

September 21, 2010
Submitted on <http://www.regulations.gov>

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

Attention: RIN 1210-AB45

The undersigned organizations, representing millions of consumers, thank you for the opportunity to comment on the interim regulations pertaining to appeals under the Affordable Care Act.

Overall, we applaud the departments for providing a clear process for consumers to resolve disputes with their health plan or issuer. It will be much easier for consumers to understand their rights and pursue appeals when the process is more uniform across states, and when people can follow similar procedures whether they are in group or individual health plans. In our experience, under current federal and state processes, consumers often lose their appeals simply because they do not understand how a health plan made its decision or what type of evidence they need to show that care is necessary. The notices described in these regulations and posted on www.dol.gov/ebsa, together with the information the health plan or issuer will provide about its criteria for approving treatment, will do a lot to remedy that problem. We are pleased that a wide range of health plan or issuer determinations are subject to appeals. Whether a plan pays for treatment often hinges on a mix of issues, including whether the plan believed a benefit was covered, whether the individual had the coverage, and whether the care was necessary, so it is appropriate that appeals also address multiple issues. Further, the appeals process outlined will begin to remedy glaring weaknesses in some states' laws: For example, we are aware of cases won at the external appeal level where the plan decided not to comply because the decision was not binding in that particular state. We are also aware of concerns that some plans only hire reviewers that generally decide in favor of the plan. We encourage states and plans to modify their review procedures for grandfathered plans as well so that eventually, all consumers will have the same rights to appeal decisions.

Following are comments on further improvements needed as the rules are finalized:

The final regulations should make clear that state and federal external review processes must provide for external review of any final adverse benefit determination for which an internal appeals process is required. Although there is a general definition of an adverse benefit determination in the definitions section of the interim final regulations, the subsequent clarifications regarding adverse benefit determinations contained in § 54.9185-2719T(b) “Internal Claims and Appeals” and § 54.9185-2719T(c) “State Standards for External Review” create some ambiguity as to whether state external review processes would be required to provide review for all adverse benefit determinations for which a plan or issuer is required to provide an internal appeals process. In the definitions section, paragraph (a)(2)(i) of the interim final regulations states that “An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage as described in § 54.9815-2712T(a)(2)” (emphasis in original). According to 29 C.F.R. 2560.503-1(m)(4):

The term “adverse benefit determination” means any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant’s or beneficiary’s eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

In contrast, paragraph (c)(2)(i) states, “The State process must provide for the external review of adverse benefit determinations . . . that are based on the issuer’s (or plan’s) requirements for *medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit*” (emphasis added). The difference between the definition of adverse benefit determination in the definitions section and the explanation of adverse benefit determinations in the section on the requirements for the state external review process leaves room for a state’s review process to be more restrictive in the definition of an adverse benefit determination than the definition required for the internal appeals process—potentially limiting external review just to “medical” determinations. We do agree that *medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit* should be spelled out as among the reasons a plan might deny a benefit, and which would be subject to review at both the internal and external level; however, this list is not exhaustive. The preamble explains that failure to make a payment due to “a determination of an individual’s eligibility to participate in a plan or health insurance coverage” is also subject to review, but this is not clearly explained in the

regulations themselves and it is important that the final regulation clearly state that external review is available for all types of adverse benefit decisions, broadly construed.

One particular example concerns the treatment of rescissions: paragraph (c)(2)(i) on adverse benefit determinations with respect to the state external review process makes no mention of rescissions while paragraph (b)(2)(A) in the section on the internal appeals process clarifies that, “a plan or issuer must treat a rescission of coverage . . . as an adverse benefit determination.” This incongruity allows for an interpretation that excludes rescissions from the adverse benefit determinations for which states must provide external review. This would clearly hinder the application of the ban on rescissions contained in § 1001 of the Patient Protection and Affordable Care Act (Affordable Care Act). External review of rescissions and other non-medical coverage determinations are necessary to ensure that health insurance companies are in full compliance with the law and to protect consumers. The final regulations should clarify that a state’s external review process must provide for external review of any final adverse benefit determination, including rescissions, for which an internal appeals process is required. Similarly, the federal review process must also provide for external review of any final adverse benefit determination, including rescissions, for which an internal appeals process is required. This alignment is critical to assure that consumers are fully protected and to achieve the goal of simplifying and standardizing the appeals process. Moreover, since many adverse benefit determinations incorporate both medical and coverage factors, without this alignment, it is likely that insurers and plans will find cause to claim that as many denials as possible were for non-medical reasons to avoid external review. (See page 9 for a discussion of appropriate reviewers for these factual and legal issues.)

