

July 25, 2011

VIA RULEMAKING PORTAL

Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-9993-IFC2

Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration  
U.S. Department of Labor  
Attention: RIN 1210-AB45

Internal Revenue Service  
United States Treasury  
Attention: REG-125592-10

Dear Sirs/Madams:

The undersigned organizations are writing to comment on the June 22, 2011 amendments (Amendments) to the July 23, 2010 interim final rule (IFR), as well as to Technical Release 2011-02 and Technical Guidance June 22, 2011 (pertaining to culturally and linguistically appropriate standards).

We applaud the Departments for continuing to work with all stakeholders to try to develop a workable appeal process that ensures that consumers have a meaningful opportunity to contest denials of health insurance coverage. For example, we are pleased that rescissions remain subject to external appeal for self-funded plans and nonfederal government plans, and that plans must strictly comply with the rules, with the only exception being *de minimis* violations that do not harm or prejudice the claimant, that were for good cause or beyond the plan/issuer's control, taking place in the context of an ongoing good faith exchange. In addition, although we cannot support the "medical judgment" standards for federal external appeals, discussed below, we do appreciate the preliminary list of examples of issues that can be appealed, including whether a participant or beneficiary is entitled to a reasonable alternative standard in order to receive a reward under the plan's wellness program. However, there are points that we believe could benefit from additional amendment. In keeping with the Departments' goal of ensuring adequate protection of consumers, we offer some additional comments.

## **1. Content of Notices**

In response to comments from several stakeholder groups, the Departments decided not to require issuers/plans to include diagnosis and procedure codes in notices of adverse determination (final or otherwise). We support this decision with one caveat. The Amendments provide that a plan/issuer must provide notification of the opportunity to request the diagnosis code, treatment code, and an explanation of their meaning in all denial notices, and that this information must be provided upon request. However, the Amendments do not state whether the issuer/plan will provide this information verbally or in writing, and we are concerned that this ambiguity will work to the detriment of consumers.

It is our view that, to the extent possible, communication from issuers/plans should be in writing. We say this based on the cumulative years of experience some of us have had, which informs us that information provided by customer service representatives by

telephone too often is erroneous. For example, in one recent case, one of us received a denial letter that omitted the address to which appeals should be sent. That organization called customer service and were given an address, where the appeal was sent. The organization waited thirty days and called to check on the status of the appeal, and was told it was never received. Because that organization never mails anything to an insurer without delivery confirmation, they were able to demonstrate that the appeal had been filed, but customer service said that it had been sent to the wrong address, and was given a second address. The appeal, was re-sent, and after several days, the organization called to check on the status of the appeal. Again, the appeal was not logged in, and again, customer service said that it was sent to the wrong address. The third time was, indeed, a charm, and the appeal was successful. However, it took constant vigilance and three mailings of a fairly substantial appeal. Because the appeal was filed long before the deadline for filing, and there was proof of mailing, the subsequent mailings were not late. However, the consumer had to wait approximately ninety days for a decision due solely to repeatedly getting bad, very basic information over the telephone.

This is a relatively simple and straightforward example; those of us who represent consumers in appeals could give many more that would involve more substantive information that was conveyed inaccurately by customer service personnel at issuers/plans. Our point, though, is that in any instance in which written communication is feasible, it should be provided.

All notices should be required to include instructions to the consumer telling them how to request additional information. A telephone number, email address, and/or mailing address should be provided on the notice. Consumers should be told how long they can expect to wait until they receive the requested information, and they should be encouraged to contact the issuer/plan again if they have not received the information within that time frame. In addition, if the patient (who may or may not be the primary insured) wants additional information about the reasons for the denial so that she can file a meaningful appeal, she should be offered the option of receiving a written response by mail, fax, secure email, or web portal access. Privacy concerns are addressed by the consumer affirmatively choosing the best delivery mechanism for their particular circumstances. This process should allow information to be sent to the patient or his/her representative rather than the policyholder.

In addition, when a consumer asks for additional information regarding the reason for the denial, the issuer/plan should be required to provide, in plain language, not just the diagnosis and treatment code, but a narrative statement of the reason for the denial of coverage. Explanations such as "not medically necessary" or "experimental/investigational" are insufficient. For example, issuers/plans should have to explain that the service is not medically necessary because the patient does not meet the clinical criteria for the service – and a copy of the clinical criteria should be sent along with this information, without having to make a second request.

## **2. Language Access**

We appreciate the Departments' recognition that many limited English proficient (LEP) individuals will need assistance with filing claims and appeals because of language barriers. As Affordable Care Act § 1001 (enacting new Public Health Service Act § 2719) specifically called for notices to be provided in a culturally and linguistically appropriate manner, we believe the Departments must ensure that all LEP individuals have the ability to communicate effectively with their health plans and insurers when legal rights are at issue. Further, § 1557 provides further support for enhancing the provisions included in the

amended Interim Final Rule. We thus offer these suggestions to ensure the statutory intent is met.

