



**BlueCross BlueShield  
Association**

An Association of Independent  
Blue Cross and Blue Shield Plans

July 25, 2011

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The Honorable Phyllis C. Borzi  
Assistant Secretary, Employee Benefits Security Administration  
U.S. Department of Labor

Donald Berwick, M.D., M.P.H.  
Administrator  
Centers for Medicare and Medicaid Services

Emily S. McMahon  
Deputy Assistant Secretary, Tax Policy  
U.S. Department of the Treasury

Submitted via the Federal Rulemaking Portal: <http://www.regulations.gov>

**Re: Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes (RIN 1210-AB45)**

Dear Assistant Secretary Borzi, Administrator Berwick, and Deputy Assistant Secretary McMahon:

The Blue Cross and Blue Shield Association (“BCBSA”) – representing the 39 independent Blue Cross and Blue Shield “Plans” that collectively provide health coverage for more than 99 million members, or one in three Americans – appreciates the opportunity to submit comments on the Amended Interim Final Rules (the “Rule”) for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act (ACA) as issued in the *Federal Register* on June 24, 2011 (76 Fed. Reg. 37208), and on the contemporaneous Technical Release 2011-02.

BCBSA commends the Departments for providing appropriate protections for consumers while also improving the efficiency of the original July 2010 Rule by making critically important modifications in three major policy areas:

- *Internal appeals*—Streamlining requirements for urgent care claims, notice content, linguistic appropriateness, and deemed exhaustion will substantially enhance efficiency in the operation of employee benefit plans and health care delivery.
- *State external review processes*—Extending the transition date from July 1, 2011 to January 1, 2012 will give states and health plans critically needed time to bring existing processes into compliance with the new consumer protection standards.
- *Federal external review process*—Curtailing the scope to adverse benefit determinations that involve medical judgment will make claims and appeals processes more uniform, thereby further increasing efficiency in the operation of employee benefit plans and health care delivery as well as health insurance and labor markets.

BCBSA greatly appreciates these modifications. BCBSA and its Plans were concerned about not having enough time to make the changes required by the additional internal appeals and external review standards, and about the negative implications this would have posed for consumers. The revisions to the July 2010 Rule will provide consumers with the information they need to make effective appeals without creating the risk of releasing sensitive information that would raise serious privacy concerns.

We are especially pleased that the Departments moved closer to meeting the overarching objective laid out in the July 2010 Rule's preamble of having similar claims and appeals standards for different market segments. This, plus the other modifications, will lead to efficiency gains and improvements in certainty and consistency that will benefit health plans, providers, employers, and consumers.

However, in each of the major areas addressed by the Rule and contemporaneous guidance, BCBSA believes that some generally modest modifications or clarifications will help to avoid inadvertent problems. Below we organize comments around each of the major policy areas, offering recommendations to modify or clarify potentially problematic requirements.

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## **I. INTERNAL CLAIMS AND APPEALS**

As promised in Technical Release 2011-01, the Departments have modified the additional standards that had been made subject to an extraordinarily helpful enforcement grace period: (1) the timeframe for urgent care claims; (2) diagnosis and procedure codes in notices; (3) the standard for deeming exhaustion of internal appeals; and (4) linguistically appropriate notices.

### ***Timeframe for Urgent Care Claims***

**Issue.** The Rule permits plans and issuers to follow the original rule in the DOL claims procedure regulation (requiring decision-making in the context of pre-service urgent care claims as soon as possible consistent with the medical exigencies involved but in no event later than 72 hours), provided that the plan or issuer defers to the attending *provider* [emphasis added] with respect to the decision as to whether a claim constitutes “urgent care.”

While the Rule refers to incorporating the DOL regulations, using the word “provider” expands the scope of the previous DOL definition of “urgent care claim”. The previous DOL regulation refers to a “physician,” not a “provider”: “Any claim that a physician with knowledge of the claimant's medical condition determines is a "claim involving urgent care" within the meaning of paragraph (m)(1)(i) of this section shall be treated as a "claim involving urgent care" for purposes of this section.”

Failing to define or place any governing standard on providers could be problematic. For example, the Rule would permit a hospital representative (not a physician and perhaps not even a medical professional) to contact the plan as a “provider” and advise the plan that the claim is “urgent”. The plan would be required to treat such a claim as urgent, without any further inquiry or discussion, and the plan would be required to expedite its claim determination.