The final regulations should clarify that the new consumer rights set forth in the Affordable Care Act are subject to appeal and require that notice of this information be included in plan materials and on Explanation of Benefit forms. The Affordable Care Act sets forth a number of other consumer rights in group and individual health plans which could be the subject of disputes, including: whether a plan charges appropriate premium rates, given the restrictions on age, gender, and health status rating in 2014; whether a young adult is eligible for dependent coverage; whether emergency service reimbursement is appropriate; whether a plan is allowed to restrict enrollment; whether a plan is illegally excluding coverage of a pre-existing condition; whether a plan can impose an annual limit (as well as whether that limit has been reached); or whether a plan does or does not meet the grandfathering criteria. In the individual market, some of these rights may be subject to appeals as initial eligibility determinations, although the interim final regulation does not specify what qualifies as such. In addition, the preamble explains that failure to make a payment due to “a determination of an individual’s eligibility to participate in a plan or health insurance coverage” is also subject to review, but this is not clearly explained in the regulation itself. The departments should clarify that all of these new consumer rights are subject to appeal. In addition, the departments should clarify the

appropriate forum for consumers to appeal determinations that they believe violate the new consumer protections created by the Affordable Care Act. The departments should establish a system whereby consumers could appeal or challenge such determinations directly to an appropriate federal agency, directly to an appropriate state agency, or through an independent review organization that is qualified to hear these issues (see p. 9). Besides solving the individual's problem, the state or federal government should take appropriate enforcement action to remedy any violations. Consumers should receive clear information about where to complain if they believe that any of these rights have been violated, be it directly to federal agencies or through an appeals system. This information should be included in notices, plan materials, on Explanation of Benefits forms, and included in fact sheets prepared by the federal government and on healthcare.gov.

Consumers should be allowed to provide oral testimony during an internal and external review. The law and regulations allow the consumer to provide additional evidence and testimony during an internal review. The right to provide oral testimony will be very important for consumers who have difficulty providing a written explanation of their case and to consumers who are not represented and do not have consumer assistance programs helping them. Reviewers will be able to ask consumers questions that are relevant to the matter at hand, and the consumer will be able to respond. Oral testimony has been important in Medicaid managed care hearings, and we expect that it will provide important information for private insurance appeals as well. Information about the right to present testimony should be included in the model notice of adverse benefit determinations.

The ability to present additional testimony, either in writing, or orally (at least telephonically if face-to-face testimony is not practical), would be helpful at the external review level as well. We encourage the agencies to provide for this in the final regulations.

The departments should provide additional guidance regarding the information that must be included in notices from the health plan or issuer, and should make sure that terms used in the model notices are clearly defined for consumers. To realize the full intent of a robust and tiered process of *de novo* appeals the rules and model notices should be strengthened in several respects.

- ***The final regulations should require that notice of the initial adverse benefit determination provide for access to the same information (e.g., reasons for the determination and possible therapeutic alternatives to the denied benefits) as is required in the final benefit determination.*** The IFR states that “a plan or issuer *must also ensure* that description of the reason or reasons for the denial includes a description of the standard that was used in denying the claim.” However, the interpretation of this requirement into the model notice of adverse benefit determination is limited to a required denial code, and the *option* to provide further explanation for the basis of the denial. This would appear to be the major distinction between notice of an initial adverse

determination and a final adverse determination, where plans are required to provide a discussion of the reasons for the final determination. The lack of further explanation of the basis for the initial denial of coverage will leave consumers with little information about the plan's reasoning, possible therapeutic alternative to the denied benefit, or basis upon which to develop a truly effective appeal. A denial code is not a sufficient *description of the standard used in denying the claim*. Any adverse benefit determination should clarify how the consumer can get the required description of the standards used by health plans for claims review, and such instruction should be required on the initial adverse benefit determination. The right to a *de novo* review of the claim and determination in itself should distinguish the various levels of internal review.