First, the July 2011 Interim Final Rule (IFR) changed the determination of thresholds for providing language access from the numbers of LEP enrollees in a *plan* to the number of LEP residents in the claimant's *county*. This change fails to recognize that county demographics may not be reflective of a plan's demographics because a plan may market specifically to particular ethnic/cultural/language groups in a county, a region or nationally, or may serve employers that have high LEP populations, and thus have greater numbers of LEP enrollees than a given county in which the plan operates. We strongly believe that a plan must track data on its LEP enrollees and provide translated notices when the thresholds that we recommend below are met for *plan* enrollees.

Second, the July 2011 IFR omitted a numeric threshold for plans participating in the group market and merely requires translation of notices when 10% of a county's population is LEP. Again, this fails to recognize that plan demographics may differ from a county. As recognized in the IFR, very few counties meet the 10% threshold generally, and only 6 counties meet the threshold for any language other than Spanish. Existing DOL regulations as well as LEP Guidance from the Department of Justice as well as HHS (see <[http://www.lep.gov/guidance/guidance\\_index.html](http://www.lep.gov/guidance/guidance_index.html)>) recognizes the need for a dual standard and includes both numeric and percentage thresholds. We believe that the statutory requirement for providing notices in a culturally and linguistically appropriate manner must have some meaning and indeed provides a strong rationale for enhancing current guidelines rather than weakening them. By deleting the numeric threshold, the standard for providing translated notices is now weaker after enactment of the ACA, than before and will provide fewer covered individuals with language assistance.

We thus recommend that the Departments adopt a combined threshold utilizing the existing DOL regulations and DOJ/HHS LEP Guidances. We suggest that the threshold should be 500 LEP individuals or 5% of a plan's enrollees, whichever is less. The 5% is utilized in both the DOJ/HHS LEP Guidances as well as recently revised regulations from the Centers for Medicare & Medicaid Services governing marketing by Medicare Part C & D plans.

As some plans may undertake specific marketing and outreach activities to particular ethnic/cultural/language groups, we also recommend that the Departments adopt a secondary requirement to provide language services to any language group to which the plan specifically markets. This must be *in addition to* the basic thresholds. This standard would recognize that a plan could not conduct marketing and outreach to enroll LEP members and then fail to provide assistance when those members need additional information.

We also strongly believe that the Department should require plans and insurers to provide taglines in at least 15 languages in all notices, informing LEP enrollees of how to access language services. The request for 15 languages is based on existing government practice. The Social Security Administration, through its Multilanguage Gateway <<http://www.ssa.gov/multilanguage/>>, translates many of its documents into 15 languages and CMS recently announced plans to translate Medicare forms, including notices, into 15 languages in addition to Spanish <<http://www.cms.gov/EOInfo/Downloads/AnnualLanguageAccessAssessmentOutcomeReport.pdf>>. SSA's translations include documents specifically focusing on appeals including "The Appeals Process", "Your Right to Question the Decision on Your Claim", and "Your Right to Representation." CMS' planned translations include "Notice of Denial of Payment", "Notice of Denial of Medical Coverage,"

“Notice of Medicare Non-Coverage,” “Notice of Denial of Medicare Prescription Drug Coverage” and “Detailed Explanation of Non-Coverage.” This should be a requirement regardless of whether a translation threshold is met, again to ensure that enrollees are informed about how to obtain assistance when questions or issues arise. Plans that operate in California are already required to do so and have adapted to this. As one example, Standard Insurance Company sends an insert with all Coverage of Benefits documentation that includes taglines. The tagline used by this insurer states:

“No Cost Language Services. You can get an interpreter and get documents read to you in your language. For help, call us at the number listed on your ID card or xxx-xxx-xxxx. For more help, call the CA Department of Insurance at xxx-xxx-xxxx.”

Taglines by themselves are an effective and cost-efficient manner of informing LEP individuals and will help assist plans in determining in which languages additional materials should be provided. And to reduce costs to plans, the Departments can provide tagline language and translations for plan usage if plans did not wish to develop their own. Insurers could also explore putting taglines in the most prevalent languages on the envelope itself to raise attention to the importance of the notice.

We do want to emphasize, however, that taglines must be accompanied by an English notice so that individuals have a record of communication and may be able to obtain information from advocates or others about its content. Providing oral information or a tagline is insufficient to meet the notice requirements.

We also recommend that the Department reinstate the requirement from the initial IFR that “Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language.” For a variety of reasons, plans should be collecting data on their enrollees’ language needs, both to ensure services are available as well as providing culturally and linguistically appropriate information. As one example, Standard Insurance Company recently sent enrollees a Language Assistance Survey to gather data on enrollees’ language needs. Once an LEP enrollee identifies his language needs, the plan should track this information and not require the enrollee to continue to request information in that language.