Today, when a physician contacts a plan regarding an urgent claim, plans have an opportunity to discuss the needs of the patient and the urgent nature of the claim with a person who has medical knowledge of the patient’s condition. Sometimes the discussion between the physician and the plan results in a joint conclusion that the claim is not “urgent” under DOL standards. However, if at the end of the conversation the physician believes the claim is urgent, the plan treats it as such.

Expanding the rule to “providers” – who may have little to no knowledge of the patient’s medical condition – may result in many more claims being deemed as “urgent” and requiring costly expedited plan review. Too many “false positives” could be detrimental to consumers because the haste of an expedited review may prevent the claimant from presenting the best case in such a short time span and may force the plan to make a decision it may not have made had it more time to investigate and deliberate. And claims that are truly urgent may not get the focused attention needed because of the volume of anticipated claims now being deemed urgent as a result of providers characterizing the claims as urgent to expedite the payment determination on the claim.

**Recommendation.** Modify the Rule to follow the original requirement in the DOL claims procedure regulation that the plan or issuer defer not to a “provider” but to “a physician with knowledge of the claimant's medical condition.” Moreover, we request that the Rule clarify that the physician’s judgment should be in the context of the legal definition of urgent care.

### ***Additional Notice Requirements for Internal Claims and Appeals (Diagnosis Codes)***

**Issue.** The Rule eliminates the requirement to provide automatically the diagnosis and treatment codes as part of a notice of adverse benefit determination and instead substitutes a requirement that the plan or issuer must provide notification of the opportunity to request the diagnosis and treatment codes (and their meanings) in all notices of adverse benefit determination, and a requirement to provide this information upon request, as soon as practicable.

Privacy concerns were an important factor in making this change, as the Preamble notes that concerns were raised about explanations of benefits sent to an individual who is not the patient, interference with the doctor-patient relationship, and so on. While the modification goes a long ways to mitigating privacy concerns, privacy issues could still arise when the diagnosis requested is sensitive or serious and the member inquiring appears to be unaware of the diagnosis, *unless* the plan has the flexibility to help the member obtain the information from the provider. The clause “as soon as practicable” could be construed as allowing such flexibility; “as soon as practicable” could allow a plan that does not want to cause distress to a member (by disclosing diagnostic information that the member’s physician has not yet discussed with the member) time to arrange for a discussion between the member and the member’s physician.

**Recommendation.** Clarify that in providing information upon request “as soon as practicable,” the plan has latitude to handle sensitive/serious diagnoses with discretion, such as by taking time to help the member obtain the information from the member’s physician. In addition, to ensure privacy protections, we request clarification that for security purposes plans may ask that the member request be put in writing, and that plans must comply with both federal and state privacy protections.

### ***Deemed Exhaustion of Internal Claims***

**Issue.** Under the amended approach, any violation of the procedural rules of the July 2010 regulations pertaining to internal claims and appeals would permit a claimant to seek immediate external review or court action, as applicable, unless the violation met all the following:

- (1) De minimis.
- (2) Non-prejudicial.
- (3) Attributable to good cause or matters beyond the plan’s or issuer’s control.
- (4) In the context of an ongoing good faith exchange of information.
- (5) Not part of a pattern or practice of violations.

In addition, the claimant would be entitled, upon written request, to an explanation of the plan's or issuer's basis for asserting that it meets this standard, so that the claimant could make an informed judgment about whether to seek immediate review.

This five-prong test is unduly complicated. For the typical member who lacks legal expertise, it will be difficult to explain all these criteria in plain English so that the claimant can truly exercise informed judgment. Simplifying the test down to two key criteria – de minimis and non-prejudicial – would reduce administrative burden on plans and make informed judgments by claimants more tenable.

If an error is de minimis and non-prejudicial, whether or not it is “attributable to good cause or matters beyond the plan's control” and “in the context of an ongoing good faith exchange of information” and “not part of a pattern or practice of violations” seems beside the point: any “pattern of non-compliance” that involves de minimis errors that are non-prejudicial would not seem to imply that procedures are less than full, fair, and timely. Put another way, any error that would make the internal claims or appeals procedure less than full, fair, and timely will not be de minimis and it will not be non-prejudicial.

**Recommendation.** Recommend simplifying the test to determine whether the internal claims and appeals process will be deemed exhausted based on two controlling criteria: (1) de minimis; and (2) do not cause and are not likely to cause, prejudice or harm the claimant.

