



**Comments Of
The ERISA Industry Committee**

**On The
Interim Final Regulations
Relating To
Internal Claims And Appeals
And External Review Processes
(RIN 1210-AB45)**

September 21, 2010

*Submitted through the Federal eRulemaking Portal:
<http://www.regulations.gov>*

This page is intentionally blank.

TABLE OF CONTENTS

ERIC’s Interest in the Interim Final Regulations	1
Comments Regarding Internal Claims and Appeals Procedures.....	2
A claimant should not be permitted to bypass the internal appeals process merely because a plan fails to adhere to a minor requirement of the regulations.	2
The regulations should clearly state that ACA’s “continuing coverage” requirement does not impose any new or additional requirements on group health plans. Further, the continuing coverage requirement does not require plans to continue coverage during the period of external review.	4
The regulations must more effectively balance the needs of non-English speakers against the additional significant costs imposed on plans and, ultimately, participants.....	6
The threshold test should be revised.	7
The regulations should not require plans to provide individualized notices in a non-English language.	9
The regulations should not require plans to provide customer assistance in a non-English language.	10
The regulations should not require diagnosis or treatment codes for services provided outside the United States.....	11
The period for making a final adverse benefit determination should be tolled to give plan administrators a reasonable period of time to adequately consider a claimant’s response to additional evidence or rationales.....	12
The regulations should clearly state that plans are not required to accept oral testimony during the internal claims and appeals process.	13
Comments Regarding External Review Processes.....	14
The guidance should make clear that the external review process is not binding on self-insured plans.	14
The guidance should make clear that the decision of the independent review organization is subject to judicial	

review and the plan is not required to pay a claim until that review is complete.	15
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.	16
If the IRO’s decision is binding, the guidance should acknowledge that the IRO is a fiduciary.	17
The IRO must follow the terms of the plan unless the terms are contrary to ERISA.	17
The Departments should clarify that a plan may elect to use an available state external review process on a state-by- state or plan-option-by-plan-option basis.	19
Expedited external review should be available only if a physician certifies the need for expedited review based on appropriate medical exigency.	20
The guidance should provide that, for good cause, a plan has three business days to respond to a request for expedited review.	20
Issues relating to plan design should not be eligible for review under a plan’s internal or external claims procedures.	21
The federal external review process should include an exception for de minimis claims.	22
The scope of the federal external review process should be the same as the scope of the state external review processes.	23
Comments on the Effective Date of the Regulations	24
The Departments should clarify that the interim final regulations apply to services rendered after the effective date of the regulation.	24
The Departments should withdraw the interim final regulations and re-issue them as proposed regulations. If the Departments do not grant this request, they should at least delay the general effective date of the regulations.	25



September 21, 2010

**The
ERISA
Industry
Committee**

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 interim final regulations implementing the internal claims and appeals and external review processes under the Patient Protection and Affordable Care Act (“ACA”). The interim final regulations were published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the “Departments”) in the *Federal Register* on July 23, 2010.

ERIC’s Interest in 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. For example, many members voluntarily offer participants an optional additional level of review or the opportunity to have their claims evaluated by an independent external reviewer. ERIC’s members support a claims procedure that gives participants a reasonable and responsible opportunity to appeal adverse benefit determinations.

We urge the Departments to recognize, however, that employers do not have unlimited resources to spend on health care. As American companies struggle to compete in a global economy, they labor under the burden of

a health care system that is among the most expensive in the world. This burden falls much more heavily on private companies in the United States than it does on their competitors in other developed nations, where the government plays a larger role in providing health care and controlling medical costs.

ACA has imposed a number of expensive new mandates on employer health plans that were already struggling to cope with runaway medical costs. Many of ERIC's members are approaching, and many have already reached, the tipping point: they cannot spend more money on health care, so that every additional dollar needed to satisfy a new administrative requirement is a dollar that must be recovered by reducing employees' health benefits.

ERIC is concerned that the interim final regulations include a number of features that will increase employers' administrative costs without producing a corresponding increase in employees' welfare.

ERIC also is concerned that the interim final regulations do not give its members sufficient time to implement the regulations.

Comments Regarding Internal Claims and Appeals Procedures

- 1. A claimant should not be permitted to bypass the internal appeals process merely because a plan fails to adhere to a minor requirement of the regulations.**

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. In this circumstance, the claimant may proceed straight to external review or to court, regardless of whether the plan administrator has substantially complied with the internal claims and appeals procedure, and regardless of the magnitude of the error. If the claimant chooses to bypass further review and proceed straight to court, the regulations, contrary to well settled existing law, direct the court to give no deference to the plan administrator's decision, but to assume instead that the claim has been denied on review "without the exercise of discretion by an appropriate fiduciary."¹ We urge the Departments to moderate this "strict compliance" rule, which otherwise will substantially undermine the internal claims and appeals process.

Under the interim final regulations, a plan administrator's infraction of the "strict compliance" rule, however inconsequential, allows the claimant to bypass the internal claim and appeals process. *This is true even if the claimant was not prejudiced in any way by the plan administrator's error.* For example, the "strict

¹ 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).

compliance” standard permits the claimant to circumvent the internal review process if the plan administrator commits a typographical error in entering a denial code but properly describes the basis for the denial, or if the date of service shown in the denial is off by a day but the service is clearly identified.

The interim final regulations impose standards for internal claims and appeals that are so demanding that it is highly unlikely that even large group health plans will satisfy the standards. Because ACA added the internal claims and appeals requirements to the Internal Revenue Code, employers are subject to a \$100 a day excise tax if their group health plans are deemed to have failed to satisfy these requirements.² In addition, claimants who are impatient or for any reason dissatisfied with the internal review process will now have the right to request an independent external review for which they will pay (at most) a nominal fee while employers bear almost all the cost. The net result will contradict the major rationale behind the ACA, that is, either employers will cease to sponsor plans for fear of losing control over their plans and increasing litigation, or the plans they do sponsor will be replete with hundreds of detailed provisions stating all of the varied procedures they will not cover.

As ACA recognizes, the plan administrator has the right to interpret and apply the provisions of the plan in the first instance. If the plan administrator determines that a claim, based on the plan provisions, should be denied, the plan administrator has the right to develop a factual record that will assist the claimant, an external reviewer, or a court in understanding the basis for the denial. The internal review process helps to ensure that the plan provisions will be applied consistently and correctly, that the benefits will be provided pursuant to the plan, and the employer’s financial support will be expended, as the plan provisions dictate.