Finally, we strongly believe that regardless of whether a plan is required to provide written translations of notices, the Department must ensure that oral assistance – through competent interpreters or bilingual staff – is provided to **all** LEP enrollees. The current IFR only requires plans to provide language services when the thresholds are met. We do not believe this meets the letter or spirit of § 1001 or § 1557 since this would leave millions of LEP individuals without any assistance from their plans when trying to understand their legal rights and whether to file an appeal. It is hard to understand how the statutory requirement to provide culturally and linguistically appropriate notices is upheld if plans can ignore the most basic communication needs of LEP individuals. It has been a longstanding recognition under Title VI of the Civil Rights Act of 1964, reiterated with the enactment of the nondiscrimination provision in Section 1557 of the ACA, that oral communication with LEP enrollees must be provided to every individual, regardless of whether thresholds to provide written materials are met.

#### **a. Cost of compliance**

The IFR mentions that some commenters cited the “high cost associated with implementing translation requirements pursuant to California State law and the low take-up rates of translated materials in California.” A review of the comments by California health

plans to the July 2010 regulations shows that plan cost estimates are exaggerated and up-take estimates are unclear.

The California language assistance requirements are much broader than what is being proposed in the IFR. California health plans must provide written translations of numerous "vital documents", including, applications, consent forms, letters containing important information regarding eligibility and participation criteria, notices pertaining to the denial, reduction, modification, or termination of services and benefits, and the right to file a grievance or appeal and notices advising LEP enrollees of the availability of free language assistance and other outreach materials, the explanation of benefits (EOB) or similar claim processing information if the document requires a response, specified portions of the plan's disclosure forms regarding the principal benefits and coverage, exclusions, limitations, and cost-sharing requirements.<sup>1</sup>

The IFR is specific to the translation of *notices* related to adverse benefit determinations, appeals and external review, and therefore is focusing on a small fraction of what health plans have to translate under California law. So when health plans refer to the costs associated with the implementation of the California Language Assistance Program, they are referring to a much more comprehensive program that includes costs unrelated to the scope of this IFR. Additionally, the thresholds in the CA law are much lower than the IFR – 1% for a plan with 300,000-1,000,000 members and .75% for a plan with over 1,000,000 members. Thus California plans have to translate both a wider variety of documents as well as into a greater number of languages and thus one cannot conclude that the costs of complying with CA's law are a good comparison for complying with a more limited IFR focused on limited translation of notices of appeals and external review into fewer languages.

In addition, the costs identified by California plans include implementation costs, which are not ongoing costs, such as initial translation of uniform notices. Also, the cost for California plans likely includes implementing tag and track IT systems since they must collect language data on enrollees.<sup>2</sup> So if California plans also operate in other parts of the country they will have much smaller costs in expanding the use of this software. Finally, in California, the Department of Managed Health Care translated taglines for health plans to save costs.<sup>3</sup>

## **b. Uptake estimates**

When California health plans refer to "low take-up rates" of translated materials, in their comments to the July 2010 regulations, it is unclear which materials they are referring

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<sup>1</sup> See California Department of Managed Care, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0041, Sept. 21, 2010.

<sup>2</sup> The greatest challenge so far has been setting up and reworking existing information technology (IT) systems to support the collection and management of data on members' primary written and spoken languages. <http://www.ahrq.gov/populations/languageservicesbr.pdf>

<sup>3</sup> California DMHC funded and posted on its public website the translation of a language assistance notice in Spanish, Chinese (traditional), Arabic, Armenian, Khmer, Farsi, Hmong, Korean, Laotian, Russian, Tagalog, and Vietnamese. See California Department of Managed Care, Second Biennial Report to the Legislature on Language Assistance Second Biennial Report to the Legislature on Language Assistance (July 1, 2011), available at <http://www.hmohelp.ca.gov/library/reports/news/11rpt2legisla.pdf>.

to since they are required to translate the extensive list of “vital documents” referenced above. Also, not all California health plans are complying with the state law language access requirements, as a California report shows deficiencies by health plans in advising enrollees of language assistance and includes a list of the number of complaints recorded.<sup>4</sup> There may be actually be more complaints than those listed in the report since if a plan is not providing enrollees with the proper notice in their language, they may not know that they can call the HMO helpline to file a complaint.

### **c. Translation at the plan’s request**

Many employers and plan sponsors know that they employ a large number of LEP workers and should be able to request translation of notices by health insurance issuers. If an employer or plan sponsor knows that the number of LEP workers meets the thresholds that were in the July 2010 regulations and based on DOL regulations regarding style and format for a summary plan description at 29 CFR 2520.102-2(c), then the health insurance issuer should be required to provide translated notices at the request of the employer or plan sponsor. This would help ensure the intent of the law to ensure access to claims and appeals information in a culturally and linguistically appropriate manner without adding any additional burden on employers. Most employer and plan sponsors do not have large enough market power to negotiate the addition of a new translation practice by an issuer which is why the translation does not occur now. We expect there are many employers and plan sponsors that want the plan enrollees to receive the full benefit that is being paid for, which includes knowledge of the right to appeal.

## **3. Federal External Review**

We continue to have concerns about the process for the interim enforcement safe harbor for self-insured plans not subject to a state external review process or the HHS-supervised process. This interim safe harbor permits a private contract process under which plans contract with accredited IROs to perform reviews. Our specific concerns follow.

