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VIA ELECTRONIC SUBMISSION

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 Sir/Madam:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people. With the implementation of the new health reform law, it is critical to ensure that private health care plans provide the appropriate care for *all* populations, including diverse and low-income vulnerable populations. The protections that individuals need to access necessary health care, including notice and appeal rights, are an essential part of that implementation. Accordingly, NHeLP is pleased to offer our comments on the June 22, 2011 amendments (Amendments) to the July 23, 2010 Interim Final Rule for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes (IFR).

Language Access

The Affordable Care Act § 1001 (enacting new Public Health Service Act § 2719) specifically requires that notices be provided in a culturally and linguistically appropriate manner. While we applaud the Departments' recognition that many limited English proficient (LEP) individuals will need assistance with filing claims and appeals because of language barriers, 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. In addition, § 1557,

the nondiscrimination provision of the ACA, provides further support for enhancing the provisions included in the amended Interim Final Rule. The following changes to the regulations should be made to ensure the requirements of the ACA are met.

First, the June 2011 Amendments changed the determination of thresholds for providing language access from the numbers of LEP enrollees in a *plan* to the number of LEP enrollees in a *county*. This change fails to recognize that county demographics may not be reflective of a plan's demographics because a plan may operate regionally or nationally or may market specifically to particular ethnic/cultural/language groups and thus have greater numbers of LEP enrollees than a given county in which the plan operates. We strongly believe the requirements of the previous Interim Final Rule (IFR) should be restored so that a plan must track data on its LEP enrollees and provide translated notices when thresholds are met for *plan* enrollees.

Second, the June 2011 Amendments omitted a numeric threshold for plans participating in the group market and merely require 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 Amendments, very few counties meet the 10% threshold generally, and only 6 counties meet the threshold for any language other than Spanish. Existing Department of Labor (DOL) regulations and the LEP Guidance from the Department of Justice and HHS (see http://www.lep.gov/guidance/guidance_index.html) recognize the need for a dual standard that includes both numeric and percentage thresholds. We believe that the statutory requirement for providing notices in a culturally and linguistically appropriate manner 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 the enactment of the ACA, rather than before, and will provide fewer covered individuals with language assistance.

We therefore recommend that the Departments adopt a combined threshold utilizing the existing DOL regulations and DOJ/HHS LEP Guidances, and that the threshold should be 500 LEP individuals or 5% of a plan's enrollees. 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.

Third, 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.

Fourth, we strongly believe that the Departments 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. 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 requirement. 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.

Fifth, we recommend that the Departments reinstate the requirement from the initial IFR that once a request has been made by a claimant, plans or issuers must "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. Otherwise, this creates unnecessary communication between the plan and the enrollee, both in sending the unnecessary English version and requiring the enrollee to request the translation. In addition, having the notices sent out in the appropriate language will increase quality of care by making sure enrollees receive timely and understandable adverse benefit determinations and are able to act on them quickly and effectively. Without this, enrollees whose need for language services has already been established will be disadvantaged because they will have to wait to receive understandable information about an adverse benefit determination. This in turn may lengthen the time it takes to receive a final determination after appeal.

Finally, we strongly believe that regardless of whether a plan is required to provide written translations of notices, the Departments 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. The statutory requirement to provide culturally and linguistically appropriate notices cannot be upheld if plans can ignore the most basic communication needs of LEP

individuals. There 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.

Cost of compliance

Some of the commenters to the original IFR 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; 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; and specified portions of the plan's disclosure forms regarding the principal benefits and coverage, exclusions, limitations, and cost-sharing requirements.[1]

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 into a greater number of languages. 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.[2] So if California plans also operate in other parts of the country they will have

[1] *See* California Department of Managed Care, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0041, Sept. 21. 2010.

[2] 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. *See* Mathematica Policy Research Inc., Improving Access to Language Services in Health Care: A Look at National and State Efforts (Apr. 2009), available at http://www.ahrq.gov/populations/languageservicesbr.pdf.

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.[3]

Uptake estimates

When California health plans refer to "low take-up rates" of translated materials, in their comments to the original IFR, it is unclear which materials they are referring 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.[4] There may 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, enrollees may not know that they can call the HMO helpline to file a complaint.

Expedited notification of benefit determinations involving urgent care

The original IFR provided that a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account medical exigencies, but no later than 24 hours after the receipt of the claim by the plan or issuer. In the June 2011 Amendments to the IFR, the rule for notification within 24 hours was changed to 72 hours.

