

1444 I St NW, Suite 1105 Washington, DC 20005 (202) 289-7661 Fax (202) 289-7724

VIA ELECTRONIC SUBMISSION

September 21, 2010

Office of Consumer Information and Insurance Oversight Department of Health and Human Services Attn: OCIIO-9993-IFC P.O. Box 8016 Baltimore, MD 21244-1850

Re: OCIIO-993-IFC

Dear Sir/Madam:

The National Health Law Program (NHeLP) is a national public interest law firm that seeks to improve health care for America's working and unemployed poor, minorities, the elderly and people with disabilities. NHeLP serves 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. As the health care system changes during the implementation of the new health reform law, it is critical to focus on ensuring that the private market can improve health delivery for *all* populations, including diverse and low-income vulnerable populations. Accordingly, NHeLP is pleased to offer our comments on the Office of Consumer Information and Insurance Oversight's (OCIIO) interim final 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 (PPACA).

In the discussion below, we first offer comments related to language access. Thereafter, we offer more general suggestions relating to the internal and external claim reviews.

COMMENTS RELATED TO LANGUAGE AND CULTURE

Background

NHeLP's interest in these regulations derives in large part from our focus on improving access and quality of care for low/limited-income and underserved populations. In particular, we have significant experience in the area of language access and have focused much of our comments on that area.

Language Access

Almost 20% of the population speaks a language other than English at home. Over 24 million, or 8.7% of the population, speak English less than very well and should be considered limited English proficient

(LEP) for healthcare purposes. This includes 47% of Spanish speakers, 33% of speakers of other Indo-European languages, 49% of speakers of Asian and Pacific Islander languages, and 30% of speakers of other languages.

Numerous studies have documented the problems associated with a lack of language services, including one by the Institute of Medicine, which stated that:

Language barriers may affect the delivery of adequate care through poor exchange of information, loss of important cultural information, misunderstanding of physician instruction, poor shared decision-making, or ethical compromises (e.g. difficulty obtaining informed consent). Linguistic difficulties may also result in decreased adherence with medication regimes, poor appointment attendance, and decreased satisfaction with services. (Cites omitted.)

Over one quarter of LEP patients who needed, but did not get, an interpreter reported they did not understand their medication instructions, compared with only 2% of those who did not need an interpreter and those who needed and received one.³

Indeed, language barriers have been found to be as significant as the lack of insurance in predicting use of health services. Health care providers surveyed in four major metropolitan areas identified language difficulties as a major barrier to immigrants' access to health care and a serious threat to medical care quality. These providers also expressed concern that they could not get information to make good diagnoses and that patients might not understand prescribed treatment.⁴ On the other hand, while Latino children generally have much less access to medical care than do white children, that gap becomes negligible when their parents' English-speaking skills are comparable to those of Whites.⁵

NHeLP applauds OCIIO for recognizing the importance of language access by requiring insurance plans/issuers to provide culturally and linguistically appropriate notice to enrollees during the internal claims and appeals and external review processes. In our comments, we will provide more detail as to where this requirement is successfully incorporated into the interim final rule, and where we recommend additional language to appropriately implement PPACA.

The statutory language, PPACA § 1001 (adding § 2719 to the Public Health Services Act), requires that culturally and linguistically appropriate notice be provided. This provision states:

¹ American Community Survey, Selected Social Characteristics in the United States: 2006-2008. American Community Survey, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over (Table B16001) 2008, *available at* http://factfinder.census.gov.

² Inst. of Medicine, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health, 17 (2002).

³ Dennis P. Andrulis, Nanette Goodman & Carol Pryor, The Access Project, What a Difference an Interpreter Can Make 7 (Apr. 2002).

⁴ Leighton Ku & Alyse Freilich, Kaiser Commission on Medicaid & the Uninsured, Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami, and Houston ii-iii (2001). *See also* Jennifer Cho & Beatriz M. Solis, L.A. Care Health Plan, Healthy Families Culture & Linguistic Resources Survey: A Physician Perspective on their Diverse Member Population (Jan. 2001) (stating that 51 percent of doctors said their patients do not adhere to treatments because of culture and language barriers).

