



The  
ERISA  
Industry  
Committee

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Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration, Room N-5653  
U.S. Department of Labor  
200 Constitution Avenue, NW.  
Washington, DC 20210

Attention: RIN 1210-AB45

Ladies and Gentlemen:

The ERISA Industry Committee (“ERIC”) is pleased to submit these comments on the amendment to interim final regulations implementing the internal claims and appeals and external review processes under the Patient Protection and Affordable Care Act (“ACA”) (the “Amendment”). The Amendment was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the “Departments”) in the *Federal Register* on June 24, 2011.

### **ERIC’s Interest in the Amendment to the Interim Final Regulations**

ERIC is a nonprofit association committed to the advancement of the employee retirement, health, incentive, and welfare benefit plans of America’s largest employers. ERIC’s members sponsor some of the largest private group health plans in the country. These plans provide high-quality, affordable health care to tens of millions of workers and their families.

ERIC’s members seek to provide health care coverage to their employees and families in a fair and equitable manner and to ensure that they receive the benefits promised under the governing plan documents. Large employers regard these objectives not merely as legal obligations but as bedrock principles of an effective benefit program. Over the past decade, ERIC’s members have invested substantial resources in developing claims and appeals procedures that, in many cases, exceed the requirements adopted by the Department of Labor in 2000. ERIC’s members support a claims procedure that gives participants a reasonable and responsible opportunity to appeal adverse benefit determinations.

Employers do not have unlimited resources to spend on health care, however. ACA has imposed a number of expensive new mandates on employer health plans that were already struggling to cope with runaway medical costs. Before the Amendment, the interim final regulations included a number of features that would have increased employers' administrative costs without producing a corresponding increase in employees' welfare.

ERIC commends the Departments for amending the interim final regulations to provide relief regarding many of these features. Overall, we believe that the amended interim final regulations strike a more balanced approach that provide participants reasonable access to internal and external review procedures without imposing unduly burdensome requirements on employers.

ERIC especially appreciates the Departments' revisions to the requirements for providing claim denial notices in a culturally and linguistically appropriate manner. The revised test for determining whether an employer must offer assistance in a non-English language based on a survey published by the United States Census will be much easier to administer than the requirement under the initial regulations for a plan administrator to determine whether a plan's population satisfied the test based on data collected by the plan administrator itself.

ERIC also endorses the Departments' decision to replace the requirement in the interim final regulations for adverse benefit determinations to include diagnosis and treatment codes (and their corresponding meanings) with a requirement for this information to be provided only upon request.<sup>1</sup>

In addition to expressing our appreciation for certain amendments to the interim final regulations, ERIC also urges the Departments to consider adopting the recommendations made in ERIC's letter of September 21, 2010, that are not addressed in the Amendment, such as:

- Our recommendation for the Departments (a) to give plans more time to provide a claimant with any new or additional evidence or rationales discovered during internal review of a claim; and (b) to provide that the period for making the final adverse benefit determination will be tolled from the date on which the new or additional evidence or rationale is sent to the claimant until the date that the claimant has sufficient time to respond, and the plan has sufficient time to take into account, the participant's response in making its final adverse benefit determination; and

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<sup>1</sup> The Department of Labor should also revise the interim procedures for federal external review set forth in Technical Release 2010-01 to clarify that external reviewers are no longer required to include diagnosis and treatment codes (and their corresponding meanings) in notices of final external review decisions. We note that the Departments have removed this information from the model notice of final external review decisions.

- Our recommendation for the Departments to clarify that the requirement for plans to allow participants to continue receiving coverage pending the outcome of the appeals process does not impose any new or additional requirements on group health plans and does not require plans to continue coverage during the period of external review.

ERIC also encourages the Departments to give careful consideration to ERIC's earlier comments regarding the external review process. The Amendment's clarifications to the external review process have heightened the need for the Departments (1) to acknowledge that external reviewers are plan fiduciaries to the extent that their decisions are binding on plan administrators and (2) to require external reviewers to follow the terms of a plan in deciding a claim on review. Accordingly, in this letter, ERIC also renews its request for the Department of Labor to acknowledge that an external reviewer is a plan fiduciary. ERIC also offers some comments on the Amendment's changes to the requirements for *internal* claims and appeals procedures.