The Amendments provide that a claim involving "urgent care" is any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations: 1) could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or 2) in the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.[5] Given the severe consequences that a delay in claim processing could have on a patient's health, we encourage the Departments to reinstate the 24-hour decision-making requirement for health plans and issuers.

Recommendations:

- Requiring health plans and issuers to respond to urgent claims, as soon as possible, but no later than 24 hours after the receipt of the claim, unless the plan

[3] 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.

[4] 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.

[5] 45 C.F.R. §147.136(b)(2)(ii)(B) (2011) says that urgent care has the meaning given in 29 CFR 2560.503-1(m)(1).

needs additional information from the claimant's medical provider, wherefore the plan will have up to 72 hours after receipt of the claim to respond.

- For urgent claims involving prescription medications, plans or issuers who cannot respond within 24 hours because additional information from the claimant's medical provider is needed, should be required to provide the claimant with a 72-hour supply of the medication.

Reinstating 24-hour requirement with an outer limit of 72 hours only when additional information is needed from a medical provider:

Health plan commenters to the original IFR expressed concern adhering to a strict 24-hour requirement and requested flexibility for health plans and issuers to make claim decisions within 72 hours. Commenters cited administrative challenges, especially obtaining information from health care providers who may not be available for consultation during weekends or holidays.[6] After considering these comments, the Departments changed the 24-hour decision-making requirement to 72 hours.

We recommend that the Departments reinstate the 24-hour decision-making deadline and instead include language in the regulation that allows plans and issuers up to 72 hours to respond to a claim, *only* when they can document *in writing* the reasons why they were unable to contact the claimant's medical provider within 24 hours, and therefore need additional time.[7] This will allow health plans and issuers to conduct timely reviews while at the same time protecting patient's rights.

a) "As soon as possible" language in the regulations is not enough to protect patients

Reinstating the 24-hour decision-making requirement is imperative due to the potential impact on the health and well-being of patients that untimely claim responses can have. The Departments recognize that this is a quality of care issue and in the Preamble to the June 2011 IFR, underscore that the 72-hour timeframe remains only an outside limit and that claims should be decided "as soon as possible" taking into account medical exigencies. Yet it is not enough to say that the standard should be "as soon as possible" because that gives too much discretion to the health plans and issuers with no criteria or standard to enforce it. Instead, the requirement should be 24 hours with the flexibility for plans or issuers to use up to 72 hours only when they need additional time to communicate with the claimant's medical provider.

[6] America's Health Insurance Plans, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0042, Sept. 21, 2010.

[7] 29 CFR 2560.503-1(f)(2)(i) already outlines the steps that health plans and issuers must take when a claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan. In a similar way, language should be added to address this extension of the 24 hour rule when plans need more time to communicate with the claimant's medical provider.

b) Urgent care vs. emergency care

A health plan commenter to the original IFR indicated that an urgent care claim is not a medical emergency, in which case a patient is given immediate care and coverage without need for prior authorization.[8] Yet if a claimant does not receive a prompt response on an urgent care claim, it can lead to an unnecessary emergency, which will be more costly for the plan or issuer and for the claimant (an emergency room visit usually has a higher co-payment). Also, plan enrollees should not be forced to go to the emergency room when they do not have a true emergency just because they are not able to get a timely response from their health plan or issuer. Emergency rooms around the country are scarce and over-crowded, so this is not a reasonable way for patients to access care.

Special rule for prescription drugs:

In the Medicaid context, managed care plans must ensure the "timely and efficient" processing of prior authorization requests for prescription drugs. Plans must respond to these requests within 24 hours, and dispense at least a 72-hour supply of a covered outpatient drug in an emergency situation.[9] Health plans and issuers subject to the IFR should also be required to provide a 72-hour supply of a medication for urgent claims when a response to the claim cannot be provided within 24 hours.

Elimination of requirement to automatically provide diagnosis and treatment codes as part of the notice of adverse benefit determination

In response to comments to the original IFR, the Departments decided not to require health plans or issuers to include diagnosis and procedure codes in notices of adverse benefit determinations (final or otherwise). We understand the privacy concerns and the reasons why the Departments made this decision. The Amendments indicate that a plan or 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.

Recommendations:

- Plans or issuers must provide information about diagnosis and treatment codes in writing (not just verbally).
- All notices should include clearly written and prominently placed instructions to enrollees telling them how to request additional information.