### ***Form and Manner of Notice (Linguistic Appropriateness)***

**Issue.** The Rule establishes a single threshold of 10 percent with respect to the proportion of people who are literate only in the same non-English language for both the group and individual markets. However, the Departments seek comment whether it would be appropriate to include a provision in the final rules requiring health insurance issuers providing group health insurance coverage to provide language services in languages that do not meet the requisite threshold for an applicable non-English language, if requested by the administrator or sponsor of the group health plan to which the coverage relates.

**Recommendation.** Keep as is, do not add to, the amended requirements for linguistic appropriateness in the final rule. The 10 percent threshold for providing written notices in the non-English language upon request is a reasonable standard for balancing the needs of the vast majority of participants and beneficiaries likely to need language help and the costs to the system of translating technical and medical documents. At the same time, nothing in the Rule precludes and, indeed, other federal law supports, the widespread practice of providing extensive oral interpretive services.

**Issue.** The Departments will update language guidance annually on their Web sites if there are changes to the list of the counties determined to meet the 10 percent threshold for the county's population being literate only in the same non-English language.

However, because the Rule is not specific about the timing, plans and issuers face uncertainty and the risk that they may not have sufficient time to implement any changes.

**Recommendation.** To provide sufficient time to make changes if language thresholds require updating, modify effective date of any change to ensure that there is at least a six-month period between the time the update is published and the start of the next plan year.

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## II. STATE EXTERNAL REVIEW PROCESSES

BCBSA greatly appreciates the Departments' efforts to reduce market disruption by extending the transition from plan years beginning on or after July 1, 2011, to those beginning on or after January 1, 2012.

### *Time Permitted for Transition*

**Issue.** The new timeline may give plans and issuers no more than three months to transition to a different external review process, a timeframe that will likely not be adequate. If by July 31, 2011, HHS determines that a state external review process meets the standards for neither an NAIC-parallel or NAIC-similar process, and the State requests reevaluation, HHS will make the final determination by October 1, 2011.

We appreciate how the Departments recognize the need for a transition. However, three months is too tight a timeframe for plans to revamp their internal procedures and information systems, file the necessary forms with and conduct discussions with state regulators, and give states time to review and approve.

**Recommendation.** To give plans and issuers sufficient time to implement procedures, make workflow and systems changes, and go through state review/approval processes, recommend that the Rule provide an enforcement grace period for any plan or issuer in a state that does not receive a final determination until October 1, 2011. As in Technical Release 2010-02, the Departments would not take any enforcement action against a plan or issuer that is working in good faith to transition to a different process, if warranted by HHS's determination. Similarly, HHS would encourage States to provide similar grace periods with respect to issuers.

### *Clarification Regarding Requirement That External Review Decision Be Binding*

**Issue.** Technical Release 2010-01 Section A(4) requires that upon receiving a notice of a final external review decision reversing the plan's adverse benefit determination, the plan immediately must not only provide coverage but also immediately pay benefits for the claim.

However, this requirement to immediately pay benefits is not in the NAIC Model Act, which states:

“(I)(3) Upon receipt of a notice of a decision pursuant to paragraph (1) reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.”

Requiring immediate payment is not only a departure from the NAIC Model Act, it also would impose an unnecessarily heavy administrative burden on plan’s financial systems. To put this in context, under current CMS guidance, the Medicare fee-for-service claims processing contractor has 30 days subsequent to appeals’ decision date to effectuate the claim for a reversed/ favorable decision.

**Recommendation.** BCBSA has no problem with immediately approving the coverage – thus lifting any liability concerns from the patient – but requests that the Rule establish a more reasonable, 30-day timeframe for paying the claim, the same as is required of Medicare contractors. This modification would apply to state and federal external review processes.

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### III. FEDERAL EXTERNAL REVIEW PROCESSES

#### *Scope of the Federal External Review Process*

**Issue:** The Rule suspends (until at least January 1, 2014) the original rule in the July 2010 regulations regarding the scope of claims eligible for external review for plans using a federal external review process, narrowing the scope to claims that involve (1) medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment), *as determined by the external reviewer* [emphasis added]; or (2) a rescission of coverage. The amendment illustrates this new scope with examples of situations in which a claim is considered to involve medical judgment in making adverse benefit determinations. By excluding claims that “involve only contractual or legal interpretation without any use of medical judgment,” the amendment implies that if there is any use of medical judgment – even if the medical judgment is a trivial part of the decision-making process – then a claim is eligible for external review.

