DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2560 RIN 1210-AB39

Claims Procedure for Plans Providing Disability Benefits

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document contains a final regulation revising the claims procedure regulations under the Employee Retirement Income Security Act of 1974 (ERISA) for employee benefit plans providing disability benefits. The final rule revises and strengthens the current rules primarily by adopting certain procedural protections and safeguards for disability benefit claims that are currently applicable to claims for group health benefits pursuant to the Affordable Care Act. This rule affects plan administrators and participants and beneficiaries of plans providing disability benefits, and others who assist in the provision of these benefits, such as third-party benefits administrators and other service providers.

DATES: *Effective Date:* This rule is effective January 18, 2017.

Applicability Date: This regulation applies to all claims for disability benefits filed on or after January 1, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 503 of ERISA requires every employee benefit plan, in accordance with regulations of the Department, to "provide adequate notice in writing to any 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 "afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim."

In 1977, the Department published a regulation pursuant to section 503, at 29 CFR 2560.503–1, establishing minimum requirements for benefit claims procedures for employee benefit plans

covered by title I of ERISA (hereinafter 'Section 503 Regulation'').¹ The Department revised and updated the Section 503 Regulation in 2000 by improving and strengthening the minimum requirements for employee benefit plan claims procedures.² As revised in 2000, the Section 503 Regulation provided new time frames and enhanced requirements for notices and disclosure with respect to decisions at both the initial claims decision stage and on review for group health and disability benefits. The regulations were designed to help reduce lawsuits over benefit disputes, promote consistency in handling benefit claims, and provide participants and beneficiaries a nonadversarial method of having a plan fiduciary review and settle claims disputes. Although the Section 503 Regulation applies to all covered employee benefit plans, including pension plans, group health plans, and plans that provide disability benefits, the more stringent procedural protections under the Section 503 Regulation apply to claims for group health benefits and disability benefits.3

The Department's experience since 2000 with the Section 503 Regulation and related changes in the governing law for group health benefits led the Department to conclude that it was appropriate to re-examine the rules governing disability benefit claims. Even though fewer private-sector employees participate in disability plans than in group health and other types of plans, disability cases dominate the ERISA litigation landscape today. An empirical study of ERISA employee benefits litigation from 2006 to 2010 concluded that cases involving

long-term disability claims accounted for 64.5% of benefits litigation whereas lawsuits involving health care plans and pension plans accounted for only 14.4% and 9.3%, respectively. 5 Insurers and plans looking to contain disability benefit costs may be motivated to aggressively dispute disability claims.6 Concerns exist regarding conflicts of interest impairing the objectivity and fairness of the process for deciding claims for group health benefits. Those concerns resulted in the Affordable Care Act recognizing the need to enhance the Section 503 Regulation with added procedural protections and consumer safeguards for claims for group health benefits.⁷ The Departments of Health and Human Services, Labor, and the Department of the Treasury issued regulations improving the internal claims and appeals process and establishing rules for the external review processes required under the Affordable Care Act ("ACA").8 These additional protections for a fair process include the right of claimants to respond to new and additional evidence and rationales and the requirement for independence and impartiality of the persons involved in making benefit determinations.

The Department's independent ERISA advisory group also urged the

¹ 42 FR 27426 (May 27, 1977).

 $^{^2\,65}$ FR 70246 (Nov. 21, 2000), amended at 66 FR 35887 (July 9, 2001).

³ A benefit is a disability benefit, subject to the special rules for disability claims under the Section 503 Regulation, if the plan conditions its availability to the claimant upon a showing of disability. 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 Section 503 Regulation, and 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. On the other hand, when a plan, including a pension plan, provides a benefit the availability of which is conditioned on a finding of disability made by a party other than the plan, (e.g., the Social Security Administration or the employer's long-term disability plan), then a claim for such benefits is not treated as a disability claim for purposes of the Section 503 Regulation, See FAOs About The Benefit Claims Procedure Regulation, A-9 (www.dol.gov/sites/default/files/ebsa/about-ebsa/ our-activities/programs-and-initiatives/outreachand-education/hbec/CAGHDP.pdf).

⁴ BLS National Compensation Survey, March 2014, at www.bls.gov/ncs/ebs/benefits/2014/ebbl0055.pdf.

⁵ See Sean M. Anderson, ERISA Benefits Litigation: An Empirical Picture, 28 ABA J. Lab. & Emp. L. 1 (2012).

 $^{^{6}}$ See, e.g., Salomaa v. Honda Long Term Disability Plan, 642 F.3d 666, 678 (9th Cir. 2011) (''The plan's reasons for denial were shifting and inconsistent as well as illogical. . . . Failing to pay out money owed based on a false statement of reasons for denying is cheating, every bit as much as making a false claim."); Lauder v. First Unum Life Ins. Co., 76 F. App'x 348, 350 (2d Cir. 2003) (reversing district court's denial of attorneys' fees to plaintiff-insured and describing "ample demonstration of bad faith on First Unum's part, including . . . the frivolous nature of virtually every position it has advocated in the litigation."); Schully v. Continental Cas. Co., 634 F. Supp. 2d 663, 687 (E.D. La. 2009) ("In concluding that plaintiff was not disabled, the Hartford not only disregarded considerable objective medical evidence, but it also relied heavily on inconclusive and irrelevant evidence . . . Hartford's denial of coverage results from its preferential and predetermined conclusions."); Rabuck v. Hartford Life and Accident Ins. Co., 522 F. Supp. 2d 844, 882 (W.D. Mich. 2007) (insurer "obviously motivated by its own self-interest, engaged in an unprincipled and overly aggressive campaign to cut off benefits for a gravely ill insured who could not possibly have endured the rigors of his former occupation on a full-time basis."); Curtin v. Unum Life Ins. Co. of America, 298 F. Supp. 2d 149, 159 (D. Me. 2004) ("[T]his Court finds that Defendants exhibited a low level of care to avoid improper denial of claims at great human expense.").

⁷The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, was enacted on March 30, 2010. (These statutes are collectively known as the "Affordable Care Act.") ⁸ 80 FR 72192 (Nov. 18, 2015).

Department to re-examine the disability claims process. Specifically, in 2012, the ERISA Advisory Council undertook a study on issues relating to managing disability in an environment of individual responsibility. The Council concluded based on the public input it received that "[n]ot all results have been positive for the participant under ERISA-covered plans and the implementing claim procedures regulations, even though these rules were intended to protect participants" and noted that "[t]he Council was made aware of reoccurring issues and administrative practices that participants and beneficiaries face when appealing a claim that may be inconsistent with the existing regulations." The Advisory Council's report included the following recommendation for the Department:

Review current claims regulations to determine updates and modifications, drawing upon analogous processes described in health care regulations where appropriate, for disability benefit claims including: (a) Content for denials of such claims; (b) rule regarding full and fair review, addressing what is an adequate opportunity to develop the record and address retroactive rescission of an approved benefit; (c) alternatives that would resolve any conflict between the administrative claims and appeals process and the participants' ability to timely bring suit; (d) the applicability of the ERISA claim procedures to offsets and eligibility determinations.

2012 ERISA Advisory Council Report, Managing Disability Risks in an Environment of Individual Responsibility, available at www.dol.gov/sites/default/files/ebsa/ about-ebsa/about-us/erisa-advisorycouncil/2012ACreport2.pdf.

The Department agreed that the amendments to the claims regulation for group health plans could serve as an appropriate model for improvements to the claims process for disability claims. Those amendments aimed to ensure full and fair consideration of health benefit claims by giving claimants ready access to the relevant evidence and standards; ensuring the impartiality of persons involved in benefit determinations; giving claimants notice and a fair opportunity to respond to the evidence, rationales, and guidelines for decision; and making sure that the bases for decisions are fully and fairly communicated to the claimant. In the Department's view, these basic safeguards are just as necessary for a full and fair process in the disability context as in the health context. Moreover, as in the group health plan context, disability claims are often reviewed by a court under an abuse of discretion standard

based on the administrative record. Because the claimant may have limited opportunities to supplement the record, the Department concluded that it is particularly important that the claimant be given a full opportunity to develop the record that will serve as the basis for review and to respond to the evidence, rationales, and guidelines relevant to the decision.

The Department's determination to revise the claims procedures was additionally affected by the aggressive posture insurers and plans can take to disability claims as described above coupled with the judicially recognized conflicts of interest insurers and plans often have in deciding benefit claims.9 In light of these concerns, the Department concluded that enhancements in procedural safeguards and protections similar to those required for group health plans under the Affordable Care Act were as important, if not more important, in the case of claims for disability benefits.

The Department decided to start by proposing to amend the current standards applicable to the processing of claims and appeals for disability benefits so that they included improvements to certain basic procedural protections in the current Section 503 Regulation, many of which already apply to ERISA-covered group health plans pursuant to the Department's regulations implementing the requirements of the Affordable Care Act.

On November 18, 2015, the Department published in the Federal **Register** a proposed rule revising the claims procedure regulations for plans providing disability benefits under ERISA.¹⁰ The Department received 145 public comments in response to the proposed rule from plan participants, consumer groups representing disability benefit claimants, employer groups, individual insurers and trade groups representing disability insurance providers. The comments were posted on the Department's Web site at www.dol.gov/agencies/ebsa/laws-andregulations/rules-and-regulations/ public-comments/1210-AB39. After careful consideration of the issues raised by the written public comments, the Department decided to adopt the improvements in procedural protections and other safeguards largely as set forth in the November 2015 proposal. The

Department revised some of the requirements in response to public comments as part of its overall effort to strike a balance between improving a claimant's reasonable opportunity to pursue a full and fair review and the attendant costs and administrative burdens on plans providing disability benefits.

The Department believes that this action is necessary to ensure that disability claimants receive a full and fair review of their claims, as required by ERISA section 503, under the more stringent procedural protections that Congress established for group health care claimants under the ACA and the Department's implementing regulation at 29 CFR 2590.715-2719 ("ACA Claims and Appeals Final Rule").11 This final rule will promote fairness and accuracy in the claims review process and protect participants and beneficiaries in ERISAcovered disability plans by ensuring they receive benefits that otherwise might have been denied by plan administrators in the absence of the fuller protections provided by this final regulation. The final rule also will help alleviate the financial and emotional hardship suffered by many individuals when they are unable to work after becoming disabled and their claims are denied.

II. Overview of Final Rule

A. Comments on Overall Need To Improve Claims Procedure Rules for Disability Benefits

Numerous disabled claimants and their representatives submitted comments stating general support for the proposed rule. For example, some commenters described the proposal as reinforcing the integrity of disability benefit plan administration and markedly improving the claims process by strengthening notice and disclosure protections, prescribing more exacting standards of conduct for review of denied claims, ensuring claimants' more effective access to the claims process, and providing safeguards to ensure full court review of adverse benefit determinations. Some commenters supported the proposed amendments as "good first steps" towards providing more transparency and accountability, but advocated additional steps to strengthen, improve, and update the current rules. Some commenters emphasized that disability and lost earnings impose severe hardship on many individuals, arguing that disability claimants have a "poor" prospect of fair review under the current

⁹ Metropolitan Life Ins. Co. v. Glenn, 554 U.S. 105 (2008) (insurance company plan administrator of an ERISA long-term disability plan that both evaluates and pays claims for the employer has a conflict of interest that courts must consider in reviewing denials of benefit claims).

^{10 80} FR 72014.

^{11 80} FR 72192 (Nov. 18, 2015).

regulation primarily because of the economic incentive for insurance companies to deny otherwise valid claims and because plans are often able to secure a deferential standard of review in court.

Commenters, primarily disability insurers and benefit providers, commented that the disability claims regulation should not mirror Affordable Care Act requirements because unlike disability claims: (i) The vast majority of medical claims are determined electronically with little or no human involvement, i.e., no reviewers studying materials and consulting with varied professionals; (ii) medical claims typically involve only a limited treatment over a relatively short period of time, whereas disability claims require a series of determinations over a period of several years; (iii) medical claims rarely involve a need to consult with outside professionals; (iv) medical claims involve an isolated issue, whereas disability claims involve a more complex, multi-layered analysis; and (v) medical claim files may consist of only a few pages of materials, whereas disability claim files can consist of hundreds, sometimes thousands of pages of information. As a result of these factors, the commenters stressed that it can take significant time to review and render a decision. Some of those commenters argued that applying ACA protections to disability benefit claims was contrary to Congressional intent because disability plans were not subject to the ACA's group health plan provisions. Some claimed that the proposed rules in their current form will have unintended consequences (undue delay and increased costs and litigation), and will result in expenses and burdens that will increase the cost of coverage and discourage employers from sponsoring disability benefit plans. Finally, some claimed that the increased protections and transparency that would be required under the proposal would weaken protection against disability fraud and were unnecessary because the current regulations provide ample protections for claimants, are written to benefit the insured, and have worked well for more than a decade as evidenced by the asserted fact that the vast majority of disability claims incurred by insurers are paid, and, of the claims denied, only a very small percentage are ultimately litigated. Some argued that technological advances that have expedited processing of health care claims do not apply to disability claims adjudication, contended that the Department had not

properly quantified or qualified the benefits associated with the proposed regulations or provided a sufficient cost analysis associated with the proposed regulations, and commented that the Department should withdraw the proposal until better data is collected.

After careful consideration of the issues raised by the written comments, the Department does not agree with the commenters' assertion that the ACA changes for group health plans are not an appropriate model for improving claims procedures for disability benefits. The enactment of the ACA, and the issuance of the implementing regulations, has resulted in disability benefit claimants receiving fewer procedural protections than group health plan participants even though litigation regarding disability benefit claims is prevalent today. As noted above, the Department's Section 503 Regulation imposes more stringent procedural protections on claims for group health and disability benefits than on claims for other types of benefits. The Department believes that disability benefit claimants should continue to receive procedural protections similar to those that apply to group health plans, and that it makes sense to model the final rule on the procedural protections and consumer safeguards that Congress and the President established for group health care claimants under the ACA. These protections and safeguards will allow some participants to receive benefits that might have been incorrectly denied in the absence of the fuller protections provided by the regulation. It will also help alleviate the financial and emotional hardship suffered by many individuals when they lose earnings due to their becoming disabled.

Moreover, the Department carefully selected among the ACA amendments to the claims procedures for group health plans, and incorporated into the proposal only certain of the basic improvements in procedural protections and consumer safeguards. The proposal, and final rule, also include several adjustments to the ACA requirements to account for the different features and characteristics of disability benefit claims.

The Department agrees with the commenters who supported the proposed changes who emphasized that disability and lost earnings impose severe hardship on many individuals. Under those circumstances, and considering the judicially recognized economic incentive for insurance companies to deny otherwise valid claims, the Department views enhancements in procedural safeguards

and protections similar to those required for group health plans under the Affordable Care Act as being just as important, if not more important, in the case of claims for disability benefits. This view was supported by the assertions by some plans and disability insurance providers that disability claims processing involves more human involvement, with reviewers studying pages of materials and consulting with varied professionals on claims that involve a more complex, multi-layered analysis. Even assuming the characteristics cited by the commenter fairly describe a percentage of processed disability claims, the Department does not believe those characteristics support a decision to treat the processing of disability benefits more leniently than group health benefits. The Department believes there is potential for error and opportunity for the insurer's conflict of interest to inappropriately influence a benefit determination under highly automated claims processing, as well as claims processing with more human involvement.¹² Increased transparency and accountability in all claims processes is important if claimants of disability benefits are to have a reasonable opportunity to pursue a full and fair review of a benefit denial, as required by ERISA section 503. Also, and as more fully discussed in the Regulatory Impact Analysis section of this document, the Department does not agree that the adoption of these basic procedural protections will cause excessive increases in costs and litigation, or result in expenses and burdens that will discourage employers from sponsoring plans providing disability benefits. In fact, comments from some industry groups support the conclusion that the protections adopted in the final rule reflect best practices that many insurers and benefit providers already follow on a voluntary basis.

Thus, while the Department has made some changes and clarifications in response to comments, the final rule, described below, is substantially the same as the proposal. Specifically, the major provisions in the final rule

¹² While commenters contended that disability claim files are larger than health benefit claim files, in the Department's view, this is not a reason for denying claimants the same procedural protections and safeguards that the ACA provided for group health benefit claims. Furthermore, in the 2000 claims regulation, the Department already accommodated differences between health and disability claims by allowing more time for decisions on disability claims. See 29 CFR 2560.503–1(f)(2)(iii)(B) (up to 30 days after receipt of claim with up to 15 days for an extension for post-service health claims); id. § 2560.503–1(f)(3) (up to 45 days after receipt of claim with two possible 30-day extensions for disability claims).

require that: (1) Claims and appeals must be adjudicated in a manner designed to ensure independence and impartiality of the persons involved in making the benefit determination; (2) benefit denial notices must contain a complete discussion of why the plan denied the claim and the standards applied in reaching the decision, including the basis for disagreeing with the views of health care professionals, vocational professionals, or with disability benefit determinations by the Social Security Administration (SSA); (3) claimants must be given timely notice of their right to access to their entire claim file and other relevant documents and be guaranteed the right to present evidence and testimony in support of their claim during the review process; (4) claimants must be given notice and a fair opportunity to respond before denials at the appeals stage are based on new or additional evidence or rationales; (5) plans cannot prohibit a claimant from seeking court review of a claim denial based on a failure to exhaust administrative remedies under the plan if the plan failed to comply with the claims procedure requirements unless the violation was the result of a minor error; (6) certain rescissions of coverage are to be treated as adverse benefit determinations triggering the plan's appeals procedures; and (7) required notices and disclosures issued under the claims procedure regulation must be written in a culturally and linguistically appropriate manner.