⁵ Robin M. Weinick & Nancy A. Krauss, *Racial and Ethnic Differences in Children's Access to Care*, 90 Am. J. Public Health 1771 (2000).

"A group health plan and a health insurance issuer offering group or individual coverage shall implement an effective appeals process for appeals of coverage determinations and claims, under which the plan or issuer shall, at a minimum... (B) provide notice to enrollees, *in a culturally and linguistically appropriate manner*, of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman established under section 2793 to assist such enrollees with the appeals process..." (emphasis added).

The language is clear about the requirement of appropriate notice, thus we believe the rules must implement this requirement at every step of the appeals process.

It is also important to note that PPACA § 1557 extends the application of existing federal civil rights laws prohibiting discrimination on the basis of race, color or national origin; sex; disability; or age to any health program or activity receiving Federal financial assistance; any program or activity administered by an Executive agency; or any entity established under Title 1 of PPACA. This provision prohibits any individual from being excluded from participation in, denied the benefits of, or subjected to discrimination under "any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)."8 (emphasis added). Because the requirements related to notices and the appeals process are "administered by an Executive agency," the anti-discrimination protections in § 1557 therefore should apply to the health plans/issuers subject to this interim final rule. Further, many plans/issuers receive or may soon receive federal financial assistance, which also subjects them to Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d et. seq.). This will be particularly relevant as many of the plans and issuers covered by this rule are likely to participate in the Exchanges which will provide Federal financial assistance to these plans/issuers through the form of subsidies and additional assistance to offset cost-sharing costs for Exchange participants. As we will describe when answering OCIIO's Request for Comments related to the Exchanges, we believe that all plans/issuers participating in the Exchange must provide culturally and linguistically appropriate services because they are subject both to § 1557 and Title VI of the Civil Rights Act of 1964. Plans/issuers must provide information in a culturally and linguistically appropriate manner in order to comply with the relevant anti-discrimination provisions.

Literacy

It is also important that all information addressed in this interim final rule that is provided by plans, issuers, IROs and state agencies be written at a low literacy level so that individuals, and particularly LEP individuals, can understand the information. The issue of health literacy is a growing problem in the United States. According to the IOM, more than 90 million Americans have low health literacy and this includes many of the LEP individuals as well. So having materials written at a low "register" (literacy level) is essential to ensure comprehension so that the provision of information is not merely

⁶ Patient Protection and Affordable Care Act §1001 (adding § 2719 to the Public Health Services Act) (2010). ⁷ *Id.* at § 1557.

⁸ *Id.* at § 1557(a) (emphasis added).

⁹ Insitute of Medicine, Health Literacy: A Prescription to End Confusion (Lynn Nielsen-Bohlman, Allison M. Panzer & David A. Kindig eds., National Academies Press 2004).

pro forma but offers a real opportunity for enrollees to understand the information. We suggest that OCIIO specify the literacy level at which materials should be provided.

Overview

In general, NHeLP supports the significant enrollee protections laid out in the overview. We are particularly pleased that Section (e) in each of the interim final rules (for HHS, DOL and DOT) is solely devoted to language access and requires that all notices of available internal claims and appeals and external review processes be provided in a culturally and linguistically appropriate manner. This protection is essential to ensure that enrollees will understand and be able to participate meaningfully in the appeals process.

Page 43337 (footnote 16)

NHeLP is concerned, however, about the specific proposal for internal claims involving urgent care. The current language states, in footnote 16, that where the current DOL claims procedure regulation "permits an initial oral determination must be made within 24 hours and follow-up in written or electronic notification within 3 days of the oral notification, it may not be reasonable, practicable, or appropriate to provide notice in a non-English language within 24 hours. In such situations, the requirement to provide notice in a culturally and linguistically appropriate manner is satisfied if the initial notice is provided in English and the follow-up notice is provided in the appropriate non-English language."