A plan administrator should not be deprived of the right to interpret the plan and develop an administrative record solely because the administrator inadvertently commits a “de minimis” error with no prejudice to the claimant. We urge the Departments to revise the interim final regulations to make clear that the claimant is deemed to have exhausted the internal claims and appeals process only if the plan administrator fails to establish an appropriate claim and appeal procedure or fails to follow the procedure in a material respect. The test should be whether the defect in the internal claim and appeal procedure is sufficiently serious to interfere with the claimant’s exercise of his or her right to administrative review.

While we strongly urge the Departments to adopt ERIC’s recommendation, if the Departments do not, the interim final regulations should, at a minimum, be revised to clarify that the strict compliance standard does not apply for purposes of the \$100-a-day excise tax. An employer sponsoring a health plan should not be

² I.R.C. § 4980D.

penalized by an excise tax solely because a plan fails to follow in every minute degree the detailed claims and appeals procedures in the interim final regulations. In addition, if the claimant is permitted to abandon the internal claims and appeals process as soon as the plan commits any error, however minor, the plan will not have any opportunity to correct the error in order to reduce or avoid the excise tax. The excise tax should apply, if at all, only to a situation where the plan fails to establish an appropriate internal claims and appeal procedure or external review process.

2. The regulations should clearly state that ACA’s “continuing coverage” requirement does not impose any new or additional requirements on group health plans. Further, the continuing coverage requirement does not require plans to continue coverage during the period of external review.

ACA requires group health plans to allow participants to continue receiving coverage pending the outcome of the appeals process. The regulations provide that for purposes of this rule, plans “must comply” with the requirements of 29 C.F.R. § 2560.503-1(f)(2)(ii), which provides that plans may not terminate or reduce benefits for an ongoing course of treatment for which they have given prior approval without providing advance notice and an opportunity for advance review.³ We request that the Departments make clear that compliance with paragraph (f)(2)(ii) of the Labor Department claims procedure regulation is the *only* requirement that plans must meet in order to satisfy ACA’s continuing coverage requirement.⁴

This clarification is important because paragraph (f)(2)(ii) of the Labor Department claims procedure regulation appears to be appropriately limited in the following respects:

³ 26 C.F.R. § 54.9815-2719T(b)(2)(iii); 29 C.F.R. § 2590.715-2719(b)(2)(iii); 45 C.F.R. § 147.136(b)(2)(iii).

⁴ This clarification is consistent with the statement in the preamble that the continuing coverage provision “would not impose any additional cost on plans and issuers that comply with the DOL claims procedure regulation.” 75 *Fed. Reg.* 43329, 43345 (July 23, 2010).

- The continuing coverage requirement applies only if a group health plan has approved an ongoing course of treatment: it does not apply, for example, if the plan has merely paid for individual physical therapy sessions but has not approved a twelve-week course of physical therapy.
- The continuing coverage requirement applies only to the specific course of treatment the plan has approved: if the plan has approved a course of radiation treatment, and the treating physician subsequently adds chemotherapy to the treatment regimen, the continuing coverage requirement does not apply to the chemotherapy unless the plan separately approves that course of treatment.
- The continuing coverage requirement applies only to the period of treatment or number of treatments approved by the plan: if the plan has approved ten treatments, for example, no advance notice or continuing coverage requirement applies if the plan refuses to pay for an eleventh treatment.
- Although the continuing coverage requirement requires the plan to extend coverage provisionally while the claimant has an opportunity to appeal the plan's decision, it does not require the plan to assume financial responsibility for benefits that are not otherwise covered. Accordingly, if the plan's decision to terminate the course of treatment is upheld in the internal appeal, the plan may recover any payments made during the period of provisional coverage.

We request that the Departments also clarify that the continuing coverage requirement does not require a group health plan to continue coverage during the external review process. The purpose of the continuing coverage rule is to give participants who are faced with early termination of a pre-approved course of treatment "adequate opportunity to contest the termination or reduction of already granted benefits before it takes effect."⁵

Under paragraph (f)(ii) of the Labor Department claims procedure regulation, this requirement is satisfied if the participant has notice of the plan's decision to terminate coverage of the course of treatment and an opportunity to appeal the decision under the plan's internal review process. If the initial decision is upheld by the internal appeal process, the plan may terminate the course of treatment even if the claimant pursues additional review through the external review process or through a lawsuit. The plan must reinstate the benefits retroactively if the decision to terminate the course of treatment is subsequently overturned, but the plan is not required to continue coverage while the period for requesting external review is still open or the external review is pending.

⁵ 65 *Fed. Reg.* 70245, 70249 (Nov. 21, 2000).

This clarification is essential to keep administrative costs within tolerable bounds, as the plan administrator will not control the timing or duration of the external review process. Under the interim external review procedure described in the Labor Department's Technical Release 2010-01, a claimant may wait up to four months before filing a request for external review; thus, it could be several months before the administrator will even know if the claimant has decided to appeal.

Thus, if a plan is forced to wait until an external reviewer has upheld the administrator's decision before terminating or reducing coverage, the plan or plan sponsor will face the onerous task of attempting to recover the benefits that were improperly paid to the provider or claimant during the external review. Recovering benefits after they have been paid is often difficult and expensive, and the plan commonly is not able to recover all or even a substantial portion of the improper payments. As the Departments recognized in the preamble, the continued coverage rule is not intended to impose additional costs on plans that are subject to ERISA's claim procedures.

In order to clarify the continuing coverage requirement, we recommend that the Departments add the following sentence at the end of the current paragraph (b)(2)(iii) in the interim final regulations: "A plan or issuer that complies with the requirements of 29 C.F.R. § 2560.503-1(f)(2)(ii) during the internal claim and appeal process will satisfy the requirements of this paragraph (b)(2)(iii)." This sentence will make clear that the interim final regulations merely extend the existing requirement of the Labor Department's ERISA claims procedures to plans that were not previously subject to ERISA: the interim final regulations do not impose any new continuing-coverage obligation on ERISA-governed plans or require plans to continue coverage during the external review period.

3. The regulations must more effectively balance the needs of non-English speakers against the additional significant costs imposed on plans and, ultimately, participants.

The interim final regulations require plans to provide relevant notices in a culturally or linguistically appropriate manner if at least a threshold number of participants are literate only in the same non-English language. For plans with 100 or more participants, the threshold is the lesser of 500 participants or 10 percent of participants. If the applicable threshold is met, the plan must (1) include a statement in the English versions of all notices offering to provide the notice in the non-English language, (2) provide the notice in the non-English language upon request by any claimant and automatically provide any subsequent notices to that claimant in the non-English language, and (3) to the extent that plans provide a customer assistance process, provide this assistance in the non-English language.