[8] America's Health Insurance Plans, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0042, Sept. 21, 2010; WellPoint Inc., Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0035, Sept. 21, 2010.

[9] 42 U.S.C. §1396r-8(d)(5)(A), 42 U.S.C. §1396r-8(d)(5)(B).

- Enrollees should be informed how long they can expect to wait until they receive the requested information, and encouraged to contact the plan or issuer again if they have not received the information within that timeframe.
- Plans should send this information to enrollees within a set timeframe to allow enrollees enough time to have all of the information necessary in case they request an appeal.
- Plans or issuers should send the information to the mailing address, email, fax number, etc., that the enrollee requests the information be sent to rather than to the policyholder, in order to protect the enrollee's privacy.

Deemed exhaustion of internal claims and appeals processes

As the Departments noted, when plans and issuers offer full and fair internal procedures for resolving claims, it is reasonable to insist that claimants first turn to those procedures before seeking judicial or external review of benefit denials. But there is less justification, however, for insisting that a claimant exhaust administrative procedures that do not comply with the law. Accordingly, the original IFR permitted claimants to immediately seek review if a plan or issuer failed to ''strictly adhere'' to all of the requirements for internal claims and appeals processes, regardless of whether the plan or issuer asserted that it ''substantially complied'' with the July 2010 regulations.

Yet, in response to comments, the Departments made amendments to the original IFR providing an exception to the strict compliance standard for errors that are minor and meet certain other specified conditions. 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 was: (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; and (5) Not reflective of a pattern or practice of non-compliance.

According to the Amendments, claimants will be entitled, upon *written* request, to an explanation of the plan's or issuer's basis for asserting that it meets this new standard, so that the claimant can make an informed judgment about whether to seek immediate external review. If the external reviewer or the court rejects the claimant's request for immediate review on the basis that the plan met this standard, the claimant has the right to resubmit and pursue the internal appeal of the claim. This is an onerous requirement for claimants that will cause unnecessary delays in care or treatment.

The Amendments to the IFR do not provide guidance as to how much time the plans or issuers will have to provide this information to the claimant. They also offer no clarity about what it means for a plan or issuer to comply with this standard. In addition, there is an unreasonable expectation that upon receiving the information from the plan or issuer, the claimant will be able to decipher whether the plan or issuer meets the required standard and whether the claimant has the right to bypass the internal review process and pursue an external review.

Commenters to the original IFR indicated that the "strict adherence" requirement would force plans and issuers to make significant changes to adopt the new measures and expressed concern about doing so in a short period of time.[10] Yet instead of providing additional time for compliance, the Departments eliminated this requirement.

Recommendations:

- The Departments should keep the "strict adherence" requirement.
- Given that plans and issuers argue that the previous requirements were unreasonable because the plans would have to make significant operation changes in a short timeframe to comply, the Departments should provide a temporary safe harbor by using the "substantial compliance" standard while plans are implementing procedures rather than moving to an ongoing "substantial compliance" standard. Plans have in fact suggested using such a safe harbor if the Department retains the standard.[11]

There is no evidence that over-utilization will occur:

Commenters to the original IFR expressed concern about claimants trying to "game" the system by finding small flaws in a plan's administrative process so the claimant can circumvent the internal review process.[12] There is no evidence that this will occur. On the contrary, studies show that consumers have difficulty navigating multilevel review processes and fail to complete them, especially when they first have to exhaust their health plan's internal appeals and grievance process before seeking external review.[13]

Conclusion

In sum, while we are encouraged that in the original IFR the Departments made several strong statements that will benefit plan enrollees, we feel that some of the amendments made in the most recent IFR will be harmful to enrollees. Reversing course on those points, as set forth above, is necessary to protect enrollees to the fullest extent without unduly burdening plans or issuers. Thank you.

Sincerely,
/s/
Emily Spitzer
Executive Director

[10] U.S. Chamber of Commerce, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0040, Sept. 21, 2010.
[11] GroupHealth, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0037, Sept. 21, 2010.
[12] John J. McGowan, Jr., Baker & Hostetler LLP, Comment on FR Doc # 2010-18043, Doc. ID No. HHS-OS-2010-0019-0050, Sept. 21, 2010.
[13] Kaiser Family Foundation, Assessing State External Review Programs and the Effects of Pending Federal Patients' Rights Legislation (May 2002), available at http://www.kff.org/insurance/externalreviewpart2rev.pdf.