NHeLP disagrees with the assertion that it may not be reasonable, practicable, or appropriate to provide notice in a non-English language within 24 hours. While we recognize that it may be difficult to obtain a translated written document within 24 hours, we believe that it is reasonable, appropriate, practicable and in fact necessary, to provide initial oral notice of determination in a non-English language. Otherwise, LEP individuals will not have meaningful access to urgent care appeals which could have significant adverse health consequences. The interim final rule requires that plans/issuers notify all English proficient enrollees of initial determinations regarding claims for urgent care within 24 hours, thus the standard should be the same for LEP enrollees. If the rule stays as currently written, LEP enrollees will effectively have no notice of determinations regarding urgent care claims within 24 hours because they may not be able to understand the initial notice provided in English. This likely will leave many LEP individuals unable to effectuate their rights to urgent appeals because they do not understand information provided only in English.

Further, NHeLP believes that it is practicable to provide initial oral notice in a non-English language within 24 hours. Ideally, plans/issuers should have existing contracts with over-the-phone interpreting (OPI) agencies which can usually offer access to at least 150 different languages with very short connection times. Even without existing contracts, these phone interpreting agencies are easy to contact. There are many different companies offering OPI services and they can often connect a customer with an interpreter in under 30 seconds. Additionally, the costs for these services have gone

¹⁰ N. Kelly, R.S. Beninatto & D. DePalma, Common Sense Advisory, Inc., Telephone Interpretation: The Demand Side (June 2008).

¹¹ N. Kelly, R.S. Beninatto & D. DePalma, Common Sense Advisory, Inc., Telephone Interpretation: The Supply Side (June 2008).

down and while much of the cost information is proprietary, we have learned that most health care buyers pay between \$1/minute and \$1.50/minute for OPI services. ¹² In fact, due to the wide-spread availability of phone interpreting agencies, it may well be easier for plans /issuers to provide the initial oral determination in non-English languages than the written determination within 3 days. We do believe, however, that both requirements are practicable.

Recommendation:

We urge OCIIO to strike parts of this footnote from the interim final rules. We recommend changing the text as follows:

"For internal claims involving urgent care (for which the claim is generally made by a health care provider), where paragraph (g) of the DOL claims procedure regulation permits an initial oral determination must be made within 24 hours and follow-up in written or electronic notification within 3 days of the oral notification, it may not be reasonable, practicable, or appropriate to provide written notice in a non-English language within 24 hours. In such situations, the requirement to provide notice in a culturally and linguistically appropriate manner is satisfied if the initial notice is provided orally in the non-English language in English and the follow-up written notice is provided within 3 days in the appropriate non-English language."

Interim Final Rule

As stated above, NHeLP applauds OCIIO for ensuring language access protections by including §147.136 (e) in the interim final rule, which extends the culturally and linguistically appropriate notice requirement to both individual and group coverage. We urge you, however, to add the phrase "culturally and linguistically appropriate manner" in the following five places throughout the interim final rule in order to clarify when this requirement applies. This will ensure that LEP individuals have advance information about how the appeals process will work. Without these added requirements, many LEP individuals may not have the appropriate information to know that they can file an appeal and how to do so.

§ 147.136 (b)(2)(ii)(E)(3)

NHeLP recommends that this paragraph be revised by adding the following: "The plan and issuer must provide *in a culturally and linguistically appropriate manner* a description of available internal appeals and external review processes, including information regarding how to initiate an appeal." This language will ensure meaningful notice of available appeals processes. Similar to the requirements for translating appeals notices when certain thresholds are met, we also recommend that those thresholds apply to translating information about the appeals processes.

$\S 147.136 (c)(2)(x)$

NHeLP recommends that this section be revised by adding the following: "The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and it requires that the claimant is notified *in a*

¹² N. Kelly, Common Sense Advisory, Inc., Telephone Interpretation Procurement (June 2009).

culturally and linguistically appropriate manner of the right to do so."