B. Comments on Major Provisions of Final Rule

1. Independence and Impartiality— Avoiding Conflicts of Interest

Consistent with the ACA Claims and Appeals Final Rule governing group health plans, paragraph (b)(7) of this final rule explicitly provides that plans providing disability benefits "must ensure that all claims and appeals for disability benefits are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision." Therefore, this final rule requires that decisions regarding hiring, compensation, termination, promotion, or similar matters with respect to any individual must not be made based upon the likelihood that the individual will support the denial of disability benefits. For example, a plan cannot provide bonuses based on the number of denials made by a claims adjudicator. Similarly, a plan cannot contract with a medical expert based on the expert's reputation for outcomes in contested cases, rather than based on the expert's

professional qualifications. These added criteria for disability benefit claims address practices and behavior which cannot be reconciled with the "full and fair review" guarantee in section 503 of ERISA, and with the basic fiduciary standards that must be followed in implementing the plan's claims procedures. For the reasons described below, paragraph (b)(7) of the final rule therefore remains largely unchanged

from the proposal.

The Department received numerous comments either generally supporting or not objecting to the idea that the independence and impartiality requirements for claims procedures for disability claims should be consistent with the ACA's claims procedures requirements for group health plans. Several commenters pointed out that even prior to the proposal, many disability plans had already taken affirmative steps to ensure the independence and impartiality of the persons involved in the decisionmaking process. Other commenters who opposed the provision as unnecessary similarly cited the fact that the proposed amendments reflect current industry practice and argued that issues regarding the independence and impartiality of the appeal process is already the subject of the welldeveloped body of case law. Although the Department agrees that the proposal was intended to be consistent with industry best practice trends and developing case law in the area, the Department does not believe that industry trends or court decisions are an acceptable substitute for including these provisions in a generally applicable regulation.

Several commenters suggested that the examples of individuals covered by this provision should include vocational experts. The commenters pointed out that vocational experts are often actively involved in the decision-making process for disability claims and play a role in the claims process similar to the role of a medical or health care professional. They noted that opinions of vocational experts are often relied on in making determinations on eligibility for and the amount of disability benefits. Although the list in the proposed provision was intended to merely reflect examples, not be an exhaustive list, the Department nonetheless agrees that it would be appropriate to add vocational experts to avoid disputes regarding their status under this provision of the final rule. This clarification of the provision from its proposed form is also consistent with the current regulation's express acknowledgement of the important role of vocational experts in the disability

claims process. Specifically, paragraph (h)(3)(iv) of the current regulation already requires that the claims procedure for disability benefit claims must 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. Accordingly, the final rule adds "vocational expert" to the examples of persons involved in the decision-making process who must be insulated from the plan's or issuer's conflicts of interest. Decisions regarding hiring, compensation, termination, promotion, or other similar matters must not be based upon the likelihood that the individual will support the denial of benefits.

Commenters also asked the Department to clarify whether "consulting experts" are "involved in making the decision" for purposes of the independence and impartiality requirements. Some commenters were concerned that consulting experts would fall outside of these requirements because plans or claims administrators might assert that consulting experts merely supply information and do not decide claims. In the Department's view, the text of paragraph (b)(7) is clear that the independence and impartiality requirements are not limited to persons responsible for making the decision. For example, paragraph (b)(7) of the final rule, as in the proposal, refers to a "medical expert" as an example of a person covered by the provision. The text also refers to individuals who may "support the denial of benefits." Thus, in the Department's view, the independence and impartiality requirements apply to plans' decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to consulting experts. Although some commenters suggested that the Department expand the regulatory text to expressly include "consulting experts," in the Department's view, the regulatory text is sufficiently clear to address commenters' concerns especially with the inclusion of "vocational experts" in this provision of the final rule as described above. The Department also believes that it should avoid creating differences in the text of parallel provisions in the rules for group health benefits under the ACA Claims and Appeals Final Rule and disability benefits absent a reason that addresses a specific issue for disability claims

(like the vocational expert issue discussed above).

Several commenters asked the Department to clarify that the independence and impartiality requirements apply even where the plan does not directly hire or compensate the individuals "involved in making the decision" on a claim. The text of the rule does not limit its scope to individuals that the plan directly hires. Rather, the rule's coverage extends to individuals hired or compensated by third parties engaged by the plan with respect to claims. Thus, for example, if a plan's service provider is responsible for hiring, compensating, terminating, or promoting an individual involved in making a decision, this final rule requires the plan to take steps (e.g., in the terms of its service contract and ongoing monitoring) to ensure that the service provider's policies, practices, and decisions regarding hiring, compensating, terminating, or promoting covered individuals are not based upon the likelihood that the individual will support the denial of benefits.

One commenter, who supported applying independence and impartiality requirements, expressed concern about a statement in the preamble to the proposed rule that a plan cannot contract with a medical expert based on the expert's reputation for outcomes in contested cases rather than based on the expert's professional qualifications. The commenter did not object to the prohibition on hiring a medical expert based on a reputation for denying claims, but expressed concern that the statement in the preamble might result in claimants requesting statistics and other information on cases in which the medical expert expressed opinions in support of denying rather than granting a disability benefit claims. Another commenter who opposed the provision also expressed concern about court litigation and discovery regarding "reputation" issues arising from the text in the preamble. In the Department's view, the preamble statement accurately describes one way that the independence and impartiality standard could be violated. That said, the independence and impartiality requirements in the rule do not modify the scope of "relevant documents" subject to the disclosure requirements in paragraphs (g)(1(vii)(C) and (h)(2)(iii) of the Section 503 Regulation, as amended by this rule. Nor do the independence and impartiality requirements in the rule prescribe limits on the extent to which information about consulting experts would be discoverable in a court proceeding as part of an evaluation of

the extent to which the claims administrator or insurer was acting under a conflict of interest that should be considered in evaluating an adverse benefit determination.

Several commenters urged the Department to implement the independence and impartiality requirements with specific quantifiable limitations on the relationship between plans and consultants. For example, one commenter suggested a medical consultant be required to certify that no more than 20% of the consultant's income is derived from reviewing files for insurance companies and/or selffunded disability benefit plans. Several commenters recommended that plans be required to disclose to claimants a range of quantifiable information regarding its relationship with certain consultants (e.g., number of times a plan has relied upon the third-party vendor who hired the expert in the past year). A few commenters suggested that the Department establish rules on the qualifications, credentials, or licensing of an expert and the nature and type of such expert's professional practice. For example, one commenter suggested that the rule provide that when a fiduciary relies on a physician or psychologist or other professional, such as a vocational specialist, the person must be licensed in the same jurisdiction where the plan beneficiary resides. Although the Department agrees that more specific quantifiable or other standards relating to the nature and type of an expert's professional practice might provide additional protections against conflicts of interest, the parallel provisions in the claims procedure rule for group health plans under the ACA Claims and Appeals Final Rule do not contain such provisions. Moreover, an attempt to establish specific measures or other standards would benefit from a further proposal and public input. Accordingly, the final rule does not adopt the commenters' suggestions.

2. Improvements to Disclosure Requirements

The Department proposed to improve the disclosure requirements for disability benefit claims in three respects. First, the proposal included a provision that expressly required adverse benefit determinations on disability benefit claims to contain a "discussion of the decision," including the basis for disagreeing with any disability determination by the SSA or other third party disability payer, or any views of health care professionals treating a claimant to the extent the determination or views were presented by the claimant to the plan. Second,

notices of adverse benefit determinations must contain the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were relied upon in denying the claim (or a statement that such criteria do not exist). Third, consistent with the current rule applicable to notices of adverse benefit determinations at the review stage, a notice of adverse benefit determination at the initial claims stage must contain a statement that the claimant is entitled to receive, upon request, relevant documents.

In the Department's view, the existing claims procedure regulation for disability claims already imposes a requirement that denial notices include a reasoned explanation for the denial.¹³ For example, the rule requires that the notice must be written in a manner calculated to be understood by the claimant, must include any specific reasons for the adverse determination, must reference the specific provision in governing plan documents on which the determination is based, must include a description of any additional information required to perfect the claim, must include a description of the internal appeal process, and must include the plan's rules, if any, that were used in denying the claim (or a statement that such rules are available upon request).

The Department's experience in enforcing the claims procedure requirements and its review of litigation activity, however, leads it to conclude that some plans are providing disability claim notices that are not consistent with the letter or spirit of the Section 503 Regulation. Accordingly, the Department believes that expressly setting forth additional requirements in the regulation, even if some may already apply under the current rule, is an appropriate way of reinforcing the need for plan fiduciaries to administer the plan's claims procedure in a way that is transparent and that encourages an appropriate dialogue between a claimant and the plan regarding adverse benefit determinations that ERISA and the current claims procedure regulation contemplate.

Commenters generally either supported or did not object to the requirement to explain a disagreement with a treating health care professional in adverse benefit determinations. The

¹³ For example, the Department noted in the preamble to the proposed rule the fact that several federal courts concluded that a failure to provide a discussion of the decision or the specific criteria relied upon in making the adverse benefit determination could make a claim denial arbitrary and capricious.

Department, accordingly, is adopting this provision from the proposal. This provision in the final rule would not be satisfied merely by stating that the plan or a reviewing physician disagrees with the treating physician or health care professional. Rather, the rule requires that the adverse benefit determination must include a discussion of the basis for disagreeing with the health care professional's views. Several commenters suggested, similar to their comments described above on the need to subject vocational experts to the independence and impartiality requirements, that this disclosure provision should also apply to vocational professionals. As noted above, the commenters pointed out that vocational experts have a role somewhat similar to the role of a medical or health care professional in the claims determination process. The Department agrees, and, accordingly, added "vocational professional" to this provision.

An issue raised in the comments related to whether the plan is required to address only third party views presented to the plan by the claimant. The concern was that plans may not know whether other third party views even exist so that any requirement to address third party views should be limited to third party findings where they are presented by the claimant. Although the Department does not believe it would be appropriate to require plans to address views that they were not aware of and had no obligation to discover, the Department's consideration of this comment led it to conclude that the provision needed to be revised to include medical or vocational experts whose advice was obtained on behalf of the plan in connection with a claimant's adverse benefit determination. The Department's experience enforcing the current regulation has revealed circumstances where claims adjudicators may consult several experts and deny a claim based on the view of one expert when advice from other experts who were consulted supported a decision to grant the claim. Some of these cases may have involved intentional "expert shopping." Requiring plans to explain the basis for disagreeing with experts whose advice the plan sought would not present the problem raised in the comments of addressing third party views the plan does not know even exist, but it would be consistent with and enhance the requirement in paragraph (h)(3)(iv) of the current regulation which already requires that the claims procedure for disability benefit claims must 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. In fact, the Department believes that a request for relevant documents under the current regulation would require the plan to disclose materials related to such a consultation. The plan would also be required under the current regulation to explain its basis for not adopting views of an expert the plan consulted who supported granting the claim if the claimant raised the expert's views as part of an appeal of an adverse benefit determination. In the Department's view, this is not a new substantive element of the requirement that plans explain the reasons for a denial, but rather is a process enhancement that removes unnecessary procedural steps for claimants to get an explanation of the reasons the plan disagrees with the views of its own consulting experts.

Accordingly, the final rule revises paragraphs (g)(1)(vii)(A) and (j)(6)(i) to require that adverse benefit determinations on disability benefit claims contain a discussion of the basis for disagreeing with the views of health care professionals who treated the claimant or vocational professionals who evaluated the claimant, when the claimant presents those views to the plan. The final rule also revises paragraphs (g)(1)(vii)(A) and (j)(6)(i) to clarify that adverse benefit determinations on disability benefit claims must contain a discussion of the basis for disagreeing with the views 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.

One commenter suggested that references to the "views" of treating health care professionals is very broad and that it is not clear what is intended to be covered by this reference. The commenter argued that "views" is not synonymous with an opinion or conclusion about whether a claimant is disabled, and that, in many cases, health care professionals do not provide an opinion on the claimant's disability at all, and if they do, they are not providing an opinion on disability as defined by the plan. Another commenter asserted that a health care professional's focus is on the patient's diagnosis and treatment and that the claims adjudicator considers the long-

term effect of the individual's condition on their ability to work. These commenters argued that claims adjudicators are not necessarily agreeing or disagreeing with medical findings by a treating health care provider, rather they are considering if the claimant's disease or illness significantly impairs their work skills. The commenters said that to require a plan to discuss why it did not agree with the views expressed by a myriad of health care professionals does nothing to help explain why a claims administrator found that the claimant was not disabled under the terms of the plan.

The Department does not believe it is appropriate to limit the scope of the final rule to opinions or conclusions about whether a claimant is disabled. Medical and vocational professionals provide views that may be important to the ultimate determination of whether a person is disabled. In the Department's view, to the extent the claims adjudicator disagrees with foundational information in denying a claim, the claimant has a right to know that fact to the same extent the claimant should be made aware that the claims adjudicator disagrees with an opinion from a medical or vocational expert that the claimant is disabled. Further, it is part of the fiduciary role of the ERISA claims adjudicator to weigh input from medical and vocational experts in reaching a conclusion on a benefit claim. When the claims adjudicator acting in a fiduciary capacity disagrees with the judgments of medical and vocational professionals in denying a claim, the claims adjudicator as a matter of basic fiduciary accountability should be able to identify those circumstances and explain the basis for that decision. The Department also notes that the final rule requires this explanation in cases where the plan or claims adjudicator disagrees with the views of the medical or vocational expert. There is no disagreement to explain if, as the commenter posed, a treating health care consultant expresses a view only on a diagnosis or treatment which the plan fully accepts in evaluating the question of whether the claimant meets the definition of a disability under the plan. Rather, in such a case, the plan would be under the same obligation that exists under the current regulation to explain why it reached the conclusion that the diagnosed illness or treatment did not impair the claimant's work skills or ability to work or otherwise failed to satisfy the plan's definition of disability. In summary, the Department believes that an explanation of the basis for disagreement with the judgments of

health care and vocational professionals is required in order to be responsive to the information submitted by the claimant or developed during evaluation of the claim, and is also necessary for a reasoned explanation of a denial.

With respect to the requirement to explain the basis for disagreeing with or not following disability determinations by the SSA and other payers of disability benefits, several commenters who supported the requirement pointed out that reviewing courts in evaluating whether a plan's adverse benefit determination was arbitrary and capricious have found an SSA determination to award benefits to be a factor that the plan fiduciary deciding a benefit should consider. Courts have criticized the failure to consider the SSA determination, especially if a plan's administrator operates under a conflict of interest and if the plan requires or encourages claimants to pursue SSA decisions in order to offset any SSA award against the amount they pay in disability benefits. See, e.g., Montour v. Hartford Life and Accident Ins. Co., 588 F.3d 623, 637 (9th Cir. 2009) ("failure to explain why it reached a different conclusion than the SSA is yet another factor to consider in reviewing the administrator's decision for abuse of discretion, particularly where, as here, a plan administrator operating with a conflict of interest requires a claimant to apply and then benefits financially from the SSA's disability finding."); Brown v. Hartford Life Ins. Co., 301 F. App'x 772, 776 (10th Cir. 2008) (insurer's discussion was "conclusory" and "provided no specific discussion of how the rationale for the SSA's decision, or the evidence the SSA considered, differed from its own policy criteria or the medical documentation it considered"). Other commenters, however, urged the Department to remove the requirement to discuss the basis for disagreeing with the disability determinations of the SSA or other pavers of benefits. Those commenters argued that it would not be reasonable to require an ERISA plan fiduciary to go outside the plan's governing document and make a judgment about a disability determination made by some other party that is based upon another plan or program's definition of disability, which may have entirely different or inconsistent definitions of disability or conditions. The commenters further argued that the plan fiduciary might not be able to get from the SSA or other payer of benefits the documents, case file or other information necessary even

to try to conduct such an evaluation. Those commenters also requested that, if such a requirement was to be included in the final rule, then the rule should allow plans to take into account in the discussion of its decision the extent to which the claimant provided the plan, or gave the plan a way to obtain, sufficient documentation from the SSA or other third party to allow a meaningful review of such third-party findings.

The Department is persuaded that the final rule should limit the category of 'other payers of benefits' to disability benefit determinations by the SSA. The Department accepts for purposes of this final rule that claims adjudicators generally are trained to understand their own plan or insurance policy requirements and apply those standards to claims in accordance with the internal rules, guidelines, policies, and procedures governing the plan. The Department also agrees that a determination that an individual is entitled to benefits under another employee benefit plan or other insurance coverage may not be governed by the same definitions or criteria, and that it may be difficult for the adjudicator to obtain a comprehensive explanation of the determination or relevant underlying information that was relied on by the other payer in making its determination.