### **a. Choice Of IROs**

Under the guidance accompanying the June 2011 Amendments, self-insured ERISA plans will be eligible for a safe harbor from enforcement from the Department of Labor and Internal Revenue Service if they contract with at least two IROs by January 1, 2012 and with at least three IROS by July 1, 2012 and rotate assignments among them. Permitting plans to choose the IRO undermines a key principle of the appeals and external review (incorporated in the IFR) that the external review be conducted by an entity that is completely independent from the plan, with no potential for conflicts of interest, so as to provide for a fully impartial review. Given the lack of clarity in this rulemaking, it also appears possible for a plan to vary its approach to selecting an IRO, raising the possibility that a plan might choose the IRO based on the nature of the dispute, the participant or beneficiary or the particular coverage. This opens up the external review process to the potential for what is in effect forum shopping for an IRO that is likely to produce a review in favor or the plan.

Our second concern is that the conflict of interest standards related to external review in the IFR and now the Amendments to the IFR do not include a provision to prohibit

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<sup>4</sup> California Department of Managed Care, Second Biennial Report to the Legislature on Language Assistance Second Biennial Report to the Legislature on Language Assistance (July 1, 2011), available at <http://www.hmohelp.ca.gov/library/reports/news/11rpt2legisla.pdf>.

ex parte, unwritten communications between the plan and the reviewing organization. This is a major omission and places the consumer at considerable disadvantage in presenting his or her case and rebutting plan arguments. We strongly urge the Departments to require that a consumer/patient who is the claimant be a party to all communications between the plan and the reviewing organization.

An additional concern is that the regulations lack on a prohibition on a plan using an entity/contractor that wrote its clinical guidelines as its IRO. For example, if an organization has established the clinical guidelines for the plan, it is inherently conflicted in making a determination related to a plan's coverage decisions and should therefore not be qualified to serve at the IRO for external appeals that originate with that plan. If a total prohibition is not possible, then we urge the inclusion of a provision that requires the creation of effective firewalls so that those individuals responsible for development of the clinical guidelines are not the same individuals (or accountable to the same individuals) as those responsible for carrying out the independent, external review.

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

For coverage subject to either the HHS-administered process or the private accredited IRO process, the July 2010 IFR provided that any adverse benefit determination (or final internal adverse benefit determination) could be reviewed unless it was related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of the group health plan. The June 2011 Amendment introduces a troubling modification of the scope of claims eligible for external review under this Federal process, effective through the end of 2013.

As the Departments and we previously have noted, self-funded ERISA plans are different from fully insured plans with respect to the process for external review. Challenging a plan decision is almost impossible for a consumer (participant or beneficiary) enrolled in such a self-funded plan to adjudicate contractual claims, such as a billing code errors or non-covered services, through traditional ERISA enforcement (which generally relies on federal court adjudication). This means that they have no effective means of enforcing their rights to benefits under the plan. The requirement for independent external review is so important because it offers a viable option to adjudicate such disputes. This remains true, however, only to the extent that a broad scope of claims is eligible for external review.

The June 2010 IFR provided for such a broad scope of claims and we strongly supported that policy. Under the June 2011 Amendment, the broad scope of claims is suspended to those that involve medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment) as determined by the external reviewer, and a rescission of coverage. We appreciate that medical judgment is retained but are very concerned by the limitation on the scope of medical judgment. The examples of medical judgment included in the Preamble are helpful but given the modification of scope, it would also be helpful to provide an FAQ on when billing/coding disputes involve medical judgment. We also request that you include the examples of medical judgment in consumer education materials and employer compliance materials on the DOL and HHS websites since future readers may easily miss examples that are only in the preamble.

The Preamble for the suspension of the standard relating to scope of the external Federal review process made by the June 2011 Amendment states that the reason for the amendment is—

to give the marketplace time to adjust to providing external review . . . [and] allow the Departments time to evaluate IRO's capacity for handling external reviews; to consider whether current accreditation standards are sufficient to ensure that IROs are capable of making accurate and consistent decisions regarding legal and contractual issues that do not involve medical judgment or rescissions; and to assess the mechanics of the Federal external review process (and any potential adjustments. . . .

But the Preamble also notes that IRO groups have already indicated that the standard established by the July 2010 IFR does not create problems for them because they already have the appropriate personnel and capacity to conduct reviews that involve both medical judgment issues and legal and contractual issues. In addition, URAC has already indicated that the organization's accreditation standards address capacity of IROs to address disputes involving both medical judgment issues and legal and contractual issues. We thus question the rationale for imposing this suspension and urge the Departments to reconsider.

Further, the "medical judgment" standard also is ambiguous. Its construction is delegated to external reviewers, and while this is far better than leaving it to plans to decide whether medical judgment is involved, this still allows the possibility of different, conflicting interpretations of this phrase. If a doctor chooses a procedure code after considering alternatives, is that the exercise of medical judgment, as contrasted with a clerical person who simply assigns a procedure code based on a clinician's notes? If so, will external reviewers conduct evidentiary hearings to determine whether a particular coding (for example) involves the exercise of medical judgment? We can imagine that there will be much litigation over the phrase "medical judgment," opening the door to disputes that otherwise would not have to be litigated. This limitation -- intended to alleviate the need for IROs to make legal judgments -- actually ensures that external reviewers will be required to parse each party's interpretation of the phrase "medical judgment."

