to bring a civil action under section 502(a) of ERISA. Pending further review, therefore, the

department will not seek to enforce compliance with the requirements of § 2560.503-1(j)(5)(iii).

E-1: Under what circumstances may a plan afford claimants the ability to appeal their benefit claim beyond the review level required by the regulation?

While the regulation limits a plan's claims procedure to a maximum of two mandatory appeal levels, the regulation does permit plans to offer voluntary additional levels of appeal, including arbitration or any other form of alternative dispute resolution, provided that certain conditions are met. The conditions of the regulation focus on ensuring that the claimant elects the additional appeal voluntarily. Specifically, the regulation provides that, in the case of such voluntary levels of appeal, the plan's claims procedure must provide:

- The plan will not assert a failure to exhaust administrative remedies where a claimant elects to pursue a claim in court rather than through the voluntary level of appeal
- The plan agrees that any statute of limitations applicable to pursuing the claimant's claim in court will be tolled during the period of the voluntary appeal process
- The voluntary level of appeal is available only after the claimant has pursued the appeal(s) required by the regulation
- The plan provides the claimant with sufficient information to make an informed judgment about whether to submit a claim through the voluntary appeal process, including the specific information delineated in the regulation
- No fees or costs are imposed on the claimant as part of the voluntary appeal process. See § 2560.503-1(c)(3)

E-2: Can a plan's voluntary level of appeal include binding arbitration as a form of benefit dispute resolution?

Yes. Provided that a plan's claims procedure otherwise complies with the conditions of the regulation applicable to voluntary levels of appeal, there is nothing in the regulation that would preclude a plan from using binding arbitration or any other method of dispute resolution. See § 2560.503-1(c)(3). Also see 65 FR at 70253.

E-3: Do the regulation's special rules on voluntary additional levels of appeal, including arbitration, apply to pension plans or welfare plans other than group health plans or plans providing disability benefits?

No. The special rules on post-appeal level reviews apply, under the regulation, only to group health plans and plans that provide disability benefits. All other ERISA-covered plans are not required by the regulation to comply with these rules. However, if such other plans elect to establish voluntary additional levels of review, those levels would have to comport with the general requirements for a reasonable procedure described in § 2560.503-1(b).

F-1: What are the effective date and applicability dates of the new claims procedure rules?

The regulation became effective as of January 20, 2001. The effective date is the date the regulations became legally effective as part of the Code of Federal Regulations.

The applicability dates are the dates on which plans must begin to comply with the regulation. The applicability date for claims other than group health claims is January 1, 2002. This means that such plans must comply with the regulation beginning with new claims filed on or after January 1, 2002.

As amended on July 9, 2001, the regulation contains separate applicability dates for group health claims and all other claims. Under the regulation as amended on July 9, 2001, the applicability date for group health claims was the first day of the first plan year that begins on or after July 1, 2002, but not later than January 1, 2003. This means

that group health plans were required to comply with the regulation beginning with new claims filed on or after the first day of the first plan year beginning on or after July 1, 2002, but not later than January 1, 2003. For all calendar year group health plans, the applicability date was January 1, 2003.

Claims that were filed under a plan before the relevant applicability date, and that were not yet resolved as of the applicability date, may be handled in accordance with the plan's old benefit claims procedures, or, if the plan so chooses, in accordance with the new procedures.

F-2: What principles are likely to be applied when a claimant elects to abandon the plan's administrative claims process in favor of pursuing his or her benefit claim in court?

Section 503 of ERISA requires plans to set up procedures to provide a full and fair review of denied benefit claims. With limited exceptions, claimants must exhaust those internal procedures before filing a civil action for benefits under section 502(a)(1)(B). This requirement reflects a legal presumption favoring exhaustion of internal procedures.

Paragraph (I) of § 2560.503-1 provides that where a plan fails to establish or follow claims procedures consistent with the requirements of the regulation, a claimant shall be deemed to have exhausted the administrative remedies available under the plan. The claimant shall be entitled to pursue any available remedies under section 502(a) on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits.

However, the regulation does not undermine the principle that claimants bear the burden of proving to the satisfaction of the court that the plan failed to establish or follow claims procedures consistent with the requirements of the regulation. In addition, many of the requirements in the regulation give a plan significant discretion in establishing and following reasonable procedures. For example, paragraph (b)(3) of the regulation prohibits a plan from establishing or administering its procedures so as to unduly inhibit or hamper the initiation or processing of claims for benefits. Accordingly, a plan will be accorded significant deference in evaluating whether it failed to follow a procedure consistent with those aspects of the regulation.

Moreover, not every deviation by a plan from the requirements of the regulation justifies proceeding directly to court. A plan that establishes procedures in full conformity with the regulation might, in processing a particular claim, inadvertently deviate from its procedures. If the plan's procedures provide an opportunity to effectively remedy the inadvertent deviation without prejudice to the claimant, through the internal appeal process or otherwise, then there ordinarily will not have been a failure to establish or follow reasonable procedures as contemplated by § 2560.503-1(I). Thus, for example, a plan that issues a notice of adverse benefit determination fully advising the claimant of the right to review and to request additional information from the plan may be able to correct an inadvertent failure to include in the notice the specific plan provision on which the denial was based. Ordinarily in that circumstance the plan will have provided access to a reasonable claims procedure consistent with the regulations. On the other hand, systematic deviations from the plan procedures, or deviations not susceptible to meaningful correction through plan procedures, such as the failure to include a description of the plan's review procedures in a notice of an adverse benefit determination, would justify a court determination that the plan failed to provide a reasonable procedure.

In addition, filing a lawsuit without exhausting plan procedures could limit claimants' appeal rights and cause claimants to lose benefits to which they otherwise might be entitled. This could be the case when, during the time it takes for a court to dismiss the claimant's suit, the plan's deadline for filing an appeal expires. In this regard, there is nothing in the regulation that would serve to toll internal plan deadlines for filing or appealing claims when suit is brought under section 502(a)(1)(B).