The Department does not believe, however, that those same difficulties are involved in the case of SSA determinations. SSA determinations may include a written decision from an ALJ, and the definitions and presumptions are set forth in publicly available regulations and SSA guidance. Accordingly, the final rule revises paragraphs (g)(1)(vii)(A) and (j)(6)(i) to require that adverse benefit determinations on disability benefit claims contain a discussion of the basis for disagreeing with an SSA disability determination regarding the claimant presented by the claimant to the plan. Although the plan's claims procedures may place the burden on the claimant to submit any SSA determination that the claimant wants the plan to consider, claims administrators working with an apparently deficient administrative record must inform claimants of the alleged deficiency and provide them with an opportunity to resolve the stated problem by furnishing missing information. It also would not be sufficient for the benefit determination merely to include boilerplate text about possible differences in applicable definitions, presumptions, or evidence. A discussion of the actual differences would be necessary. Further, although

the final rule does not, as some commenters requested, require that plans defer to a favorable SSA determination, a more detailed justification would be required in a case where the SSA definitions were functionally equivalent to those under the plan.

Several commenters requested that the Department adopt a rule requiring deference to a treating physician's opinion for disability determinations, with some commenters suggesting a rule identical to the one applied under the SSA disability program. Nothing in ERISA or the Department's regulations mandates that a plan administrator give special weight to the opinions of a claimant's treating physician when rendering a benefit determination. The Department also does not believe the public record on this rulemaking supports the Department imposing such a rule. In the Department's view, a treating physician rule is not necessary to guard against arbitrary decisionmaking by plan administrators. In addition to the various improvements in safeguards and procedural protections being adopted as part of this final rule, courts can review adverse benefit determinations to determine whether the claims adjudicator acted unreasonably in disregarding evidence of a claimant's disability, including the opinions of treating physicians. Nor does the Department believe it would be appropriate to adopt the treating physician rule applicable under the Social Security disability program. That rule was adopted by the Commissioner of Social Security in regulations issued in 1991, to bring nationwide uniformity to a vast statutory benefits program and to address varying decisions by courts of appeals addressing the question. ERISA, by contrast, governs a broad range of private benefit plans to which both the statute and implementing regulations issued by the Secretary of Labor permit significant flexibility in the processing of claims. Moreover, the SSA's treating physician rule has not been uniformly or generally applied even under statutory disability programs other than Social Security. See Brief for the United States as amicus curiae supporting petitioner, Black & Decker Disability Plan v. Nord, 538 U.S. 822 (2003).

Under the current Section 503
Regulation, if a claim is denied based on a medical necessity, experimental treatment, or similar exclusion or limit, the adverse benefit determination must include 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. These requirements in paragraphs (g)(1)(v)(B)and (j)(5)(ii) apply to notices of adverse benefit determinations for both group health and disability claims. In proposing new paragraphs (g)(1)(vii) and (j)(6) applicable to disability claims, these requirements were intended to be subsumed in the general requirement in the proposal that adverse benefit determinations include a "discussion of the decision." The Department is concerned, however, that removing the explicit requirement in the disability claims procedure to explain a denial based on medical necessity, experimental treatment, or similar exclusion may be misinterpreted by some as eliminating that requirement (especially with the group health plan claims procedures continuing to have that explicit requirement). That clearly was not the Department's intention, and, accordingly, the final rule expressly sets forth in paragraphs (g)(1)(vii)(B) and (j)(6)(ii) the requirement of an explanation of the scientific or clinical judgment for such denials.14

The Department received numerous comments in favor of the disclosure requirement in paragraphs (g)(1)(vii)(B) and (j)(6)(ii) of the proposal that notices of adverse benefit determinations include the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were relied upon in denying the claim (or a statement that such criteria do not exist). Commenters who supported the proposal noted that the proposed requirement should not be onerous given that adverse benefit determinations are already required to include the reasons for the denial and the applicable plan terms, and also argued that this further level of

transparency would promote the dialogue between claimant and plan regarding adverse benefit determinations that ERISA contemplates. These commenters also pointed out that this requirement would address a problem confronted by some claimants where a plan or claims adjudicator says it is relying on an internal rule in denying a claim, and then refuses to disclose it to the claimant based on an assertion that the internal rule is confidential or proprietary. Commenters who opposed the provision argued that the proposal would be overly burdensome for plans and insurers. They read the provision as requiring disclosure of "details of internal processes that are irrelevant to the claim decision and that would provide little in the way of useful information to claimants." The comments included concerns about the time and cost to review claims manuals and other internal documents that may include rules, guidelines, protocols, standards or other similar criteria to determine that no provision has any application to a claim in order to make the statement that such internal rules, etc. do not exist.

The final rule, like the proposal, provides that internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making an adverse benefit determination must be provided with the adverse benefit determination. The Department does not agree with commenters who asserted that the requirement will be overly burdensome to plans. Even under the existing claims procedure regulation, internal rules, guidelines, protocols, standards or similar criteria relied upon in denying the claim already must be provided to the claimant upon request. Although the additional requirement to affirmatively include them in the adverse benefit determination adds an incremental paperwork burden, 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. With respect to the comments about disclosing an internal process that is irrelevant to the claim decision, it is hard to see how something that is in fact "irrelevant" can be something that was "relied upon" in denying the claim. Furthermore, the Department does not agree that it should change the proposed text based on expressed concerns about the time and cost to review claims manuals and other internal documents to determine that nothing in those

materials have application to a claim. Aside from the fact that this provision of the final rule requires the plan to affirmatively include only rules, guidelines, protocols, standards or other similar criteria that were relied on in denying the claim, in the Department's view, it would present substantial questions about whether the plan or claims adjudicator complied with ERISA's fiduciary standards if a claim was denied without the claims adjudicator having considered a rule, guideline, protocol or standard that was intended to govern the determination of the claim. Moreover, the current Section 503 regulation for disability plans gives claimants the right to reasonable access to and copies of documents, records, and other information "relevant" to the claimant's claim for benefits. In addition to capturing documents, records, and other information "relied upon" in making the benefit determination, the definition of "relevant" also captures information submitted, considered or generated in the course of making the benefit determination or that demonstrates compliance with the administrative processes and safeguards designed to ensure and verify that benefit claim determinations have been made in accordance with governing plan documents and that those provisions have been applied consistently with respect to similarly situated claimants. In the case of plans providing group health or disability benefits, "relevant" also includes documents, records, or other information that constitutes a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit, without regard to whether such advice or statement was relied upon in making the benefit determination. Such a statement of policy or guidance would include any policy or guidance generated or commissioned by the plan or issuer concerning the denied benefit that would or should contribute to deciding generally whether to pay the claim (e.g., studies, surveys or assessments generated or commissioned by the plan or issuer that implicate a denied treatment option or benefit but do not relate specifically to the plan itself). Thus, in the Department's view, even under the current rule, plans would be required, on request, to verify that the plan has produced all the internal rules, guidelines, protocols, standards or other similar criteria concerning the denied claim that were or should have been considered in deciding the claim.

Another commenter argued that it did not make sense to require plans to

¹⁴ The current Section 503 Regulation in paragraph (j)(5)(iii) requires a statement concerning voluntary dispute resolution options in notices of adverse benefit determinations on review for both group health and disability claims. The Department previously issued an FAQ on that provision noting that information on the specific voluntary appeal procedures offered under the plan must be provided under paragraph (j)(4) of the regulation 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. The Department, therefore, stated in the FAQ that, pending further review, it will not seek to enforce compliance with the requirements of paragraph (j)(5)(iii). See FAQs About The Benefit Claims Procedure Regulation, D-13 (www.dol.gov/sites/ default/files/ebsa/about-ebsa/our-activities/ programs-and-initiatives/outreach-and-education/ hbec/CAGHDP.pdf). In light of the fact that this proposal was limited to disability benefit claims, the Department does not believe it would be appropriate to modify the requirement in paragraph (j)(5)(iii) as part of this final rule. Accordingly, the Department will continue the enforcement position articulated in FAQ D-13.

affirmatively state in an adverse benefit determination that plans did not rely on any rule or guideline. They argued that, if the adverse benefit determination failed to cite reliance on such a rule or guideline, the claimant could ask and the plan would respond with a statement that none were relied on. They argued that such a process gives the claimant the ability to obtain that information in cases where the claimant believes that information is important to understanding or contesting the basis for the denial. It is the Department's view, however, that an affirmative statement would be helpful to the claimant by providing certainty about the existence of any applicable rule or guideline. The Department also does not believe the absence of a statement of reliance in an adverse benefit statement fairly puts a claimant on notice to request confirmation that no rule or guideline was relied upon. Further, the Department does not believe merely requiring such an affirmative statement is burdensome on plans because the plan should know whether it relied on a rule or guideline in denying a claim.

Finally, the existing Section 503 regulation already requires that rules, guidelines, protocols, standards or other similar criteria that were relied on in denying the claim must be disclosed to claimants on request. Nothing in the current regulation allows a plan fiduciary to decline to comply with that requirement based on an assertion that the information is proprietary or confidential. Indeed, the Department 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 FAQs About The Benefit Claims Procedure Regulation, C-17 (www.dol.gov/sites/default/files/ ebsa/about-ebsa/our-activities/ programs-and-initiatives/outreach-andeducation/hbec/CAGHDP.pdf).15

Similarly, this final rule does not permit a plan to conceal such information from the claimant under an assertion that the information is proprietary or constitutes confidential business information.

The third new disclosure requirement, set forth in paragraph (g)(1)(vii)(C) of the proposal, adds a requirement that an adverse benefit determination at the initial claims stage must include a statement that the claimant is entitled to receive, upon request, documents relevant to the claim for benefits. Although the current Section 503 Regulation provides that claimants challenging an initial denial of a claim have a right to request relevant documents, a statement advising claimants of their right to relevant documents currently is required only in notices of an adverse benefit determination on appeal. No commenters objected to the addition of this statement to the adverse benefit determination at the initial claims stage. The Department believes such a statement in the initial denial notice simply confirms rights claimants already have under the current claims regulation and will help ensure claimants understand their right of access to the information needed to understand the reasons for the denial and decide whether and how they may challenge the denial on appeal. Accordingly, this provision was adopted without change in the final rule.

3. Right To Review and Respond to New Information Before Final Decision

The Department continues to believe that a full and fair review requires that claimants have a right to review and respond to new evidence or rationales developed by the plan during the pendency of the appeal and have the opportunity to fully and fairly present his or her case at the administrative appeal level, as opposed merely to having a right to review such information on request only after the claim has already been denied on appeal. Accordingly, the final rule adopts those provisions of the proposal with certain modifications described below.

Paragraph (h)(4) of the final rule, consistent with the proposal, requires that plans provide claimants, free of charge, with new or additional evidence considered, relied upon, or generated by the plan, insurer, or other person making the benefit determination (or at the direction of the plan, insurer or such

other person) during the pendency of the appeal in connection with the claim. Consistent with the proposal, paragraph (h)(4) also provides a similar disclosure requirement for an adverse benefit determination based on a new or additional rationale. The evidence or rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to address the evidence or rationale prior to that date. These requirements already apply to claims involving group health benefits under the ACA Claims and Appeals Final Rule. Further, the Department has interpreted ERISA section 503 and the current Section 503 Regulation as already requiring that plans provide claimants with new or additional evidence or rationales upon request and provide them an opportunity to respond in at least certain circumstances. 16

The objective of these provisions is to ensure the claimant's ability to obtain a full and fair review of denied disability claims by explicitly providing that claimants have a right to review and respond to new or additional evidence or rationales developed by the plan during the pendency of the appeal, as opposed merely to having a right to such information on request only after the claim has already been denied on appeal, as some courts have held under the Section 503 Regulation. These protections are direct imports from the ACA Claims and Appeals Final Rule, and they would correct procedural problems evidenced in litigation even predating the ACA.¹⁷ It was and continues to be the view of the Department that claimants are deprived of a full and fair review, as required by

¹⁵ FAQ C-17 states: "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 $\S 2560.503-1(g)(v)$ (A) and (j)(5)(i); 65 FR at 70251. Also see $\S 2560.503-1(h)(2)(iii)$ and 2560.503-1(m)(8)(i); Advisory Opinion 96–14A (July 31, 1996).

¹⁶ As a practical matter, these requirements to provide claimants with evidence or rationales that were relied on or used as a basis for an adverse benefit determination largely conforms the rule to the existing process by which benefits claims should be handled in such cases. E.g., Saffon v. Wells Fargo & Co. Long Term Disability Plan, 511 F.3d 1206, 1215 (9th Cir. 2008) (finding that a full and fair review requires a plan administrator to disclose the reasons for denial in the administrative process); 75 FR at 43333 n.7 (noting the DOL's position that the existing claims procedure regulation already requires plans to provide claimants with new or additional evidence or rationale upon request and an opportunity to respond in certain circumstances)

¹⁷ See, e.g., Metzger v. Unum Life Ins. Co. of America, 476 F.3d 1161, 1165–67 (10th Cir. 2007) (holding that "subsection (h)(2)(iii) does not require a plan administrator to provide a claimant with access to the medical opinion reports of appeallevel reviewers prior to a final decision on appeal."). Accord Glazer v. Reliance Standard Life Ins. Co., 524 F.3d 1241 (11th Cir. 2008); Midgett v. Washington Group Int'l Long Term Disability Plan, 561 F.3d 887 (8th Cir. 2009).

section 503 of ERISA, when they are prevented from responding, at the administrative stage level, to all evidence and rationales.¹⁸

As an example of how these new provisions would work, assume the plan denies a claim at the initial stage based on a medical report generated by the plan administrator. Also assume the claimant appeals the adverse benefit determination and, during the 45-day period the plan has to make its decision on appeal, the plan administrator causes a new medical report to be generated. The proposal and the final rule would require the plan to automatically furnish to the claimant any new or additional evidence in the second report. The obligation applies to any new or additional evidence, including, in particular, evidence that may support granting the claim. The plan would have to furnish the new or additional evidence to the claimant before the expiration of the 45-day period. The evidence would have to be furnished as soon as possible and sufficiently in advance of the applicable deadline (including an extension if available) in order to give the claimant a reasonable opportunity to address the new or additional evidence. The plan would be required to consider any response from the claimant. If the claimant's response happened to cause the plan to generate a third medical report containing new or additional evidence, the plan would have to automatically furnish to the claimant any new or additional evidence in the third report. The new or additional evidence would have to be furnished as soon as possible and sufficiently in advance of the applicable deadline to allow the claimant a reasonable opportunity to respond to the new or additional evidence in the third report.

Several commenters asked for clarification regarding the application of the rights in paragraph (h)(4)(i) of the proposal which would have required that the plan's claims procedures must allow a claimant to review the claim file and to present evidence and testimony as part of the "disability benefit *claims* and appeals process." The commenters noted that, although subsection (h) deals with the appeals portion of the claim process, use of the phrase "claims and appeals process" could cause confusion as to whether the requirements of that subsection are intended to apply only to the appeals portion of the process or also to the initial stage of the claim

process. Those commenters also suggested that this provision be deleted in its entirety because it was redundant and unnecessary. They pointed out that paragraph (g)(1)(vii)(C) of the proposal already added a requirement that claimants be notified as part of a denial at the initial claims stage of their right to review copies of documents and other information relevant to the claim for benefits. They pointed to the definition of "relevant" in the current regulation at paragraph (m)(8), which includes documents, records or other information that were relied upon in making the benefit determination, submitted, considered or generated in the course of making the benefit determination, demonstrates compliance with the certain administrative safeguards and requirements required under the regulation, or constitutes a statement of policy or guidance with respect to the plan concerning a denied treatment option or benefit or the claimant's diagnosis. The commenters also noted that paragraph (h)(2)(ii) of the regulation currently gives claimants the right to "submit written comments, documents, records, and other information" as part of an initial claim. Consequently, they asserted that a provision stating that they can also submit "evidence" and "testimony" does not appear to add to the current requirements.

The text in paragraph (h)(4)(i) was intended to parallel text in the regulation for group health plans under the ACA Claims and Appeals Final Rule. The ACA Claims and Appeals Final Rule specifically addressed rights to review and respond to new or additional evidence or rationales during the appeal stage. The Department agrees with the commenters that the provision is intended to be limited to the appeal stage. The Department also agrees that the new text in proposed paragraph (h)(4)(i) on rights to review the claims file and to present evidence is unnecessary in the disability claims procedure regulation because those rights already exist under the current Section 503 regulation. Accordingly, because that provision in the proposal would not have added new substantive requirements, the Department has deleted the provision from the final rule. In light of the deletion of proposed paragraph (h)(4)(i) from the final rule, the definition in the proposal of "claim file" is also unnecessary, and, accordingly, the Department is not including that definitional provision in the final rule. The changes from the proposal should not be viewed, however, as in any way restricting claimant's rights to documents, records,

or other information under the regulation, or to restrict claimant's rights to present evidence. For example, in the Department's view, if the plan or claims adjudicator maintains a claims file or other similar compilation of documents, records, and other information, such a file by definition would constitute relevant materials and be subject to mandatory disclosure under the final rule.