In the amendment, the Departments ask whether limiting the scope of claims during the suspension period will impose administrative costs in determining whether a claim is eligible for external review. The answer is likely to be yes, in part because plans will have to pay reviewers for making this eligibility determination, and in larger part because the amended requirement creates a conflict of interest: the external reviewer who stands to benefit financially from taking on an external review has carte blanche to determine whether a claim “involves” medical judgment. Since the amendment offers no criteria or guidance on how reviewers are to determine whether a claim involves any use of medical judgment, reviewers have incentive to find medical judgment involved more often than not. (In addition, some of the examples of situations that involve medical judgment are flawed and should not serve as a basis for making eligibility determination – these examples are discussed below.)

**Recommendation.** BCBSA recommends circumventing any conflict of interest by defining more precisely what it means to involve medical judgment and relying on current enforcement mechanisms to ensure that plans are not holding back legitimate claims from external review. Questions about external review eligibility should not be shoehorned into the external review process.

For example, in the case of adverse benefit determinations that involve a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit (but not for a denial, etc., based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of the plan for an individual policy), the standard could be: the determination involves questions of medical judgment if it can be determined only after a medical professional with appropriate training and experience has considered the standards of care pertaining to the medical issue and exercised judgment in selecting among acceptable courses of action.

For adverse benefit determinations that involve a denial, reduction, or termination of, or a failure to provide or make payment based on a determination that a participant or beneficiary fails to meet the plan's requirements for eligibility for an individual policy, the standard could be: the determination involves questions of medical judgment if it can be determined only after a medical professional with appropriate training and experience has determined that the participant or beneficiary had any condition for which symptoms were present. (Under this standard, a determination that a medical condition is a preexisting condition because there are factual records that the participant or beneficiary received medical advice, care, diagnosis, or treatment for that condition prior to enrollment would not be considered as involving medical judgment.)

In addition, BCBSA believes it would be helpful for the Departments to clarify the other types of initial eligibility determinations that would not be eligible for external review, such as eligibility denials because the applicant is not a state resident.

***Example of Claims Considered to Involve Medical Judgment: Preventive Services***

**Issue.** The Rule considers claims to involve medical judgment if the adverse benefit determination concerns the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified, in the recommendation or guideline of the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or the Health Resources and Services Administration.

This would not be consistent with current regulatory guidance for preventive services. The Departments have stated that if a recommendation or guideline for a recommended preventive health service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques (which generally limit or exclude benefits based on medical necessity or medical appropriateness using prior authorization requirements, concurrent review, or similar practices) to determine any coverage limitations under the plan. Thus,



to the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant evidence base and these established techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive health service.

Such flexibility could lead to a contractual determination to exclude a particular treatment from the benefit package. For example, the USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. It discusses various pharmacological interventions –nicotine replacement therapy (gum, lozenge, transdermal patch, inhaler, and nasal spray), sustained-release bupropion, varenicline – but does not specify them. Nor does it specify the frequency of recommended counseling. Therefore, a plan may wish to design its benefits to track Medicare policy: Medicare’s Smoking Cessation Program will cover up to eight face-to-face visits during a 12-month period for people who are diagnosed with a smoking related illness (e.g., heart disease, cerebrovascular disease, multiple cancers, lung disease, weak bones, blood clots, and cataracts) or are taking medicine whose effectiveness is complicated by tobacco use (e.g., insulin).

Although the design of the benefit package involves medical judgment, a determination not to cover treatments/interventions that lie outside the contours of the Medicare Smoking Cessation Program and, therefore, outside of the plan’s contract involves only contractual or legal interpretation – not medical judgment.

**Recommendation.** Delete from the list of examples of adverse benefit determinations that are eligible for external review claims that involve the frequency, method, treatment, or setting for recommended preventive services to the extent not specified by the applicable Agency.

### ***Example of Claims Considered to Involve Medical Judgment: Wellness***

**Issue.** The Rule considers whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a plan’s wellness program an example of a claim that is considered to involve medical judgment.

However, this example is misplaced because no claims are involved in wellness programs. Failure to offer a participant or beneficiary a reasonable alternative standard for a reward could be grounds for determining that the wellness program violates federal requirements. To cite one example included in 26 CFR 54.9802–1, suppose a plan gives an annual premium discount of 20 percent of the cost of employee-only coverage to participants who take an annual cholesterol test and achieve a count under 200. If a participant is unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard or waive the cholesterol standard, then the plan’s program fails to satisfy federal requirements. In cases such as this, there is no claim involved, and the plan’s failure to provide the participant a reasonable alternative standard is exclusively a contractual/legal issue; that is, the plan may have a wellness program compliance issue and be subject to penalties and other enforcement actions.