This added language will extend the appropriate notice requirements to IROs. While we recognize the potentially limited authority of federal agencies over IROs, it is essential to ensure that enrollees are adequately informed about how to access an external State review. If OCIIO determines that it cannot extend this requirement to the IROs then we ask that OCIIO require plans/issuers to ensure that information from the IRO is provided to the LEP enrollee who submitted information to the IRO in a culturally and linguistically appropriate manner (depending on timing, this could be accomplished via oral communication using bilingual staff or interpreters or written translation of the IRO information). Otherwise, if an LEP enrollee is unable to understand information from the IRO and thus is unable to respond or proceed with an appeal, the plan/issuer would benefit merely because of an enrollee's language barrier rather than based on the merits of the plan/issuer's actual decision.

§ 147.136 (c)(2)(xii)

NHeLP recommends that this paragraph be revised by adding the following: "The State process must require, for standard external review, that the IRO provide written notice *in a culturally and linguistically appropriate manner* to the claimant and the issuer (or, if applicable, the plan) of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO."

This addition will ensure that enrollees understand the result of the IRO decision. If OCIIO determines that it cannot extend this requirement to the IROs, then we ask that OCIIO require plans/issuers to ensure that decision from the IRO is provided to the LEP enrollee in a culturally and linguistically appropriate manner (depending on timing, this could be accomplished via oral communication using bilingual staff or interpreters or written translation of the IRO information).

§ 147.136 (c)(2)(xiv)

NHeLP recommends that this section be revised by adding the following: "The State process must require that issuers (or, if applicable, plans) include a description of the external review process *in a culturally and linguistically appropriate manner* in or attached to the summary plan description, policy...."

This added language will ensure that enrollees understand the State external review process and their rights under the process. This will ensure that LEP enrollees have advance information about how the appeals process will work. Without these added requirements, many LEP individuals may not have the appropriate information to know that they can file an appeal and how to do so.

§ 147.136 (d)(2)(vi)

NHeLP also recommends that the following section of the Federal external review process be amended: "These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants, beneficiaries, and enrollees describing the Federal external review procedures *in a culturally and linguistically appropriate manner* (including the right to file a request

for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees."

This additional language is necessary to ensure that enrollees have meaningful notice and understanding of the Federal external review process and thus will know how to exercise their rights if denied a service by a plan/issuer.

In addition to these revisions, NHeLP would like to make the following recommendations about the thresholds at which the culturally and linguistically appropriate notice requirements become applicable.

§ 147.136 (e)(1) – Group health coverage

This section of the interim final rule differentiates between "small" plans (those having fewer than 100 enrollees) and "large" plans (with over 100 enrollees) for purposes of establishing a threshold. For small plans, the rule requires translation if 25 percent or more enrollees are literate only in the same non-English language. § 147.136 (e)(1)(i)(A). For large plans, the rule requires that notices be translated in instances where the lesser of 500 enrollees or 10 percent of all enrollees speak the same language. § 147.136 (e)(1)(i)(B). These thresholds are based on the Department of Labor's (DOL) regulations regarding summary of coverage and benefits. (See Overview § (e) at 43337). While we appreciate DOL's current regulations, since these regulations also are adopted by HHS and DOT, we also suggest that OCIIO consider additional thresholds that have been developed by the Department of Health and Human Services (HHS) and the Department of Treasury (DOT) that apply to the provision of written translated materials by federal fund recipients. These "LEP Guidances" offer "safe harbors" for translating vital written documents – when a federal fund recipient complies with the safe harbor guidelines then the entity is deemed in compliance with Title VI. DOL's LEP Guidance does not have "safe harbor" guidelines for federal fund recipients for translating documents, as does DOT and HHS.¹³ Since there are some stronger aspects to HHS' and DOT's LEP Guidances as compared to DOL's existing regulations, NHeLP recommends that this interim final rule establish a threshold standard for translating documents in the claims and appeals process that combines different aspects of the three agency's varying guidelines which can be applied consistently.