In response to the paragraph (h)(4)(i) as drafted in the proposal, several commenters expressed concern that some plans would have read the language as imposing courtroom evidentiary standards for claimants submitting proof of their claim. Others expressed concern about a statement in the proposal's preamble that referenced "written" testimony because they thought some plans might rely on that reference to prohibit claimants from submitting audio or video evidence. The Department did not intend that the provision be read to limit the types of evidence that claimants can submit or otherwise put claimants in a worse position than they face under the current regulation. For example, the Department does not believe that plans could refuse to accept evidence submitted in the form of video, audio or other electronic media. Further, in the Department's view, even under the current regulation, it would not be permissible for a plan to impose courtroom evidentiary standards in determining whether the plan will accept or consider information or materials submitted by a claimant.

Several commenters argued that giving claimants new or additional evidence or rationales developed during the pendency of the appeal and requiring plans to consider and address claimant submissions regarding the new or additional evidence or rationale would set up an unnecessary cycle of review and re-review leading to delay and increased costs. The Department is not persuaded by this argument. The requirement conforms the disability claims regulation to the group health plan claims process requirements under the ACA Claims and Appeals Final Rule. Granting both parties (the claimant and the plan) the opportunity to address the other side's evidence has not resulted in an endless loop of submissions in group health claims under the ACA Claims and Appeals Final Rule, and there is no reason to believe that this would occur in the disability claims administrative process. The Department also has previously stated its view that the supposed "endless loop" is necessarily limited by claimants' ability to generate new or

¹⁸ Brief of the Secretary of Labor, Hilda L. Solis, as Amicus Curiae in Support of Plaintiff-Appellant's Petition for Rehearing, Midgett v. Washington Group Int'l Long Term Disability Plan, 561 F.3d 887 (8th Cir. 2009) (No. 08–2523).

additional evidence requiring further review by the plan. Such submissions ordinarily become repetitive in short order, and are further circumscribed by the limited financial resources of most claimants. If a claimant's assertions do not include new factual information or medical diagnoses, a plan need not generate report after report rather than relying on the reports it already has in hand merely because a claimant objects to or disagrees with the evidence or rationale. The process also necessarily resolves itself when the plan decides it has enough evidence to properly decide the claim and does not generate new or additional evidence or rationales to support its decision. 19 The fiduciary obligation to pay benefits in accordance with the terms of the plan does not require a fiduciary to endlessly rebut credible evidence supplied by a claimant that, if accepted, would be sufficient to justify granting the claim. In fact, an aggressive claims processing practice of routinely rejecting or seeking to undermine credible evidence supplied by a claimant raises questions about whether a fiduciary, especially one operating under a conflict of interest, is violating the fiduciary's loyalty obligation under ERISA to act solely in the interest of the plan's participants and beneficiaries.

Several commenters complained about the possibility of claimants arguing that plans failed to comply with the claims procedure whenever any additional evidence was relied on to support a rationale that was already used as a basis for denying a claim. They expressed similar concerns about determining whether a rationale relied on in denying a claim on review was a "new" or "additional" rationale. They asked the Department to include in the final rule a definition of what constitutes "new or additional" evidence or a "new or additional" rationale. They asserted that the rule might be read to permit a claimant to receive and rebut medical opinion reports generated in the course of an administrative appeal, even when those reports contain no new factual information and deny benefits on the same basis as the initial decision.

The Department does not believe it is necessary or appropriate to include definitions of the terms "new evidence" or "new rationale" in the final rule. Those same terms exist in the parallel claims procedure requirement applicable to group health plans under

the ACA Claims and Appeals Final Rule, and have been part of the claims procedure requirements for those plans for several years. The Department does, however, intend that the terms be applied broadly so that claimants have the opportunity to respond at the administrative stage level to all evidence and rationales. Many federal courts have held that in reviewing a plan administrator's decision for abuse of discretion, the courts are limited to the "administrative record"—the materials compiled by the administrator in the course of making his or her decision. See Miller v. United Welfare Fund, 72 F.3d 1066, 1071 (2d Cir.1995) (compiling cases and stating that "[m]ost circuits have declared that, in reviewing decisions of plan fiduciaries under the arbitrary and capricious standard, district courts may consider only the evidence that the fiduciaries themselves considered"). While some courts have held that when conducting a de novo review, any party may be free to submit additional evidence outside the administrative record, 20 most circuits have adopted rules allowing the admission of additional evidence in de novo cases only in limited circumstances. In addition to requiring the deciding fiduciary to consider the claimant's response to new or additional evidence or rationales, the Department believes it is important that the claimant have the right and opportunity to ensure that a full administrative record is before a reviewing court when new or additional evidence or rationales are introduced into the record by the plan or deciding fiduciary.²¹

The Department requested comments on whether, and to what extent, modifications to the existing timing rules are needed to ensure that disability benefit claimants and plans will have ample time to engage in the back-and-forth dialogue that is contemplated by these new review and response rights. The current Section 503

Regulation requires that the plan must decide claims and appeals within a reasonable period, taking into account all circumstances. The following timeframes reflect the maximum period by which a plan must make a determination: (1) Initial claim: 45 days after submission; additional 30 days with prior notice for circumstances beyond control of the plan; and (2) Appeal: 45 days after receipt of appeal; additional 45 days with prior notice for "special circumstances." A special deadline for deciding appeals applies when the named fiduciary is a board or committee of a multiemployer plan that meets at least quarterly. The Department received several comments with suggestions on possible new timing requirements for the claimant to respond to the new evidence and a time deadline for the claims administrator to make its final decision. Other commenters asserted that the current regulations are sufficient for the needs of consumers covered under this final regulation and provide "ample" time for plans and claimants to engage in the necessary dialogue. One commenter raised an issue concerning this rule and its impact on the prompt administration of disability claims. The commenter described, by way of example, that the plan would have to send claimants new or additional evidence before the plan may have determined whether and how the evidence may contribute to an adverse appeal decision, claimants would receive new or additional evidence piecemeal as the appeals process continues and claimants could be required to provide comments back without necessarily knowing how that information may, if at all, affect the decision. The Department does not believe that the rule envisions this kind of process. This provision by its terms does not apply if a plan grants the claim on appeal. Instead, when the plan has decided that it is going to deny the claim on appeal, that is the point at which the rule requires new or additional evidence must be provided to the claimant, sufficiently in advance of final decision so that the claimant can address such evidence. The provision does not require that the plan provide the claimant with information in a piecemeal fashion without knowing whether, and if so how, that information may affect the decision.

The Department noted in the preamble to the proposal that the group health plan claims regulation provides that if the new or additional evidence or rationale is received by a plan so late that it would be impossible to provide it to the claimant in time for the

¹⁹ Brief of the Secretary of Labor, Hilda L. Solis, as Amicus Curiae in Support of Plaintiff-Appellant's Petition for Rehearing, Midgett v. Washington Group Int'l Long Term Disability Plan, 561 F.3d 887 (8th Cir. 2009) (No. 08–2523), p. 13.

²⁰ See Moon v. Am. Home Assurance Co., 888 F.2d 86, 89 (11th Cir.1989).

 $^{^{21}}$ Some commenters suggested that the Department define "new or additional evidence" to 'new and additional medical reviews, including independent medical reports." As noted above, these requirements already apply to claims involving group health benefits under the ACA Claims and Appeals Final Rule and we do not think that it is appropriate to restrict this rule to medical reviews since other types of evidence, if new, would clearly need to be provided to claimants to ensure the full and fair review as described above. For example, if a plan were to obtain video evidence of a disability benefit claimant during the pendency of the appeal, but only provide the claimant with a portion of that video evidence, e.g., the portion that supports the denial of benefits, while withholding the portions that favor the claimant, that would be a failure by the plan to provide new evidence developed to the claimant.

claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. The Department did not include this special tolling provision in the proposed amendments because the current disability claims regulation, as described above, already permits plans to take extensions at the appeals stage. In the Department's view, the current disability claims regulation "special circumstances" provision permits the extension and tolling expressly added to the group health plan rule under the ACA Claims and Appeals Final Rule. 22 Although the Department is not including special timing provisions in the final rule, the Department is open to considering comments on whether subregulatory guidance regarding the current provisions on extensions and tolling would be helpful in the context of the new review and response rights.

Commenters asked the Department to confirm that a plan could satisfy the new review and response requirements through a current procedure, which was described as "universal and a result of established case law." Specifically the commenters stated that some plans currently provide claimants with a voluntary opportunity to appeal any rationale raised for the first time in an appeal denial letter. They contended that this process works well because it gives the claimant a choice of whether to appeal and supplement the administrative record based on a challenge to the new evidence or rationale. They also asserted that the procedure would address commenters' concern that this requirement may conflict with claims administrator's obligation to meet the requisite time requirements for deciding claims and appeals. In fact, a few other commenters specifically asked that the new requirement not apply to plans that currently offer a voluntary additional

level of appeal. The Department does not agree that a voluntary additional level of appeal provides the same rights to claimants because the additional level of appeal is not subject to the rule's provisions on timing of notification of benefit determinations on appeal. In the Department's view, it would not be appropriate to condition a claimant's right to review and respond to new evidence on the claimant effectively being required to give up rights to a timely review and decision at the appeal stage.

Finally, the Department's experience enforcing the current regulation for group health plans has revealed circumstances where claims adjudicators assert that they are satisfying this requirement by providing claimants with a notice informing them that the plan relied on new or additional evidence or a new or additional rationale in denying the claim, and offering to provide the new evidence or rationale on request. As the Department explained in the preamble to the ACA Claims and Appeals Final Rule for group health plans,²³ in order to comply with this requirement, a plan or issuer must send the new or additional evidence or rationale automatically to the claimant as soon as it becomes available to the plan. Merely sending a notice informing claimants of the availability of such information fails to satisfy the requirement, and if a plan's claims procedure says the plan will send a notice of the availability of such information, the responsible plan fiduciary similarly would fail to have met the requirement under ERISA section 503 for the plan to establish and

maintain a reasonable procedure governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefit determinations.

4. Deemed Exhaustion of Claims and Appeals Processes

The final rule tracks the proposal and provides that if a plan fails to adhere to all the requirements in the claims procedure regulation, the claimant would be deemed to have exhausted administrative remedies, with a limited exception where the violation was (i) de minimis; (ii) non-prejudicial; (iii) attributable to good cause or matters beyond the plan's control; (iv) in the context of an ongoing good-faith exchange of information; and (v) not reflective of a pattern or practice of noncompliance. The rule thus mirrors the existing standard applicable to group health plans under the ACA Claims and Appeals Final Rule and is stricter than a mere "substantial compliance"

requirement.

The Department received a number of generally favorable comments regarding the deemed exhaustion provisions in paragraphs (l)(1) and (2) of the proposal. Those commenters argued that claimants should not have to follow a claims and appeals process that is less than full, fair, and timely. Some of those commenters expressed concern that the language in proposed paragraph (l)(2)(i) was potentially inconsistent with language in the preamble. The commenters noted that the preamble stated that "in those situations when the minor errors exception does not apply, the proposal clarifies that the reviewing tribunal should not give special deference to the plan's decision, but rather should review the dispute de novo." By contrast, they point out that proposeď paragraph (l)(2)(i) provides that "[i]f a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary." According to the commenters, plans could argue that the language in proposed paragraph (1)(2)(i) does not go far enough and suggested that the regulation should expressly require de novo review.

The Department does not intend to establish a general rule regarding the level of deference that a reviewing court may choose to give a fiduciary's decision interpreting benefit provisions in the plan's governing documents. However, the cases reviewing a plan fiduciary's decision under a deferential arbitrary or capricious standard are

based on the idea that the plan

²² In connection with the ACA Claims and Appeals Final Rule, the Department explained the process as follows: "To address the narrow circumstance raised by some comments that the new or additional information could be first received so late that it would be impossible to provide it, these final regulations provide that if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan or issuer must notify the claimant of the benefit determination as soon as a plan or issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies."

²³ That rulemaking notice (at 80 FR 72207) included the following explanation in responding to public comments on that rule: "Commenters requested additional guidance related to the timing and amount of information required to be provided in order to satisfy this requirement. Specifically, individuals asked whether such information actually must be provided automatically to participants and whether or not it would be sufficient to send participants a notice informing them of the availability of new or additional evidence or rationale. The Departments retain the requirement that plans and issuers provide the new or additional evidence or rationale automatically. In the Departments' view, fundamental fairness requires that participants and beneficiaries have an opportunity to rebut or respond to any new or additional evidence upon which a plan or issuer may rely. Therefore, plans and issuers that wish to rely on any new or additional evidence or rationale in making a benefit determination must send such new or additional evidence or rationale to participants as soon as it becomes available to the plan or issuer. In order to comply with this requirement, a plan or issuer must send the new or additional evidence or rationale to the participant. Merely sending a notice informing participants of the availability of such information fails to satisfy this requirement." This same explanation applies with equal force to the identical requirement in this final rule applicable to disability benefit claims.

documents give the fiduciary discretionary authority to interpret the plan documents. By providing that the claim is deemed denied without the exercise of fiduciary discretion, the regulation relies on the regulatory authority granted the Department in ERISA sections 503 and 505 and is intended to define what constitutes a denial of a claim. The legal effect of the definition may be that a court would conclude that de novo review is appropriate because of the regulation that determines as a matter of law that no fiduciary discretion was exercised in denying the claim.

A number of commenters expressed concern with proposed paragraph (l)(2)(i), arguing that the proposal encourages claimants to circumvent a plan's claims and appeals process, to seek remedies in court in the case of insignificant missteps in claims management practices that have no impact on claim outcomes, and, therefore, will result in increased litigation. One commenter asked that the proposal be deleted. A few commenters suggested alternative approaches to the proposal. For example, they suggested that the Department consider a rule which first requires claimants to notify the plan that they intend to pursue judicial review based upon the plan's procedural error, and provide plans with a reasonable period of time to cure the error before the claimant can dispense with further administrative review. The Department does not believe that the typical participant pursuing a disability benefit claim in the context of a fair and timely review process will, as the commenters claimed, seek remedies in court in the case of insignificant missteps in claims management processes that have no impact on the ultimate decision on the claim. Further, the Department does not believe it would be appropriate to create a rule that could create incentives for plans and insurers to violate procedural requirements designed to protect claimants and ensure transparency in the decision-making process knowing that before the claimant could seek redress that the claimant would have to identify the violation, notify the plan of the violation, and give the plan time to cure the error. Rather, after careful consideration of these comments, the Department continues to believe that claimants should not have to follow a claims and appeals process that is less than full, fair, and timely. Accordingly, the Department decided to retain the deemed exhaustion provisions as proposed, including the exception to the strict compliance standard for errors that are minor and that meet certain other specified conditions.²⁴

5. Coverage Rescissions—Adverse Benefit Determinations

Paragraph (m)(4) of the final rule amends the definition of an adverse benefit determination to include, for plans providing disability benefits, a rescission of disability benefit coverage that has a retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage. The Department did not receive any comments objecting to this provision in the proposed rule, and, accordingly, the provision is adopted without change in the final rule.

Several commenters suggested that the provision be expanded to expressly include situations, particularly in cases involving mental health and substance use disorder claims, where a plan approves treatment for a period less than that requested, but defers the right to appeal until the date the approved benefits end. The Department did not make such a modification to paragraph (m)(4) in the final rule because the Department does not agree that such cases should be addressed as rescissions.

Rather, it appears that the commenters were making a more general point that the claims procedure regulation should expressly define an adverse benefit determination to include instances in which such a limitation is invoked. In that regard, the current regulation provides that the term "adverse benefit determination" includes any denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit. The Department issued a set of FAQs under the current regulation explaining the application of that definition to various situations. One FAQ stated that if 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. Rather, the Department concluded that any request by a

claimant for payment of disability benefits beyond the specified period would constitute a new claim.25 Another FAQ, however, addressed the different situation where the plan pays less than the total amount of expenses submitted with regard to a post-service claim. We explained that, 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, that decision is required to be treated as an adverse benefit determination under the regulation.²⁶ Whether the situation presented by the commenters should be treated more like the former or latter FAQ will depend on the terms of the plan and the particular facts and circumstances.

One commenter asked whether the proposed rule regarding rescissions of coverage applies to adjustments or suspensions of benefits that reduce or eliminate a disability pension benefit under section 305 of ERISA, which corresponds to section 432 of the Internal Revenue Code of 1986 (Code). It is the Department's view that a retroactive reduction or elimination of disability pension benefits pursuant to section 305 of ERISA is not a rescission of coverage under paragraph (m)(4)(ii) of the final rule. However, a retroactive reduction or elimination of disability pension benefits, that results from a finding by the plan that the claimant was not disabled within the meaning of the plan when the disability pension benefits were reduced or eliminated under ERISA section 305, would be an adverse benefit determination under the claims procedure regulation. 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 Section 503 Regulation.²⁷

²⁴ The provisions in this final rule supersede any and all prior Departmental guidance with respect to disability benefit claims to the extent such guidance is contrary to this final rule, including but not limited to the deemed exhaustion discussion in FAQ F–2 in FAQs About The Benefit Claims Procedure Regulation. (www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/programs-and-initiatives/outreach-and-education/hbec/CAGHDP.pdf).