These requirements will impose extraordinary costs and administrative burdens on group health plans that will generally far exceed the benefits they will confer on non-English-speaking participants. In some cases, the requirements will have the unintended effect of reducing the services available to all participants.

ERIC recommends several changes in these requirements to achieve a better balance between the needs of plan participants and the costs and practical realities of plan administration. First, ERIC recommends changes in the threshold tests to make them more understandable and workable. Second, ERIC strongly recommends that plans not be required to issue individualized benefit notices in non-English languages. Third, ERIC urges the Departments to eliminate the requirement that plans provide customer assistance in non-English languages.

a. The threshold test should be revised.

The threshold test should not be based on the language in which participants are literate. It is often impossible for employers to know whether workers are *literate*—that is, able to read and write—in a particular language, and many workers are not literate in any language, including English. The statutory claims and appeal procedures (and ERISA’s other statutory disclosure requirements) do not require the plan administrator to determine whether a participant is literate in English, let alone in a non-English language. Employers are not equipped, assuming it were lawful, to perform literacy tests on employees who are not required to read and write as part of their job responsibilities. Moreover, employers are concerned that any inquiry concerning an employee’s degree of literacy in English might be construed as prohibited discrimination based on national origin.

The Department of Health and Human Services has already acknowledged that claimants’ spoken language should be the basis for any requirement to provide information in a non-English language. The interim final regulations require health insurance issuers offering individual health insurance coverage to provide notices in a culturally and linguistically appropriate manner if ten percent or more of the people residing in the claimant’s county are literate only in the same non-English language.⁶ The Department of Health and Human Services has interpreted “literate only in the same non-English language” to mean “speaks English less than very well and speaks the same non-English language.”⁷ If health insurers in the individual insurance market are not required to perform literacy tests, employers also should not be required to perform these tests. Accordingly, the threshold tests should be based on the number of employees who are able to speak and to understand oral instructions only in a non-English language.

⁶ 45 C.F.R. § 147.136(e)(2)(i).

⁷ Department of Health and Human Services Office of Consumer Information and Insurance Oversight, *Technical Guidance for Issuers in the Individual Market to Establish County Level Estimates Pertaining to the Culturally and Linguistically Appropriate Standards Set Forth in the Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act*, available at: http://www.hhs.gov/ociio/regulations/consumerappeals/guidance_for_individual_market.pdf.

Further, the Departments should explain what it means for employees to be literate only in “the same non-English language.” For example, an employee from Mexico and an employee from Spain both speak Spanish, but they do not speak the same dialect of Spanish. Similarly, there are many dialects and languages that fall under the category of “Chinese.” The regulations should be revised to make clear that an employer may disregard regional dialects and may treat what the employer reasonably determines to be the standard language as the “non-English language” of that group of employees.

We recognize that the test for determining whether a plan must provide culturally and linguistically appropriate notices is the same as the existing test for determining whether a plan must include a non-English statement in a summary plan description (“SPD”) or summary annual report (“SAR”).⁸ If a plan satisfies the test with respect to SPDs and SARs, however, it is merely required to include a standard statement in the non-English language explaining how participants may obtain assistance in understanding these documents. The vast majority of large employers simply comply with this requirement for any substantial group of non-English-speaking participants without actually performing the test. (We also question whether complex provisions of benefits law can, without creating greater confusion, be accurately translated into languages that have no comparable terms or cultural context.)

In contrast, the interim final regulations impose much more substantial and costly burdens on plans that meet these thresholds, while also significantly increasing the penalties for plans that do not comply in some minor respect and thus inadvertently fail to meet the “strict compliance” rule described above. Accordingly, large employers need a test that they can easily apply to determine when they are required to provide information in a non-English language, such as a test based on the number of employees who are able to speak and to understand oral instructions only in a non-English language. Further, the test should be one that does not raise sensitive concerns of individual privacy.

The Departments should make corresponding changes in the SPD and SAR regulations, so that employers may apply a single uniform test to determine whether they are subject to non-English disclosure requirements.

⁸ 29 C.F.R. §§ 2520.102-2(c)(2) and 2520.104b-10(e).

b. The regulations should not require plans to provide individualized notices in a non-English language.

The statutory language of ACA merely requires plans to provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes. This requirement would be satisfied if the plan administrator included in the plan's SPD an informational statement similar to the statement currently required for non-English-speaking participants under the Department of Labor's SPD regulations. The statement would be provided in each relevant non-English language; it would describe the plan's claims and appeal procedures, and it would explain how participants may obtain assistance in understanding these procedures.

Nothing in ACA requires plans to provide notices of adverse benefit determinations in non-English languages. Because these notices must be produced individually for each initial claim denial and for each denial on review, they will be difficult and costly to produce. In order to provide individualized benefit determinations in each relevant non-English language, the plan would need to retain a staff of translators who were fluent in the non-English language, conversant with medical terminology and plan provisions, and able to understand and accurately translate the decision of the plan administrator. The plan would also need to retain additional administrative staff who were literate in the non-English language and could review the translation and verify its accuracy.

Even assuming that a plan were able to locate linguistically and dialectically competent translators and could afford to keep them on staff or even on retainer, it would be virtually impossible for the plan to meet some of the regulatory requirements regarding translation into a non-English language. For example, it is not clear how a group health plan would translate diagnosis codes, treatment codes, and denial codes into a non-English language. In addition, the time necessary to prepare and review the translation would far exceed the time allowed to resolve an urgent care claim.

The requirement to prepare individualized notices in non-English languages is unworkable and should be deleted from the interim final regulations. If the Departments retain this requirement, it will dramatically increase plans' administrative costs, delay the review process, and increase the potential for confusing and inaccurate communications. These problems significantly outweigh any benefit to participants of receiving individualized notices in non-English languages.

If the Departments continue to require that plans provide individual notices of benefit determinations in non-English languages, the Departments should publish model notices in order to assist plan administrators to satisfy this requirement. For example, it is incumbent on the Departments, at a minimum, to issue a Model Notice of Adverse Benefit Determination, a Model Notice of Final Internal Adverse Benefit Determination, and a Model Notice of Final External

Review Decision in Spanish, Chinese, French, German, Tagalog, Vietnamese, and Italian, and other non-English languages most commonly spoken in the United States.⁹ The Departments should also provide a translation of all standard diagnosis codes, treatment codes, and denial codes, and an explanation of the meaning of each code, in those non-English languages.