### **Comments Regarding Internal Claims and Appeals Procedures**

#### **1. The exception to the strict compliance standard should be clarified to apply to unintentional de minimis errors.**

The interim final regulations state that if a plan fails to strictly adhere to all requirements of the internal claims and appeals process, the claimant is deemed to have exhausted his or her right to internal review.<sup>2</sup> In this circumstance, the claimant may proceed straight to external review or to court.

ERIC strongly endorses the Departments' decision to amend the regulations to provide an exception to this "strict compliance" rule for "de minimis" errors that do not prejudice the claimant or the claimant's right to administrative review. ERIC appreciates that the Departments have recognized that a plan administrator should not be deprived of the right to interpret the plan and develop an administrative record solely because the administrator commits a minor error with no prejudice to the claimant. However, the exception to the strict compliance rule is too narrow.

The exception requires errors to be "for good cause or due to matters beyond the control of the plan."<sup>3</sup> It is reasonable for the Departments to exclude from the exception de minimis *intentional* errors unless they are attributable to good cause or reasons beyond the plan administrator's control. However, the Departments should also exclude from the strict compliance rule unintentional errors that are not attributable to

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<sup>2</sup> 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(F); 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F); 45 C.F.R. § 147.136(b)(2)(ii)(F).

<sup>3</sup> 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(F)(2); 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F)(2); 45 C.F.R. § 147.136(b)(2)(ii)(F)(2).

any reason. These errors are no more prejudicial to a claimant or likely to interfere with his or her right to administrative review than errors that are committed for “good cause” or for reasons beyond the administrator’s control.

For example, a mistake in the date of service reported on a claim denial notice when all of the other reported information sufficiently identifies a claim will be just as harmless whether it is due to a typographical error or due to a mistake by the provider in submitting the claim to the plan. However, under the current exception, claimants will bypass the internal claims and appeals process in cases where the error is just as benign as an error for good cause or for reasons beyond the plan administrator’s control. If the Departments do not also include within the exception unintentional errors, regardless of the reason that they are committed, plan administrators will be deprived of the right to interpret and apply the provisions of the plan in the majority of instances in which a de minimis error occurs.

The exception also requires the error to occur in the context of an *ongoing* good-faith exchange of information. The Departments should clarify that errors that occur in a plan administrator’s first response to a claimant will be considered part of an ongoing exchange of information. There is no reason to disqualify a de minimis mistake from the exception solely because it occurs in the plan administrator’s initial attempt to respond to a claimant. To the contrary, if the timing of an error is taken into account at all, a de minimis error that occurs early in the review process should be treated more favorably under the exception to make it more difficult for a claimant to exit the internal review process before the plan administrator has been given a fair opportunity to develop the administrative record.

## **2. The regulations should allow plans to impose reasonable limitations on a claimant’s right to explanations of violations.**

The amended interim final regulations permit claimants to request a written explanation of a plan administrator’s failure to strictly adhere to requirements of the internal claims and appeals process.<sup>4</sup> The plan administrator must provide the explanation within ten days of the request. The explanation must include the reasons, if any, that the violation meets the requirements for the de minimis exception and does not cause the internal claims and appeals process to be deemed exhausted. The purpose of the explanation is to provide claimants with sufficient information to make an informed decision about whether to pursue immediate external review.

However, the Amendment does not adequately explain the parameters of a claimant’s right to an explanation of a violation. ERIC recommends several changes to this requirement to achieve a better balance between the intended purpose of the

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<sup>4</sup> 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(F)(2); 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F)(2); 45 C.F.R. § 147.136(b)(2)(ii)(F)(2).

explanation and the administrative resources that will be required to provide the explanation.

***a. Plan administrators should be permitted to deny requests for explanations if a violation is not sufficiently identified.***

The Departments should clarify that a plan administrator is permitted to deny a claimant's request for an explanation of a violation if the claimant does not provide sufficient information for the plan administrator to identify the violation. Plan administrators do not have systems in place to track failures to follow the internal claims procedures. Moreover, many errors are unknown to the plan administrator unless they are identified by a claimant. For example, a plan administrator may not know that information it includes in a claim response that was originally provided by a health provider, such as a denial code or date of service, is inaccurate unless a claimant informs the administrator of the error. Accordingly, it is impossible for plan administrators to accurately respond to a blanket request by a claimant for an explanation of any and every violation that occurred with respect to the claimant's claim for benefits.<sup>5</sup>

The Department of Labor's claim procedures under section 503 of ERISA permit plan administrators to deny claims at any point in the administrative process on the basis that the plan does not have sufficient information to process the claim.<sup>6</sup> Without sufficient information, a plan administrator will be no more able to provide a written explanation of a violation than to process a claim for benefits under the plan. Accordingly, a plan administrator should be permitted to deny a claimant's request for an explanation of a violation if the claimant has not described the violation with enough specificity for the plan administrator to identify, research, analyze, or explain the alleged violation.