²⁵ See FAQs About The Benefit Claims Procedure Regulation, C–18 (www.dol.gov/sites/default/files/ ebsa/about-ebsa/our-activities/programs-andinitiatives/outreach-and-education/hbec/ CAGHDP.pdf).

²⁶ See FAQs About The Benefit Claims Procedure Regulation, C–12 (www.dol.gov/sites/default/files/ ebsa/about-ebsa/our-activities/programs-andinitiatives/outreach-and-education/hbec/ CAGHDP.pdf).

²⁷ See footnote 3, supra, and FAQs About The Benefit Claims Procedure Regulation, A–9 (www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/programs-and-initiatives/outreach-and-education/hbec/CAGHDP.pdf) discussing when a benefit is a disability benefit, subject to the special rules for disability claims under the Section 503 Regulation.

6. Culturally & Linguistically Appropriate Notices

Paragraphs (g)(1)(vii)(C), (j)(7) and (o) of the final rule require plans to provide notice to claimants in a culturally and linguistically appropriate manner. The final rule adopts the standards already applicable to group health plans under the ACA Claims and Appeals Final Rule. Specifically, if a claimant's address is in a county where ten percent or more of the population residing in that county are literate only in the same non-English language as determined in guidance based on American Community Survey data published by the United States Census Bureau, notices of adverse benefit determinations to the claimant would have to include a statement prominently displayed in the applicable non-English language clearly indicating how to access language services provided by the plan. In addition, plans must provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request.28

À few commenters requested clarification that the culturally and linguistically appropriate standards (CLAS) requirements in the regulation apply only to notices of adverse benefit determinations and not to other communications regarding disability claims. In the Department's view, the text of paragraphs (g)(1)(vii)(C) and (j)(7) is clear that the CLAS requirements are applicable to notices of adverse benefit determinations. The final rule does not address whether, and under what circumstances, the fiduciary duty or other provisions in ERISA would require plans to provide plan participants and beneficiaries with access to language services (see, for example, the discussion below regarding summary plan description (SPD) requirements).

A few commenters requested that the Department remove the CLAS standards. Other commenters supported the CLAS requirements but requested that the Department provide a reasonable time for compliance with this provision, citing operational changes and costs associated with the CLAS requirements. Other commenters requested that the threshold percentage

that triggers the CLAS requirements be reduced to a lower percentage to capture a greater number of counties or to reflect a percentage of plan participants as opposed to the population of a relevant county. One commenter suggested that the Department may have unintentionally reduced protections for non-English speaking participants. The commenter pointed out that although a particular county may not meet the threshold under this rule, particular workforces may meet the Department's thresholds under section § 2520.102–2(c).

In light of all the comments received, this final rule retains the CLAS requirements as set forth in the proposal. The Department believes that the CLAS requirements impose reasonable language access requirements on plans and appropriately balance the objective of protecting claimants by providing reasonable language assistance to individuals who communicate in languages other than English with the goal of mitigating administrative burdens on plans. The Department continues to believe that it is important to provide claims denial notices in a culturally and linguistically appropriate manner to ensure that individuals get the important information needed to properly evaluate the decision denying a claim and to allow for an informed decision on options for seeking review of a denial. Therefore, the final rule adopts the requirements in the proposal without change.

The Department does not agree that the final rule supersedes the summary plan description foreign language rules in § 2520.102–2(c) which include a requirement to offer assistance (which could include language services) calculated to provide participants with a reasonable opportunity to become informed as to their rights and obligations under the plan. Non-English speaking participants could be eligible for language services under either this final rule or § 2520.102–2(c), depending on the circumstances.

Finally, one commenter asked that the Department clarify that the English version of the notices takes precedence in the event of any conflict with the translated documents. Another commenter asked for clarification that the requirement to provide "assistance with filing claims and appeals in any applicable non-English language" is limited to procedural, not substantive, assistance. The Department was not persuaded that including such provisions in the final rule is necessary or appropriate. Notices provided to participants or beneficiaries should be

complete and accurate notwithstanding the language used. Further, a "substantive versus procedural" distinction between the type of assistance required is not, in the Department's view, particularly meaningful or helpful. Rather, the final rule requires plan fiduciaries to provide disability benefit claimants with the requisite level and amount of assistance necessary to assist the claimants in understanding their rights and obligations so that they can effectively file claims and appeals in pursuing a claim for disability benefits.

7. Miscellaneous

a. Technical Correction

The Department determined that a minor technical fix to the Section 503 Regulation is required with respect to disability claims. The Department proposed to clarify that the extended time frames for deciding disability claims, provided by the quarterly meeting rule found in the current regulation at 29 CFR 2560.503-1(i)(1)(ii), are applicable only to multiemployer plans. The Department did not receive any adverse comments on the proposed technical fix, and, accordingly, the final rule amends paragraph (i)(3) to correctly refer to the appropriate subparagraph in (i)(1) of the Section 503 Regulation.

b. Contractual Limitations Periods for Challenging Benefit Denials

In the proposal, the Department asked for comments on whether the claims procedure rule should address limitations periods in plans that govern the period after a final adverse benefit determination within which a civil action may be filed under section 502(a)(1)(B) of ERISA. We pointed out that ERISA does not specify that period and noted that the federal courts have generally looked to analogous state laws to determine an appropriate limitations period. Analogous state law limitations periods vary, but they generally start with the same event, the plan's final benefit determination. We acknowledged that the Supreme Court recently upheld the use of contractual limitations periods in plan documents and insurance contracts which may override analogous state laws so long as they are reasonable. See Heimeshoff v. Hartford Life & Accident Ins. Co., 134 S.Ct. 604, 611 (2013). We pointed out that contractual limitations periods are not uniform, the events that trigger the clock vary, and the documents in which the limitations periods are embedded may be difficult for claimants to obtain and understand. We also highlighted a

²⁸ Each year the U.S. Census Bureau publishes a list of counties that meet the 10% threshold. For 2016, the applicable languages are Chinese, Tagalog, Navajo and Spanish. A complete list of counties is available at www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/foremployers-and-advisers/internal-claims-and-appeals.

separate issue, not before the Supreme Court in *Heimeshoff*, of whether plans must provide participants notice with respect to contractual limitations periods in adverse benefit determinations on review. Although many federal courts have held that plans should provide such notice under the Section 503 Regulation, the court decisions are not uniform.²⁹

²⁹ See Moyer v. Metropolitan Life Ins. Co., 762 F.3d 503, 505 (6th Cir. 2014) ("The claimant's right to bring a civil action is expressly included as a part of those procedures for which applicable time limits must be provided" in the notice of adverse benefit determination on review) and Kienstra v. Carpenters' Health & Welfare Trust Fund of St. Louis, 2014 WL 562557, at *4 (E.D. Mo. Feb. 13, 2014), aff'd sub nom. Munro-Kienstra v. Carpenters' Health & Welfare Trust Fund of St. Louis, 790 F.3d 799 (8th Cir. 2015) ("an adverse benefit determination must include [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 [ERISA] following an adverse benefit determination on review."); Ortega Candelaria v. Orthobiologics LLC, 661 F.3d 675, 680 (1st Cir.2011) ("[The employer] was required by [29 CFR 2560.503–1(g)(1)(iv)] to provide [the employee] with notice of his right to bring suit under ERISA, and the time frame for doing so, when it denied his request for benefits."); McGowan v. New Orleans Empl'rs Int'l Longshoremen's Ass'n, 538 F. App'x 495, 498 (5th Cir.2013) (finding that a benefit termination letter substantially complied with 29 CFR 2560.503-1(g)(1)(iv) because, in addition to enclosing the benefit booklet and specifying the pages containing the review procedures and time limits, the letter "mentioned McGowan's right to file suit under § 502(a) of ERISA, as well as the one-year time limit"); White v. Sun Life Assurance Co. of Canada, 488 F.3d 240, 247 n. 2 (4th Cir.2007) (emphasizing that the right to bring a civil action is an integral part of a full and fair benefit review and that the adverse benefit determination letter must include the relevant information related to that right) (abrogated on other grounds by Heimeshoff v. Hartford Life & Acc. Ins. Co., 134 S.Ct. 604, 612 (2013)); Novick v. Metropolitan Life Ins. Co., 764 F.Supp.2d 653, 660-64 (S.D.N.Y.2011) (concluding that 29 CFR 2560.503-1(g) requires that the adverse benefit determination letter include the time limits for judicial review); Solien v. Raytheon Long Term Disability Plan # 590, 2008 WL 2323915, at 8 (D.Ariz. June 2, 2008) (holding that "[j]udicial review is an appeal procedure for an adverse benefit determination and is therefore a part of the claim procedures covered by these regulations, especially when the time limit for filing a judicial action is established contractually by the Plan"). But see Wilson v. Standard Ins. Co., 613 F. App'x 841, 844 n.3 (11th Cir. 2015) (unpublished) (finding that 29 CFR 2560.503–1(g)(1)(iv) "can also be reasonably read to mean that notice must be given of the time limits applicable to the 'plan's review procedures,' and the letter must also inform the claimant of her right to bring a civil action without requiring notice of the time period for doing so"); Scharff v Raytheon Co. Short Term Disability Plan, 581 F.3d 899, 907-08 (9th Cir. 2009) (declining to supplement ERISA's comprehensive scheme for regulating disclosures to participants with a California law requiring the express disclosure of a statute of limitations). In an unpublished decision, the Tenth Circuit similarly interpreted language in a plan that was virtually identical to section 2560.503-1(g)(1)(iv) as only requiring denial letters to include time limits applicable to internal review procedures. See Young v. United Parcel Services, 416 F. App'x 734, 740 (10th Cir. 2011)

Accordingly, the Department solicited comments on whether the final regulation should require plans to provide claimants with a clear and prominent statement of any applicable contractual limitations period and its expiration date for the claim at issue in the final notice of adverse benefit determination on appeal and with an updated notice of that expiration date if tolling or some other event causes that date to change.

In response, the Department received many comments from claimants and participant advocates supporting a contractual limitations period notice requirement. Numerous commenters further requested that any required notice include the date on which the relevant contractual limitations period expires. They also asked the Department to include a definition of a "reasonable limitations period." One commenter argued to the contrary that a rule requiring inclusion of a specific date would create confusion for claimants and carries a risk that the insurer or other administrative entity is seen as providing legal advice. Another commenter urged that such a rule should not be adopted because the date by which suit must be filed may be subject to dispute in litigation. A commenter expressed concern that such a notice requirement is largely unnecessary as the information is generally already included in plan documents, (e.g., the summary plan description), and that it could impose significant administrative burden. The commenter suggested that a more appropriate rule would be to require that the notice of adverse benefit determination on review include a statement alerting participants that they should review the terms of the applicable plan documents to determine any deadline by which they must file a civil action. Finally, a number of commenters asked the Department to specifically address whether it is allowable for a contractual limitations period to be structured so that it could actually expire before the plan's appeals process is completed.

In light of the issues identified regarding contractual limitations periods, the Department concluded that it was appropriate in this final rule to address certain basic points.

First, section 503 of ERISA requires that a plan afford a reasonable opportunity to any participant whose claim for benefits has been denied for a

(unpublished) (concluding that requiring a notification of the time limit for filing suit "conflates the internal appeals process, and its associated deadlines, with the filing of a legal action after that process has been fully exhausted").

full and fair review of that decision by an appropriate named fiduciary. The Department does not believe that a claims procedure would satisfy the statutory requirement if the plan included a contractual limitations period that expired before the review was concluded. In the Department's view, this is clear from the Supreme Court's holding in *Heimeshoff*. In that case, the Supreme Court held that an ERISA disability plan's three-year limitations period, running from the date of proof of loss, was enforceable even though the statute of limitations began to run before the participant's cause of action accrued. The Court pointed out that there was nothing to suggest the 3-year contractual limitations period was not "reasonable" in light of the Department's regulation that would require the internal claims and appeals process to be completed well inside a three-year period. Heimeshoff, 134 S.Ct. at 612 (citing Order of United Commercial Travelers of America v. Wolfe, 67 S.Ct. 1355 (1947)). A limitations period that expires before the conclusion of the plan's internal appeals process on its face violates ERISA section 503's requirement of a full and fair review process. A process that effectively requires the claimant to forego the right to judicial review and thereby insulates the administrator from impartial judicial review falls far short of the statutory fairness standard and undermines the claims administrator's incentives to decide claims correctly.

Further, in rejecting the challenge to the contractual limitations period at issue in *Heimeshoff*, the Court emphasized that the claimant was allowed a year or more to bring suit after the close of the internal claims review process. ³⁰ A contractual limitations period that does not allow such a reasonable period after the conclusion of the appeal in which to bring a lawsuit is unenforceable. ³¹ Moreover, as the

³⁰ Heimeshoff, 134 S.Ct. at 612 ("Neither Heimeshoff nor the United States claims that the Plan's 3-year limitations provision is unreasonably short on its face. And with good reason: the United States acknowledges that the regulations governing internal review mean for 'mainstream' claims to be resolved in about one year, Tr. of Oral Arg. 22, leaving the participant with two years to file suit. Even in this case, where the administrative review process required more time than usual, Heimeshoff was left with approximately one year in which to file suit. Heimeshoff does not dispute that a hypothetical 1-year limitations period commencing at the conclusion of internal review would be reasonable. Id., at 4") (footnote omitted).

³¹ The Department also believes that additional public input beyond the public record for this rulemaking would be needed for the Department to define a minimum period of time necessary for such a period to constitute a reasonable period in which to bring an action under ERISA section 502(a).

Supreme Court also recognized in Heimeshoff, even in cases with an otherwise enforceable contractual limitations period, traditional doctrines, such as waiver and estoppel, may apply if a plan's internal review prevents a claimant from bringing section 502(a)(1)(B) actions within the contractual period. Heimeshoff, 134 S.Ct. at 615. In addition to such traditional remedies, plans that offer appeals or dispute resolution beyond what is contemplated in the claims procedure regulations must agree to toll the limitations provision during that time. See 29 CFR 2560.503-1(c)(3)(ii).

Second, the Department agrees with the conclusion of those federal courts that have found that the current regulation fairly read requires some basic disclosure of contractual limitations periods in adverse benefit determinations. In fact, in the Department's view, the statement of the claimant's right to bring a civil action under section 502(a) of ERISA following an adverse benefit determination on review would be incomplete and potentially misleading if it failed to include limitations or restrictions in the documents governing the plan on the right to bring such a civil action. Accordingly, this final rule includes in new paragraph (j)(4)(ii) a requirement that the notice of an adverse benefit determination on review must include a description of any applicable contractual limitations period and its expiration date.

The Department is not persuaded that inclusion in the notice of adverse benefit determination on review of any applicable contractual limitations period and its expiration date will result in confusion. The Department also does not agree that a statement of the plan's view as to the exact date the limitations period expires will somehow inappropriately foreclose or otherwise prejudice legitimate arguments about application of the limitations period in individual cases. Nor does the Department believe that disclosure of a contractual limitations period requires the plan to provide legal advice. Additionally, as described below, the Department does not believe that including a description of any contractual limitations period, including the date by which the claimant must bring a lawsuit, would impose more than a minimal additional burden. Although the final rule provision is technically applicable only to disability benefit claims, as explained above, the Department believes that notices of adverse benefit determinations on review for other benefit types would be required to

include some disclosure about any applicable contractual limitations period. What would be sufficient will depend on the controlling judicial precedent and the individual facts and circumstances, but the Department would consider the inclusion of the information in paragraph (j)(4)(ii) to be an appropriate disclosure for all plan types.

Several comments raised other issues pertaining to the disclosure of contractual and statutory limitations on a claimant's right to bring a civil action under section 502(a) of ERISA. Issues beyond this final rule may be addressed in a future regulatory action or other guidance by the Department.

c. Comments Beyond the Scope of the Rulemaking

Some commenters raised disability claims procedure issues pertaining to matters that the Department considers to be beyond the scope of this rulemaking. For example, one commenter suggested that the Department amend its Model Statement of ERISA Rights for SPDs for disability plans to include notification of eligibility for language services. Other commenters requested that the Department propose a rule requiring that adverse benefit determinations on review notify disability benefit claimants of the ERISA venue provisions. Other issues raised by some commenters relate to substantive limitations on recoupment of benefit overpayments, rights to supplement the administrative record for court review, and the validity of discretionary clauses in plans that are used as a basis for seeking a deferential "arbitrary or capricious" standard for court review of benefit denials. Although the Department agrees that the issues raised by the commenters may merit an evaluation of additional regulatory actions on procedural safeguards and protections, those subjects are beyond the scope of this rulemaking. As the Department noted in the preamble to the proposal, this rulemaking was a start to improving the current standards applicable to the processing of claims and appeals for disability benefits so that they include improvements to certain basic procedural protections in the current Section 503 Regulation. Issues beyond this final rule may be addressed in a future regulatory action or other guidance by the Department.