- ***A health plan or issuer should, at a minimum, be required to provide a consumer's health plan file to the consumer at the same time that the health plan or issuer sends the file to the IRO for an external review.*** The law requires that consumers have access to the health plan file about their case. It appears from the model notices on Department of Labor's website that the consumer would have to request the file to see it. We suggest that, at a minimum, when the case moves to external review and the health plan or issuer sends its file to the IRO, it should also send a copy to the consumer. From that point, the consumer should have at least 5 days to respond with additional evidence.
- ***The final regulations should clarify when information at every level of review, including expedited benefit determinations, can be handled by phone, email, fax, or text message.*** The regulations should also clarify when information that is required about appeals at any level, including expedited benefit determinations for urgent care, can be handled by phone, email, fax, or text messaging, and under what circumstances. In all instances, acknowledgement of receipt of an appeal request and confirmation that it has been properly submitted, as well as additional information in support of a pending appeal, must be provided to the consumer.
- ***Any terms that may be confusing to consumers, including all terms used to describe specific dollar amounts, should be clearly defined in the model notices.*** Certain terms appearing on the model notices may be confusing to consumers and should be clarified, including all terms used to describe specific dollar amounts, (i.e., amounts "charged," "allowed," "other not covered," as well as "amount paid"). Referring the enrollee to their member handbook for such definitions is an option, provided it includes a glossary with these terms. Acronyms, such as IRO, should never appear without explanation. "Statements" to be listed on the final external review decision should be clarified to be meaningfully distinct from "documents."
- ***The Appeal Filing Form should include the contact information of the individual completing the appeal, clarification of confusing terms, and an instruction to consumers to "Retain a copy for your records."*** The Appeal Filing Form should be further developed to include the contact information of the individual completing the appeal to acknowledge receipt and other communications. The distinction between "Covered Person," "Patient," and "Authorized Representative" is unclear and needs

explanation. The appeal filing form should also instruct consumers to “Retain a copy for your records.”

The final regulations should indicate that plans or issuers receiving federal financial assistance must comply with the nondiscrimination provisions of section 1557 of the Affordable Care Act. Section 1557 of the Affordable Care Act prohibits entities receiving federal funds or otherwise meeting the criteria of that section from discriminating upon the protected bases under Title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and section 504 of the Rehabilitation Act of 1973. The final regulations should clarify that plans or issuers receiving federal financial assistance must comply with the nondiscrimination provisions of section 1557 and that exercising the right to seek internal and/or external review will not affect any rights a consumer may have under section 1557, nor will making a claim under section 1557 affect any rights a consumer may have as part of the internal and external review process

Comments on Culturally and Linguistically Appropriate Notice Requirements

Section 2719 of the Public Health Service Act, which became law in the Affordable Care Act, provides that a group health plan and a health insurance issuer offering group or individual health insurance coverage shall “provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes....” This provision takes an important step toward ensuring that consumers with limited English proficiency (LEP) are able to access the same protections and avenues for recourse as other consumers.

The IFR requires plans or issuers—that meet the specified threshold—to include in all notices a prominent statement in the non-English language offering to provide these same notices in the non-English language. As currently proposed, the thresholds are based on the number of people who are literate in the same non-English language. We believe it is important that plans and issuers take into account the primary language literacy (including health literacy) and numeracy levels of enrollees when preparing consumer materials and notices. Plans and insurers should, upon request from enrollees, provide oral communications including in a non-English language. Providing notices in a form, manner, and language that recipients can easily understand will improve care, speed efficient communication of claims information, and reduce confusion about claims outcomes and claims processes.