***b. Plan administrators should be required to explain only violations that they assert meet the de minimis exception.***

In the Preamble to the Amendment, the Departments state that the purpose of the explanation is to provide the claimant with the reasons the plan asserts that an error meets the de minimis exception so that the claimant can make an informed judgment about whether to seek immediate external or judicial review.<sup>7</sup> However, the relevant provisions of the regulations do not make clear that a claimant is entitled to an explanation of a violation only in circumstances where the plan administrator asserts that the violation meets the de minimis exception.

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<sup>5</sup> 76 Fed. Reg. 37208, 37213 (June 24, 2011).

<sup>6</sup> Department of Labor, *Frequently Asked Questions about the Benefit Claims Procedure Regulation*, C-21 available at [http://www.dol.gov/ebsa/faqs/faq\\_claims\\_proc\\_reg.html](http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html).

<sup>7</sup> 76 Fed. Reg. 37208, 37213 (June 24, 2011).

The requirement for a plan administrator to provide an explanation of a violation is reasonable if it is a condition for the plan to receive the benefit of the de minimis exception. However, it would be unreasonable and unduly burdensome to require plan administrators to provide such an explanation in circumstances where there is no question regarding whether a violation has occurred. Accordingly, if a claimant requests an explanation of a violation that has not occurred or that the plan administrator does not assert is de minimis, the plan administrator should be permitted to respond that the plan is not required to provide an explanation.

ERIC urges the Departments to clarify the rules to require a plan administrator to provide an explanation of a violation only if the plan administrator asserts that the violation satisfies the de minimis exception.

***c. Plans should be permitted to impose time limits on a claimant's right to an explanation.***

The Departments should also revise the regulations to make clear that it is permissible for plans to place reasonable limits on the period of time in which a claimant may request an explanation of the violation. Although plans are required under section 107 of ERISA to retain records for at least six years, in many cases it will not be possible to identify from plan records whether there has been a failure, or the reason for the failure. For example, if a plan administrator includes the wrong claim amount on the participant's denial notice because the provider incorrectly inputs the amount when it submits its claim to the plan administrator, the reason for the error will not be discoverable in plan records—rather the error can only be discoverable by inquiring whether the provider correctly submitted the claim.

Accordingly, plan administrators should be permitted to impose reasonable limits on the period of time in which a claimant may request an explanation of a violation. For example, it should be reasonable for a plan administrator to deny any request for an explanation after the period for filing a request for external review of the claim has expired.

***d. Plan administrators should have more time to respond to a request for an explanation.***

Plan administrators should be given more than ten days to respond to a request for an explanation of a violation. In many cases, the plan administrator may not be aware that a violation has occurred until a claimant requests an explanation. Accordingly, plan administrators need time to research the violation, determine the source of the violation, determine whether the violation complies with the “de minimis” exception, and prepare the requested explanation. This undertaking will, at a minimum, require the plan administrator to interview the individuals who processed the claim and review the claim record.

The steps involved to prepare a written explanation of a violation are at least as numerous and time-sensitive as the steps required to determine whether a claim for benefits should be pre-approved. Under existing Department of Labor regulations, plan administrators are allowed at least 15 days to process a request for pre-approval of benefits.<sup>8</sup> Accordingly, plan administrators should be given no less than 15 days to provide written explanations of violations.

**3. Plan administrators should not be required to provide a telephone customer assistance hotline.**

The interim final regulations would have required plan administrators to provide oral non-English assistance with filing claims and appeals or answering questions only to the extent the plan administrator already maintained a customer assistance process.<sup>9</sup> However, the Amendment requires plan administrators to provide oral non-English assistance, such as a telephone customer assistance hotline, regardless of whether the plan administrator already maintains a customer assistance process.<sup>10</sup>

Nothing in the statutory language of ACA requires plan administrators to make call centers and other customer assistance services available to participants in English or in non-English languages. Maintaining a customer assistance hotline or call center is an expensive undertaking for a plan administrator because the administrator typically must engage a third-party vendor to provide this service and dedicate its own resources to oversee the vendor and ensure that the vendor is responding accurately to questions regarding the plan. The decision to maintain such a service should remain within the discretion of a plan administrator which is in the best position to determine the needs of its participants and the most efficient way to leverage its resources to meet these needs. The Departments should revise the rule to clarify that a plan is required to provide oral customer assistance in a non-English language only to the extent the plan already maintains a customer assistance process for its English-speaking participants.