III. Economic Impact and Paperwork Burden

A. Background and Need for Regulatory Action

As discussed in Section I of this preamble, the final amendments would revise and strengthen the current rules regarding claims and appeals applicable to ERISA-covered plans providing disability benefits primarily by adopting several of the new procedural protections and safeguards made applicable to ERISA-covered group health plans by the Affordable Care Act. Before the enactment of the ACA, group health plan sponsors and sponsors of ERISA-covered plans providing disability benefits were required to implement claims and appeal processes that complied with the Department's regulation establishing minimum requirements for benefit claims procedures for employee benefit plans covered by Title I of ERISA.³² The enactment of the ACA and the issuance of the implementing interim final regulations in 2010 resulted in disability benefit claimants receiving fewer procedural protections than group health plan participants even though disputes and litigation regarding disability benefit claims are more prevalent than health care benefit claims.³³ In order to ensure fundamental fairness in the claim and appeals procedure process, health and disability plan claimants are entitled to receive the same procedural protections as they did when the 2000 regulation was issued.

The Department believes this action is necessary to ensure that disability claimants receive a full and fair review of their claims under the more stringent procedural protections that Congress established for group health care claimants under the ACA. The final rule will promote fairness and accuracy in the claims review process and protect participants and beneficiaries in ERISAcovered disability plans by ensuring they receive benefits that otherwise might have been denied by plan administrators in the absence of the fuller protections provided by this final regulation. The final rule also will help alleviate the financial and emotional hardship suffered by many individuals when they are unable to work after becoming disabled and their claims are

As stated earlier in this preamble, this action also is necessary to correct

 $^{^{32}}$ 65 FR 70246 (Nov. 21, 2000), amended at 66 FR 35877 (July 9, 2001).

³³ See Sean M. Anderson, ERISA Benefits Litigation: An Empirical Picture, 28 ABA J. Lab. & Emp. L. 1(2012).

procedural problems evidenced in litigation under the 2000 regulation predating the ACA, which in the Department's view, resulted in claimants not receiving a full and fair review as required by ERISA section 503. Specifically, some courts held that under the 2000 regulation, claimants only have the right to review and respond to new evidence or rationales developed during the pendency of an appeal after the claim has been denied on appeal. The final rule levels the playing field by explicitly requiring plan administrators to provide claimants, free of charge, with any new evidence or rationale relied upon, considered, or generated by the plan in connection with the claim and a reasonable opportunity for the claimant to respond.

The Department disagrees with commenters' assertion that disability plan claim procedures should not mirror the ACA group health plan amendments because of the difference between health and disability claims. For reasons discussed earlier in this preamble, after careful consideration, the Department incorporated into the final rule only certain of the ACA group health plan claims procedure amendments to ensure that disability plan claimants receive the same opportunity to pursue a full and fair review of their claims as required by ERISA section 503 with the procedural safeguards and consumer protections that are aligned with those required by group health plans under the ACA and the Department's implementing

regulation at 29 CFR 2590.715-2719. This final rule aligns the disability claims procedures with the ACA procedural safeguards and consumer protections for group health plans. The Department did not amend other provisions of the 2000 regulation that affect how disability plan claims are processed or the timing requirements. Therefore, as discussed more fully below, the Department does not expect that the final rule will lead to delays and significant increased cost for disability claims and appeals processes. The Department considered comments asserting that some of its cost estimates in the proposed Regulatory Impact Analysis ("RIA") were underestimated and made adjustments where appropriate.

The Department has crafted these final regulations to secure the protections of those submitting disability benefit claims. In accordance with OMB Circular A–4, the Department has quantified the costs where possible and provided a qualitative discussion of the benefits that are associated with these final regulations.

B. Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under Executive Order 12866 (58 FR 51735), "significant" regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive 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 in any one year, 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 a 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. It has been determined that this rule is significant within the meaning of section 3(f) (4) of the Executive Order. Therefore, OMB has reviewed the final rule pursuant to the Executive Order. The Department provides an assessment of the potential costs and benefits of the final rule below, as summarized in Table 1, below. The Department concludes that the economic benefits of these final regulations justify their costs.

TABLE 1—ACCOUNTING TABLE

Category	Estimate	Year dollar	Discount rate	Period covered
Benefits—Qualitative	. The Department expects that these final regulations will impreted the procedural protections for workers who become disal and make claims for disability benefits from ERISA-covered ployee benefit plans. This would result in some participants ceiving benefits they might otherwise have been denied about the fuller protections provided by the final regulation. Grecertainty and consistency in the handling of disability berolaims and appeals and improved access to information at the manner in which claims and appeals are adjudicated will achieved. Fairness and accuracy will increase as fuller and er disability claims processes provide claimants with sufficinformation to evaluate the claims process and defend trights under their plan.			
Costs: Annualized	\$15,806,000 15,806,000	2016 2016	7% 3%	2018–2027 2018–2027

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TARLE 1—	-ACCOUNTING	TARIF—	.Continued

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Category	Estimate	Year dollar	Discount rate	Period covered		
Qualitative	The Department believes that these requirements have modest costs associated with them, since many chiefly clarify provisions of the current DOL claims procedure regulation. As discussed in detail in the cost section below, the Department quantified the costs associated with two provisions of the final regulations for which it had sufficient data: The requirements to provide (1) additional information to claimants in the appeals process and (2) information in a culturally and linguistically appropriate manner.					

1. Estimated Number of Affected Entities

The Department does not have complete data on the number of plans providing disability benefits or the total number of participants covered by such plans. ERISA-covered welfare benefit plans with more than 100 participants generally are required to file the Form 5500 Annual Return/Report. Currently, only a small number of ERISA-covered welfare benefit plans with less than 100 participants are required to file the form. Based on current trends in the establishment of pension and health plans, there are many more small plans than large plans, but the majority of participants are covered by the large plans.

Data from the 2014 Form 5500 Schedule A indicates that there are 39,135 plans reporting a code indicating they provide temporary disability benefits covering 40.1 million participants, and 26,171 plans reporting a code indicating they provide longterm disability benefits covering 22.4 million participants.34 To put the number of large and small plans in perspective, the Department estimates that there are 150,000 large group health plans and 2.1 million small group health plans using 2016 Medical Expenditure Panel Survey-Insurance Component. While most plans are small plans most participants are in large plans.

2. Benefits

In developing these final regulations, the Department closely considered their potential economic effects, including both benefits and costs. The Department does not have sufficient data to quantify the benefits associated with these final regulations due to data limitations and a lack of effective measures. Therefore, the Department provides a qualitative discussion of the benefits below.

These final regulations implement a more uniform, rigorous, and fair

disability claims and appeals process as required by ERISA section 503 that conforms to a carefully selected set of the requirements applicable to group health plans under the ACA Claims and Appeals Final Rule. In general, the Department expects that these final regulations will improve the procedural protections for disabled workers who make claims for disability benefits from ERISA-covered employee benefit plans. This will cause some participants to receive benefits that, absent the fuller protections of the regulation, they might otherwise have been incorrectly denied. In other circumstances, expenditures in the claims process incurred by plans may be reduced as a fuller and fairer system of claims and appeals processing helps facilitate participant acceptance of cost management efforts. The Department expects that greater certainty and consistency in the handling of disability benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated will lead to efficiency gains in the system, both in terms of the allocation of spending at a macro-economic level as well as operational efficiencies among individual plans. This certainty and consistency also are expected to benefit, to varying degrees, all parties within the system and lead to broader social welfare gains, particularly for disability benefit plan claimants.

The Department expects that these final regulations also will improve the efficiency of disability benefit plans by improving their transparency and fostering participants' confidence in their fairness. The enhanced disclosure and notice requirements contained in these final regulations will help ensure that benefit participants and beneficiaries have a clear understanding of the reasons underlying adverse benefit determinations and their appeal rights.

For example, the final regulations require all adverse benefit determinations to contain a discussion of the decision, including an

explanation of the basis for disagreeing with the views of a treating health care professional or vocational professional who evaluated the claimant or any disability determination regarding the claimant made by the Social Security Administration and presented to the plan by the claimant. This provision would address the confusion often experienced by claimants when there is little or no explanation provided for their plan's determination and/or their plan's determination is contrary to their treating professional's opinion or their SSA award of disability benefits.

The final rule also requires adverse benefit determinations to contain the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were relied upon in denying the claim (or a statement that these do not exist), and a notice of adverse benefit determination at the claims stage must contain 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 benefit claim. These provisions will benefit claimants by ensuring that they fully understand the reasons why their claim was denied so they are able to meaningfully evaluate the merits of pursuing an appeal or litigation.

The requirement to include a discussion of the decision, as well as the requirement to include specific internal rules, guideline, protocols, standards, or similar criteria relied upon by the plan will improve the accuracy of claims determinations. The process of documenting and explaining the reasoning of the decision will help ensure that plans' terms are followed and accurate information is used, and will enable plan participants to challenge inadequate or faulty evidence or reasoning.

Under the final rule, adverse benefit determinations must be provided in a culturally and linguistically appropriate manner for certain participants and beneficiaries that are not fluent in

 $^{^{\}rm 34}$ Almost all plans reporting this code are welfare plans.

English. Specifically, if a claimant's address is in a county where 10 percent or more of the population residing in that county, as determined based on American Community Survey (ACS) data published by the United States Census Bureau, are literate only in the same non-English language, notices of adverse benefit determinations to the claimant would have to include a prominent one-sentence statement in the relevant non-English language about the availability of language services. This provision will ensure that certain disability claimants that are not fluent in English understand the notices received from the plan regarding their disability claims and their right to appeal denied claims.

These important protections would benefit participants and beneficiaries by correcting procedural wrongs evidenced in the litigation even predating the

The voluntary nature of the employment-based 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. 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 or handling of appeals, they will discount the value of such benefits to adjust for this risk. This discount drives a wedge in compensation negotiation, limiting its efficiency. If workers undervalue the full benefit of disability coverage, fewer employers will provide such coverage or fewer participants will enroll. To the extent that workers perceive that the final rule, supported by the Department's enforcement authority, will reduce the risk of inappropriate denials of disability benefits, the differential between the employers' costs and workers' willingness to accept wage offsets is minimized.

These final regulations would reduce the likelihood of inappropriate benefit denials by requiring all disability claims and appeals to be adjudicated by persons that are independent and impartial. Specifically, the final rule would prohibit hiring, compensation, termination, promotion, or other similar decisions with respect to any individual (such as a claims adjudicator or a medical or vocational expert) to be made based upon the likelihood that the individual will support the plan's benefits denial. This will ensure that all disability benefit plan claims and appeals processes are adjudicated in a manner designed to ensure the

independence and impartiality of persons involved in making the decisions and enhance participants' perception that their disability plan's claims and appeals processes are operated in a fair manner.

As stated above, the final rule requires claimants to have the right to review and respond to new evidence or rationales developed by the plan during the pendency of an appeal, as opposed merely to having a right to such information upon request only after the claim has already been denied on appeal, as some courts have held under the Section 503 Regulation. These provisions will benefit claimants by correcting certain procedural flaws that currently occur when disability benefit claims are litigated and ensuring that they have a right to review and respond to new evidence or rationales developed by the plan during the pendency of the

appeal. In summary, the final rules provide more uniform standards for handling disability benefit claims and appeals that are comparable to the rules applicable to group health plans under the ACA Claims and Appeals Final Rule. These rules will reduce the incidence of inappropriate denials, averting serious financial hardship and emotional distress for participants and beneficiaries that are impacted by a disability. They also would enhance participants' confidence in the fairness of their plans' claims and appeals processes. Finally, by improving the transparency and flow of information between plans and claimants, the final regulations will enhance the efficiency

3. Costs and Transfers

of labor and insurance markets.

The Department has quantified the costs related to the final regulations' requirements to (1) provide the claimant free of charge with any new or additional evidence considered, and (2) to providing notices of adverse benefit determinations in a culturally and linguistically appropriate manner. These requirements and their associated costs are discussed below

Provision of new or additional evidence or rationale: As stated earlier in this preamble, before a plan providing disability benefits can issue an adverse benefit determination on review on a disability benefit claim, these final regulations require such plans to provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or any new or additional rationale upon which the adverse determination is based as soon as possible and

sufficiently in advance of the date the notice of adverse benefit determination on review is required to be provided. This requirement may increase the administrative burden on plans to prepare and deliver the enhanced information to claimants. The Department is not aware of a data source substantiating how often plans rely on new or additional evidence or rationale during the appeals process or the volume of materials that comprise the new evidence or rationale. Based on comments and discussions with the regulated community, the Department understands that few plans base adverse benefit determinations on appeal on new evidence or rationales. The Department also understands that the most critical new information relied on by plans when issuing adverse benefit determinations on review are new independent medical reports, and that at least some plans and insurers have a practice of providing claimants with rights to a voluntary additional level of appeal to respond to the new independent medical report if they disagree with its findings.

These final rules further require adverse benefit determinations on review for disability benefit plans to include a description of any contractual limitations period, including the date by which the claimant must bring a lawsuit. In the regulatory impact analysis for the proposal, the Department estimated these costs by assuming that compliance will require medical office staff, or other similar staff for another service provider with a labor rate of \$30, five minutes 35 to collect and distribute the additional evidence or rationale considered, relied upon, or generated by (or at the direction of) the plan during the appeals process. Additionally, including a description of any contractual limitations period, including the date by which the claimant must bring a lawsuit would have minimal additional burden as plans already maintain such information in the ordinary course of their claims administration process and would just need to add it to the notice.

One commenter questioned the Department's assumption asserting that it does not account for time to identify the additional or new information or rationale and for staff to respond. Commenters also asserted that providing the information will trigger a response by the claimant to which they

³⁵ For a description of the Department's methodology for calculating wage rates, see https:// www.dol.gov/sites/default/files/ebsa/laws-andregulations/rules-and-regulations/technicalappendices/labor-cost-inputs-used-in-ebsa-opr-riaand-pra-burden-calculations-august-2016.pdf.

will have to respond. The commenter provided no alternative estimates or data supporting their assertions that the Department could use to revise its cost estimate.

In the absence of such data, the Department disagrees with the comments. While some effort is required to provide claimants with the new information or rationale, the Department does not find the commenters' assertion of significant burden to be credible. As part of its customary and usual business practices, the insurer or TPA should have an existing system in place to track any new information or rationale it relies on in making an adverse benefit determination in order to identify, document, and evaluate the information during its claim adjudication process. The Department acknowledges, however, that an average of five minutes may be inadequate time to collect the information and provide it to the claimants; therefore, it has increased the estimate to an average of 30 minutes, which should provide a reasonable amount of time to perform this task.

The Department also agrees that making the new or additional information or rationale available to the claimant may trigger a response from the claimant. However, the Department does not have sufficient data to estimate the number of claimants that will respond with information that the insurer or TPA will need to evaluate or how much time will be required to evaluate the information. Moreover, the Department's consultations with EBSA field investigators that investigate disability plan issues indicate that many disability plans already allow claimants to respond to the new information or rationale in a back-and-forth process. The requirement imposes no new costs on these plans, insurers, and TPAs. The requirement does impose an additional burden on plans that do not allow claimants to respond to the new information or rationale, but the Department does not have sufficient data to estimate the increased costs. One industry commenter agreed that that it would be difficult to estimate the burden associated with responding to claimants.

Commenters also raised concern regarding a potentially endless cycle of appeals, responses, and reconsiderations that would extend the claim determination process and substantially increase costs. As discussed elsewhere in the preamble, the Department also does not find this claim to be credible. The requirement only requires action if the insurer or TPA produces new or additional information or rationale after reviewing

the new information submitted by the claimant, not if it just evaluates the information submitted by the claimant, and the Department's consultations with its investigators indicated that this occurs infrequently.

Additionally, while a plan fiduciary has a responsibility to ensure the accurate evaluation of all claims, that responsibility does not require the fiduciary to rebut every piece of evidence submitted or seek to deny every claim. Indeed, an endless effort to rebut every piece of evidence submitted by the claimant would call into question whether the fiduciary was impartially resolving claims as required by the duties of prudence and loyalty.

Furthermore, the Department has interpreted ERISA section 503 and the current Section 503 Regulation as already requiring that plans provide claimants with new or additional evidence or rationales upon request and an opportunity to respond in certain circumstances. See Brief of the Secretary of Labor, Hilda L. Solis, as Amicus Curiae in Support of Plaintiff-Appellant's Petition for Rehearing, Midgett v. Washington Group Int'l Long Term Disability Plan, 561 F.3d 887 (8th Cir. 2009) (No. 08-2523), (expressing disagreement with cases holding that there is no such requirement). The supposed "endless loop" is necessarily limited by claimants' ability to generate new evidence requiring further review by the plan. Such submissions ordinarily become repetitive in short order, and are further circumscribed by the limited financial resources of most claimants.