NHeLP recommends that the threshold for translating written documents by small plans remain as stated in the rule, thus the 25% of enrollees. In the case of small plans, DOL existing regulations are preferable to HHS OCR guidance in terms of making translated documents available to more LEP enrollees. For large plans, however, NHeLP recommends that the threshold be changed to the lesser of 5% or 500 enrollees. This change would represent a combination of HHS, DOT and DOL standards, and would ensure that a greater number of LEP enrollees receive notice about critical information, such as an adverse benefits determination, that they can understand. HHS and DOT LEP Guidances' thresholds refer to the lesser of 10% or 1000, while the DOL regulation refers to 5% or 500 – the combination

_

¹³ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 70 FR 6067 (February 4, 2005), *available at* http://www.lep.gov/guidance/depttreas_lep_guide_final.htm. Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 153, 47311, 47319-20 (Aug. 8, 2003), *available at* http://www.justice.gov/crt/cor/lep/hhsrevisedlepguidance.pdf.

would utilize the 5% from HHS/DOT and 500 from DOL, providing the higher level of protections from existing policies while also ensuring consistency across all three agencies.

This will be particularly relevant as many of the group plans and issuers covered by this rule are likely to participate in the Exchanges which will provide Federal financial assistance to these plans/issuers through the form of subsidies and additional assistance to offset cost-sharing costs for Exchange participants. As we will describe when answering OCIIO's Request for Comments related to the Exchanges, we believe that all plans/issuers participating in the Exchange must provide culturally and linguistically appropriate services because they are subject both to § 1557 and Title VI of the Civil Rights Act of 1964, and thus the existing LEP Guidances would apply to them.

Recommendation:

NHeLP recommends changing the language in § 147.136 (e)(1)(i)(B) as follows:

(B) For a plan that covers 100 or more participants at the beginning of a plan year, if the plan and issuer provides notices upon request in a non-English language in which the lesser of 500 or more participants, or 10 5 percent or more of all plan participants, are literate in only the same non-English language."

§ 147.136 (e)(2) – Individual health insurance coverage

The interim final rule establishes the threshold for translating written documents in the individual market as "10 percent or more of the population residing in the claimant's county are literate only in the same non-English language." § 147.136 (e)(2)(i). This standard is also adapted from DOL's regulations regarding summary of coverage and benefits, as well as the approach used by the Medicare Advantage program. (See Overview § (e) at 43337). NHeLP recommends that the threshold be changed to 5% or more of the county's population. A lower threshold is needed to ensure that LEP enrollees receive crucial information about claims denials and appeal opportunities. The 10% threshold may be appropriate when it applies to summary plan descriptions, as in the DOL regulations, but the threshold in this claims and appeals rule needs to be more stringent. This will be particularly relevant as many of the plans/insurers providing coverage in the individual market are likely to participate in the Exchanges which will provide Federal financial assistance to these plans/issuers through the form of subsidies and additional assistance to offset cost-sharing costs for Exchange participants. As we will describe when answering OCIIO's Request for Comments related to the Exchanges, we believe that all plans/issuers participating in the Exchange must provide culturally and linguistically appropriate services because they are subject both to § 1557 and Title VI of the Civil Rights Act of 1864.

Recommendation:

NHeLP recommends changing the language in § 147.136 (e)(2)(i) as follows:

"(i) For purposes of this section, a health insurance issuer offering individual health insurance coverage is considered to provide relevant notices in a culturally and linguistically appropriate manner if the issuer provides notices upon request in a non-English language in which $\frac{10}{5}$ percent or more of the population residing in the claimant's county are literate only in the same

non-English language, determined in guidance published by the Secretary of Health and Human Services."

§ 147.136 (e)

Finally, we have several recommendations that apply to both the group health coverage (§ 147.136 (e)(1)) and individual health coverage (§ 147.136 (e)(2)) sections of this rule. NHeLP recommends that regardless of whether the threshold for translating written documents is met, plans should provide oral interpreting services for *all* LEP enrollees. The rule in its current form requires oral interpreting services only when the thresholds are met. This standard contradicts both HHS and DOT guidance for federal find recipients. HHS' guidance states that the thresholds for translating written documents "do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where an application of the four factor test leads to the determination that oral language services are needed and are reasonable." Similarly, DOT guidance states that the provisions establishing thresholds for written translation "do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where oral language services are needed and are reasonable." The provision of the four factor test leads to the determination that oral language services are needed and are reasonable.