#### **4. State External Appeals**

In implementing the ACA's federal minimum standards for consumer internal and appeals rights, the Secretary has appropriately recognized that laws providing for an external appeals process vary widely by state and that a few states lack such laws altogether. Moreover, those states that do have such laws are unable to protect participants and beneficiaries in self-insured, ERISA plans because of federal preemption.

To give states time to adopt the broader and more uniform federal standards called for by the Affordable Care Act, the June 17, 2010 Interim Final Rules (IFR) and subsequent guidance included a transition process, providing that existing state external appeals laws that did not yet conform to the NAIC's Uniform Health Carrier External Review Model Act would be given until July 1, 2011 to meet these minimum standards. Under the June 24, 2011 Amendment, a state's external review process does not have to satisfy the 16 consumer protections detailed in the IFR until January 1, 2014; prior to that date, the amendment establishes multiple "transition periods" during which state external review processes will be deemed compliant with the IFR if specified criteria are satisfied, and the 16 consumer protections are pared to 13. We appreciate the need for a transition period to enable states, issuers and plans time to adjust to broader and more uniform consumer protection standards, but those needs must be balanced against those of consumers.



The NAIC's Uniform Health Care External Review Model Act, upon which the uniform federal standards for state external review are based, includes sixteen minimum consumer protections. Under the June 2011 Amendment and guidance issued concurrent with the Amendment, certain of these protections have been weakened or temporarily set aside for the NAIC-similar external review process that states may adopt to meet federal requirements. The NAIC Model Act consumer protections do not create a high bar for compliance and to weaken them marks a disturbing turn away from the improvements in consumers' appeals rights called for by the ACA. Therefore, we urge you to implement all sixteen minimum consumer protections as soon as possible.

#### **a. Timeframe for Filing a Request for External Review**

Under the June 2010 IFR, and as called for under the NAIC Model Act, the external appeal process must allow the consumer/claimant least four months to file a request for external review after receipt of the notice of adverse benefit determination or final internal benefit determination. Under the Amendment, this period has been reduced to 60 days, a period that may foreclose the chance for patients, some who may be very sick, to seek a reversal of an adverse decision. This seems to us to be an especially arbitrary change, for which no explanation is given. The four months required by the Model Act recognizes the potential need for more than a couple of months to initiate an appeal and does not impose undue burden on plans and issuers. If a state process allows fewer than four months to appeal, in this interim period before 2014, consumers who pass the state's appeal deadline should have the option of using the federal appeals process for the remainder of the four months.

#### **b. Filing Fee**

Under the June 2010 IFR and Model Act, a state may require a nominal filing fee from the claimant requesting an external review. To be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single year must not exceed \$75. Under Technical Release 2011-02 published concurrently with the June 2011 Amendment, a \$25 fee may be charged to the claimant for filing an appeal. The annual cap on filing fees has been removed as has the provision for a hardship exception in the event that any one filing fee creates a financial hardship, and no explanation has been provided for this policy change. This modification exposes the consumer to the possibility that if any single or multiple filings are needed in a year, the associated financial cost could become significant and create a financial hardship for some consumers.

#### **c. Maintenance by IROs of Written Records**

Under the July 2010 IFR, a state process would have to require that IROs maintain written records and make them available upon request to the State (a requirement that is "substantially similar" to section 15 of the NAIC Uniform Model Act). Technical Release 2011-02 that was published concurrently with the June 2011 Amendment deletes this provision. No rationale for deleting this requirement is provided. The maintenance of records requirement provided an important safeguard to the integrity of the process and should not be eliminated, even on a temporary basis.

In addition to concerns about the dilution of the consumer protections, we are concerned that the approach adopted by the June 2011 Amendment may have the

unintended effect of lowering the bar for minimum consumer protection standards for all states over the longer term. Even if states legislative sessions are over, they should be able to amend their contracts with IROs to require maintenance of written records. We thus recommend that the agencies work with states to accomplish this standard.

## 5. Model Notices

We have taken the liberty of editing the model notices that are appended to Technical Release 2011-2. Our proposed revised notices are attached.

Our concern is that the models drafted by the Departments are too complex and should be written in plainer terms with more guidance and information to consumers. The federal government has made many statements about plain language. See, e.g., J. Locke, *A History of Plain Language in the United States Government* (2004) <<http://www.plainlanguage.gov/whatisPL/history/locke.cfm>> (last accessed July 5, 2011); Plain Language: A Promising Strategy for Clearly Communicating Health Information and Improving Health Literacy <<http://www.health.gov/communication/literacy/plainlanguage/PlainLanguage.htm>> (last accessed July 5, 2011). We cannot imagine an instance in which plain language could be more critical.