**Comments Regarding External Review Processes**

**1. The scope of the federal external review process should be the same as the scope of the state external review processes.**

ERIC commends the Departments for narrowing, at least on a temporary basis, the scope of adverse benefit determinations eligible for the federal external review process to any adverse benefit determination or final internal adverse benefit

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<sup>8</sup> 29 C.F.R. § 2560.503-1(f)(2)(iii)(A).

<sup>9</sup> 26 C.F.R. § 54.9815-2719T(e)(2)(iii); 29 C.F.R. § 2590.715-2719(e)(2)(iii); 45 C.F.R. § 147.136(e)(2)(iii) (as published in 75 *Fed. Reg.* 43329, 43354 (July 23, 2010)).

<sup>10</sup> 26 C.F.R. § 54.9815-2719T(e)(2)(i); 29 C.F.R. § 2590.715-2719(e)(2)(i); 45 C.F.R. § 147.136(e)(2)(i).

determination that involves “medical judgment” or a rescission of coverage.<sup>11</sup> However, ERIC urges the Departments to further narrow and clarify, on a permanent basis, the scope of adverse benefit determinations eligible for external review by defining adverse benefit determinations involving “medical judgment” to include only the types of adverse benefit determinations eligible for review through a state external review process.

The amended interim final regulations do not include a definition of adverse benefit determinations that involve “medical judgment”, but rather illustrate the meaning of “medical judgment” through examples that include determinations based on the plan’s requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or for covering experimental or investigational treatments.<sup>12</sup>

Plan administrators and participants need a clear definition of the types of determinations that are eligible for external review so that plan administrators can clearly advise participants of the circumstances in which a claim is eligible for external review and so that participants can make an informed decision about whether to request external review of a claim. A participant will look to the plan administrator to provide him or her with clear guidelines for whether a claim is eligible for external review and will become frustrated by responses that provide only illustrative examples of the types of claims eligible for review—none of which may provide guidance with respect to the participant’s claim.

ACA requires the federal external review process to be similar to the process described in the NAIC Uniform Model Act.<sup>13</sup> The interim final regulations and the NAIC Uniform Model Act, clearly define the types of adverse benefit determinations that are eligible for review through a state external review process: claims that are denied on the basis that the admission, availability of care, continued stay or other health care service does not meet the plan’s requirements for “medical necessity, appropriateness, health care setting, level of care, or effectiveness.”<sup>14</sup> This definition captures precisely the types of claims that involve “medical judgment”. For example, it is clear under this definition that claims that merely involve whether a claimant was charged the correct co-pay, met his or her deductible, or exceeded the plan’s visit limitations are not eligible for external review.

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<sup>11</sup> 26 C.F.R. § 54.9815-2719T(d)(1)(ii); 29 C.F.R. § 2590.715-2719(d)(1)(ii); 45 C.F.R. § 147.136(d)(1)(ii).

<sup>12</sup> 26 C.F.R. § 54.9815-2719T(d)(1)(ii)(A); 29 C.F.R. § 2590.715-2719(d)(1)(ii)(A); 45 C.F.R. § 147.136(d)(1)(ii)(A).

<sup>13</sup> Public Health Service Act § 2719 as added by PPACA § 1001(5) and amended by PPACA § 10101(g).

<sup>14</sup> 26 C.F.R. § 54.9815-2719T(c)(2)(i); 29 C.F.R. § 2590.715-2719(c)(2)(i); 45 C.F.R. § 147.136(c)(2)(i); NAIC Model Uniform Act § 3(A).

We are not aware of any reason for claims involving “medical judgment” that are eligible for federal external review to be defined differently from claims that are eligible for state external review. Therefore, we urge the Departments to define, on a permanent basis, adverse benefit determinations involving “medical judgment” to mean adverse benefit determinations based on the plan’s requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness—*i.e.*, the types of adverse benefit determinations that are subject to state external review pursuant to the NAIC Uniform Model Act.