Employers generally do not have the in-house resources necessary to translate adverse benefit determinations, which frequently include medical terms and other technical information, into non-English languages. As a result, the plan administrator often will need to engage a third-party translation service or to use translation software programs in order to provide notices in a non-English language. It will be impossible for plan administrators to verify the accuracy of non-English information when the plan administrator is not fluent in the non-English language. The interim final regulations should make clear that a plan will be deemed to have satisfied the requirement to provide non-English notices (and will not violate the “strict compliance” standard discussed above) if the plan administrator makes a reasonable, good-faith attempt to have the notice translated accurately from English to a non-English language.

c. The regulations should not require plans to provide customer assistance in a non-English language.

Nothing in the statutory language of ACA requires plan administrators to make participant hotlines and other customer assistance services available in non-English languages if the employer chooses to offer these services in English. These services generally are provided by third-party claims administrators. It is difficult enough for a plan administrator to ensure that individuals answering a participant hotline provide accurate information in English: it will be nearly impossible to ensure that they do so in Chinese, Vietnamese, Tagalog, and other non-English languages as well as their various dialects.¹⁰

Moreover, workers literate in the same non-English language are not necessarily able to understand each other’s spoken language. For example, while some workers might be able to read a document written in Mandarin Chinese, they might not be able to understand a call center employee who speaks Mandarin. Plan administrators would thus be required not only to determine the non-English language in which the worker was literate, but they would also need to ascertain the language spoken and understood by the worker if they actually wished to make the call center a viable option for communication.

⁹ U. S. Census Bureau, Census 2000 Summary File 3.

¹⁰ See Lewis, M. Paul (ed.), 2009. *Ethnologue: Languages of the World, Sixteenth edition*. Dallas, Tex.: SIL International available at <http://www.ethnologue.com/> (showing at least 14 different dialects of Chinese and at least eight different dialects of Spanish within Spain alone).

We urge the Departments to recognize that employers offer customer assistance services voluntarily. ACA does not require group health plans to provide these services as part of the claim and appeals process. If employers are faced with the burden, risk, and expense (and, in many cases, the near impossibility) of providing customer assistance services in non-English languages, their only practical response might be to eliminate the customer assistance service entirely. The result will be that English-speaking employees will lose a useful voluntary service, and non-English-speaking employees will gain nothing in the process. Accordingly, the Departments should revise the interim final regulations to remove the requirement that customer services be offered in non-English languages.

4. The regulations should not require diagnosis or treatment codes for services provided outside the United States.

To help participants understand the claim that is the subject of an adverse benefit determination, the interim final regulations require plans to ensure that benefit determination notices include the diagnosis code (and its corresponding meaning) and the treatment code (and its corresponding meaning) for the claim.¹¹

Federal law generally requires health care providers to include standard diagnosis and treatment codes in medical bills submitted to group health plans and insurers for payment.¹² If a health care provider submits requests for payment by paper rather than electronically, however, the provider is not required to include standard diagnosis or treatment codes in the request.¹³ Health care providers located outside of the United States also generally do not include standard diagnosis and treatment codes in medical bills that they submit to plans and insurers. In these cases, the plan administrator often is able to determine from the provider's description of the service whether the claim is covered by the plan.

If a non-U.S. health care provider does not provide diagnosis and treatment codes when it seeks payment from a group health plan, the plan administrator generally will not be able to correct this problem by contacting the provider to obtain appropriate codes. Non-U.S. health care providers generally are not familiar with the coding system in the United States and will not be able to identify the appropriate codes. As a result, the plan administrator must either issue a notice to the claimant without diagnosis or treatment codes, or else must supply the codes itself.

¹¹ 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(E)(1); 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E)(1); 45 C.F.R. § 147.136(b)(2)(ii)(E)(1).

¹² 42 U.S.C. §§ 1320d through 1320d-9 (sections 1171 through 1179 of the Social Security Act); 45 C.F.R. parts 160, subpart A, and 162 subparts A, and I through R.

¹³ 45 C.F.R. § 162.402.

Although a plan administrator might have enough information about a service provided outside the U.S. to determine that the claim should be denied, the administrator will not necessarily have sufficient information or technical expertise to apply the correct diagnosis and treatment code to the service. Accordingly, we request that the Departments revise the interim final regulations to provide that diagnosis and treatment codes must be included in notices of adverse benefit determinations and final adverse benefit determinations only if standard codes are furnished by a non-U.S. provider when the provider seeks payment from the plan for services provided.

5. The period for making a final adverse benefit determination should be tolled to give plan administrators a reasonable period of time to adequately consider a claimant's response to additional evidence or rationales.

The interim final regulations require plans to provide a claimant, free of charge, any new or additional evidence considered, relied upon, or generated by the plan in connection with a claim or any new or additional rationale on which a final adverse benefit determination will be based.¹⁴ This new or additional evidence or rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

For reasons beyond the plan administrator's control, a plan might not receive new or additional evidence or develop a new or additional rationale that will serve as a basis for its determination until shortly before the deadline for responding to a claimant. For example, a plan administrator might need to obtain relevant medical records from third parties or might need to have a medical expert review the claim and provide a second opinion. If the plan administrator does not receive information from these third parties until shortly before the deadline for responding to a claimant, the plan will not be able to provide the information or any new or additional rationale based on the information sufficiently in advance of the deadline for a participant to respond and for the administrator to take into account the participant's response in making its final determination. The potential for plan administrators to violate this rule for reasons beyond their control discourages them from seeking new or additional information to assist them in evaluating claims. A plan administrator's inability to pursue new or additional information will be to the detriment of claimants whose initial adverse benefit determination would otherwise have been reversed on appeal.

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

The Department of Labor established the time periods for making final adverse benefit determinations in its claims procedure regulations under section 503 of ERISA after a lengthy process of considering both plans' and participants' views on what constitutes a reasonable period of time for making these determinations. In addition, Congress endorsed these time periods in ACA by requiring group health plans, including insured group health plans, to comply with the ERISA claims procedures. The Departments have effectively shortened these time periods by requiring plan administrators to make a determination early enough in these time periods to give claimants an adequate opportunity to consider and respond to any additional evidence or rationale that arises in the course of making the final adverse benefit determination. This requirement is contrary to statutory intent and also ignores prior determinations by the Department of Labor regarding the length of the period that plans need to make final adverse benefit determinations.

Accordingly, we urge the Departments to revise this rule (a) to require plans to provide any new or additional evidence or rationale as soon as possible and before the date on which the notice of final internal adverse benefit determination is otherwise required to be provided under 29 C.F.R. § 2560.503-1(i), 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 participant 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.

6. The regulations should clearly state that plans are not required to accept oral testimony during the internal claims and appeals process.