When a consumer lacks a basic framework, or mental map, it is very difficult for them to make sense of new, tangentially related information. For example, in the *Model Notice Of Adverse Benefit Determination*, the purpose of the document seems to be that it is an "adverse benefit determination." Most consumers would not know what this is. Plus, on the next page, embedded in a helpful discussion, this is referred to as a "denial" and the *Appeal Filing Form* says that the "denial notice" must be included in the filing. It is unlikely that consumers will understand these are all the same thing. In our revised notices, we have attempted to address these types of issues.

We also have several questions that should be answered before Form Notices should be used. First, it is most common to receive an Explanation of Benefits (EOB) listing all of the claims for a date of service or even multiple dates of service, with some claims granted and others denied. However, the Form Notices are only for denials. Will insurers send both an EOB and a Notice of Denial? The Form Notices do not appear to contemplate reporting claims that were paid along with those that were denied.

## Conclusion

In sum, while we are encouraged that the Departments have made several strong statements that will inure to the benefit of consumers, we feel that some of the changes that were made will harm consumers. Reversing course on those points, as set forth above, is necessary to protect consumers to the fullest extent without unduly burdening plans/issuers. Thank you.

Respectfully submitted,

Advocacy for Patients with Chronic Illness, Inc.  
American Cancer Society Cancer Action Network  
California Pan-Ethnic Health Network  
Consumers for Affordable Health Care (Maine)  
Consumers Union  
Families USA

Health Access California  
Health Law Advocates  
Timothy Jost  
National Health Law Program  
Office of Health Care Ombudsman, Vermont Legal Aid  
National Partnership for Women & Families  
National Women's Law Center  
State Associations of Addiction Services  
State of Connecticut Office of the Healthcare Advocate

**NOTICE OF DENIAL**

**Date of Notice**

**Name of Plan**

**Address**

**Telephone/Fax**

**Website/Email Address**

**This document contains important information that you should retain for your records.**

This document ~~serves as notice of an adverse benefit determination. We have~~ is to let you know that ~~[insert name of insurer] has decided not declined~~ to provide benefits, in whole or in part, for the requested treatment or service described below in Case Details.

If you think this ~~denial/termination~~ was made in error, you have the right to have the decision reviewed/appeal. ~~(see the back of this page for information about your appeal rights).~~

If you wish to appeal, see the back of this page for information. **You must file your appeal no later than 180 days from the date of this notice.**

**Denial Details:**

**Date of Notice**

**Name of Plan**

**Address**

**Telephone/Fax**

**Website/Email Address**

**Case Details:**

<b>Patient Name:</b>	<b>ID Number:</b>
<b>Address: (street, county, state, zip)</b>	
<b>Claim #:</b>	<b>Date(s) of Service:</b>
<b>Provider(s):</b>	
<b><u>Description of service(s):</u></b>	

<b>Reason for Denial (in whole or in part):</b>
<b><u>Denial Code(s):</u></b>

<b><u>Amount Charged</u></b>	<b><u>Allowed Amount</u></b>	<b><u>Other Insurance Paid</u></b>	<b><u>Your share of these costs</u></b>		<b><u>Other Amounts Not Covered</u></b>	<b><u>Amount This Plan Paid</u></b>	<b><u>Patient Balance (Amount You Owe)</u></b>
			<b><u>Deductible</u></b>	<b><u>Co-pay</u></b>	<b><u>Coinsurance</u></b>		
<b><u>To date, you have paid this much towards your YTD Credit toward Deductible:</u></b>			<b><u>To date, you have paid this much towards your YTD Credit toward Out-of-Pocket Maximum:</u></b>				
<b><u>Description of service:</u></b>			<b><u>Denial Codes:</u></b>				

*[If denial is not related to a specific claim, only name and ID number need to be included in the box. The reason for the denial would need to be clear in the narrative below.]*

**Explanation of Denial Basis for Determination:**

*If the claim is denied (in whole or in part) and there is more explanation for the basis of the denial, such as the definition of a plan or policy term, include that information here.*

**[Insert language assistance disclosure here, if applicable.]**

SPANISH (Español): Para obtener asistencia en Español, llame al [insert telephone number].

TAGALOG (Tagalog): Kung kailangan ninyo ang tulong sa Tagalog tumawag sa [insert telephone number].

CHINESE (中文): 如果需要中文的帮助, 请拨打这个号码 [insert telephone number]。

NAVAJO (Dine): Dinek'ehgo shika at'ohwol ninisingo, kwijigo holne' [insert telephone number]. ]

## Important Information about Your Appeal Rights

### **What if I need help understanding this denial?**

Contact us at [insert contact information] if you need ~~help assistance~~ understanding this notice or our decision to deny you a service or coverage.

**Can I request copies of information relevant to my claim?** Yes, you may request copies (free of charge) of any documents upon which we based our decision. You have the right to have billing and diagnosis codes sent to you, as well, along with explanations of those codes, so that you can decide whether you think there has been a billing error. To request copies of this information, contact us at [insert contact information] and specify whether you prefer mail or email.