## **2. Plan administrators should be permitted to determine whether an adverse benefit determination involves “medical judgment”.**

The Amendment provides that whether an adverse benefit determination involves “medical judgment” and is eligible for external review will be determined by the external reviewer.<sup>15</sup> This responsibility should be assigned to the plan administrator. Assigning this responsibility to the external reviewer diminishes the administrative relief and cost savings that we believe the Departments intended to provide by narrowing the scope of claims eligible for external review.

In the interim federal external review process described in Department of Labor Technical Release 2010-01, plans are responsible for completing a preliminary review of a request to determine whether it is eligible for external review. An adverse benefit determination is assigned to an independent review organization (“IRO”) only if the *plan administrator* determines that it is eligible for external review. Before the Amendment, any adverse benefit determination was eligible for external review unless it was based on a determination that the claimant is not eligible to participate in the plan (*i.e.*, “an eligibility claim”).<sup>16</sup> Because the Amendment requires the IRO to determine whether an adverse benefit involves “medical judgment”, the scope of eligible claims that a plan administrator must assign to an IRO will remain the same even after September 20<sup>th</sup>—the effective date of the change in the scope of claims eligible for external review.

Therefore, plan sponsors will not realize any cost savings from the change in scope of claims eligible for external review because all claims (except for eligibility claims) must continue to be assigned to IROs. Even worse, plan sponsors will incur additional expenses for IROs to determine whether a claim meets the requirements for “medical judgment”. Plan sponsors should not have to pay for IROs to consider adverse benefit determinations that are not ultimately eligible for external review.

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<sup>15</sup> 26 C.F.R. § 54.9815-2719T(d)(1)(ii)(A); 29 C.F.R. § 2590.715-2719(d)(1)(ii)(A); 45 C.F.R. § 147.136(d)(1)(ii)(A).

<sup>16</sup> 26 C.F.R. § 54.9815-2719T(d)(1)(i); 29 C.F.R. § 2590.715-2719(d)(1)(i); 45 C.F.R. § 147.136(d)(1)(i).

ERIC urges the Departments to revise the rule to allow plan administrators, not external reviewers, to determine whether an adverse benefit determination involves medical judgment.

**3. Issues relating to plan design or a plan's compliance with law should not be eligible for review under a plan's internal or external claims procedures.**

Only adverse benefit determinations or final adverse benefit determinations are eligible for the new external review procedures.<sup>17</sup> An adverse benefit determination is a denial, reduction, or termination of, or a failure to provide or pay for, a benefit.<sup>18</sup> Although the term "benefit" is not defined under the regulations, the term is used throughout ERISA and always refers to the benefit provided "under a plan". In other words, a right to coverage or reimbursement of a medical expense must be provided under and by the terms of a plan in order to be a benefit. Thus, a benefit denial must refer to a denial under the governing terms of a plan in order to constitute an adverse benefit determination or final adverse benefit determination.

***a. Claims relating to plan design are not eligible for internal or external review.***

A claim involving a plan design matter or relating to a matter clearly not provided under the terms of a plan cannot be a claim involving an adverse benefit determination.

The Preamble to the Amendment provides that an adverse benefit determination based on "the frequency, method, treatment, or setting for a recommended preventive service" is an adverse benefit determination eligible for external review.<sup>19</sup> However, as described in the interim final regulations implementing ACA's preventive care mandate under section 2713 of the Public Health Service Act, plan sponsors are permitted to use reasonable medical management techniques to include in the terms of their plans "coverage limitations" on a mandated preventive service for which the appropriate governmental agency has not specified a frequency, method, treatment, or setting.<sup>20</sup> The determination by plan sponsors to impose coverage limitations on these preventive services is a plan design matter. A claim regarding whether a plan's limitation on a preventive service is appropriately based on, or permissible under, reasonable medical management techniques is not an adverse benefit determination eligible for external review. In contrast, a claim regarding whether a preventive service for which a claimant seeks reimbursement is covered under the terms of the plan, including its

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<sup>17</sup> 26 C.F.R. § 54.9815-2719T(d); 29 C.F.R. § 2590.715-2719(d); 45 C.F.R. § 147.136(d).

<sup>18</sup> 29 C.F.R. § 2560.503-1(m)(4).