For purposes of this regulatory impact analysis, the Department assumes, as an upper bound, that all appealed claims will involve a reliance on additional evidence or rationale. Based on that assumption, the Department assumes that this requirement will impose an annual aggregate cost of \$14.5 million. The Department estimates this cost by assuming that compliance will require medical office staff, or another service providers' similar staff with a labor rate of \$42.08, thirty minutes 36 to collect and distribute the additional evidence considered, relied upon, or generated by (or at the direction of) the plan during the appeals process. The Department estimates that on average, material, printing and postage costs will total \$2.15 per mailing (20 pages * 0.05 cents per copy + \$1.15 postage). The

Department further assumes that 30 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.³⁷

The Department does not have sufficient data on the number of disability claims that are filed or denied. Therefore, the Department estimates the number of short- and long-term disability claims based on the percentage of private sector employees (122 million) 38 that participate in shortand long-term disability programs (approximately 39 and 33 percent respectively).39 The Department estimates the number of claims per covered life for long-term disability benefits based on the percentage of covered individuals that file claims under the Social Security Disability Insurance Program (SSDI) (two percent of covered individuals). The Department notes that SSDI uses a standard for disability determinations that is stricter than the standard used in many longterm disability plans offered by private employers. However, the number of claims filed with the SSDI is an acceptable proxy as most employer plans require claimants to file with the SSDI as a condition of receiving benefits from the plan as they offset the benefits paid by plan with the amount received from SSDI.

The Department does not have sufficient data to estimate the percentage of covered individuals that file short-term disability claims. Therefore, for purposes of this analysis, the Department estimates, as it did in

³⁶ For a description of the Department's methodology for calculating wage rates, see https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf.

 $^{^{\}rm 37}\,\rm Commenters$ disagreed in general with the estimates of the burden for providing the notice in a culturally and linguistically appropriate manner. Their concern was that most notices would be delivered on paper and not electronically. While one commenter did not provide any supporting evidence for this assertion, another commenter reported that a large company's past experience was that 30 percent of the claims filed under its disability plan were electronic. For purposes of this regulatory impact analysis, the Department accepted the suggestion posited in the comment that a significant percentage of disability benefit claimants are at home without access to an electronic means of communication at work that is required by the Department's electronic disclosure rule. Therefore, the Department assumes that a higher percentage of notices will be transmitted via mail even though data was provided only for a single company.

³⁸ BLS Employment, Hours, and Earnings from the Current Employment Statistics survey (National) Table B–1, May 2016. It should be noted that this estimate differs from the estimates from the Form 5500 reported in the affected entities section. The Form 55000 numbers only include large plans, and some filings could combine estimates for both short and long term disability.

³⁹ "Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost," February 2015 Vol. 4 No. 4. http:// www.bls.gov/opub/btn/volume-4/disabilityinsurance-plans.htm.

the proposal, that six percent of covered lives file such claims, because it believes that short-term disability claims rates are higher than long-term disability claim rates. The Department received no comments regarding this assumption.

The Department estimates the number of denied claims that would be covered by the rule in the following manner: For long-term disability, the percent of claims denied is estimated using the percent of denied claims for the SSDI Program (75 percent). This estimate may overstate the denial rates for ERISA-covered long-term disability plans, because as discussed above, many plans require claimants to file for SSDI benefits as a requirement to receive benefits from their plan. Plans often have a lower benefit determination standard, at least initially, than the SSDI

Program resulting in less denied claims. Therefore, using the SSDI denied claims rate as a proxy for the ERISA-covered plan claims denial rate may overstate the number of private long-term disability plan denied claims. For short-term disability, the estimate of denied claims (three percent) is an assumption based on previous regulations and feedback. The estimates are provided in the table below.

TABLE 2—FAIR AND FULL REVIEW BURDEN [In thousands]

	Short-term		Long-term		Total		
	Electronic	Paper	Electronic	Paper	Electronic	Paper	All
Denied Claims and lost Appeals with Additional Information	26 \$0.00	60 \$2.15	168 \$0.00	391 \$2.15	193 \$0.00	451 \$2.15	644
Total Mailing Cost Preparation Cost per event Total Preparation cost	\$0.00 \$21.04 \$540	\$129 \$21.04 \$1,260	\$0.00 \$21.04 \$3,526	\$841 \$21.04 \$8,227	\$0.00 \$21.04 \$4,066	\$969 \$21.04 \$9,487	\$969 \$21.04 \$13,553
Total	\$540	\$1,388	\$3,526	\$9,068	\$4,066	\$10,456	\$14,522

Adverse benefit determinations on disability benefit claims would have to contain a discussion of the decision, including the basis for disagreeing with SSA Disability Determination and Views of Treating Physician: Commenters on the proposal noted that costs were not quantified for the added burden of including in the benefit determination a discussion of why the plan did not follow the determination of the SSA or views of health care professionals that treated the claimant. Commenters did not provide data or information that would provide the Department with sufficient data to quantify such costs. Thus, while the Department agrees that there could be added burden imposed on plans to provide this discussion in adverse benefit determinations, the Department is unable to estimate the burden because it does not have sufficient data on the number or percent of claims that would need to contain this discussion.

Departmental investigators reviewing disability claims report that if the plan deviates from an attending physician's recommendation, a review is conducted by a supervisor, nurse, medical director or a consultant. This additional review usually generates documentation in the claim file. While this documentation may not be adequate in its current form to satisfy the requirement, the incremental costs to comply could be small, because it appears that deviations from physician's recommendations are documented currently. Plans or insurers may still need to prepare a response

using the already available information. The Department does not know how many claim determinations would require this discussion. The average hourly labor rate of a nurse is \$46.02 and that of a physician is \$157.80, and the Department estimates that preparing a report with information already available should not take more than one hour.

Adverse benefit determination would have to contain the internal rules, guidelines, protocols, standards, or other similar criteria of the plan used in denying the claim. The Department believes that this requirement will have minimal costs. In the process of determining a claim, plans will know, or should know, the internal rules, guidelines or protocols that were used to make a benefit determination. A commenter was concerned about the time and costs that would be required to comb through hundreds of pages of a claim manual to determine that no provision has any conceivable application to a particular claim in order to substantiate this requirement. The Department believes that neither the proposal nor the final rule requires this type of costly and time consuming process. The rule requires only the inclusion of those items that were relied upon and that should already be documented in the claim file at the time it was used to make a determination.

A notice of adverse benefit determination at the claims stage would have to contain a statement that the claimant is entitled to receive relevant

documents upon request. The Department believes that this requirement will have a negligible cost impact, because an insignificant amount of time will be required to add the statement to the notice. Although the current claims procedure regulation provides claimants with the right to request relevant documents when challenging an initial claims denial, a statement was required to be included only in notices of adverse benefit determinations on appeal. Including the statement in the initial denial notice as required by the final rule, in the Department's view, merely confirms claimants' rights under the current claims procedure regulation and will help ensure that they understand their right to receive such information to help them understand the reasons for the denial and to make informed decisions regarding whether and how they challenge a denial on appeal. The Department acknowledges that it is likely that more claimants will request this information when they are informed of their right to receive it; however, the Department does not have sufficient data to estimate the number of requests that will be made.

Culturally and Linguistically
Appropriate Notices: The final
regulations require notices of adverse
benefit determinations with respect to
disability benefits to be provided in a
culturally and linguistically appropriate
manner in certain situations. This
requirement is satisfied if plans provide
oral language services including

answering questions and providing assistance with filing claims and appeals in any applicable non-English language. The final regulations also require each notice sent by a plan to which the requirement applies to include a one-sentence statement in the relevant non-English language that translation services are available. The Department believes that this requirement will have a negligible cost impact. Plans also must provide, upon request, a notice in any applicable non-English language.

Although, one commenter reported that oral translation services are not provided by plans, the Department's conversations with the regulated community indicate that oral translation services generally are offered as a standard service. Based on this

information, the Department assumes that only a small number of plans will need to begin offering oral translation services for the first time upon the issuance of the final rule. Therefore, the Department assumes that this requirement will impose minimal additional costs.

The Department expects that the largest cost associated with the requirement is for plans to provide notices in the applicable non-English language upon request. Based on 2014 ACS data, the Department estimates that there are about 22.7 million individuals living in covered counties that are literate only in a covered non-English Language. ⁴⁰ To estimate the number of these individuals that might request a notice in a non-English language, the Department estimated the number of

workers in each county (total population in county * state labor force participation rate * (1—state unemployment rate)) 41 42 and calculated the number with access to short-term and long-term disability insurance by multiplying those estimates by the estimates of the share of workers participating in disability benefit programs (39 percent for short-term and 33 percent for long term disability.) 43 It should be noted that the sums in the right two columns are all workers in the county with disability insurance, not just workers with disability insurance that are eligible to receive notices in the applicable non-English language, because the calculation for the number of requests for translation is based on workers with insurance.

TABLE 3—WORKERS IN AFFECTED COUNTIES BY STATE

	Pop in the county	Total effected foreign language pop in county	State labor force participation rate (2015) (%)	State unemployment rate (2015) (%)	Workers with short-term disability coverage	Workers with long-term disability coverage
Alabama	29,519	3.979	56	6	6.097	5,159
Alaska	8,634	2,677	67.1	6.5	2,113	1,788
Arizona	296,362	160,492	59.8	6.1	64,901	54,917
Arkansas	15.864	4,598	57.9	5.2	3,396	2,874
California	26,248,619	8,845,211	62.2	6.2	5,972,612	5,053,748
Colorado	513,177	122,183	66.7	3.9	128,287	108,550
Florida	3,166,261	1,785,759	59.3	5.4	692,719	586,147
Georgia	284,282	72,578	61.3	5.9	63,953	54,114
Idaho	87,012	21,145	63.9	4.1	20,795	17,596
Illinois	484,509	126,443	64.7	5.9	115,043	97,344
lowa	35,029	7,861	69.9	3.7	9,196	7,781
Kansas	254,997	72,446	67.9	4.2	64,690	54,737
Missouri	6,170	919	65.6	5.0	1,500	1,269
Nebraska	106,532	26,134	70.1	3.0	28,251	23,905
Nevada	1,869,086	431,029	63.2	6.7	429,826	363,699
New Jersey	1,736,310	563,516	64.1	5.6	409,753	346,714
New Mexico	512,864	218,554	57.2	6.6	106,859	90,419
New York	4,983,647	1,472,029	61.1	5.3	1,124,613	951,596
North Carolina	55,317	10,260	61.2	5.7	12,450	10,535
Oklahoma	23,150	7,325	61.9	4.2	5,354	4,530
Oregon	31,532	8,897	61.1	5.7	7,085	5,995
Texas	12,541,167	5,304,121	63.7	4.5	2,975,400	2,517,646
Virginia	50,989	15,060	65.2	4.4	12,395	10,488
Washington	437,583	164,140	63.0	5.7	101,386	85,788
Puerto Rico	3,433,930	3,252,314	39.8	11.2	473,317	400,499
Total	57,212,542	22,699,670			12,825,893	10,852,679

The Department's discussions with the regulated community indicate that in California, which has a State law requirement for providing translation services for health benefit claims, requests for translations of written documents averages 0.098 requests per 1,000 members (note that requirement applies to all members not just foreign language speaking) for health claims.

While the requirements of California differ from those contained in these final regulations and the demographics for California do not match those of covered counties, for purposes of this

⁴⁰ http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data.pdf.

 $^{^{41}} Labor$ force Participation rate: http:// www.bls.gov/lau/staadata.txt. Unemployment rate: http://www.bls.gov/lau/lastrk14.htm.

⁴² Please note that using state estimates of labor participation rates and unemployment rates could lead to an over estimate as those reporting in the ACS survey that they speak English less than "very well" are less likely to be employed. Also, this estimate includes both private and public workers,

instead of just private workers leading to an overestimate of the costs.

⁴³ "Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost," February 2015 Vol. 4 No. 4. http:// www.bls.gov/opub/btn/volume-4/disabilityinsurance-plans.htm.

analysis, the Department used this percentage to estimate the number of translation service requests that plans could expect to receive. The Department believes that this estimate significantly overstates the number of translation requests that will be received, because there are fewer disability claims than health claims. Industry experts also told the Department that while the cost of translation services varies, \$500 per document is a reasonable approximation of translation cost, and the Department used this amount in its cost estimate for the final rule. This number was provided to the Department in 2010; therefore, for purposes of this analysis, the Department has adjusted this amount to \$553 to account for inflation.44

Based on the foregoing, the Department estimates that the cost to provide translation services pursuant to the final rule will be approximately \$1,283,840 annually (23,678,572 lives * 0.098/1000 * \$553).

Commenters questioned the data the Department used in the regulatory impact analysis for the proposed rule to estimate the costs incurred by TPAs and insurers to provide culturally and linguistically appropriate notices. One commenter questioned whether the \$500 per document translation cost accurately reflects the costs to comply with this provision. The commenter, however, failed to explain its rationale or provide any alternative information the Department could use to refine its estimate.

Another commenter questioned whether it was valid to rely on cost estimates to translate a notice into a non-English language based on data used by the Department to quantify the costs of complying with the a similar ACA requirement for group health plans. The Department believes that its experience with ACA group health plan claims and appeals regulations is directly applicable to this final regulation regarding disability claims and appeals. Contrary to the commenter's assertion that disability claims are so different from health claims that information about one cannot inform the other, the Department believes that translation of a notice into a different language is very similar for health and disability benefits, particularly as the same translation companies offer services for both types of notices. Also, while commenters argue that disability claims files are

much larger than medical claim files, the distinction is not relevant here, because the claim file is not required to be translated; only the notice is.

Another comment received was that there would be additional costs due to privacy issues arising from sharing personal information with a third-party. The same privacy issues arise in the health claims context. Pricing for translation services used in the analysis, therefore already have the costs for privacy issues built into the estimates.

The Department did not have sufficient data to quantify other costs associated with the final rule; and therefore, has provided a qualitative discussion of these costs below and a response to cost-related comments received in response to the regulatory impact analysis for the proposed regulation.

Independence and Impartiality-Avoiding Conflicts of Interest: The Department's claims and appeals regulation required certain standards of independence for persons making claims decisions before the final rules were issued. These final rules add new criteria for avoiding conflicts that require plans providing disability benefits to ensure "that all claims and appeals for disability benefits are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decisions." Also decisions regarding hiring, compensation, termination, promotion, or other similar matters must not be made based on the likelihood that the individual will support the denial of benefits.

These requirements provide protections to claimants by ensuring that their claims are processed impartially and already are considered best practice by many plan administrators who comply with this standard. Some plans and insurers may need to evaluate their policies and procedures to ensure they are compliant with this this requirement. The Department did not have sufficient data to quantify the costs of these requirements.

One commenter, who supported applying independence and impartiality requirements, expressed concern about a statement in the preamble to the proposed rule where the Department explained, as an example, that a plan cannot contract with a medical expert based on the expert's reputation for outcomes in contested cases rather than based on the expert's professional qualifications. The commenter expressed concern that the statement in the preamble might result in claimants requesting statistics and other

information on cases in which the medical expert expressed opinions in support of denying versus granting a disability benefit claims.

In the Department's view, the preamble statement is an accurate example of one way that the independence and impartiality standard would be violated, and, accordingly, does not believe it would be appropriate to disclaim or caveat the statement in the final rule. That said, the independence and impartiality requirements in the rule do not modify the scope of what would be "relevant documents" subject to the disclosure requirements in paragraphs (g)(1)(vii)(C) and (h)(2)(iii) of the Section 503 Regulation, as amended by this rule. Nor does the rule prescribe limits on the extent to which information about consulting experts would be discoverable in a court proceeding as part of an evaluation of the extent to which the claims administrator or insurer was acting under a conflict of interest that should be considered in evaluating an adverse benefit determination. Thus, the Department acknowledges that plans may incur costs to respond to claimants' requests for statistics and other information described by the commenter. However, the commenter provided no evidence or data to support their assertion and did not quantify the additional cost, thus the Department does not have sufficient data to quantify such costs.

Deemed Exhaustion of Claims and Appeals Process: The final rule tracks the proposal and provides that if a plan fails to adhere to all the requirements in the claims procedure regulation, the claimant would be deemed to have exhausted administrative remedies, with a limited exception where the violation was (i) de minimis; (ii) nonprejudicial; (iii) attributable to good cause or matters beyond the plan's control; (iv) in the context of an ongoing good-faith exchange of information; and (v) not reflective of a pattern or practice of non-compliance. Litigation costs are the primary cost related to this requirement, because claimants may proceed directly to court after a deemed exhaustion. Pursing litigation is more expensive than the plan appeals process, however, it may be the only option claimants have available to obtain denied benefits. Deemed exhaustion is available for the situations when plans are not following the procedural rules of the regulation. At times it may still be in a claimant's best interest to pursue an appeal inside the plan due to cost and time to resolve issues instead of using the court system. Commenters raised a concern the

⁴⁴The 2010 and 2016 GDP Deflator was 100.056 in 2010 and 110.714 in 2016. The adjustment is \$500 * (110.714/100.056) = \$553. https://fred.stlouisfed.org/series/GNPDEF.

claimants would be hurt by the higher costs and delay in obtaining a resolution if they sought resolution through litigation. However, this provision allows claimants to decide if the added costs and time of litigation are offset by the cost to them of remaining in an appeals process that is in violation of the procedural rules.