Recommendation:

To explicitly require oral interpreting for all LEP enrollees, the rule should be changed by striking the beginning of both § 147.136 (e)(1)(ii) and § 147.136 (e)(2)(ii) as follows:

"(ii) If an applicable threshold described in paragraph (e)(1)(i) (and (e)(2)(i) respectively) of this section is met, the issuer must also—

Eliminating this qualifying clause will require plans to provide oral interpreting services for all limited English proficient members regardless of whether the threshold for written translation is met.

We also suggest adding (D) to both § 147.136 (e)(1)(ii) and § 147.136 (e)(2)(ii) as follows:

(D) provide meaningful access to all non-English speaking enrollees through competent oral interpreters or competent bilingual staff where oral language services are needed.

This will clarify that there is a separate requirement regarding oral communication, notwithstanding requirements for translating written vital documents. As stated above, this is recognized by the HHS and DOT LEP guidances which clarify requirements to provide oral communication are separate and distinct from translating written documents.

Automated Voice Systems. NHeLP also recommends that large plans be required to add voice prompts to their customer service centers to the extent that they use automated voice prompt systems. Currently, many voice prompts are only available in English and, if any additional language, Spanish. Voice prompts should be added for at least those languages for which the thresholds are met, so that LEP individuals can quickly access competent, bilingual customer service representatives or English-

_

¹⁴ HHS Guidance, *supra* note 13.

¹⁵ DOT Guidance, *supra* note 13.

speaking representatives who obtain assistance from interpreters. Further, plans should ensure that the customer service staff of plans/insurers are trained to respond appropriately to LEP callers and how to access bilingual staff or interpreters.

Recommendation:

NHeLP recommends changing the rule be adding the following language to the end of § 147.136 (e)(1)(ii)(C) and (e)(2)(ii)(C): "Large plans that use automated voice prompt systems must add voice prompts in all non-English languages for which the threshold (described in paragraph (e)(1)(i) and (e)(2)(i) respectively)-is met."

Taglines. Finally, NHeLP recommends that regardless of whether the threshold is met, taglines should be included on all English documents. As currently written, the rule requires taglines only when the threshold for written translation is met. (§ 147.136 (e)(1)(ii)(A) and § 147.136 (e)(2)(ii)(A)). Since most private health plans/issuers do not have comprehensive language data on enrollees, however, it is not always possible to identify LEP enrollees who would need notices in non-English languages. Thus, we recommend that, as a supplement to requiring translation of notices into threshold languages, plans be required to include a "tagline" in 15 languages – at the top of the notice or as an insert in the same mailing – that informs recipients that the notice is important and to call an insurer's customer service center to obtain assistance in understanding it.

For example, SSA has used multilingual attachments to notices when sending out notices dealing with immigrant eligibility issues. 16 And plans that serve California – and thus approximately 12% of the nation's population – are already required to provide such notice. As an example, California's Department of Managed Healthcare offers a sample language access notice with taglines in 12 languages. 17

The development of the tagline is an easy process and should not involve significant cost or time. Plans can adopt existing taglines from other agencies or organizations. For example, California's tagline is available in 13 languages. As another example, the Arizona Department of Economic Security has a "Language Notification Flyer" that states – "If you need this notice translated into your language, please call xxx-xxx-xxxx or xxx-xxxx." The notice includes 23 languages – 9 of which are included in SSA's 15. HHS could request permission to use California and/or Arizona's taglines and a plan would merely insert its number in place of the state's numbers. HHS could then translate the tagline into other prevalent languages, using the SSA languages as a guide or USDA which translates SNAP information into 37 languages. 18 This is a small price to pay to ensure language access for LEP enrollees and reduce the burdens on healthcare providers and community based organizations.