<sup>19</sup> 76 *Fed. Reg.* 37208, 37216 (June 24, 2011).

<sup>20</sup> 26 C.F.R. § 54.9815-2713T(a)(4); 29 C.F.R. § 2590.715-2713(a)(4); 45 C.F.R. § 147.130(a)(4).

coverage limits, could involve an adverse benefit determination that is eligible for external review.

The Departments should clarify that claims involving plan design issues, such as coverage limitations on preventive services, the exclusion of a provider from a network, the established and specified co-payments for benefits under the in-network and out-of-network provisions of a plan, the exclusion of a drug from a formulary, and similar design issues do not involve benefit determinations and are not eligible for either internal appeal or external review. In addition, the Departments should revise the example in the Preamble to clarify that a plan sponsor's decision to impose coverage limitations on the frequency, method, treatment or setting for a mandated preventive service will not be subject to internal or external review.

***b. Claims regarding a plan's compliance with the law are not eligible for internal or external review.***

The Preamble to the Amendment provides that a determination regarding whether a treatment limitation imposed by the plan on mental health and substance abuse benefits satisfies the Mental Health Parity and Addiction Equity Act (the "MHPAEA") is an adverse benefit determination eligible for external review.<sup>21</sup> However, a claim regarding whether a plan complies with an applicable provision of the law, such as the MHPAEA, cannot be a claim involving an adverse benefit determination.

A participant's legal challenge to a particular provision of a plan may be pursued only in accordance with any private enforcement right available under the statute that the participant seeks to enforce. For example, a participant could not seek to enforce compliance with the MHPAEA under section 503 of ERISA (*i.e.*, the internal claims procedure process); instead, the participant would have to pursue a civil action to enjoin an act or practice that the participant believes violates the MHPAEA under section 502(a)(3).

Accordingly, the Departments should clarify that claims questioning a plan's compliance with the law do not involve adverse benefit determinations and are not eligible for review under the plan's internal or external review procedures. In addition, the Departments should delete their statement in the Preamble that a determination regarding whether a plan is complying with the nonquantitative treatment limitation provisions of the MHPAEA is an adverse benefit determination eligible for external review.

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<sup>21</sup> 76 *Fed. Reg.* 37208, 37216 (June 24, 2011).

#### **4. The example in the Amendment regarding wellness reward determinations should be removed to prevent confusion.**

The Preamble to the Amendment includes as an example of an adverse benefit determination eligible for external review, a determination regarding “whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan’s wellness program”.<sup>22</sup> Although it is theoretically possible, it is very rare that denying a participant’s request for a wellness reward would be an adverse benefit determination under ERISA’s claims procedures. ERIC urges the Departments to remove this example from the Preamble to eliminate any implication that denying a participant’s request for a wellness incentive is the same as denying a claim for benefits under a plan for purposes of the plan’s internal or external review procedures.

The Department of Labor has specifically provided that requests for determinations of eligibility under a group health plan are not claims for benefits for purposes of ERISA’s claims procedures.<sup>23</sup> Wellness incentives are typically adjustments to the financial terms of plans that apply to benefits, such as a discount or rebate of a premium or a waiver of all or part of a deductible, copayment, or coinsurance amount.<sup>24</sup> Therefore, a determination regarding whether an individual is eligible to receive a wellness incentive normally involves only a determination regarding whether an individual is eligible to participate in a plan on the most favorable terms. For example, a typical determination would involve whether an individual is eligible for a premium discount because the individual is able to certify that he or she has not used tobacco products in the last twelve months. The determination would also involve evaluating whether the requirement for the premium discount should be waived or modified for an individual who is able to show that he or she is addicted to nicotine.

As the Department of Labor has explained, there are other ways that an individual can resolve disputes regarding the terms under which an individual is eligible to participate in a plan, such as by bringing a civil action under section 502(a)(1)(B) of ERISA.<sup>25</sup> The same is true for disputes regarding whether an individual is eligible for a reward under a wellness program. If a participant’s request to receive a premium discount is denied, the participant cannot appeal this denial under ERISA’s claims procedures, but he or she may bring a civil action under section 502(a)(1)(B) of ERISA to establish his or her right to participate in the plan on more favorable terms.