The interim final regulations state that a plan provides a reasonable opportunity for a full and fair review of a claim on appeal if it allows a claimant to "present evidence and testimony as part of the internal claims and appeals process."¹⁵ Under 29 C.F.R. 2560.503-1(h)(2), a plan provides a reasonable opportunity for a full and fair review of a claim if the plan provides a claimant "the opportunity to submit *written* comments, documents, records, and other information relating to the claim for benefits." Because the Departments do not include in the interim final regulations a discussion of the meaning of the term "testimony," ERIC assumes that the Departments intend for this term to refer to a claimant's existing right under 29 C.F.R. 2560.503-1(h)(2) to submit *written* records or comments during the internal claims and appeals process.

For years, claimants have received a full and fair review of their claim based on written comments and evidence that they submit during the internal claims and

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

appeals process. There is no reason that claimants will not continue to receive full and fair reviews of their claims based solely on the written record. Moreover, requiring plans to provide participants with an opportunity to submit oral testimony would impose enormous demands on the time and resources of plan sponsors and administrators. The imposition of such a requirement would also fundamentally disrupt the existing internal claims and appeals process because it would be impossible, in many cases, for plan administrators to gather all of the interested parties for a hearing and decide the claim or appeal within the allotted time periods.

Accordingly, the Departments should revise the interim final regulations to clearly state that plans are not required to allow participants to present oral testimony as part of the internal claims and appeals process in order to satisfy the requirements for a full and fair review under 29 C.F.R. § 2560.503-1(h)(2) and the interim final regulations.

Comments Regarding External Review Processes

7. The guidance should make clear that the external review process is not binding on self-insured plans.

ACA creates separate external review procedures for insured and self-insured plans. Insured plans must satisfy an applicable state external review process if the state has established a process that “includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans.” During a transition period ending July 1, 2011, insured plans will be permitted to comply with any external review process that a State has in effect even if the process does not include these consumer protections.¹⁶ In contrast, self-insured plans are required to satisfy a federal external review process established by the Departments that is similar to the state process. ACA originally required that the external review process for all plans be “binding on the plans.” Significantly, however, the final legislation does not require that the federal external review process be binding, but only that it be “similar” to the state process.¹⁷

¹⁶ Department of Health and Human Services Office of Consumer Information and Insurance Oversight, *Technical Guidance for Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review for Health Insurance Issuers in the Group and Individual Markets and under the Patient Protection and Affordable Care Act*, available at: http://www.hhs.gov/ociio/regulations/consumerappeals/interim_appeals_guidance.pdf.

¹⁷ Compare PHSA § 2719 as added by ACA § 1001(5) with PHSA § 2719 as amended by ACA § 10101(g). The final legislation also gives the Departments discretion to deem existing external review procedures of insured or self-insured plans to be compliant.

We urge the Departments to provide that the federal external review will not be binding on self-insured plans. Employers do not operate these plans with a profit motive. To the contrary, they establish group health plans voluntarily in order to provide health benefits to their employees. In order to ensure that the plans are consistently administered and provide only the benefits that the employer has agreed to provide, however, plan sponsors must retain control over the administration of their self-insured plans.

A number of ERIC's members currently offer claimants an advisory external review procedure. The claimant may, if he or she wishes, obtain the opinion of an independent third party concerning the claim. The external reviewer considers the plan terms, the medical evidence, and any other information the parties wish to submit, and renders an advisory opinion concerning the claim. Because the external reviewer merely provides advice, the reviewer is not a fiduciary of the plan. Nevertheless, the plan administrator or other plan fiduciary gives significant weight to the external reviewer's opinion before the fiduciary reaches a final decision concerning the claim.

In cases where the external reviewer recommends that the claim be granted and the plan administrator denies the claim in spite of this recommendation, the plan administrator must explain why it did not accept the recommendation of the external reviewer. A claimant who is dissatisfied with the result may challenge it in court. In the judicial proceeding, the court will give appropriate weight to the decision of the external reviewer. For example, the contrary decision of the external reviewer might provide a basis for the court to conclude that the plan administrator's decision was arbitrary or that the plan administrator operated under a conflict of interest, so that the administrator's decision should be set aside in favor of the decision recommended by the external reviewer.

An advisory external review procedure achieves an appropriate balance between the need of plan sponsors to ensure that their self-funded plans will be interpreted in a way that is consistent with the sponsor's intent and the need of claimants for an independent and objective assessment of the merits of their claims. Accordingly, we urge the Departments to adopt a rule under which the federal external review procedure for self-funded plans will be an advisory procedure that does not prevent the plan fiduciary from reaching a different resolution of the claim after giving appropriate weight to the findings and conclusion of the external reviewer.

8. The guidance should make clear that the decision of the independent review organization is subject to judicial review and the plan is not required to pay a claim until that review is complete.

Under the National Association of Insurance Commissioners' Uniform External Review Model Act (the "NAIC Uniform Model Act"), no further administrative appeals are allowed after the external reviewer reaches a decision, but either party is permitted to pursue other available remedies. Accordingly, the

State external review process described in the interim final regulations makes clear that the decision of the independent review organization (“IRO”) is not binding to the extent that other remedies are available at law.

The Labor Department’s Technical Release 2010-01 and the Department of Health and Human Services’ Technical Guidance for federal external review¹⁸ incorporate this standard. The technical releases state that the IRO’s determination is binding “except to the extent that other remedies may be available under State or Federal law to either the group health plan or to the claimant.” The technical releases do not describe the other remedies available to the plan or health insurance issuer. Under section 502(a)(3) of ERISA, however, a plan fiduciary may sue in federal court to enforce the terms of the plan or any provision of Title I of ERISA. The Departments should make clear that any fiduciary of an ERISA-governed plan may sue to overturn a decision of the IRO if the fiduciary concludes that the decision is contrary to the terms of the plan or of applicable law. The Departments should make clear that the plan has recourse to the federal courts regardless of whether the plan is subject to the state external review procedure or the federal external review procedure.

The technical releases state that if an IRO reverses an adverse benefit determination, the plan or health insurance issuer must immediately provide coverage or payment for the claim. As a practical matter, once a plan or issuer pays a claim, it is often impossible to recover the payment even if a court concludes that the IRO’s decision was incorrect. Accordingly, in the case of a non-urgent claim, we recommend that the Departments revise the guidance to provide that a plan is required to reach a decision whether to appeal the IRO’s decision within a reasonable period (for example, 30 days) after the IRO’s decision, and that the plan is not required to pay the claim until it has exhausted its right to judicial review of the IRO’s decision.

9. 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. We believe that the federal external review process described in the technical release should be modified in two significant respects: (1) to the extent

¹⁸ Department of Health and Human Services Office of Consumer Information and Insurance Oversight, *Technical Guidance for Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review for Health Insurance Issuers in the Group and Individual Markets and under the Patient Protection and Affordable Care Act*, available at: http://www.hhs.gov/ociio/regulations/consumerappeals/interim_appeals_guidance.pdf.