**Recommendation.** Delete from the list of examples of adverse benefit determinations that are eligible for external review whether a participant or beneficiary is entitled to a reasonable alternative standard for a wellness program reward.

***Example of Claims Considered to Involve Medical Judgment: Mental Health Parity***

**Issue.** The Rule considers claims to involve medical judgment if the adverse benefit determination concerns whether a plan is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques. [A nonquantitative treatment limitation is a limitation that is not expressed numerically, but otherwise limits the scope or duration of benefits for treatment.]

The mental health parity interim final rule includes several illustrative examples of nonquantitative treatment limitations that would violate the Rule. However, none of these adverse benefit determinations involve use of medical judgment.

- *Example 1.* A group health plan that limits benefits to treatment that is medically necessary, and that requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits violates the nonquantitative treatment limitation provisions. In this example, if a claimant disputes the outcome of a concurrent review, that would involve medical judgment based on medical necessity and would clearly be eligible for external review. But challenging the concurrent review process itself as impermissible does not involve medical judgment. In cases such as this, medical judgment plays no role in assessing whether review processes applying to mental health benefits are comparable to review processes applying to other medical/surgical benefits.
- *Example 2.* A plan that requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits, but that pays no benefits for mental health and substance use disorder treatments that do not have prior approval, and that pays a 25 percent reduction for medical/surgical treatments that do not have prior approval, violates the rules. In cases such as this, medical judgment plays no role in determining whether a specified penalty for failing to follow procedures for mental health benefits differs from penalties for failing to follow procedures for medical/surgical benefits.
- *Example 4.* In determining whether prescription drugs are medically appropriate, a plan that automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects), but that for other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), provide

coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care, violates the rules. In cases such as this, medical judgment plays no role in determining whether a plan's exclusion of a certain mental health drug given a black box warning is comparable with exclusions for non-mental health drugs.

**Recommendation.** Delete from the list of examples of adverse benefit determinations that are eligible for external review whether a plan is complying with the Mental Health Parity Act's nonquantitative treatment limitation. Disputes over compliance should be handled through available enforcement mechanisms by the Departments, or by participants or beneficiaries bringing a private action, not shoehorned into the external review process.

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#### **IV. OTHER ISSUES**

Finally, a few other issues would benefit from further clarification.

##### ***Individual Market***

**Issue.** In an inadvertent oversight, the Rule omits the individual market from the amended rules for (1) the timeframe for urgent care claims; (2) diagnosis and procedure codes in notice; and (3) the standard for deeming exhaustion of internal appeals.

**Recommendation.** Plans would greatly appreciate clarification of when the correction will be published.

##### ***Effective Date***

**Issue.** The Rule, which amends provisions subject to the enforcement grace period under Technical Release 2011-01, is not overt about the effective date – though it notes that at the expiration of the enforcement grace period the Departments will begin enforcing the relevant requirements.

**Recommendation.** Clarify the effective date of the amended provisions in the Rule.

##### ***Levels of Review***

**Issue.** The July 2010 Rule permits health insurance issuers offering individual health coverage to have only one level of internal appeal and the amended Rule makes no modification. This provision, by running counter to the Rule's overarching objective of having similar claims and appeals standards for different market segments, creates unnecessary administrative burdens. It also has been a source of confusion in states that require that claimants go through two levels of internal review – often because states view two-levels as a pro-consumer requirement that offers consumers a greater opportunity for a successful internal appeal.

**Recommendation.** Modify the Rule to allow any State requirement to provide individuals with two levels of appeal to supersede the federal requirement.

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We appreciate your consideration of our comments on the amendment to the interim final rules and thank you for considering our suggested recommendations. Again, we commend the Departments for their efforts to enhance efficiency in the operation of employee benefit plans and health care delivery. We look forward to continuing to work with the Departments on this and other implementation issues related to ACA. If you have questions, please contact Joel Slackman at 202.626.8614 or [Joel.Slackman@bcbsa.com](mailto:Joel.Slackman@bcbsa.com).

Sincerely,



Justine Handelman  
Vice President, Legislative and Regulatory Policy  
Blue Cross Blue Shield Association