**What if I don't agree with this decision?** You have a right to have the decision reviewed. This is called requesting an appeal. ~~any decision not to provide or pay for an item or service (in whole or in part)~~. You must file your appeal no later than 180 days from the date of this notice.

**How do I file an appeal?** You may use the form on the next page, or you can write us a letter. In your appeal, please describe why you believe we were wrong in deciding not to cover the item. Provide as much information as you can, including especially information that we may not already have, such as medical records, a letter from your treating professional, or any other documents that will help us to understand why you think we should have covered the item. Send your appeal to the address indicated below and keep a copy for your records. ~~[Complete the bottom of this page, make a copy, and send this document to {insert address}.] [or] [insert alternative instructions]~~ See also the “Other resources to help you” section of this form for assistance filing a request for an appeal.

**What if my situation is urgent?** If your medical situation meets the definition of urgent under the law, your review will generally be conducted within 72 hours. Generally, an urgent situation is one in which your health may be in serious jeopardy or, in the opinion of your treating professional/physician, you may experience pain that cannot be adequately controlled while you wait for a decision on your appeal. If you believe your situation is urgent, you may request an expedited-faster appeal either by requesting that your appeal be EXPEDITED or

checking the “URGENT” box on the form on the next page by following the instructions above for filing an internal appeal and also [insert instructions for filing request for simultaneous external review]. See also “What Happens Next” on this page for information on external reviews.

**Who may file an appeal?** You or someone you name to act for you (your authorized representative) may file an appeal. If you would like someone to act for you, you must sign a short form indicating this. You can find the form at [insert web address] or by calling us at xxx-xxx-xxxx and asking us to mail or email you a copy of the form.~~[Insert information on how to designate an authorized representative.]~~

**Can I provide additional information about my claim in the appeal?** Yes, actually, you should provide additional information. Providing additional information may help the reviewer(s).~~you may supply additional information.~~ [Insert any applicable procedures for submission of additional information.]

~~**Can I request copies of information relevant to my claim?** Yes, you may request copies (free of charge). If you think a coding error may have caused this claim to be denied, you have the right to have billing and diagnosis codes sent to you, as well. You can request copies of this information by contacting us at [insert contact information].~~

**What happens next?** If you appeal, we will review our decision and provide you with a written determination. If we continue to deny the payment, coverage, or service requested or you do not receive a timely decision, you may be able to request an external review of your claim by an independent ~~n-independent~~ third-party medical professional, who will review the denial and issue a final decision.

**Other resources to help you:** For questions about your rights, this notice, or for assistance, you can contact: [if coverage is group health plan coverage, insert: the Employee Benefits Security Administration at 1-866-444-EBSA (3272)] [and/or] [if coverage is insured, insert State Department of Insurance contact information]. [Insert, if applicable in your state: Additionally, a consumer assistance program can help you file your appeal. Contact [insert contact information].]

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**Appeal Filing Form**

**NAME OF PERSON FILING APPEAL:** \_\_\_\_\_

**Circle/Check** one:  Covered person  Patient  Authorized Representative

**Contact information of person filing appeal (if different from patient)**

**Address:** \_\_\_\_\_

**Daytime phone:** \_\_\_\_\_ **Email:** \_\_\_\_\_

**If person filing appeal is other than patient, patient must indicate authorization by signing here:**

\_\_\_\_\_

**Are you requesting an urgent appeal?**  Yes, urgent.  No

**Briefly describe why you disagree with this decision.** (~~Y~~You will want to may attach additional information, such as a medical professional-physician's letter, bills, medical records, or other documents to support your claim. You may attach as many additional pages as you like, and you do not have to use this form at all if you would prefer to write a letter):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Send this form and your NOTICE OF DENIAL (the first page in this packet) along with any additional information you would like to include ~~denial notice~~ to: [Insert name and contact information]

**Be certain to keep copies of this form, your denial notice, and all documents and correspondence related to this claim.**

**NOTICE OF DENIAL**

**Date of Notice**

**Name of Plan**

**Telephone/Fax**

**Address**

**Website/Email Address**

**This document contains important information that you should retain for your records.**

This document ~~serves as notice of a final internal adverse benefit determination~~ is to let you know that ~~[insert name of insurer] has.~~ We have decided not declined to provide benefits, in whole or in part, for the requested treatment or service described below in Case Details.

If you think this ~~denial/termination~~ was made in error, you may have the right to have the decision reviewed. appeal ~~(see the back of this page for information about your appeal rights).~~

If you wish to have the decision reviewed, see the back of this page for information. **You must file your request for review no later than [# of days] from the date of this notice.**

**Denial Details:**

**Date of Notice**

**Name of Plan**

**Telephone/Fax**

**Address**

**Website/Email Address**

**Internal Appeal Case Details:**

<b>Patient Name:</b>	<b>ID Number:</b>
<b>Address: (street, county, state, zip)</b>	
<b>Claim #:</b>	<b>Date of Service:</b>
<b>Provider:</b>	
<b><u>Description of service(s):</u></b>	