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.

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

As we explain above, the IRO's decision should be advisory rather than binding on a self-funded plan. To the extent that an IRO's decision is binding on the plan, however, the Labor Department'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.¹⁹ 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.

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 instruments are consistent with the provisions of" ERISA.²⁰ 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

¹⁹ 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").

²⁰ ERISA § 404(a)(1)(D).

instruments governing the plan that are relevant to its decision.²¹ 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. 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."²² 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. We urge the Department of Labor to clarify these points as soon as possible.

The Departments should make clear that the duty to follow the terms of the plan applies to any binding decision of an IRO, regardless of whether the plan is subject to the state external review process or the federal external review process. For example, the NAIC Uniform Model Act provides that the decision whether an experimental or investigational treatment should be covered is not based on a plan's standard for determining whether a treatment is experimental or investigational. Instead, the determination is based on whether medical or scientific evidence or evidence-based standards demonstrate that (1) the expected benefits from the treatment are more likely than not to be beneficial to the participant than any available standard treatment and (2) the adverse risks of the treatment would not be substantially increased over those of available standard treatments.²³ The interim final regulations require states to adopt "substantially similar" procedures for review of benefit denials involving experimental or investigational treatment. The interim final regulations also suggest that comparable consumer protections will apply under the federal external review procedures, although the interim guidance in the technical release does not incorporate these provisions.

The standard in the NAIC Uniform Model Act for external review of experimental and investigational treatments is inappropriate as applied to an ERISA-governed plan, regardless of whether the plan is insured or self-insured, and regardless of whether it is subject to the state or federal external review process. When an IRO reviews a claim involving the coverage of experimental or investigational treatment under an ERISA-governed plan, the IRO must apply the plan's standards for determining whether a treatment is experimental or investigational. The IRO may consider clinical and scientific experience and

²¹ 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).

²² 29 C.F.R. § 2560.503-1(b)(5).

²³ NAIC Uniform Model Act § 10(I)(5)(b).

protocols only to the extent permitted under the terms of the plan. We urge the Departments to amend the interim final regulations to make this point clear.

10. The Departments should clarify that a plan may elect to use an available state external review process on a state-by-state or plan-option-by-plan-option basis.

Technical Release 2010-01 provides that a self-insured plan not subject to state external review requirements may satisfy the ACA external appeal requirement by voluntarily complying with state external review processes, assuming that the state has made the process available to self-insured plans and other plans that are not subject to such state processes. It is our understanding that currently no states make their processes available to self-insured plans.

If and when states expand the availability of their external review processes, plans should have the flexibility to use the state processes on a state-by-state and plan-option-by-plan-option basis. For example, a plan should be able to use a state's external review process for participants in one state and not for participants in other states. Thus, a plan could apply one state's process for some participants and another state's process or the new federal external review process for other participants not resident or working in that state. Similarly, a plan should be able to use an available state process for one option under a plan and not for other options under a plan. For example, a plan should be able to apply one or more state processes to a preferred provider network option and not to a high deductible account-based option (or vice versa).

Some states might timely expand access to their processes and some might not; some state processes might operate more effectively and efficiently than others. Application of one state's process to claimants who are resident or employed in another state might be inappropriate. Allowing a plan to determine whether to apply one or more state processes or the new federal process on a state-by-state or option-by-option basis would recognize and accommodate these practical considerations.

The flexibility that ERIC requests is consistent with ACA's requirement for external review of final adverse benefit determinations. Every eligible claim would have a designated process for independent review and determination, and the process would satisfy ACA, the interim final regulations, and the technical release requirements regarding external review. Moreover, this flexibility would allow plans to apply the external review process that was most efficient and appropriate to each set of participants or plan benefit options under a plan

11. Expedited external review should be available only if a physician certifies the need for expedited review based on appropriate medical exigency.

Under Technical Release 2010-01, a plan must allow a claimant to request an expedited external review whenever the claimant receives an adverse benefit determination and the time frame for an expedited internal review would jeopardize the claimant's life or health or ability to regain maximum function. Alternatively, a plan must allow a claimant to request an expedited external review if the time frame for a standard review would jeopardize the claimant's life or health or ability to regain maximum function or if the final adverse benefit determination involves services related to emergency treatment and the claimant has not been discharged from the treating facility.

Other than matters involving emergency services, a plan will not normally be in a position to properly and timely evaluate a claim for expedited review without further information from the claimant. The technical release indicates that the plan's basic procedure to determine whether a claim is eligible for external review is essentially the same for both standard and expedited review except the process is greatly attenuated if the claim is for an urgent review. If a request for review is deemed incomplete, a plan must notify the claimant, specify the additional information required to make the request complete, and allow additional time to the participant to file the missing information.

The Department of Labor's existing claims and appeal regulations under ERISA section 503 provide that a request for urgent review from a physician with knowledge of the claimant's medical condition shall be treated as a claim involving urgent care.²⁴ Thus, the current section 503 regulations recognize the additional value of a treating physician's statement when filing a request for an urgent internal review (but don't require a physician's statement). For requests regarding urgent external review, we recommend that the Departments require the claimant to include a statement from a treating physician confirming that an urgent review is recommended or necessary. Such a statement will assist the plan in evaluating and processing the request and avoid unnecessary delays for claimants.

12. The guidance should provide that, for good cause, a plan has three business days to respond to a request for expedited review.

The interim final regulations and the technical release reduce the time for evaluating and deciding urgent internal review claims and determining eligibility for expedited external appeals. The plan has 24 hours to respond to requests for expedited internal reviews; it must respond immediately to requests for expedited

²⁴ 29 C.F.R. § 2560.503-1(m)(1)(iii).

external reviews. In some cases, such as around holidays or during weekends, these time constraints might be virtually impossible to satisfy.

The preamble to the interim final regulations indicates that, in an age of electronic communication, less time should be required to process these requests. It is true that the pace and speed of communications have become faster in recent times. However, it still requires real people serving as plan administrators and fiduciaries to process, evaluate, determine, and respond to claims, whether for standard or urgent review. It is not always possible for these individuals to be available 24 hours a day, seven days a week. Additionally, it should be noted that significant penalties apply under ACA for a failure to satisfy its requirements.

A rule of reason should apply for processing urgent review and appeal claims by recognizing the real world demands on the plan officials involved. Accordingly, the rules should be modified to provide that the plan shall respond as soon as practicable to either a request for urgent internal review or expedited external review, but in no case shall the plan fail to respond within three business days of receiving the request for expedited review or appeal (with the first business day being the day of receipt of the request). To the extent that the Departments adopt ERIC's suggestion discussed above that requests for urgent external appeals be accompanied by a treating physician's supporting statement, it is much less likely that additional time will be required by plans in order to respond to such requests.