Toward this end we would recommend expansive application of the requirements—and thus relatively low thresholds for triggering these requirements. At the same time, we recognize that incorporating existing thresholds is helpful. Accordingly, we recommend that the thresholds for large plans (100 or more participants) be lowered to 5 percent or 500 (whichever is lower) in keeping with existing thresholds for addressing limited English proficiency under guidance issued by HHS. Additionally, the departments specifically requested comments on the 10 percent threshold in the individual market. Given that other agencies have used lower thresholds for other programs, such as 5 percent of a population, we would recommend that the

agency consider a lower threshold of 5 percent. Such a threshold would be in keeping with other federal limited English proficiency guidelines.¹

In addition, we encourage you to issue guidance elaborating on how group plans, and issuers offering group insurance should collect data for and calculate their thresholds. Many do not currently track language data and the IFR leaves many questions unanswered. We recommend that the plan or issuer should, at the very least, be required to ascertain whether an individual has requested oral communications in a non-English language or reported speaking English “less than very well.” (OCIHO made a similar clarification in its Technical Guidance for Issuers in the Individual Market to Establish County Level Estimates.)

The final regulations should indicate that plans receiving federal financial assistance may be required to meet additional culturally and linguistically appropriate standards. Entities subject to section 1557—which may include plans or issuers—must not only comply with the requirements flowing from PHSA section 2719(a)(1)(B), but must also ensure that their communications do not discriminate upon the basis of national origin. They may therefore be subject to requirements like those which HHS and the Department of Justice have previously issued as LEP guidance.² We recommend that the final rule indicate that plans or issuers will be subject to such requirements if they are covered by section 1557. Moreover, to the extent the final rule can reflect existing thresholds and frameworks, it would improve access for consumers and minimize confusion from multiple requirements.

The final regulations should make clear that the federal requirements of the Affordable Care Act pre-empt any state or local English-only laws. The regulations should explicitly state that while some plans and issuers may operate in jurisdictions in which English has been declared the official language, they must still comply with federal requirements.

The culturally and linguistic notice requirements should be extended to the external review process and determinations. We strongly support the requirement that once a request has been made by a claimant for the provision of notices in a threshold-reaching non-English language, the plan or issuer must provide all subsequent notices to a claimant in the non-English language. Unfortunately, the culturally and linguistically appropriate notice requirements are not extended to Independent Review Organizations. Consequently, an LEP claimant is likely to receive important notices pertaining to the external review process and determinations in English. While we recognize that federal agencies have limited authority over IROs unless they are receiving federal funds, we encourage you to consider alternative methods to ensure that LEP claimants can fully participate in and benefit from the external review process. For example, should issuers and plans be required to translate these notices for claimants or, at least, offer oral interpretation services for them?

Regardless of whether thresholds are met regarding translated notices, plans and issuers should provide oral communication in all languages. The departments should develop a

¹ See, e.g. 7 C.F.R. § 272.4(b)(2) (2010); 28 C.F.R. § 55.6 (2010).

² Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47,311 (Aug. 8, 2003).

model notice that informs consumers of their right to receive competent oral interpretation of appeals notices free of cost and is translated in, at a minimum, the fifteen languages in which the Social Security Administration provides Medicare information.³ Oral interpretation services can be easily provided via over-the-phone interpreting agencies which can usually offer access to at least 150 different languages with very short connection times (under one minute). This is a particularly critical service in urgent care situations necessitating expedited appeals processes.

Furthermore, regardless of language, all notices should be written in plain language, ideally, at a 5th grade reading level and never greater than an 8th grade reading level. In addition to being in relevant primary languages, notices should be written in plain language and at appropriate reading levels for a wide variety of readers. We suggest a 5th grade reading level, or at most, an 8th grade reading level.

Representation

Model notices and other information about an enrollee's appeal rights should clearly state when or if the prescribing health care provider may act as a patient's authorized representative for the purpose of exercising the patient's appeal rights. Many consumers rely on their healthcare providers to support, and sometimes, initiate appeals. Some healthcare providers and/or their clinical staff act on information about a whole or partial denial of their patients' benefits, and occasionally do so without their patient's full knowledge. Just as enrollees have been known to mistakenly exhaust one or more appeal opportunities through lack of understanding about appeal procedures, clinicians have been known to inadvertently exhaust appeal rights by calling the health plan to discuss a denial or limitation in benefit.