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<sup>22</sup> 76 *Fed. Reg.* 37208, 37216 (June 24, 2011)

<sup>23</sup> 65 *Fed. Reg.* 70245, 70255 (Nov. 21, 2000); Department of Labor, *Frequently Asked Questions about the Benefit Claims Procedure Regulation*, A-3 available at [http://www.dol.gov/ebsa/faqs/faq\\_claims\\_proc\\_reg.html](http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html).

<sup>24</sup> 29 C.F.R. § 2590.702(f)(2)(i), 26 C.F.R. § 54.4980(f)(2)(i); and 45 C.F.R. § 146.121(f)(2)(i).

<sup>25</sup> 65 *Fed. Reg.* at 70255 n. 38.

In contrast, if a participant's claim for benefits, such as a pre-service or post-service claim, is denied because a participant is not eligible to participate in a plan, the Department of Labor has ruled that the denial of benefits is eligible for review under ERISA's claims procedures.<sup>26</sup> Accordingly, in the rare case in which a participant's claim for a benefit is denied, at least in part, because the plan administrator determines that a participant is not eligible for a wellness reward, the denial of benefits would be eligible for review under the plan's internal claims and appeals procedures and, if the denial involves medical judgment, its external review process. For example, if a participant seeks reimbursement for a covered service and the plan administrator requires the participant to pay a higher copayment for the service because the participant is not eligible for a wellness reward, the partial denial of the participant's claim because of his ineligibility for the wellness reward would be an adverse benefit determination.

However, the vast majority of disputes regarding whether a participant is eligible to participate in a plan under its most favorable financial terms (such as disputes regarding whether an individual is entitled to a reasonable alternative standard for a reward under the plan's wellness program) will not arise in connection with a claim for benefits, and therefore, will not be adverse benefit determinations. The rare instances in which a participant's request for a wellness reward would be considered an adverse benefit determination do not justify the Departments' implication that all determinations regarding a participant's eligibility for a wellness program are eligible for internal and external review. Accordingly, we urge the Departments to remove this example from the Preamble to avoid confusing and misleading plan participants and administrators.

**5. In any case where external review is binding, the guidance should make clear that the external reviewer acts as a fiduciary and must follow plan terms.**

In Technical Release 2010-01, the Department of Labor published interim procedures for group health plans that are subject to the federal external review process. The federal external review process described in the technical release should be modified in two significant respects: (1) to the extent that the federal external review is binding on the group health plan, the technical release and any future guidance should make clear that the IRO acts as a fiduciary of the plan; and (2) as a plan fiduciary, the IRO should be required to follow the terms of the plan.

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<sup>26</sup> 29 C.F.R. § 2560.503-1(m)(4); 65 Fed. Reg. at 70255; Department of Labor, *Frequently Asked Questions about the Benefit Claims Procedure Regulation*, A-3 available at [http://www.dol.gov/ebsa/faqs/faq\\_claims\\_proc\\_reg.html](http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html).

**a. If the IRO's decision is binding, the guidance should acknowledge that the IRO is a fiduciary.**

The interim final regulations provide that an external review decision is binding on the plan, except to the extent other remedies are available under state or federal law.<sup>27</sup> The amendments to the interim final regulations clarify that a plan must provide any benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan intends to seek judicial review of the decision and unless there is a judicial decision otherwise.<sup>28</sup> Accordingly, an IRO is not merely advising the plan administrator on a claim but is issuing a final decision on a claim that the plan administrator is bound to follow unless the decision is overturned on judicial review. Because of the binding effect of an IRO's decision on the plan, particularly if a plan sponsor chooses not to seek judicial review of the IRO's decision, the Department of Labor's guidance should acknowledge that the IRO acts as a plan fiduciary.

A person or entity that has discretionary authority or discretionary responsibility for the administration of an ERISA-governed plan is a fiduciary.<sup>29</sup> In any case where the IRO reviews the record de novo and reaches a decision that is binding on the plan, the IRO clearly is exercising discretionary responsibility for the administration of the plan. The IRO's status as a fiduciary is centrally important in defining the scope of the IRO's authority and responsibility under the plan. In addition, under established case law, the federal courts generally defer to the decision of a plan fiduciary. To the extent that the IRO acts as a fiduciary, it should receive the same deference. Accordingly, the guidance should state that the IRO is acting as a fiduciary of the plan when it conducts a binding review.

If the Departments do not agree that an IRO is a fiduciary, the Departments should at least issue guidance explaining the status of an IRO.