<b>Reason for Upholding Denial (in whole or in part):</b>
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<b><u>Amount Charged</u></b>	<b><u>Allowed Amount</u></b>	<b><u>Other Insurance Paid</u></b>	<b><u>Your share of these Costs</u></b>			<b><u>Other Amounts Not Covered</u></b>	<b><u>Amount this plan Paid</u></b>	<b><u>Patient Balance (Amount You Owe)</u></b>
			<b>Deductible</b>	<b>Co-pay</b>	<b>Coinsurance</b>			
<b><u>YTD Credit toward To date, you have paid this much towards your Deductible:</u></b>			<b><u>YTD Credit toward To Date, you have paid this much towards your Out-of-Pocket Maximum:</u></b>					
<b><u>Description of Service:</u></b>			<b><u>Denial Codes:</u></b>					



*[If denial is not related to a specific claim, only name and ID number need to be included in the box. The reason for the denial would need to be clear in the narrative below.]*

**Background Information:** *Describe facts of the case including type of appeal and date appeal filed.*

**Final- ~~Denial~~Internal Adverse Benefit Determination:** *State that adverse benefit determination has been upheld. List all documents and statements that were reviewed to make this final internal adverse benefit determination.*

**Findings:** *Discuss the reason or reasons for the final internal adverse benefit determination.*

**[Insert language assistance disclosure here, if applicable.**

SPANISH (Español): Para obtener asistencia en Español, llame al [insert telephone number].

TAGALOG (Tagalog): Kung kailangan ninyo ang tulong sa Tagalog tumawag sa [insert telephone number].

CHINESE (中文): 如果需要中文的帮助, 请拨打这个号码 [insert telephone number]。

NAVAJO (Dine): Dinek'ehgo shika at'ohwol ninisingo, kwijigo holne' [insert telephone number]. ]

## Important Information about Your Rights to External Review

### What if I need help understanding this denial?

Contact us [insert contact information] if you need ~~assistance-help~~ understanding this notice or our decision to deny you a service or coverage.

**Can I request copies of information relevant to my claim?** Yes, you may request copies (free of charge) of any documents upon which we based our decision. You have the right to have billing and diagnosis codes sent to you, as well, along with explanations of those codes, so that you can decide whether you think there has been a billing error. To request copies of this information, contact us at [insert contact information] and specify whether you prefer mail or email.

**What if I don't agree with this decision?** For certain types of claims, you are entitled to request an ~~other-independent, external~~ review of our decision by a medical professional who does not work for us. You have to submit this request no later than [number of days] from the date of this Notice. See below, How do I file a request for external review? for instructions. You also may ~~contact~~ [insert external review contact information] with any questions on your rights to external review. [For insured coverage, insert: If your claim is not the type of claim that can be reviewed again eligible for independent external review but you still disagree with the denial, call your state insurance Department regulator may be able to help to resolve the dispute for help.] See the "Other resources section" of this form for help filing a request for external review.

### How do I file a request for external review?

You may use the form on the ~~Complete the bottom of this-next~~ page, or you can write us a letter. In your request, please describe why you believe we were wrong in deciding not to cover the item. Provide as much information as you can, including especially information that we may not already have, such as medical records, a letter from your treating professional, or any other documents that will help us to understand why you think we should have covered the item. Send, make a copy, and send your request for review along with a copy of the Notice of Denial (the other side of this page) this document to {insert address}. [or] [insert alternative instructions.], but keep a copy for your records See also the "Other resources to help you" section of this form for ~~helpassistance~~ filing a request for external review.

**What if my situation is urgent?** If your medical situation meets the definition of urgent under the law, the external review of your claim will be conducted as expeditiously as possible. Generally, an urgent situation is one in which your health may be in serious jeopardy or, in the opinion of your treating professional physician, you may experience pain that cannot be adequately controlled while you wait for a decision on the external review of your claim. If you believe your situation is urgent, you may request an ~~faster expedited~~ external review by requesting that your appeal be EXPEDITED or ehcking the "URGENT" box on the form on the next page and also [insert instructions to begin the process (such as by phone, fax, electronic submission, etc.)].

### Who may file a request for external review?

You or someone you name to act for you (your authorized representative) may file a request for external review. [Insert information on how to designate an authorized representative.]

### Can I provide additional information about my claim?

Yes, actually, you should provide additional information. once your external review is initiated, you will receive instructions on how to supply additional information. Providing additional information may help the reviewer(s).

~~Can I request copies of information relevant to my claim?~~ Yes, you may request copies (free of charge) by contacting us at [insert contact information].

**What happens next?** If you request an external review, an independent organization will review our decision and provide you with a written ~~decision termination~~. If the reviewer(s) is organization decides to overturn our decision, we will provide coverage or payment for your health care item or service.

**Other resources to help you:** For questions about your rights, this notice, or for assistance, you can contact: [if coverage is group health plan coverage, insert: the Employee Benefits Security Administration at 1-866-444-EBSA (3272)] [and/or] [if coverage is insured, insert State Department of Insurance contact information]. [Insert, if applicable in your state: Additionally, a consumer assistance program can help you file your appeal. Contact:[insert contact information].]