13. Issues relating to plan design 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. An adverse benefit determination is a denial, reduction, or termination of, or a failure to provide or pay for, a benefit.²⁵ 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. Similarly, the NAIC Uniform Model Act acknowledges that a claim is eligible for external review only if it involves a service that is covered under a claimant's health plan.²⁶

Thus, a benefit denial must refer to a denial under a plan in order to constitute an adverse benefit determination or final adverse benefit determination. 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. For example, a claim relating to dental benefits such as benefits for

²⁵ 29 C.F.R. § 2560.503-1(m)(4).

²⁶ NAIC Uniform Model Act § 8(B)(2).

a tooth restoration or dental hygienic cleaning does not arise from an adverse benefit determination if (1) the plan with respect to which the claim is made does not provide dental benefits and (2) the claimant is not alleging that the benefits are non-dental benefits or that the benefits are medically necessary.

Therefore, the Departments should clarify that claims involving plan design issues, such as 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. Additionally, the Departments should clarify that claims from providers for additional payments for services rendered to participants or beneficiaries (such as an out-of-network provider's claim for payments exceeding the plan's allowable charge) are not claims for benefits under a plan and are not eligible for either the internal or external review processes.

14. The federal external review process should include an exception for de minimis claims.

The interim final regulations provide that a state external review process may not impose a minimum dollar threshold that a claim must meet in order to be eligible for external review. For example, a plan may not provide that a claim will be eligible for external review only if the amount at issue exceeds \$500. Although the interim federal external review process described in Technical Release 2010-01 does not explicitly incorporate this requirement, the federal process lists only three requirements that a claimant must meet in order to be eligible for external review: eligibility to participate in the plan, coverage under the plan at the time of the claim, and exhaustion of the internal appeal process to the extent that exhaustion is required. Accordingly, the interim federal external review process also appears to prohibit a plan from imposing a minimum dollar threshold that a claim must meet in order to be eligible for external review.

The new external review process imposes significant new burdens and costs on plans. With the exception of a nominal fee of \$25 or less that may be charged to claimants, the plan is required to bear the entire cost of the external review. The Departments should weigh the potential benefit to claimants of external review against the substantial costs that the external review process imposes on plans. Claims involving relatively minor matters or small costs should not be eligible for external review because the costs and burdens of external review far outweigh the benefits.

ERIC recommends that the Departments limit external review to claims involving amounts greater than \$1,000. For smaller claims, claimants will have the right to pursue other available remedies, including litigation, once they have received a final adverse benefit determination under the internal review process. Establishing a minimum dollar threshold for external review will assure greater

efficiency of plan administration, better reflect costs and burdens to plans of the external process, and allow claimants to pursue other remedies in a timely manner.

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

ACA requires the federal external review process to be similar to the process described in the NAIC Uniform Model Act.²⁷ The interim final regulations, Technical Release 2010-01, and the Department of Health and Human Services' Technical Guidance for federal external review provide that the federal external review process applies to any adverse benefit determination or final internal adverse benefit determination within the meaning of the claims and appeals regulations under section 503 of ERISA, except for determinations that an individual fails to meet a plan's eligibility requirements.²⁸ Under the interim final regulations and the NAIC Uniform Model Act, only the following types of adverse benefit determinations 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."²⁹ Therefore, contrary to the terms and intent of the statute, plans might be required to allow more types of claims to be reviewed under the federal external review process than are currently eligible for review under the NAIC Uniform Model Act and state external review processes.

We are not aware of any reason for the claims that are eligible for federal external review to be different from the claims that are eligible for state external review. Therefore, we urge the Departments to amend the interim final regulations to limit the scope of the federal external review process to the types of adverse benefit determinations that are subject to state external review pursuant to the NAIC Uniform Model Act.

²⁷ Public Health Service Act § 2719 as added by PPACA § 1001(5) and amended by PPACA § 10101(g).

²⁸ 26 C.F.R. § 54.9815-2719T(d)(1); 29 C.F.R. § 2590.715-2719(d)(1); 45 C.F.R. § 147.136(d)(1).

²⁹ 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).

Comments on the Effective Date of the Regulations

16. The Departments should clarify that the interim final regulations apply to services rendered after the effective date of the regulation.

The interim final regulations state that they apply to non-grandfathered group health plans for plan years beginning on or after September 23, 2010.³⁰ It is unclear, however, whether the new rules apply to claims for services rendered after the effective date, or whether they apply to claims filed after the effective date.

We urge the Departments to make clear that the new internal claims and appeal procedures and external review procedures apply only to claims for services rendered after the effective date. Although the Department of Labor's revised internal claims and appeal regulations issued in 2000 applied to claims filed after the effective date of the regulations, those regulations did not require a wholesale revision of administrative procedures and participant notices and communications regarding the claim and appeal process, nor did they require (for most plans) substantial changes in the actual handling of specific claims. In contrast, the interim final regulations change the claims and appeal process in ways that are far more significant, and that will affect every claim from the outset. For example, in many cases providers do not submit diagnosis codes or treatment codes when they submit statements for reimbursement, and plans do not have computer systems that are designed to capture this information and add it to the plan's notices of claim denial. If the new claim and appeal procedures applied to services rendered before the effective date of the regulations, it would be difficult for plans to obtain this information and add it to an initial adverse benefit determination issued after the effective date, as the new rules require.

The new timing rules for handling urgent claims, the significantly expanded information to be provided in initial and final adverse benefit determinations, the new requirements to provide notices of adverse benefit determinations in a culturally and linguistically appropriate manner, and the entirely new administrative and communication procedures required for the external review process impose significant new burdens on plans. These burdens should not apply to services rendered and costs incurred before the effective date of the new requirements.

Accordingly, ERIC recommends that the changes to the internal claims and appeal procedures and the new external appeal process apply only to claims related to services rendered and costs incurred after the effective date.

If the Departments do not adopt this recommendation, ERIC urges the Departments to provide, at a minimum, that eligibility for the new external review

³⁰ 75 *Fed. Reg.* 43329, 43330 (July 23, 2010).

process will be limited to adverse benefit determinations and final adverse benefit determinations relating to services rendered and costs incurred after the effective date of the new rules. In addition, ERIC requests that the Departments clarify that the new rules do not apply to any claim that was initially filed under the plan's internal claim process before the effective date of the new rules.

17. The Departments should withdraw the interim final regulations and re-issue them as proposed regulations. If the Departments do not grant this request, they should at least delay the general effective date of the regulations.