**b. The IRO must follow the terms of the plan unless the terms are contrary to ERISA.**

ERISA states that a fiduciary has a duty to act "in accordance with the documents and instruments governing the plan insofar as such documents and

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<sup>27</sup> 26 C.F.R. § 54.9815-2719T(d)(2)(iv); 29 C.F.R. § 2590.715-2719(d)(2)(iv); 45 C.F.R. § 147.136(d)(2)(iv).

<sup>28</sup> 26 C.F.R. § 54.9815-2719T(d)(2)(iv); 29 C.F.R. § 2590.715-2719(d)(2)(iv); 45 C.F.R. § 147.136(d)(2)(iv).

<sup>29</sup> ERISA § 3(21)(A); *see also* 29 C.F.R. § 2509.75-8, Q&A D-3 (a person is a fiduciary if the person "has the final authority to authorize or disallow benefit payments in cases where a dispute exists as to the interpretation of plan provisions relating to eligibility for benefits").

instruments are consistent with the provisions of ERISA.<sup>30</sup> In contrast, Technical Release 2010-01 says that an IRO will consider the terms of the plan only “to the extent the information or documents are available and the IRO considers them appropriate,” and then only as one of a number of factors that will influence the IRO’s decision. We urge the Department of Labor to make clear that an IRO has the same duty as any other fiduciary to follow the terms of an ERISA-governed plan.

ACA did not change the fundamental fiduciary provisions of ERISA. Like other fiduciaries, the IRO has a duty to obtain and review all documents and instruments governing the plan that are relevant to its decision.<sup>31</sup> If a plan clearly does not cover a particular medical expense, and the terms of the plan are consistent with ERISA, the IRO must deny the claim. Similarly, if a plan includes a standard of medical necessity that complies with ERISA, the IRO must decide a claim based on medical necessity in accordance with the plan’s specified standard. An IRO can neither ignore nor modify the terms of a plan regardless of any other evidence-based standards or the opinions of the IRO’s reviewers.

In addition, the Department of Labor’s claim procedures under section 503 of ERISA emphasize the importance of ensuring that “plan provisions have been applied consistently with respect to similarly-situated claimants.”<sup>32</sup> Accordingly, if it is necessary for the IRO to interpret a provision of the plan, the IRO should consider any information provided by the plan showing how that provision has been interpreted and applied in the past to similarly-situated claimants. Conversely, an IRO should be required to issue clearly reasoned decisions that identify the standard the IRO applied to decide the claim, the IRO’s interpretation of the provision, and how the interpretation is consistent with other relevant fiduciary interpretations of the plan so that the interpretation can be applied to future similarly-situated claimants. We urge the Department of Labor to clarify these points as soon as possible.

If the Departments do not agree that IROs are fiduciaries, the Departments should nevertheless require IROs to follow the terms of an ERISA-governed plan in deciding claims on external review. Nothing in ACA or any other statute gives an external reviewer the authority to require an employer to provide benefits that are not otherwise covered under the terms of an employer’s ERISA-governed plan. We urge the Departments to recognize that employers provide group health plans voluntarily. If employers are faced with the burden, risk, and expense of providing benefits that are

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<sup>30</sup> ERISA § 404(a)(1)(D).

<sup>31</sup> See 29 C.F.R. § 2560.503-1(b)(5) (a plan’s claims procedures must contain “administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents”); see also Lab. Dep’t Adv. Op. 2004-03 (Dec. 17, 2004) (describing a fiduciary’s duty to obtain and review plan documents).

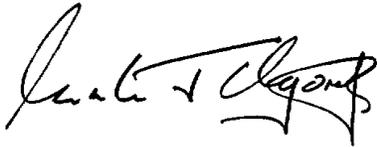
<sup>32</sup> 29 C.F.R. § 2560.503-1(b)(5).

not covered under the terms of their plans, their only practical response might be to terminate their group health plans entirely. Accordingly, the Departments should require IROs to be bound by the terms of an ERISA-governed plan even if the Departments do not conclude that IROs are fiduciaries.

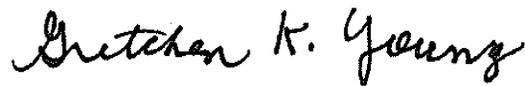
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ERIC appreciates the opportunity to provide comments on the interim final regulations. If the Departments have any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,



Mark J. Ugoretz  
President



Gretchen K. Young  
Senior Vice President, Health Policy