The model notices and all other information about enrollees' appeal rights should explicitly state when or if the prescribing health care provider may act as an authorized representative for the purposes of exercising his/her patient's appeal rights. They should explain that the provider's actions, such as his or her adherence to time standards for submitting additional information, may affect the outcome of the appeal. The final regulations should require the plan or issuer to automatically provide to the patient copies of any information or notices sent to the provider in conjunction with an appeal.

The final regulations should include the right for a consumer to be represented by anyone (not only health care providers) whom the consumer designates in writing. The NAIC model law discusses a consumer's right to be represented by someone whom the consumer has designated in writing. We believe that a right to representation is among the consumer protections in the model law and should be included in federal regulations as one of the minimum protections.

Other consumer protections

³ Arabic, Armenian, Chinese, Farsi, French, Greek, Haitian-Creole, Italian, Korean, Polish, Portuguese, Russian, Spanish, Tagalog, and Vietnamese.

The final regulations should include additional consumer protections that are included in the NAIC model rules. These include:

- Consumers should have the ability to file internal and external appeals simultaneously for expedited review.
- The external review should be de novo.
- The carrier must immediately act to implement a reviewer's decision.
- The IRO must consider medical records, attending professional's recommendation, consultant reports, and practice guidelines in addition to the carrier's criteria.
- In addition to being accredited, IROs must meet timeframes for review, have qualified reviewers with relevant medical expertise and no conflicts of interest and no disciplinary history, maintain confidentiality, and have a phone system capable of receiving information at all hours and instructing callers.

The final regulations should ensure the independence of all IROs, including those not subject to state review, and should require that either state and federal regulators review issues related to a health plan's or issuer's adherence to its contracts or to state and federal law, or that IROs have reviewers with the legal experience needed to conduct such reviews.

We are concerned that for self-insured plans and others not subject to state review, there will still be inherent conflicts of interest if the plan contracts with IROs and pays the expenses associated with a review. Federal or state regulators should contract with IROs and assign them randomly to cases. These regulations and guidelines for the federal external review process should require that the plan pay the government entity, which in turn pays the IRO expenses. Further, IROs should certify under penalty of law that they have no conflict of interest.

In addition, some issues that consumers should be able to appeal necessitate a review of the health plan's or issuer's adherence to its contract and to state and federal law. Independent Review Organizations that are comprised mainly of clinical reviewers are not the appropriate decision-makers for this type of case, but consumers must still have a right to appeal those issues outside of the health plan. The regulations could address this by either (a) having regulators themselves review these issues, perhaps using administrative law judges, or (b) requiring that independent review organizations also have legal expertise, including knowledge of the relevant state and federal laws. In any event, it is important that consumers are afforded a full and fair review and are not denied because of the IRO structure.

The final regulations should immediately expand the scope of issues subject to review in order to provide consumers with a mechanism with which to enforce the new rights that go into effect on September 23 as part of the Affordable Care Act, and health plans and issuers should be required to comply fully with the new process as of July 2011 rather than health plan years that begin after that time. Under the interim regulations, plans do not have to fully comply with the new rules until plan years beginning after July 2011, but they must be subject to binding reviews before then. We believe the final regulations should immediately expand the scope of issues subject to review, using the new definition of adverse benefit determination for individual as well as group plans. Consumers need an immediate mechanism to appeal and assert the various rights that go into effect on September 23 as part of the Affordable Care Act. Plans and issuers should fully comply with the new process as of July 2011, not in

health plan years that begin after that time. It will be easier to monitor the new appeals system and educate consumers about their rights if there is a clear date by which the system is effective. Though we understand that it may take until the next plan year for plans to conform their evidences of coverage and handbooks to explain the new requirements, they can begin providing appropriate information on claims denials on a given date that does not vary by plan year.

Thank you for your work on these important issues.

Sincerely,

Families USA

National Partnership for Women and Families

National Women's Law Center

American Diabetes Association

National Multiple Sclerosis Society

U.S. PIRG