The Departments contend in the preamble to the interim final regulations that it would be impracticable and contrary to the public interest to delay implementing the provisions in the final regulations until a full public notice and comment process is completed because (1) the internal claims and appeals and external review provisions of ACA are applicable for plan years beginning on or after September 23, 2010 for non-grandfathered plans and (2) the agencies wanted to give plans definitive requirements that they could implement before this deadline because the requirements in the interim final regulations require significant lead time in order to implement.³¹

ERIC agrees with the Departments that the interim final regulations will require significant lead time to implement, including for the reasons that the Departments have stated in the preamble. However, ERIC disagrees with the Departments that the interim final regulations can be implemented within the short period that the Departments have provided. The majority of group health plans have less than four months to comply with the regulations; for plans with a plan year that begins in the last quarter of 2010, even less time remains. As explained below, it is unreasonable to require plans to comply with the significant, complex, and costly requirements in such a short period of time.

The interim final regulations require a number of significant changes to the ERISA internal claim and review procedures under 29 C.F.R. 2560.503-1. The changes include new types of claims that are subject to review (*i.e.* rescissions), new conflict standards, and substantial new information that must be included in notices to plan participants. Plans are already subject to numerous burdens and complications in administering the overall claim and review process, including gathering and evaluating information from multiple sources, evaluating sometimes complex and ambiguous medical and treatment issues, managing relationships with multiple third parties, and communicating with participants (including new requirements for communicating with participants who might not speak or understand English). Changing the ongoing processes for each of these factors

³¹ 75 *Fed. Reg.* 43337-38 (July 23, 2010).

requires thought and time to evaluate, design, possibly negotiate with third parties, communicate, and implement.

Plan sponsors and administrators are currently in the final planning and rollout stages of the 2011 open enrollment process. In many cases, it is just not practicable to add new or revised claim and appeal processes that must be communicated in advance and implemented in less than four months.

The new federal external appeal process set out in Technical Release 2010-01 creates an entirely new detailed administrative regimen that plans must follow in administering new external plan appeal rights for claimants who challenge a plan's adverse benefit determination or final adverse benefit determination. The new external appeal process requires plans to select at least three external IROs to adjudicate external plan appeals, negotiate appropriate mandated terms in contractual arrangements with IROs, establish new procedures for coordinating with IROs, establish new processes for the exchange of information between plans and IROs as well as between plans and claimants (as to the eligibility of claims for external review), implement new procedures for dealing with urgent appeal claims, and communicate all of this to participants. When dealing with less significant changes in 2000 under the revised claim and review regulations in 29 C.F.R. § 2560.503-1, the Department of Labor recognized that the amount of time necessary to implement its new rules was one full plan year after the date of publication of the revised rules.

Moreover, it may be impossible for plans to comply with the interim external review process because there are so few accredited external IROs available. Technical Release 2010-01 requires plans to contract with at least three IROs that are accredited by URAC or a similar nationally-recognized accrediting organization. Currently, the National Association of Independent Review Organizations lists among its members only 18 URAC accredited independent review organizations.³² Although there may be other accredited independent review organizations, it will be difficult for plan sponsors to identify them because no comprehensive listing of accredited IROs is available to plan sponsors. Moreover, many IROs may only be accredited to provide services in a limited number of states.

Not only does the Technical Release require IROs to have a URAC or similar accreditation, but it also requires IROs to use legal experts to make coverage determinations under plans. This requirement further reduces the number of available accredited IROs because many IROs may not be qualified to perform both clinical and legal reviews of a claim.

³² National Association of Independent Review Organizations, *Find an Independent Review Organization* available at <http://nairo.org/payors-find.php>.

In addition to the fact that plans cannot reasonably comply with the interim final regulations' significant, complex, and costly requirements in such a short period of time, ERIC disagrees with the Departments' contention that ACA requires the provisions of the interim final regulations to be adopted or implemented by plan years beginning on or after September 23, 2010. Although ACA includes requirements for an internal claims appeal process that are not currently in the Department of Labor claims procedure regulations under 29 C.F.R. 2560.503-1, ACA provides that group health plans and health insurance issuers will be in compliance with these new requirements if they adopt internal claims and appeals procedures that comply with 29 C.F.R. 2560.503-1 until the regulations are updated by the Departments.³³ The statute does not impose any deadline on the Departments for updating the existing Department of Labor claims procedure regulations. ACA also gives the Departments plenty of time to adopt requirements for an external review process by giving the Departments the authority to deem the external review process of a group health plan, in operation as of March 23, 2010, to be in compliance with the statute.³⁴

The sweeping changes made by the interim final regulations are complicated and require significant plan administrative changes; many cannot be reasonably implemented in less than four months and will likely have a material effect on the operation and cost of plans. To develop appropriate rules and requirements regarding claim and appeal processes, the Departments must take into account thoughtful input from plan sponsors, administrators, participants, and other interested parties. Moreover, the Departments must consider the public's input *before* the rules become effective because it is wholly unreasonable and disruptive for plan sponsors, participants, and the external review industry to make changes now to comply with the interim final regulations only to have the Departments change the requirements later in response to comments. ACA gives the Departments ample time to take into account public comments before its new requirements for internal claims and appeals procedures and external review processes are implemented.

Therefore, ERIC strongly urges the Departments to withdraw the interim final regulations and Technical Release 2010-10 and undertake both of the following measures in order to ensure that the claims and appeals requirements of ACA can, in fact, reasonably be complied with:

First, re-issue the interim final regulations in proposed form with a full notice and comment period and provide that, until the proposed regulations are finalized, plans will be in compliance with ACA's interim claims and appeals

³³ PHS § 2719(a).

³⁴ PHS § 2719(e).

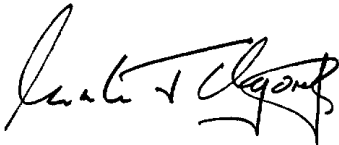
requirements by meeting the requirements of the existing Department of Labor claims and appeals procedure regulations.

Second, issue interim requirements for the external review process to provide (1) that plans that currently have an external review process will be deemed to be in compliance with ACA and (2) that plans that do not currently have an external review process will be considered in compliance with ACA if they contract with at least one accredited IRO by June 30, 2011. Such a transition rule would give plan administrators and the market an opportunity to prepare for the new external review process.

If the Departments do not grant these requests in full, ERIC strongly urges the Departments to at least delay the effective date of the new claims and appeal rules to the first plan year commencing after September 23, 2011.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Ugoretz". The signature is fluid and cursive, with a large initial "M" and "U".

Mark Ugoretz
President & CEO