Some commenters maintained that their liability exposure increases when claimants' ability to go to court is enhanced. These commenters expressed concern about the expense of discovery to even determine if the procedural requirements have not been followed and asserted that claimants will allege that plans have violated their procedures and go to court to force a settlement.

While all of these scenarios are possible, the Department does not know of, nor did commenters provide, any data or information that would even be suggestive of, the frequency of these events, or the added expense resulting from their occurrence. The Department is not aware of systematic abuses or complaints of abuse with respect to a similar deemed exhaustion requirement contained in the ACA and the Departments' implementing regulation at 29 CFR 2590.715.2719. Thus, the Department believes these occurrences will be infrequent.

Covered Rescissions-Adverse Benefit Determinations: The final rule adds a new provision to address coverage rescissions. Specifically, the 2000 regulation already covered a rescission if it is the basis, in whole or in part, of an adverse benefit determination. The final regulation amends the definition of adverse benefit determination to include a rescission of disability benefit coverage that has a retroactive effect, whether or not there is an adverse effect on a benefit at that time.

The Department understands that this situation occurs infrequently. When it does occur, plans will incur the cost of providing an appeal of the rescission. The Department does not have sufficient data to estimate the cost to review and appeal a rescission of coverage. However, the Department expects that it would be less than the cost to appeal other disability benefit denials because medical or vocation professionals are not needed to review the claim. Instead, the facts of the coverage situation are required. When a rescission is reversed, the provision of future benefits would be considered a transfer from the plan to the claimant whose rescission was reversed.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 et seq.) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a final rule is not likely to 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 (FRFA) of the final rule describing the rule's impact on small entities and explaining how the agency made its decisions with respect to the application of the rule to small entities. Pursuant to section 605(b) of the RFA, the Assistant Secretary of the **Employee Benefits Security** Administration hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The Department discusses the impacts of the final rule and the basis for its certification below.

Need for and Objectives of the Rule: As discussed in section II above, the final rule will revise and strengthen the current rules regarding claims and appeals applicable to ERISA-covered plans providing disability benefits primarily by adopting several of the new procedural protections and safeguards made applicable to ERISA-covered group health plans by the Affordable Care Act. Before the enactment of the Affordable Care Act, group health plan sponsors and sponsors of ERISAcovered plans providing disability benefits were required to implement internal claims and appeal processes that complied with the Section 503 Regulation. The enactment of the Affordable Care Act and the issuance of the implementing interim final regulations resulted in disability plan claimants receiving fewer procedural protections than group health plan participants even though litigation regarding disability benefit claims is prevalent today.

The Department believes this action is necessary to ensure that disability claimants receive the same protections that Congress and the President established for group health care claimants under the Affordable Care Act. This will result in some participants receiving benefits they might otherwise have been incorrectly denied in the absence of the fuller protections provided by the final

regulation. This will help alleviate the financial and emotional hardship suffered by many individuals when they lose earnings due to their becoming disabled.

Affected Small Entities: The Department does not have complete data on the number of plans providing disability benefits or the total number of participants covered by such plans. ERISA-covered welfare benefit plans with more than 100 participants generally are required to file a Form 5500. Only some ERISA-covered welfare benefit plans with less than 100 participants are required to file for various reasons, but this number is very small. Based on current trends in the establishment of pension and health plans, there are many more small plans than large plans, but the majority of participants are covered by the large plans.

Data from the 2014 Form 5500 Schedule A indicates that there are 39,135 plans reporting a code indicating they provide temporary disability benefits covering 40.1 million participants, and 26,171 plans reporting a code indicating they provide long-term disability benefits covering 22.4 million participants. To put the number of large and small plans in perspective, the Department estimates that there are 150,000 large group health plans and 2.1 million small group health plans using 2016 Medical Expenditure Panel Survey-Insurance Component.

Impact of the Rule: The Department has quantified some of the costs associated with these final regulations' requirements to (1) provide the claimant free of charge with any new or additional evidence considered, and (2) to providing notices of adverse benefit determinations in a culturally and linguistically appropriate manner. These requirements and their associated costs are discussed in the Costs and Transfers section above. Additionally other costs are qualitatively discussed in the Costs section. Comments addressing the burden of the regulations were received and are discussed above as well.

Provision of new or additional evidence or rationale: As stated earlier in this preamble, before a plan can issue a notice of adverse benefit determination on review, the final rule requires plans to provide disability benefit claimants, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan as soon as possible and sufficiently in advance of the date the notice of adverse benefit determination on review is required to be provided and any new or additional

rationale sufficiently in advance of the due date of the response to an adverse benefit determination on review.

The Department is not aware of data suggesting how often plans rely on new or additional evidence or rationale during the appeals process or the volume of materials that are received. The Department estimated the cost per claim by assuming that compliance will require medical office staff, or other similar staff in other service setting with a labor rate of \$30, 30 minutes to collect and distribute the additional evidence considered, relied upon, or generated by (or at the direction of) the plan during the appeals process. The Department estimates that on average, material, printing and postage costs will total \$2.50 per mailing. The Department further assumes that 30 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.

Providing Notices in a Culturally and Linguistically Appropriate Manner: The final rule would require notices of adverse benefit determinations with respect to disability benefits to be provided in a culturally and linguistically appropriate manner in certain situations. This requirement is satisfied if plans provide oral language services including answering questions and providing assistance with filing claims and appeals in any applicable non-English language. The final rule also requires such notices of adverse benefit determinations sent by a plan to which the requirement applies to include a one-sentence statement in the relevant non-English language about the availability of language services. Plans also must provide, upon request, such notices of adverse benefit determinations in the applicable non-English language.

The Department expects that the largest cost associated with the requirement for culturally and linguistically appropriate notices will be for plans to provide notices in the applicable non-English language upon request. Industry experts also told the Department that while the cost of translation services varies, \$553 per document is a reasonable approximation of translation cost.

In discussions with the regulated community, the Department found that experience in California, which has a State law requirement for providing translation services, indicates that requests for translations of written documents averages 0.098 requests per 1,000 members for health claims. While the California law is not identical to the final rule, and the demographics for California do not match other counties,

for purposes of this analysis, the Department used this percentage to estimate of the number of translation service requests plans could expect to receive. Based on the low number of requests per claim, the Department expects that translation costs would be included as part of a package of services offered to a plan, and that the costs of actual requests will be spread across multiple plans.

Duplication, Overlap, and Conflict With Other Rules and Regulations: The Department does not believe that the final rule will conflict with any relevant regulations, federal or other.

D. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Department submitted an information collection request (ICR) to OMB regarding the ICRs contained in the final rule in accordance with 44 U.S.C. 3507(d), for OMB's review. OMB approved the ICR under OMB Control Number 1210–0053, which currently is scheduled to expire on November 30, 2019.

As discussed earlier in this preamble, the Department's final amendments to its claims and appeals procedure regulation would revise and strengthen the current rules regarding claims and appeals applicable to ERISA-covered plans providing disability benefits primarily by adopting several of the procedural protections and safeguards made applicable to ERISA-covered group health plans by the ACA. Some of these amendments revise disclosure requirements under the current rule that are information collections covered by the PRA. For example, benefit denial notices must contain a full discussion of why the plan denied the claim, and to the extent the plan did not follow or agree with the views presented by the claimant to the plan or health care professional treating the claimant or vocational professionals who evaluated the claimant, or a disability determination regarding the claimant presented by the claimant to the plan made by the SSA, the discussion must include an explanation of the basis for disagreeing with the views or disability determination. The notices also must include either (1) the specific internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making the adverse determination or, alternatively, or (2) a statement that such rules, guidelines, protocols, standards or other similar criteria of the plan do not exist.

A copy of the ICR may be obtained by contacting the PRA addressee shown

below or at http://www.RegInfo.gov. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

After the implementation of the ACA claims regulations, disability plans claimants received fewer procedural protections than group health plan participants even though disability plan claimants experience more issues with the claims review process. These final regulations will reduce the inconsistent procedural rules applied to health and disability benefit plan claims and provide similar procedural protections to claimants of both types of plans.

The burdens associated with the regulatory requirements of the ICRs contained in the final rule are summarized below.

Type of Review: Revised collection.
Agencies: Employee Benefits Security
Administration, Department of Labor.
Title: ERISA Claims Procedures.
OMB Number: 1210–0053.
Affected Public: Business or other for-

profit; not-for-profit institutions.

Total Respondents: 5,808,000.

Total Responses: 311,790,000.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 516,000.

Estimated Total Annual Burden Cost: \$814,450,000.

IV. Congressional Review Act

The final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory
Enforcement Fairness Act of 1996 (5
U.S.C. 801 et seq.) and will be transmitted to Congress and the Comptroller General for review. The final rule is not a "major rule" as that term is defined in 5 U.S.C. 804, because it is not likely to result in an annual effect on the economy of \$100 million or more.

V. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.), as well as Executive Order 12875, this final rule does not include any federal mandate that may result in expenditures by state, local, or tribal governments, or the private sector, which may impose an annual burden of \$100 million or more (as adjusted for inflation).

VI. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism,

and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final regulation.

In the Department of Labor's view, these final regulations have federalism implications because they would have direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government to the extent states have enacted laws affecting disability plan claims and appeals that contain similar requirements to the final rule. The Department believes these effects are limited, because although section 514 of ERISA supersedes State laws to the extent they relate to any covered employee benefit plan, it preserves State laws that regulate insurance, banking, or securities. In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Department solicited input from affected States, including the National Association of Insurance Commissioners and State insurance officials, regarding this assessment at the proposed rule stage but did not receive any comments.

List of Subjects in 29 CFR Part 2560

Claims, Employee benefit plans. For the reasons stated in the preamble, the Department of Labor amends 29 CFR part 2560 as set forth below:

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

■ 1. The authority citation for part 2560 is revised to read as follows:

Authority: 29 U.S.C. 1132, 1135, and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012). Section 2560.503–1 also issued under 29 U.S.C. 1133. Section 2560.502c–7 also issued under 29 U.S.C. 1132(c)(7). Section 2560.502c–4 also issued under 29 U.S.C. 1132(c)(4). Section 2560.502c–8 also issued under 29 U.S.C. 1132(c)(8).

- 2. Section 2560.503-1 is amended by:
- a. Adding paragraph (b)(7).
- b. Revising paragraph (g)(1)(v).
- c. Adding paragraphs (g)(1)(vii) and (viii).
- d. Revising paragraphs (h)(4) and (i)(3)(i).
- e. Revising paragraphs (j)(4) and (j)(5) introductory text.
- \blacksquare f. Adding paragraphs (j)(6) and (7).
- \blacksquare g. Revising paragraphs (l) and (m)(4).
- i. Redesignating paragraph (o) as (p), and adding new paragraph (o).
- j. Revising newly redesignated paragraph (p).

The revisions and additions read as follows:

§ 2560.503-1 Claims procedure.

(b) * * *

(7) In the case of a plan providing disability benefits, the plan must ensure that all claims and appeals for disability benefits are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical or vocational

adjudicator or medical or vocational expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(v) In the case of an adverse benefit determination by a group health plan—

(vii) In the case of an adverse benefit determination with respect to disability benefits—

(A) A discussion of the decision, including an explanation of the basis for disagreeing with or not following:

(i) The views presented by the claimant to the plan of health care professionals treating the claimant and vocational professionals who evaluated the claimant:

(ii) The views 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; and

(iii) A disability determination regarding the claimant presented by the claimant to the plan made by the Social Security Administration;

(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;

(C) Either the specific internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making the adverse determination or, alternatively, a statement that such rules, guidelines, protocols, standards or other similar criteria of the plan do not exist; and

(D) 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.

(viii) In the case of an adverse benefit determination with respect to disability benefits, the notification shall be provided in a culturally and linguistically appropriate manner (as described in paragraph (o) of this section).

* * * * * (h) * * *

- (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, in addition to complying with the requirements of paragraphs (h)(2)(ii) through (iv) and (h)(3)(i) through (v) of this section, the claims procedures—
- (i) Provide that before the plan can issue an adverse benefit determination on review on a disability benefit claim, the plan administrator shall provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan, insurer, or other person making the benefit determination (or at the direction of the plan, insurer or such other person) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided under paragraph (i) of this section to give the claimant a reasonable opportunity to respond prior to that date; and

(ii) Provide that, before the plan can issue an adverse benefit determination on review on a disability benefit claim based on a new or additional rationale, the plan administrator shall provide the claimant, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided under paragraph (i) of this section to give the claimant a reasonable opportunity to respond prior to that date.

* * * * * * * * * * (i) * * * *

(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)(i) of this section, except that a period of 45 days shall apply instead of 60 days for purposes of that paragraph.

* * * * * * (j) * * *

(4)(i) 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,

- (ii) In the case of a plan providing disability benefits, in addition to the information described in paragraph (j)(4)(i) of this section, the statement of the claimant's right to bring an action under section 502(a) of the Act shall also describe any applicable contractual limitations period that applies to the claimant's right to bring such an action, including the calendar date on which the contractual limitations period expires for the claim.
- (5) In the case of a group health plan—
- (6) In the case of an adverse benefit decision with respect to disability benefits—
- (i) A discussion of the decision, including an explanation of the basis for disagreeing with or not following:
- (A) The views presented by the claimant to the plan of health care professionals treating the claimant and vocational professionals who evaluated the claimant;
- (B) The views 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; and
- (C) A disability determination regarding the claimant presented by the claimant to the plan made by the Social Security Administration;

- (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 change upon request; and
- (iii) Either the specific internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making the adverse determination or, alternatively, a statement that such rules, guidelines, protocols, standards or other similar criteria of the plan do not exist
- (7) In the case of an adverse benefit determination on review with respect to a claim for disability benefits, the notification shall be provided in a culturally and linguistically appropriate manner (as described in paragraph (o) of this section).

* * * * *

- (1) Failure to establish and follow reasonable claims procedures. (1) In general. Except as provided in paragraph (1)(2) of this section, 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.
- (2) Plans providing disability benefits. (i) In the case of a claim for disability benefits, if the plan fails to strictly adhere to all the requirements of this section with respect to a claim, the claimant is deemed to have exhausted the administrative remedies available under the plan, except as provided in paragraph (l)(2)(ii) of this section. Accordingly, the claimant is 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. If a claimant chooses to pursue remedies under section 502(a) of the Act under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(ii) Notwithstanding paragraph (l)(2)(i) of this section, the administrative remedies available under a plan with respect to claims for

disability benefits will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan demonstrates that the violation was for good cause or due to matters beyond the control of the plan and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan. The claimant may request a written explanation of the violation from the plan, and the plan must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the administrative remedies available under the plan to be deemed exhausted. If a court rejects the claimant's request for immediate review under paragraph (1)(2)(i) of this section on the basis that the plan met the standards for the exception under this paragraph (l)(2)(ii), the claim shall be considered as re-filed on appeal upon the plan's receipt of the decision of the court. Within a reasonable time after the receipt of the decision, the plan shall provide the claimant with notice of the resubmission.

* * * * * * (m) * * *

(4) The term "adverse benefit determination" means:

(i) 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; and

(ii) In the case of a plan providing disability benefits, the term "adverse benefit determination" also means any rescission of disability coverage with respect to a participant or beneficiary (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). For this purpose, the term "rescission" means a cancellation or discontinuance

of coverage that has retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

* * * *

(o) Standards for culturally and linguistically appropriate notices. A plan is considered to provide relevant notices in a "culturally and linguistically appropriate manner" if the plan meets all the requirements of paragraph (o)(1) of this section with respect to the applicable non-English languages described in paragraph (o)(2) of this section.

(1) Requirements. (i) The plan must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals in any applicable non-English language;

(ii) The plan must provide, upon request, a notice in any applicable non-

English language; and

(iii) The plan must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan.

(2) Applicable non-English language. With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in

the same non-English language, as determined in guidance published by the Secretary.

(p) Applicability dates and temporarily applicable provisions. (1) Except as provided in paragraphs (p)(2), (p)(3) and (p)(4) of this section, this section shall apply to claims filed under a plan on or after January 1, 2002.

(2) This section shall apply to claims filed under a group health plan on or after the first day of the first plan year beginning on or after July 1, 2002, but in no event later than January 1, 2003.

(3) Paragraphs (b)(7), (g)(1)(vii) and (viii), (j)(4)(ii), (j)(6) and (7), (l)(2), (m)(4)(ii), and (0) of this section shall apply to claims for disability benefits filed under a plan on or after January 1, 2018, in addition to the other paragraphs in this rule applicable to such claims.

(4) With respect to claims for disability benefits filed under a plan from January 18, 2017 through December 31, 2017, this paragraph (p)(4) shall apply instead of paragraphs (g)(1)(vii), (g)(1)(viii), (h)(4), (j)(6) and (j)(7).

(i) In the case of a notification of benefit determination and a notification of benefit determination on review by a plan providing disability benefits, the notification shall set forth, in a manner calculated to be understood by the claimant—

(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; and

- (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.
- (ii) 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.

Signed at Washington, DC, this 9th day of December, 2016.

Phyllis C. Borzi,

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

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