Further, having a standardized tagline utilized by all plans and issuers will assist LEP individuals who may move from plan to issuer and be able to recognize the standardized language. It is also important that the tagline be written at a low literacy level so that LEP individuals can understand. The issue of health literacy is a growing problem in the United States. As mentioned in our introduction, more than

http://www.fns.usda.gov/snap/outreach/translations.htm.

¹⁶ Social Security Information in Other Languages, *available at* http://ssa.gov/multilanguage/.

¹⁷ Sample tagline *available at* http://www.hmohelp.ca.gov/library/reports/news/snla.pdf. ¹⁸ U.S. Department of Agriculture, Supplemental nutrition assistance program information, available at

90 million Americans have low health literacy and this includes many of the LEP individuals as well. So having a standardized tagline written at a low "register" (literacy level) can also assist in comprehension. If plans/issuers are allowed to develop their own taglines, it should be specified that the information is provided at a specific low literacy level.

Recommendation:

The rule should be changed to incorporate this tagline by simply striking the beginning of both § 147.136 (e)(1)(ii) and § 147.136 (e)(2)(ii) as follows: "(ii) If an applicable threshold described in paragraph (e)(1)(i) (and (e)(2)(i) respectively) of this section is met, the issuer must also "

We then recommend adding the following text to the end of both § 147.136 (e)(1)(ii)(A) and § 147.136 (e)(2)(ii)(A):

which shall state "**IMPORTANT**: You can get an interpreter at no cost to talk to your doctor or health plan. To get an interpreter or to ask about written information in (your language), first call your health plan's phone number at 1-XXX-XXXX. Someone who speaks (your language) can help you. If you need more help, call the Help Center at 1-888-466-2219."

GENERAL COMMENTS

NHeLP supports the significant enrollee protections contained in the interim final rule. We endorse the comments submitted by our colleagues at the Center for Medicare Advocacy, Inc, and suggest in addition:

§§ 147.136(b)(2)(ii)(C), (b)(3)(ii)(C) – full and fair review

The rule should state that, during full and fair review, in addition to allowing the health plan to introduce new evidence, the claimant can do so as well.

§§ 147.136 (b)(2)(ii)(D), (b)(3)(ii)(C) – avoiding conflicts

The regulations should state that the individual or entity making the full and fair review also must not have participated in any way in the initial adverse determination.

§§ 147.136 (b)(2)(ii)(E), (b)(3)(ii)(E) – notices

The regulation should be clarified to specify that the plan's and/or insurer's explanation for the basis of the adverse benefit determination should include, free of charge to the claimant, any clinical coverage guideline or policy relied upon in making the determination. In the Medicaid context, managed care plans have contracted with private companies to use their clinical coverage policies, thereafter refusing to provide claimants with a copy of the coverage policy used to make a denial, claiming trade secret. This can make it difficult, if not impossible, for claimants to decide whether and how to challenge the coverage decision. Disclosure of the clinical coverage guidelines is necessary to assure transparency and accountability.

We ask that the preamble to these rules give as examples of an inadequate notice of benefit determination: "Not medically necessary" and "Not covered." Such cryptic responses, which have typified Medicaid managed care notices over the last decade, are plainly inadequate.

The notice to the individual of the adverse benefit determination should state the applicable time frames for the internal and external appeal processes, including for urgent matters.

The notice to the individual of the adverse benefit determination should explain the filing fee for external appeals, as well as the circumstances for when that fee will not be required (e.g. circumstances for "undue financial hardship").

The regulation should provide that the notices being developed by health plans and insurers will be submitted to the consumer assistance program for review and comment prior to first use and that copies of the notices will be provided to the consumer assistance program once they are finalized.

CONCLUSION

NHeLP looks forward to working with OCIIO on the implementation of the interim final rules for internal claims and appeals and external review. If there is any information or assistance we can provide, please do not hesitate to contact us. We look forward to continuing to provide feedback that improves the health of low-income populations and communities impacted by health disparities.

Sincerely,

/s/ Emily Spitzer Executive Director